

## Data Dictionary Codebook

**naNO-COVID - Personal data (PID: 340)**

01/10/2024 9:07am

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)						
Instrument: <b>Personal identification</b> (personal_identification)									
1	[ nano_pi_record_id ]	Screening ID	text, Required						
2	[ nano_pi_id ]	Inclusion ID	text Field Annotation: @READONLY						
3	[ nano_pi_ipp ]	IPP	text, Required						
4	[ nano_pi_firstname_e ]	First Name	text, Required						
5	[ nano_pi_lastname ]	Last Name	text, Required						
6	[ nano_pi_dob ]	Date of birth	text (date_dmy), Required						
7	[ nano_pi_yearob ]	Year of Birth	calc, Required Calculation: rounddown(datediff([nano_pi_dob], "01-01-1901", "y","dmy")) + 1901 Field Annotation: @HIDDEN						
8	[ nano_pi_street_name ]	Address (street name)	text, Required						
9	[ nano_pi_street_number ]	Address (number)	text (integer), Required						
10	[ nano_pi_postal ]	Address (postal code)	text (integer), Required						
11	[ nano_pi_town ]	Address (town)	text, Required						
12	[ nano_pi_phone ]	Phone number (Format exemple : 0791234567@sms.unisante )	text (email), Required						
13	[ nano_pi_email ]	E-mail	text (email), Required						
14	[ nano_pi_doc_name ]	General Practitioner <i>NAME First Name</i>	text, Required						
15	[ nano_pi_doc_phone ]	Doctor's phone	text, Required						
16	[ personal_identification_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Informed consent</b> (informed_consent)									
17	[ nano_ic_purpose ]	Have you explained the nature and the purpose of the study?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								

18	[ nano_ic_date_delivery ]	Date of information sheet delivery	text (datetime_dmy), Required						
19	[ nano_ic_consent_signed ]	Have the informed consent been signed ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
20	[ nano_ic_date_signature ]	Date of informed consent signature	text (datetime_dmy), Required						
21	[ nano_ic_stop ]  Show the field ONLY if: [nano_ic_consent_signed] = '0' OR [nano_ic_purpose] = '0'	Only subjects having been informed and having provided signed consent for participating in the trial and willing to follow all planned trial assessments can be included in the trial.	descriptive						
22	[ informed_consent_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

naNO-COVID - Research data (PID: 341)

01/10/2024 9:09am

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)												
Instrument: <b>Date of visit</b> (date_of_visit)															
1	[ nano_vi_id ]	Screening ID	text, Required												
2	[ dep_name1 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Research physician	descriptive												
3	[ nano_vi_date_visit ]	Date of visit	text (date_dmy), Required												
4	[ date_of_visit_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete						
0	Incomplete														
1	Unverified														
2	Complete														
Instrument: <b>Volunteer Informations</b> (volunteer_informations)															
5	[ dep_name2 ]	Research Physician	descriptive												
6	[ nano_vi_full_id ]	Inclusion ID	text Field Annotation: @READONLY												
7	[ nano_vi_ipp ]	IPP	text, Required, Identifier												
8	[ nano_vi_phone ]	Phone	text (email), Required, Identifier Field Annotation: @HIDDEN												
9	[ nano_vi_yearob ]	Section Header: <i>Demographic informations</i> Year of birth	text (integer, Min: 1800, Max: 2200), Required												
10	[ nano_vi_gender ]	Gender	radio, Required <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table>	1	Male	2	Female								
1	Male														
2	Female														
11	[ nano_vi_ethnicity ]	Ethnicity	radio, Required <table><tr><td>1</td><td>Caucasian</td></tr><tr><td>2</td><td>Black</td></tr><tr><td>3</td><td>Latino</td></tr><tr><td>4</td><td>Asian</td></tr><tr><td>5</td><td>Pacific Islander</td></tr><tr><td>6</td><td>Other</td></tr></table>	1	Caucasian	2	Black	3	Latino	4	Asian	5	Pacific Islander	6	Other
1	Caucasian														
2	Black														
3	Latino														
4	Asian														
5	Pacific Islander														
6	Other														
12	[ nano_vi_ethnicity_specify ]  Show the field ONLY if: [nano_vi_ethnicity]='6'	Specify	text, Required												
13	[ nano_vi_smoke ]	Section Header: <i>Habits</i>	yesno, Required												

		Does the volunteer smoke or use tobacco products?	<table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
14	[ nano_vi_years_smoke ]  Show the field ONLY if: [nano_vi_smoke] = '1'	How many years of smoking ?	text (number, Min: 0, Max: 100), Required				
15	[ nano_vi_cig_per_day ]  Show the field ONLY if: [nano_vi_smoke] = '1'	How many cigarettes per day ?	text (integer, Min: 0, Max: 100), Required				
16	[ nano_vi_alcohol ]	Does the volunteer consum alcohol?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
17	[ nano_vi_drink_per_week ]  Show the field ONLY if: [nano_vi_alcohol] = '1'	How many standard alcoholic drinks per week ?	text (integer, Min: 0, Max: 100), Required				
18	[ nano_vi_drug_consume ]	Has the volunteer used drugs (like opiates, cocaine or amphetamin) in the last 5 years ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
19	[ nano_vi_drugs_spec ]  Show the field ONLY if: [nano_vi_drug_consume] = '1'	Please specify drug(s)	text, Required				
20	[ nano_vi_med_problem ]	Section Header: <i>Medical history</i> Has the volunteer any medical problem ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
21	[ nano_vi_med_condition ]	Relevant medical condition	text				
22	[ nano_vi_med_condition_1 ]	Relevant medical condition	text				
23	[ nano_vi_med_condition_2 ]	Relevant medical condition	text				
24	[ nano_vi_med_condition_3 ]	Relevant medical condition	text				
25	[ nano_vi_med_condition_4 ]	Relevant medical condition	text				
26	[ nano_vi_med_condition_5 ]	Relevant medical condition	text				
27	[ nano_vi_med_condition_6 ]	Relevant medical condition	text				
28	[ nano_vi_table ]  Show the field ONLY if:	relevant medical condition day month year {nano_vi_med_condition} {nano_vi_med_condition_day} {nano_vi_med_condition_month}	descriptive				

	[nano_vi_med_proble m] = '1'	{nano_vi_med_condition_year} {nano_vi_med_condition_1} {nano_vi_med_condition_day_1} {nano_vi_med_condition_month_1} {nano_vi_med_condition_year_1} {nano_vi_med_condition_2} {nano_vi_med_condition_day_2} {nano_vi_med_condition_month_2} {nano_vi_med_condition_year_2} {nano_vi_med_condition_3} {nano_vi_med_condition_day_3} {nano_vi_med_condition_month_3} {nano_vi_med_condition_year_3} {nano_vi_med_condition_4} {nano_vi_med_condition_day_4} {nano_vi_med_condition_month_4} {nano_vi_med_condition_year_4} {nano_vi_med_condition_5} {nano_vi_med_condition_day_5} {nano_vi_med_condition_month_5} {nano_vi_med_condition_year_5} {nano_vi_med_condition_6} {nano_vi_med_condition_day_6} {nano_vi_med_condition_month_6} {nano_vi_med_condition_year_6}	
29	[ nano_vi_table_2 ]  Show the field ONLY i f: [nano_vi_med_proble m] = '1'	relevant past medical history day month year {nano_vi_past_med_his} {nano_vi_past_med_his_day} {nano_vi_past_med_his_month} {nano_vi_past_med_his_year} {nano_vi_past_med_his_1} {nano_vi_past_med_his_day_1} {nano_vi_past_med_his_month_1} {nano_vi_past_med_his_year_1} {nano_vi_past_med_his_2} {nano_vi_past_med_his_day_2} {nano_vi_past_med_his_month_2} {nano_vi_past_med_his_year_2} {nano_vi_past_med_his_3} {nano_vi_past_med_his_day_3} {nano_vi_past_med_his_month_3} {nano_vi_past_med_his_year_3} {nano_vi_past_med_his_4} {nano_vi_past_med_his_day_4} {nano_vi_past_med_his_month_4} {nano_vi_past_med_his_year_4} {nano_vi_past_med_his_5} {nano_vi_past_med_his_day_5} {nano_vi_past_med_his_month_5} {nano_vi_past_med_his_year_5} {nano_vi_past_med_his_6} {nano_vi_past_med_his_day_6} {nano_vi_past_med_his_month_6} {nano_vi_past_med_his_year_6}	descriptive
30	[ nano_vi_med_conditi on_day ]	day	text (integer, Min: 0, Max: 31)
31	[ nano_vi_med_conditi on_month ]	month	text (integer, Min: 0, Max: 12)
32	[ nano_vi_med_conditi on_year ]	year	text (integer, Min: 0, Max: 2050)

33	[ nano_vi_med_conditi on_day_1 ]	day	text (integer, Min: 0, Max: 31)
34	[ nano_vi_med_conditi on_month_1 ]	month	text (integer, Min: 0, Max: 12)
35	[ nano_vi_med_conditi on_year_1 ]	year	text (integer, Min: 0, Max: 2050)
36	[ nano_vi_med_conditi on_day_2 ]	day	text (integer, Min: 0, Max: 31)
37	[ nano_vi_med_conditi on_month_2 ]	month	text (integer, Min: 0, Max: 12)
38	[ nano_vi_med_conditi on_year_2 ]	year	text (integer, Min: 0, Max: 2050)
39	[ nano_vi_med_conditi on_day_3 ]	day	text (integer, Min: 0, Max: 31)
40	[ nano_vi_med_conditi on_month_3 ]	month	text (integer, Min: 0, Max: 12)
41	[ nano_vi_med_conditi on_year_3 ]	year	text (integer, Min: 0, Max: 2050)
42	[ nano_vi_med_conditi on_day_4 ]	day	text (integer, Min: 0, Max: 31)
43	[ nano_vi_med_conditi on_month_4 ]	month	text (integer, Min: 0, Max: 12)
44	[ nano_vi_med_conditi on_year_4 ]	year	text (integer, Min: 0, Max: 2050)
45	[ nano_vi_med_conditi on_day_5 ]	day	text (integer, Min: 0, Max: 31)
46	[ nano_vi_med_conditi on_month_5 ]	month	text (integer, Min: 0, Max: 12)
47	[ nano_vi_med_conditi on_year_5 ]	year	text (integer, Min: 0, Max: 2050)
48	[ nano_vi_med_conditi on_day_6 ]	day	text (integer, Min: 0, Max: 31)
49	[ nano_vi_med_conditi on_month_6 ]	month	text (integer, Min: 0, Max: 12)
50	[ nano_vi_med_conditi on_year_6 ]	year	text (integer, Min: 0, Max: 2050)
51	[ nano_vi_past_med_hi s ]	Relevant past medical history	text
52	[ nano_vi_past_med_hi s_1 ]	Relevant past medical history	text
53	[ nano_vi_past_med_hi s_2 ]	Relevant past medical history	text
54	[ nano_vi_past_med_hi s_3 ]	Relevant past medical history	text
55	[ nano_vi_past_med_hi s_4 ]	Relevant past medical history	text
56	[ nano_vi_past_med_hi s_5 ]	Relevant past medical history	text
57	[ nano_vi_past_med_hi s_6 ]	Relevant past medical history	text

58	[ nano_vi_past_med_his_day ]	day	text (integer, Min: 0, Max: 31)				
59	[ nano_vi_past_med_his_month ]	month	text (integer, Min: 0, Max: 12)				
60	[ nano_vi_past_med_his_year ]	year	text (integer, Min: 1920, Max: 2050)				
61	[ nano_vi_past_med_his_day_1 ]	day	text (integer, Min: 0, Max: 31)				
62	[ nano_vi_past_med_his_month_1 ]	month	text (integer, Min: 0, Max: 12)				
63	[ nano_vi_past_med_his_year_1 ]	year	text (integer, Min: 1920, Max: 2050)				
64	[ nano_vi_past_med_his_day_2 ]	day	text (integer, Min: 0, Max: 31)				
65	[ nano_vi_past_med_his_month_2 ]	month	text (integer, Min: 0, Max: 12)				
66	[ nano_vi_past_med_his_year_2 ]	year	text (integer, Min: 1920, Max: 2050)				
67	[ nano_vi_past_med_his_day_3 ]	day	text (integer, Min: 0, Max: 31)				
68	[ nano_vi_past_med_his_month_3 ]	month	text (integer, Min: 0, Max: 12)				
69	[ nano_vi_past_med_his_year_3 ]	year	text (integer, Min: 1920, Max: 2050)				
70	[ nano_vi_past_med_his_day_4 ]	day	text (integer, Min: 0, Max: 31)				
71	[ nano_vi_past_med_his_month_4 ]	month	text (integer, Min: 0, Max: 12)				
72	[ nano_vi_past_med_his_year_4 ]	year	text (integer, Min: 1920, Max: 2050)				
73	[ nano_vi_past_med_his_day_5 ]	day	text (integer, Min: 0, Max: 31)				
74	[ nano_vi_past_med_his_month_5 ]	month	text (integer, Min: 0, Max: 12)				
75	[ nano_vi_past_med_his_year_5 ]	year	text (integer, Min: 1920, Max: 2050)				
76	[ nano_vi_past_med_his_day_6 ]	day	text (integer, Min: 0, Max: 31)				
77	[ nano_vi_past_med_his_month_6 ]	month	text (integer, Min: 0, Max: 12)				
78	[ nano_vi_past_med_his_year_6 ]	year	text (integer, Min: 1920, Max: 2050)				
79	[ nano_vi_allergies ]	Allergie(s) ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
80	[ nano_vi_allergies_specify ]  Show the field ONLY if: [ nano_vi_allergies ] = '1'	Please specify allergie(s)	text, Required				

81	[ nano_vi_past_covid ]  Section Header: COVID-19 history (natural disease and vaccination)  Past COVID-19 history	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes							
0	No							
82	[ nano_vi_past_covid_no_ep ]  Show the field ONLY if: [nano_vi_past_covid] = "1"	radio <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr></table>	1	1	2	2	3	3
1	1							
2	2							
3	3							
83	[ nano_vi_which_test ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '1' OR [nano_vi_past_covid_no_ep] = '2' OR [nano_vi_past_covid_no_ep] = '3'	radio <table><tr><td>1</td><td>Serologic test</td></tr><tr><td>2</td><td>Antigenic test</td></tr><tr><td>3</td><td>PCR test</td></tr></table>	1	Serologic test	2	Antigenic test	3	PCR test
1	Serologic test							
2	Antigenic test							
3	PCR test							
84	[ nano_vi_covid_test_date ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '1' OR [nano_vi_past_covid_no_ep] = '2' OR [nano_vi_past_covid_no_ep] = '3'	text (date_dmy)						
85	[ nano_vi_which_test_2 ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '2' OR [nano_vi_past_covid_no_ep] = '3'	radio <table><tr><td>1</td><td>Serologic test</td></tr><tr><td>2</td><td>Antigenic test</td></tr><tr><td>3</td><td>PCR test</td></tr></table>	1	Serologic test	2	Antigenic test	3	PCR test
1	Serologic test							
2	Antigenic test							
3	PCR test							
86	[ nano_vi_covid_test_date_2 ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '2' OR [nano_vi_past_covid_no_ep] = '3'	text (date_dmy)						
87	[ nano_vi_which_test_3 ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '3'	radio <table><tr><td>1</td><td>Serologic test</td></tr><tr><td>2</td><td>Antigenic test</td></tr><tr><td>3</td><td>PCR test</td></tr></table>	1	Serologic test	2	Antigenic test	3	PCR test
1	Serologic test							
2	Antigenic test							
3	PCR test							
88	[ nano_vi_covid_test_date_3 ]  Show the field ONLY if: [nano_vi_past_covid_no_ep] = '3'	text (date_dmy)						



89	[ nano_vi_covid_vacc ]	COVID-19 vaccination	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
90	[ nano_vi_dose_number ]  Show the field ONLY if: [ nano_vi_covid_vacc ] = "1"	Number of doses	radio <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr></table>	1	1	2	2	3	3	4	4						
1	1																
2	2																
3	3																
4	4																
91	[ nano_vi_date_dose ]  Show the field ONLY if: [ nano_vi_dose_number ] > 0	Date dose 1	text (date_dmy)														
92	[ nano_vi_dose_brand ]  Show the field ONLY if: [ nano_vi_dose_number ] > 0	Brand of dose 1	radio <table><tr><td>1</td><td>Pfizer</td></tr><tr><td>2</td><td>Moderna</td></tr><tr><td>3</td><td>AZ</td></tr><tr><td>4</td><td>Janssen</td></tr><tr><td>5</td><td>Sinovac</td></tr><tr><td>6</td><td>Sinopharm</td></tr><tr><td>7</td><td>Sputnik</td></tr></table>	1	Pfizer	2	Moderna	3	AZ	4	Janssen	5	Sinovac	6	Sinopharm	7	Sputnik
1	Pfizer																
2	Moderna																
3	AZ																
4	Janssen																
5	Sinovac																
6	Sinopharm																
7	Sputnik																
93	[ nano_vi_date_dose_2 ]  Show the field ONLY if: [ nano_vi_dose_number ] > 1	Date dose 2	text (date_dmy)														
94	[ nano_vi_dose_brand_2 ]  Show the field ONLY if: [ nano_vi_dose_number ] > 1	Brand of dose 2	radio <table><tr><td>1</td><td>Pfizer</td></tr><tr><td>2</td><td>Moderna</td></tr><tr><td>3</td><td>AZ</td></tr><tr><td>4</td><td>Janssen</td></tr><tr><td>5</td><td>Sinovac</td></tr><tr><td>6</td><td>Sinopharm</td></tr><tr><td>7</td><td>Sputnik</td></tr></table>	1	Pfizer	2	Moderna	3	AZ	4	Janssen	5	Sinovac	6	Sinopharm	7	Sputnik
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2	Moderna																
3	AZ																
4	Janssen																
5	Sinovac																
6	Sinopharm																
7	Sputnik																
95	[ nano_vi_date_dose_3 ]  Show the field ONLY if: [ nano_vi_dose_number ] > 2	Date dose 3	text (date_dmy)														
96	[ nano_vi_dose_brand_3 ]  Show the field ONLY if:	Brand of dose 3	radio <table><tr><td>1</td><td>Pfizer</td></tr><tr><td>2</td><td>Moderna</td></tr><tr><td>3</td><td>AZ</td></tr></table>	1	Pfizer	2	Moderna	3	AZ								
1	Pfizer																
2	Moderna																
3	AZ																

	[nano_vi_dose_number] > 2		<table><tr><td>4</td><td>Janssen</td></tr><tr><td>5</td><td>Sinovac</td></tr><tr><td>6</td><td>Sinopharm</td></tr><tr><td>7</td><td>Sputnik</td></tr></table>	4	Janssen	5	Sinovac	6	Sinopharm	7	Sputnik						
4	Janssen																
5	Sinovac																
6	Sinopharm																
7	Sputnik																
97	[ nano_vi_date_dose_4 ]  Show the field ONLY if: [nano_vi_dose_number] > 3	Date dose 4	text (date_dmy)														
98	[ nano_vi_dose_brand_4 ]  Show the field ONLY if: [nano_vi_dose_number] > 3	Brand of dose 4	radio <table><tr><td>1</td><td>Pfizer</td></tr><tr><td>2</td><td>Moderna</td></tr><tr><td>3</td><td>AZ</td></tr><tr><td>4</td><td>Janssen</td></tr><tr><td>5</td><td>Sinovac</td></tr><tr><td>6</td><td>Sinopharm</td></tr><tr><td>7</td><td>Sputnik</td></tr></table>	1	Pfizer	2	Moderna	3	AZ	4	Janssen	5	Sinovac	6	Sinopharm	7	Sputnik
1	Pfizer																
2	Moderna																
3	AZ																
4	Janssen																
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6	Sinopharm																
7	Sputnik																
99	[ volunteer_informations_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete								
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Instrument: <b>Informed Consent</b> (informed_consent)																	
100	[ dep_name3 ]	Research physician	descriptive														
101	[ nano_ic_purpose ]	Have you explained the nature and the purpose of the study?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
102	[ nano_ic_date_delivery ]	Date of information sheet delivery	text (datetime_dmy), Required														
103	[ nano_ic_consent_signed ]	Have the informed consent been signed ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
104	[ nano_ic_date_signature ]	Date of informed consent signature	text (datetime_dmy), Required														
105	[ nano_ic_stop ]  Show the field ONLY if: [nano_ic_consent_signed] = '0' OR [nano_ic_purpose] = '0'	Only subjects having been informed and having provided signed consent for participating in the trial and willing to follow all planned trial assessments can be included in the trial.	descriptive														
106	[ informed_consent_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																

Instrument: Medical History (medical_history)			
107	<div>[ dep_name4 ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Research Physician	descriptive
108	<div>[ nano_mh_consent_signed ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Section Header: <i>Verifying informations</i> Have the informed consent been signed ?	yesno, Required <div><div>1</div>Yes</div> <div><div>0</div>No</div>
109	<div>[ nano_mh_consent_changed ]</div> <div>Show the field ONLY if: [event-name] = '1st_vaccination_arm_1'</div>	Changes in informed consent ?	yesno, Required <div><div>1</div>Yes</div> <div><div>0</div>No</div>
110	<div>[ nano_mh_consent_changed_message ]</div> <div>Show the field ONLY if: [nano_mh_consent_changed] = '1'</div>	Only subjects having been informed and having provided signed consent for participating in the trial and willing to follow all planned trial assessments can be included in the trial. If consent is withdraw, please complete the SCREEN FAILURE page.	descriptive
111	<div>[ nano_mh_abnormalities ]</div>	Abnormalities/new medical event reported since the last visit?	yesno, Required <div><div>1</div>Yes</div> <div><div>0</div>No</div>
112	<div>[ nano_mh_abnormalities_spec ]</div> <div>Show the field ONLY if: [nano_mh_abnormalities] = '1'</div>	Specify	notes, Required
113	<div>[ nano_mh_medication_changed ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1'</div>	Has medication changed since the last visit?	yesno, Required <div><div>1</div>Yes</div> <div><div>0</div>No</div>
114	<div>[ nano_mh_fill_med ]</div> <div>Show the field ONLY if: [nano_mh_medication_changed] = '1'</div>	Please fill the medication form	descriptive
115	<div>[ nano_mh_new_vac ]</div>	Any vaccination received since the last visit?	yesno, Required

	Show the field ONLY if: [event-name] <> 'visit_10_phone_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'		<table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
116	[ nano_mh_date_vac ]  Show the field ONLY if: [nano_mh_new_vac] = '1'	Date of vaccination	text (date_dmy), Required						
117	[ nano_mh_postpone ]  Show the field ONLY if: [nano_mh_new_vac] = '1'	If the subject has been vaccinated within 14 days (influenza vaccine) or within 28 days (other vaccines) prior to Visit 2, the subject cannot be vaccinated. Please consider postponement of vaccination or complete the SCREEN FAILURE page	descriptive						
118	[ medical_history_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: Adverse Events (adverse_events)									
119	[ dep_name5 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Study nurse	descriptive						
120	[ nano_ae_date_visit ]	Date of visit	text (datetime_dmy), Required						
121	[ nano_ae_list ]	Section Header: <i>Updating reports</i> List of current AE reports to be updated	descriptive						
122	[ nano_sae_list ]	List of current SAE reports to be updated	descriptive						
123	[ nano_ae_new_ae ]	Section Header: <i>Serious Adverse event</i> Is there any serious adverse event (SAE) since last visit?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
124	[ nano_sae_definition ]		descriptive (Attachment: Definition_Serious Adverse Event.pdf, Display format: Link)						
125	[ nano_sae_button ]  Show the field ONLY if: [nano_ae_new_ae] = '1'	Please fill a SAE form	descriptive						
126	[ nano_sae_new_pain ]  Show the field ONLY if:	Section Header: <i>Solicited adverse event at injection site</i> New pain	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								

	[event-name] = "1st_vaccination_arm_1" OR [event-name] = "visit_3_phone_arm_1" OR [event-name] = "visit_7_phone_arm_1" OR [event-name] = "visit_8_arm_1" or [event-name] = "visit_4_arm_1"						
127	[ nano_sae_new_tenderness ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "visit_3_phone_arm_1" OR [event-name] = "visit_7_phone_arm_1" OR [event-name] = "visit_8_arm_1" or [event-name] = "visit_4_arm_1"	New tenderness	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
128	[ nano_sae_new_erythema ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "visit_3_phone_arm_1" OR [event-name] = "visit_7_phone_arm_1" OR [event-name] = "visit_8_arm_1" or [event-name] = "visit_4_arm_1"	New erythema	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
129	[ nano_sae_new_swelling ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "visit_3_phone_arm_1" OR [event-name] = "visit_7_phone_arm_1" OR [event-name] = "visit_8_arm_1" or [event-name] = "visit_4_arm_1"	New swelling	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
130	[ nano_sae_button_2 ]  Show the field ONLY if: [nano_sae_new_pain] = '1' or [nano_sae_new_tenderness] = '1' or [nano_sae_new_erythema] = '1' or [nano_sae_new_swelling] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				

131	<div>[ nano_sae_unsolicited_ae_inj ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1'</div>	<div>Section Header: <i>Unsolicited adverse event at injection site</i></div> <div>Is there any new unsolicited adverse event at injection site?</div>	<div>yesno, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
132	<div>[ nano_sae_button_3 ]</div> <div>Show the field ONLY if: [nano_sae_unsolicited_ae_inj] = '1'</div>	Please fill a SAE form - Please fill a AE form	descriptive				
133	<div>[ nano_sae_new_headache ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1'</div>	<div>Section Header: <i>Solicited systemic adverse event</i></div> <div>New headache</div>	<div>yesno, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
134	<div>[ nano_sae_new_malaise ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1'</div>	New nausea/vomiting	<div>yesno, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
135	<div>[ nano_sae_new_diarrhea ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1'</div>	New diarrhea	<div>yesno</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
136	<div>[ nano_sae_new_myalgia ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-</div>	New Myalgia	<div>yesno, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	[name] <> 'visit_12_arm_1' and [event-name] <> 'visit_10_phone_arm_1' and [event-name] <> '2nd_vaccination_arm_1'						
137	<div>[ nano_sae_new_asthenia ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1'</div>	New Fatigue	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
138	<div>[ nano_sae_new_temp ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1'</div>	New Fever	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
139	<div>[ nano_sae_new_fever ]</div> <div>Show the field ONLY if: [nano_sae_new_temp] = "1"</div>	Axillary temperature	text (number_1dp, Min: 33, Max: 43), Required				
140	<div>[ nano_sae_button_4 ]</div> <div>Show the field ONLY if: [nano_sae_new_temp] = '1' or [nano_sae_new_headache] = '1' or [nano_sae_new_malaise] = '1' or [nano_sae_new_myalgia] = '1' or [nano_sae_new_asthenia] = '1' or [nano_sae_new_temp] = '1'</div>	Please fill a SAE form - Please fill a AE form	descriptive				
141	<div>[ nano_sae_unsolicited_sys_ae ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1' and [event-name] &lt;&gt; 'visit_10_phone_arm_1'</div>	<div>Section Header: <i>Unsolicited systemic adverse event</i></div> <div>Is there any new unsolicited systemic adverse event?</div>	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
142	[ nano_sae_button_5 ]	Please fill a SAE form - Please fill a AE form	descriptive				

	Show the field ONLY if: [nano_sae_unsolicited_sys_ae] = "1"								
143	[ nano_sae_unsolicited_ae ]  Show the field ONLY if: [event-name] = "visit_10_phone_arm_1" OR [event-name] = "visit_11_arm_1" OR [event-name] = "visit_12_arm_1"	Section Header: <i>Unsolicited adverse event</i>  Is there any new unsolicited adverse event ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
144	[ nano_sae_button_9 ]  Show the field ONLY if: [nano_sae_unsolicited_ae] = "1"	Please fill a SAE form - Please fill a AE form	descriptive						
145	[ adverse_events_complete ]	Section Header: <i>Form Status</i>  Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Current medication</b> (current_medication)									
146	[ dep_name6 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Research Physician	descriptive						
147	[ nano_cm_curr_medication ]  Show the field ONLY if: [event-name] = "screening_arm_1"	Is the volunteer currently taking medication (prescribed medication, over-the-counter drugs, complementary medicinal products) ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
148	[ nano_cm_fill_med ]  Show the field ONLY if: [nano_cm_curr_medication] = "1"	Please fill the medication form	descriptive						
149	[ nano_cm_contraceptive ]  Show the field ONLY if: [event-name] = "screening_arm_1" and [screening_arm_1][nano_vigender] = '2'	Has the volunteer used a continuous effective contraception since 4 weeks prior to screening)?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
150	[ nano_cm_contraceptive_spec ]	Please specify	radio, Required						



	Show the field ONLY if: [nano_cm_contraceptive] = '1'		<table><tr><td>1</td><td>Postmenopausal since at least 1 year</td></tr><tr><td>2</td><td>Surgically sterile (female or male partner)</td></tr><tr><td>3</td><td>Use of oral, injected or implanted hormonal contraception</td></tr><tr><td>4</td><td>Placement of an intrauterine device or intrauterine system</td></tr><tr><td>5</td><td>Barrier method of contraception (condom or occlusive cap with spermicide)</td></tr><tr><td>6</td><td>True abstinence</td></tr></table>	1	Postmenopausal since at least 1 year	2	Surgically sterile (female or male partner)	3	Use of oral, injected or implanted hormonal contraception	4	Placement of an intrauterine device or intrauterine system	5	Barrier method of contraception (condom or occlusive cap with spermicide)	6	True abstinence
1	Postmenopausal since at least 1 year														
2	Surgically sterile (female or male partner)														
3	Use of oral, injected or implanted hormonal contraception														
4	Placement of an intrauterine device or intrauterine system														
5	Barrier method of contraception (condom or occlusive cap with spermicide)														
6	True abstinence														
151	[ nano_cm_fill_med_2 ]  Show the field ONLY if: [nano_cm_contraceptive_spec] = "3" OR [nano_cm_contraceptive_spec] = "4"	Please fill the medication form	descriptive												
152	[ nano_cm_fill_med_3 ]  Show the field ONLY if: [nano_cm_contraceptive] = '0'	Please either consider postponement of vaccination if subject is willing to start a continuous effective contraception. Otherwise,complete the SCREEN FAILURE page	descriptive												
153	[ nano_sae_change_medication ]  Show the field ONLY if: [event-name] <> "screening_arm_1"	Is there any new or changed medication since the last visit?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
154	[ nano_sae_button_6 ]  Show the field ONLY if: [nano_sae_change_medication] = "1"	Please fill the medication form	descriptive												
155	[ nano_sae_vaccination ]  Show the field ONLY if: [event-name] <> "screening_arm_1"	Is there any vaccination since the last visit?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
156	[ nano_sae_vaccination_name ]  Show the field ONLY if: [nano_sae_vaccination] = '1'	Specify vaccine name	text, Required												
157	[ nano_sae_vaccination_date ]  Show the field ONLY if:	Date of vaccination	text (date_dmy), Required												

	[nano_sae_vaccination] = '1'								
158	[current_medication_complete]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Physical observations</b> (physical_observations)									
159	[dep_name7]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Research Physician	descriptive						
160	[nano_po_physical_exam_done]  Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> "screening_arm_1" and [event-name] <> '1st_vaccination_arm_1'	Has a physical examination been done?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
161	[nano_po_physical_exam_done_why]  Show the field ONLY if: ([nano_po_physical_exam_done] = "0" and [event-name] <> "visit_3_phone_arm_1") or ([event-name] = "visit_3_phone_arm_1" and [nano_po_physical_exam_done] = "1")	Specify why	text, Required						
162	[nano_po_height]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Body height <i>cm</i>	text (integer, Min: 0, Max: 220), Required						
163	[nano_po_weight]  Show the field ONLY if: ([event-name] = 'screening_arm_1' and [event-name] <> '2nd_vaccination_arm_1') or ([nano_po_physical_exam_done] = '1' and [event-name] <> '2nd_vaccination_arm_1')	Body weight <i>kg</i>	text (number, Min: 0, Max: 150), Required						

164	[ nano_po_bmi ] Show the field ONLY if: [event-name] = 'screening_arm_1'	BMI <i>kg/m2</i>	calc Calculation: [nano_po_weight]/([nano_po_height]/100)* ([nano_po_height]/100))
165	[ nano_po_temperature ] Show the field ONLY if: ([nano_po_physical_exam_done] = "1" or [event-name] = "2nd_vaccination_arm_1") or ([event-name] = "screening_arm_1") or ([event-name] = "1st_vaccination_arm_1")	Axillary temperature <i>°C</i>	text (number, Min: 00, Max: 42), Required
166	[ nano_po_sys_blood_pressure ] Show the field ONLY if: ([nano_po_physical_exam_done] = "1" or [event-name] = "2nd_vaccination_arm_1") or ([event-name] = "screening_arm_1") or ([event-name] = "1st_vaccination_arm_1")	Systolic blood pressure <i>mmHg</i>	text (integer, Min: 00, Max: 230), Required
167	[ nano_po_dia_blood_pressure ] Show the field ONLY if: ([nano_po_physical_exam_done] = "1" or [event-name] = "2nd_vaccination_arm_1") or ([event-name] = "screening_arm_1") or ([event-name] = "1st_vaccination_arm_1")	Diastolic blood pressure <i>mmHg</i>	text (integer, Min: 00, Max: 150), Required
168	[ nano_po_heart_rate ] Show the field ONLY if: ([nano_po_physical_exam_done] = "1" or [event-name] = "2nd_vaccination_arm_1") or ([event-name] = "screening_arm_1") or ([event-name] = "1st_vaccination_arm_1")	Heart rate <i>bpm</i>	text (integer, Min: 00, Max: 150), Required
169	[ dep_name16 ] Show the field ONLY if: [event-name] = "screening_arm_1" OR [event	Section Header: <i>Physical Examination</i> Research Physician	descriptive

	-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"		
170	[ nano_pe_cardiovascular ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [event-name] = '2nd_vaccination_arm_1' or [event-name] = '1st_vaccination_arm_1'	Cardiovascular	notes, Required
171	[ nano_pe_respiratory ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [event-name] = '2nd_vaccination_arm_1' or [event-name] = '1st_vaccination_arm_1'	Respiratory	notes, Required
172	[ nano_pe_gastrointestinal ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [event-name] = '2nd_vaccination_arm_1' or [event-name] = '1st_vaccination_arm_1'	Gastro-intestinal	notes, Required
173	[ nano_pe_dermatological ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [event-name] = '2nd_vaccination_arm_1' or [event-name] = '1st_vaccination_arm_1'	Dermatological	notes, Required
174	[ nano_pe_specify ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event	Other(s) : Specify	notes, Required

	-name] = 'screening_arm_1' or [event-name] = '2nd_vaccination_arm_1' or [event-name] = '1st_vaccination_arm_1'								
175	[ <b>physical_observations_complete</b> ]	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr><td>0</td><td>Incomplete</td></tr> <tr><td>1</td><td>Unverified</td></tr> <tr><td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
<b>Instrument: Laboratory analyses (laboratory_analyses)</b>									
176	[ <b>dep_name18</b> ]	Study nurse	descriptive						
177	[ <b>nano_la_blood_sample_date_collect</b> ]	Section Header: <i>Samples</i> Blood Sampling Date and Time	text (datetime_dmy), Required						
178	[ <b>nano_la_blood_sample_routine</b> ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' OR [event-name] = 'visit_9_arm_1' OR [event-name] = 'visit_11_arm_1'	Were the routine samples taken as per protocol ?	yesno, Required <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No		
1	Yes								
0	No								
179	[ <b>nano_la_rt_no</b> ]  Show the field ONLY if: [nano_la_blood_sample_routine] = '0'	Specify why	text, Required						
180	[ <b>nano_la_blood_sample_research</b> ]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1' OR [event-name] = '2nd_vaccination_arm_1' OR [event-name] = 'visit_9_arm_1' OR [event-name] = 'visit_11_arm_1' OR [event-name] = 'visit_12_arm_1'	Were the research samples taken as per protocol ?	yesno, Required <table border="1"> <tr><td>1</td><td>Yes</td></tr> <tr><td>0</td><td>No</td></tr> </table>	1	Yes	0	No		
1	Yes								
0	No								
181	[ <b>nano_la_rs_no</b> ]  Show the field ONLY if: [nano_la_blood_sample_research] = '0'	Specify why	text, Required						
182	[ <b>nano_la_deviation</b> ]	If necessary, please fill the following forms Please fill the minor protocol deviation form	descriptive						

	Show the field ONLY if: [nano_la_blood_sample_research] = '0'	- Please fill the major protocol deviation form									
183	[ nano_la_poc_sarscov2_antigen ]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1' or [event-name] = '2nd_vaccination_arm_1'	Section Header: <i>POC tests results</i>  SARS-CoV-2 rapid antigen test on nasopharyngeal swab	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative				
1	Positive										
2	Negative										
184	[ nano_la_poc_sarscov2_antigen_2 ]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1' or [event-name] = '2nd_vaccination_arm_1'	Oro-pharyngeal SARS-CoV-2 PCR test	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative				
1	Positive										
2	Negative										
185	[ nano_la_poc_pregnancy ]  Show the field ONLY if: ([screening_arm_1][nano_vi_gender] = '2' and [event-name] = '1st_vaccination_arm_1') OR ([screening_arm_1][nano_vi_gender] = '2' and [event-name] = '2nd_vaccination_arm_1')	Pregnancy test result	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative				
1	Positive										
2	Negative										
186	[ nano_la_poc_dengue_pos_3 ]  Show the field ONLY if: [nano_la_poc_pregnancy] = '1' and [event-name] = 'screening_arm_1'	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive								
187	[ nano_la_poc_dengue_pos_2 ]  Show the field ONLY if: ([nano_la_poc_pregnancy] = '1' and [event-name] = '2nd_vaccination_arm_1')	The volunteer CAN NOT BE VACCINATED. Please complete the END OF TRIAL page and the PREGNANCY form	descriptive								
188	[ nano_la_uri_hematuria ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Section Header: <i>Urine</i>  Hematuria	radio, Required <table><tr><td>a</td><td>0</td></tr><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	a	0	b	+	c	++	d	+++
a	0										
b	+										
c	++										
d	+++										

189	<div>[ nano_la_uri_proteins ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Proteins in urine	radio, Required <table><tr><td>a</td><td>0</td></tr><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	a	0	b	+	c	++	d	+++
a	0										
b	+										
c	++										
d	+++										
190	<div>[ nano_la_uri_glucose ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Glucose in urine	radio, Required <table><tr><td>a</td><td>0</td></tr><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	a	0	b	+	c	++	d	+++
a	0										
b	+										
c	++										
d	+++										
191	<div>[ nano_la_poc_urine_failure ]</div> <div>Show the field ONLY if: [nano_la_uri_hematuria] = 'b' or [nano_la_uri_hematuria] = 'c' or [nano_la_uri_hematuria] = 'd' or [nano_la_uri_proteins] = 'b' or [nano_la_uri_proteins] = 'c' or [nano_la_uri_proteins] = 'd' or [nano_la_uri_glucose] = 'b' or [nano_la_uri_glucose] = 'c' or [nano_la_uri_glucose] = 'd'</div>	Please repeat or, if clinically significant, directly complete the SCREEN FAILURE page	descriptive								
192	<div>[ nano_la_uri_pregnancy ]</div> <div>Show the field ONLY if: [nano_vi_gender] = '2' AND [event-name] = 'screening_arm_1'</div>	Pregnancy test result	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative				
1	Positive										
2	Negative										
193	<div>[ nano_la_uri_pregnant ]</div> <div>Show the field ONLY if: [nano_la_uri_pregnancy] = '1'</div>	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive								
194	<div>[ nano_la_hem_leukocytes ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div>	Section Header: <i>Hematology</i> Leukocytes <i>G/I - REF RANGE: 4 - 10</i>	text (number, Min: 0, Max: 100), Required								
195	<div>[ nano_la_oor ]</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes						
1	Yes										

	Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'		<table><tr><td>0</td><td>No</td></tr></table>	0	No		
0	No						
196	<div>[ nano_la_oor_deviation ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
197	<div>[ nano_la_oor_deviation_21 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
198	<div>[ nano_la_hem_erythrocytes ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Erythrocytes <i>T/I - REF RANGE: 4.4 - 5.8 (Male) - 3.8 - 5.2 (Female)</i>	text (number, Min: 0, Max: 15), Required				
199	<div>[ nano_la_oor_2 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
200	<div>[ nano_la_oor_deviation_2 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-na</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						



	me] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_2] = "1"						
201	<div>[ nano_la_oor_deviati on_22 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_2] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
202	<div>[ nano_la_hem_hemoglobin ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Hemoglobin <i>g/l - REF RANGE: 133 - 177 (male) - 117 - 157 (female)</i>	text (number), Required				
203	<div>[ nano_la_oor_3 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
204	<div>[ nano_la_oor_deviati on_3 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_3] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
205	<div>[ nano_la_oor_deviati on_23 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_3] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
206	[ nano_la_hem_hematocrit ]	Hematocrit <i>% - REF RANGE: 40 - 52 (male) - 35 - 47 (female)</i>	text (number), Required				

	Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
207	[ nano_la_oor_4 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
208	[ nano_la_oor_deviati on_4 ]  Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_4] = "1"	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
209	[ nano_la_oor_deviati on_24 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_4] = "1"	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
210	[ nano_la_hem_mcv ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'	MCV (Mean corpuscular volume) <i>fl - REF RANGE: 81 - 99</i>	text (number), Required				
211	[ nano_la_oor_5 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1'	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
212	<div>[ nano_la_oor_deviati on_5 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_5] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
213	<div>[ nano_la_oor_deviati on_25 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_5] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
214	<div>[ nano_la_hem_mch ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	MCH (Mean cell hemoglobin) <i>pg - REF RANGE: 27 - 34</i>	text (number, Min: 5, Max: 50), Required				
215	<div>[ nano_la_oor_6 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
216	<div>[ nano_la_oor_deviati on_6 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') a</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	nd [nano_la_oor_6] = "1"						
217	<div>[ nano_la_oor_deviati on_26 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_6] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
218	<div>[ nano_la_hem_mchc ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	MCHC (Mean corpuscular hemoglobin concentration) <i>g/l - REF RANGE: 310 - 360</i>	text (number), Required				
219	<div>[ nano_la_oor_7 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
220	<div>[ nano_la_oor_deviati on_7 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_7] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
221	<div>[ nano_la_oor_deviati on_27 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_7] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
222	<div>[ nano_la_hem_platelets ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-</div>	Platelets <i>G/l - REF RANGE: 150 - 350</i>	text (integer), Required				

	name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
223	<div>[ nano_la_oor_8 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
224	<div>[ nano_la_oor_deviaton_8 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_8] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
225	<div>[ nano_la_oor_deviaton_28 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_8] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
226	<div>[ nano_la_hem_neutro ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Neutrophils <i>G/I - REF RANGE: 1.8 - 7.5</i>	text (number), Required				
227	<div>[ nano_la_oor_9 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1"</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	m_1" or [event-name] = 'visit_9_arm_1'						
228	<div>[ nano_la_oor_deviati on_9 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_9] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
229	<div>[ nano_la_oor_deviati on_29 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_9] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
230	<div>[ nano_la_hem_lympho ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Lymphocytes <i>G/I - REF RANGE: 1.5 - 4</i>	text (number), Required				
231	<div>[ nano_la_oor_10 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
232	<div>[ nano_la_oor_deviati on_10 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_10] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
233	<div>[ nano_la_oor_deviati on_30 ]</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required				

	Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_10] = "1"		<table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
234	[ nano_la_hem_mono ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'	Monocytes <i>G/I - REF RANGE: 0.2 - 0.8</i>	text (number), Required				
235	[ nano_la_oor_11 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
236	[ nano_la_oor_deviaton_11 ]  Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_11] = "1"	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
237	[ nano_la_oor_deviaton_31 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_11] = "1"	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
238	[ nano_la_hem_eosino ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'	Eosinophils <i>G/I - REF RANGE: 0.05 - 0.5</i>	text (number), Required				

239	<div>[ nano_la_oor_12 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
240	<div>[ nano_la_oor_deviati on_12 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_12] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
241	<div>[ nano_la_oor_deviati on_32 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_12] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
242	<div>[ nano_la_hem_baso ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Basophils <i>G/I - REF RANGE: 0.01 - 0.05</i>	text (number), Required
243	<div>[ nano_la_oor_13 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
244	<div>[ nano_la_oor_deviati on_13 ]</div> <div>Show the field ONLY if:</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <div><div>1Yes</div><div>0No</div></div>



	<p>[(event-name) = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_13] = "1"</p>						
245	<p>[ nano_la_oor_deviati on_33 ]</p> <p>Show the field ONLY if:</p> <p>[event-name] = 'screening_arm_1' and [nano_la_oor_13] = "1"</p>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
246	<p>[ nano_la_bio_creatinine ]</p> <p>Show the field ONLY if:</p> <p>[event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</p>	Section Header: <i>Biochemistry</i>  Creatinine <i>μmol/ - REF RANGE: 62-106 (male) - 44 - 80 (female)</i>	text (integer), Required				
247	<p>[ nano_la_oor_14 ]</p> <p>Show the field ONLY if:</p> <p>[event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</p>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
248	<p>[ nano_la_oor_deviati on_14 ]</p> <p>Show the field ONLY if:</p> <p>[(event-name) = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_14] = "1"</p>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
249	<p>[ nano_la_oor_deviati on_34 ]</p> <p>Show the field ONLY if:</p> <p>[event-name] = 'screening_arm_1' and [nano_la_oor_14] = "1"</p>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

250	<div>[ nano_la_bio_bilirubin ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div>	Total bilirubin <i>μmol/l - REF RANGE: 0 - 21</i>	text (integer), Required				
251	<div>[ nano_la_oor_19 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
252	<div>[ nano_la_oor_deviation_19 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1') and [nano_la_oor_19] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
253	<div>[ nano_la_oor_deviation_39 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_19] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
254	<div>[ nano_la_bio_c_reactive ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div>	C reactive protein <i>mg/l - REF RANGE: &lt; 10</i>	text, Required				
255	<div>[ nano_la_oor_20 ]</div> <div>Show the field ONLY if:</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes		
1	Yes						

	[event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'		<table><tr><td>0</td><td>No</td></tr></table>	0	No		
0	No						
256	<div><div>[ nano_la_oor_deviati on_20 ]</div><div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1') and [nano_la_oor_20] = "1"</div></div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
257	<div><div>[ nano_la_oor_deviati on_40 ]</div><div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_20] = "1"</div></div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
258	<div><div>[ nano_la_bio_ast ]</div><div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div></div>	AST <i>UI/I - REF RANGE: 9 - 50</i>	text (integer), Required				
259	<div><div>[ nano_la_oor_15 ]</div><div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'</div></div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
260	<div><div>[ nano_la_oor_deviati on_15 ]</div><div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1')</div></div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	<p>_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_15] = "1"</p>						
261	<p>[ nano_la_oor_deviati on_35 ]</p> <p>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_15] = "1"</p>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
262	<p>[ nano_la_bio_alt ]</p> <p>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</p>	ALT <i>UI/I - REF RANGE: 9 - 50</i>	text (integer), Required				
263	<p>[ nano_la_oor_16 ]</p> <p>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'</p>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
264	<p>[ nano_la_oor_deviati on_16 ]</p> <p>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_16] = "1"</p>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
265	<p>[ nano_la_oor_deviati on_36 ]</p> <p>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_16] = "1"</p>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
266	<p>[ nano_la_bio_gct ]</p> <p>Show the field ONLY if:</p>	GGT <i>UI/I - REF RANGE: 6 - 42</i>	text (integer), Required				

	[event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'						
267	[ nano_la_oor_18 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
268	[ nano_la_oor_deviation_18 ]  Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1') and [nano_la_oor_18] = "1"	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
269	[ nano_la_oor_deviation_38 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_18] = "1"	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
270	[ nano_la_bio_alka ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'	Alkaline phosphatase <i>UI/I - REF RANGE: 36 - 120</i>	text (integer), Required				
271	[ nano_la_oor_17 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = 'visit_8_arm_1' or [event-name] = 'visit_9_arm_1'	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	nt-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
272	<div>[ nano_la_oor_deviati on_17 ]</div> <div>Show the field ONLY if: ([event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1') and [nano_la_oor_17] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
273	<div>[ nano_la_oor_deviati on_37 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_17] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
274	<div>[ nano_la_sero_aghbs ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Section Header: <i>Serologies</i> AgHbs	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative
1	Positive						
2	Negative						
275	<div>[ nano_la_sero_anti_hbc ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Antibodies anti-Hbc	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative
1	Positive						
2	Negative						
276	<div>[ nano_la_sero_anti_hcv ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Anti-HCV antibodies	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative
1	Positive						
2	Negative						
277	<div>[ nano_la_sero_hiv ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	HIV antibodies	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative
1	Positive						
2	Negative						
278	<div>[ nano_la_screen_failure ]</div> <div>Show the field ONLY if: [nano_la_sero_aghbs] = "1" OR [nano_la_sero_anti_hbc] = "1" OR [nano_la_sero_anti_hcv] = "1" OR [nano_la_sero_hiv] = "1"</div>	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				

279	<div>[ nano_la_anti_nuclear ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' or [event-name] = "visit_11_arm_1"</div>	<div>Section Header: <i>Autoimmune reactions</i></div> <div>Anti-nuclear antibodies</div> <div><i>Titer - REF RANGE &lt; 1/80</i></div>	text, Required				
280	<div>[ nano_la_oor_21 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' or [event-name] = "visit_11_arm_1"</div>	Is this value out of range?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
281	<div>[ nano_la_oor_deviation_41 ]</div> <div>Show the field ONLY if: [event-name] = "visit_11_arm_1" and [nano_la_oor_21] = "1"</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
282	<div>[ nano_la_oor_deviation_42 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_21] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
283	<div>[ dep_name8 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1' or [event-name] = 'visit_11_arm_1'</div>	<div>Section Header: <i>Deviation from normal ranges</i></div> <div>Research Physician</div>	descriptive				
284	<div>[ nano_lab_severity_grade ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1' OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1' or [event-name] = 'visit_11_arm_1'</div>		descriptive (Attachment: Severity grading for abnormal laboratory measures.pdf, Display format: Link) Field Annotation: @HIDDEN				

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	on_37] = "1" or [nano_la_oor_deviation_38] = "1" or [nano_la_oor_deviation_39] = "1" or [nano_la_oor_deviation_40] = "1") and [event-name] = "screening_arm_1"						
286	[ nano_la_comment ]	Any comment ?	radio <table><tr><td>1</td><td>Yes {nano_la_comment_2}</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes {nano_la_comment_2}	2	No
1	Yes {nano_la_comment_2}						
2	No						
287	[ nano_la_comment_2 ]  Show the field ONLY if: [nano_la_comment] = '1'		notes				
288	[ nano_la_list ]  Show the field ONLY if: ([nano_la_oor_deviation] = "1" or [nano_la_oor_deviation_2] = "1" or [nano_la_oor_deviation_3] = "1" or [nano_la_oor_deviation_4] = "1" or [nano_la_oor_deviation_5] = "1" or [nano_la_oor_deviation_6] = "1" or [nano_la_oor_deviation_7] = "1" or [nano_la_oor_deviation_8] = "1" or [nano_la_oor_deviation_9] = "1" or [nano_la_oor_deviation_10] = "1" or [nano_la_oor_deviation_11] = "1" or [nano_la_oor_deviation_12] = "1" or [nano_la_oor_deviation_13] = "1" or [nano_la_oor_deviation_14] = "1" or [nano_la_oor_deviation_15] = "1" or [nano_la_oor_deviation_16] = "1" or [nano_la_oor_deviation_17] = "1" or [nano_la_oor_deviation_18] = "1" or [nano_la_oor_deviation_19] = "1" or [nano_la_oor_deviation_20] = "1" or [nano_la_oor_deviation_21] = "1" or [nano_la_oor_deviation_22] = "1" or [nano_la_oor_deviation_23] = "1" or [nano_la_oor_deviation_24] = "1" or [nano_la_oor_deviation_25] = "1" or [nano_la_oor_deviation_26] = "1" or [nano_la_oor_deviation_27] = "1" or [nano_la_oor_deviation_28] = "1" or [nano_la_oor_deviation_29] = "1" or [nano_la_oor_deviation_30] = "1" or [nano_la_oor_deviation_31] = "1" or [nano_la_oor_deviation_32] = "1" or [nano_la_oor_deviation_33] = "1" or [nano_la_oor_deviation_34] = "1" or [nano_la_oor_deviation_35] = "1" or [nano_la_oor_deviation_36] = "1" or [nano_la_oor_deviation_37] = "1" or [nano_la_oor_deviation_38] = "1" or [nano_la_oor_deviation_39] = "1" or [nano_la_oor_deviation_40] = "1")	Complete/update the appropriate AE / SAE form(s) SAE form - AE form Ensure to provide an appropriate clinical management Assess if the patient is still eligible for the trial. If not, complete the END OF TRIAL page.	descriptive				

	r_deviation_26] = "1" or [nano_la_oor_deviation_27] = "1" or [nano_la_oor_deviation_28] = "1" or [nano_la_oor_deviation_29] = "1" or [nano_la_oor_deviation_30] = "1" or [nano_la_oor_deviation_31] = "1" or [nano_la_oor_deviation_32] = "1" or [nano_la_oor_deviation_33] = "1" or [nano_la_oor_deviation_34] = "1" or [nano_la_oor_deviation_35] = "1" or [nano_la_oor_deviation_36] = "1" or [nano_la_oor_deviation_37] = "1" or [nano_la_oor_deviation_38] = "1" or [nano_la_oor_deviation_39] = "1" or [nano_la_oor_deviation_40] = "1") and [event-name] <> "screening_arm_1"								
289	[ laboratory_analyses_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: Contraception (contraception)									
290	[ dep_name9 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Research Physician	descriptive						
291	[ nano_sae_contraception ]  Show the field ONLY if: [screening_arm_1][nano_vi_gender] = '2'	Has the volunteer used a continuous effective contraception since the last visit ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								

292	<div>[ nano_sae_contraception_specify ]</div> <div>Show the field ONLY if: [nano_sae_contraception] = "1"</div>	Please specify	radio, Required <table><tr><td>a</td><td>oral, injected or implanted hormonal methods</td></tr><tr><td>b</td><td>Intrauterine device (IUD)</td></tr><tr><td>c</td><td>Barrier methods (condom or occlusive cap with spermicide)</td></tr><tr><td>d</td><td>Male (partner) or female (self) sterilization.</td></tr><tr><td>e</td><td>True abstinence</td></tr></table>	a	oral, injected or implanted hormonal methods	b	Intrauterine device (IUD)	c	Barrier methods (condom or occlusive cap with spermicide)	d	Male (partner) or female (self) sterilization.	e	True abstinence
a	oral, injected or implanted hormonal methods												
b	Intrauterine device (IUD)												
c	Barrier methods (condom or occlusive cap with spermicide)												
d	Male (partner) or female (self) sterilization.												
e	True abstinence												
293	<div>[ nano_c_text_2 ]</div> <div>Show the field ONLY if: [nano_sae_contraception_specify] = "a" OR [nano_sae_contraception_specify] = "b"</div>	Update the medication form if needed	descriptive										
294	<div>[ nano_c_text ]</div> <div>Show the field ONLY if: [nano_sae_contraception] = "1"</div>	Contraception has to be continued until Day 90.	descriptive										
295	<div>[ nano_c_screen_failure ]</div> <div>Show the field ONLY if: [nano_sae_contraception] = "0" AND [event-name] = '1st_vaccination_arm_1'</div>	If no contraception was used in the past 4 weeks, the subject cannot be vaccinated. Please consider postponement of vaccination or complete the SCREEN FAILURE page	descriptive										
296	<div>[ nano_c_text_3 ]</div> <div>Show the field ONLY if: [nano_sae_contraception] = "0" AND [screening_arm_1][nano_vi_gender] = "2" AND [event-name] &lt;&gt; 'visit_12_arm_1'</div>	Proceed to a pregnancy test and assess with the PI if the participant can continue the trial. If indicated, fill the END OF TRIAL form. END OF TRIAL form	descriptive										
297	<div>[ nano_sae_contraception_preg_test_date ]</div> <div>Show the field ONLY if: [screening_arm_1][nano_vi_gender] = '2' and [event-name] &lt;&gt; '1st_vaccination_arm_1' and [nano_sae_contraception] = '0'</div>	Pregnancy test Date	text (date_dmy), Required										
298	<div>[ nano_sae_contraception_preg_test_result ]</div> <div>Show the field ONLY if:</div>	Pregnancy test result	radio, Required <table><tr><td>1</td><td>Positive</td></tr><tr><td>2</td><td>Negative</td></tr></table>	1	Positive	2	Negative						
1	Positive												
2	Negative												

	[screening_arm_1][nano_vi_gender] = '2' and [event-name] <> '1st_vaccination_arm_1' and [nano_sae_contraception] = '0'								
299	[ nano_c_text_4 ]  Show the field ONLY if: [nano_sae_contraception_preg_test_result] = '1'	Please fill the the PREGNANCY form	descriptive						
300	[ contraception_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Eligibility</b> (eligibility)									
301	[ dep_name10 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Research Physician (except prescription form)	descriptive						
302	[ nano_e_text ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Pre-eligibility	descriptive						
303	[ nano_e_text_2 ]  Show the field ONLY if: [event-name] <> 'screening_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_5_arm_1'	Review of eligibility	descriptive						
304	[ nano_e_aged ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Section Header: <i>Inclusion criteria</i> Aged 18 to 45 years	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
305	[ nano_e_consent ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1"	Provide written informed consent	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								

	on_arm_1" OR [event-name] = "2nd_vaccination_arm_1"						
306	<div>[ nano_e_able_willing ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Residing in Switzerland	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
307	<div>[ nano_e_failure ]</div> <div>Show the field ONLY if: [nano_e_aged] = '0' or [nano_e_consent] = '0' or [nano_e_able_willing] = '0'</div>	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
308	<div>[ nano_e_chronic ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Section Header: <i>Exclusion criteria</i>  Chronic illness that is at a stage where it might interfere with trial conduct or completion	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
309	<div>[ nano_e_addiction ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Current alcohol abuse or drug addiction (reported or suspected)	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
310	<div>[ nano_e_congenital ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Known or suspected congenital or acquired immunodeficiency or receipt of immunosuppressive therapy	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
311	<div>[ nano_e_hypersensitivity ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-</div>	Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening reaction to vaccines	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	[name] = "2nd_vaccination_arm_1"						
312	<div>[ nano_e_trombo ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Thrombocytopenia or any coagulation disorder	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
313	<div>[ nano_e_pregnancy ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Pregnancy or lactating or childbearing potential (NON-use of an effective method of contraception* from at least 4 weeks prior to the first vaccination until at least 10 weeks after the last vaccination)*Postmenopausal for at least 1 year, surgically sterile (female or male partner), use of oral, injected or implanted hormonal methods of contraception, placement of an intrauterine device (IUD) or intrauterine system (IUS), barrier methods of contraception (condom or occlusive cap with spermicide), true abstinence	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
314	<div>[ nano_e_other_clinical_trial ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Participation in another clinical trial investigating a vaccine, drug, medical device or medical procedure in the 4 weeks preceding the first vaccination, or planned participation during the study period	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
315	<div>[ nano_e_covid ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	SARS-CoV-2 clinical disease confirmed by antigenic or PCR test in the 4 weeks preceding the first trial vaccination	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
316	<div>[ nano_e_other_vaccine ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Receipt of any vaccine (including vaccination against COVID) in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received up to 2 weeks before first study vaccine) or planned receipt of any vaccine in the 4 weeks following each trial vaccination	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
317	<div>[ nano_e_immuno ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event</div>	Receipt of immunoglobulins, blood or blood-derived products in the past 3 months	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

	-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"						
318	[ nano_e_hiv ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
319	[ nano_e_linked_w_study ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Identified as an Investigator or employee of the Investigator or study centre with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural or adopted child) of the Investigator or employee with direct involvement in the proposed study (i.e. in the employment of the Tropivac clinic or DFRI unit at Unisanté)	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
320	[ nano_e_refusal ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Refusal to be informed in the event that relevant results concerning the participant's health are revealed.	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
321	[ nano_e_not_enrolled_2 ]  Show the field ONLY if: ([nano_e_chronic] = '1' or [nano_e_addiction] = '1' or [nano_e_congenital] = '1' or [nano_e_hypersensitivity] = '1' or [nano_e_trombo] = '1' or [nano_e_pregnancy] = '1' or [nano_e_other_clini_trial] = '1' or [nano_e_other_vaccine] = '1' or [nano_e_immuno] = '1' or [nano_e_hiv] = '1' or [nano_e_linked_w_study] = '1' or [nano_e_refusal] = '1' or [nano_e_covid] = '1') and [event-name] <> '2nd_vaccination_arm_1'	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
322	[ nano_e_not_enrolled_5 ]	The volunteer IS NOT ELIGIBLE anymore. Please complete the END OF TRIAL page.	descriptive				

	Show the field ONLY if: ([nano_e_chronic] = '1' or [nano_e_addiction] = '1' or [nano_e_congenital] = '1' or [nano_e_hypersensitivity] = '1' or [nano_e_trombo] = '1' or [nano_e_pregnancy] = '1' or [nano_e_other_clini_trial] = '1' or [nano_e_other_vaccine] = '1' or [nano_e_immuno] = '1' or [nano_e_hiv] = '1' or [nano_e_linked_w_study] = '1' or [nano_e_refusal] = '1' or [nano_e_covid] = '1') and [event-name] <> '2nd_vaccination_arm_1'										
323	[ nano_e_text_3 ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Pre-eligibility	descriptive								
324	[ nano_e_text_4 ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Exclusion criteria at the time of vaccination	descriptive								
325	[ nano_e_pre_date ]  Show the field ONLY if: [event-name] = "screening_arm_1"	Date of pre-eligibility verification	text (date_dmy), Required								
326	[ nano_e_pre ]  Show the field ONLY if: [event-name] = "screening_arm_1"	Is the volunteer pre-eligible for this trial?	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>Yes</td></tr><tr><td>b</td><td>Volunteer is definitely not eligible</td></tr><tr><td>c</td><td>All data are NOT yet available and eligibility will be re-considered before vaccination.</td></tr></table>	radio, Required		a	Yes	b	Volunteer is definitely not eligible	c	All data are NOT yet available and eligibility will be re-considered before vaccination.
radio, Required											
a	Yes										
b	Volunteer is definitely not eligible										
c	All data are NOT yet available and eligibility will be re-considered before vaccination.										
327	[ nano_e_prescription_form_2 ]  Show the field ONLY if: [nano_e_pre] = "a" and [event-name] = "screening_arm_1"	Go to Prescription form	descriptive								
328	[ nano_e_not_enrolled_3 ]  Show the field ONLY if: [nano_e_pre] = 'b'	Please complete the SCREEN FAILURE page	descriptive								



329	<div>[ nano_e_temp_above_375 ]</div> <div>Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Does the patient have a temperature of >37.5°C today ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
330	<div>[ nano_e_other_disease ]</div> <div>Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Does the patient have a moderate or severe acute disease today ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
331	<div>[ nano_e_other_disease_specify ]</div> <div>Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" and [nano_e_other_disease] = '1'</div>	Specify	text, Required				
332	<div>[ nano_e_temp_above_375_message ]</div> <div>Show the field ONLY if: [nano_e_temp_above_375] = '1' or [nano_e_other_disease] = '1'</div>	Vaccination is contraindicated today. Assess if the subject may be vaccinated at a later date, or complete the SCREEN FAILURE page	descriptive				
333	<div>[ nano_e_final_eligibility ]</div> <div>Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"</div>	Section Header: <i>Final Eligibility</i>  For the subjects who were pre-eligible at Visit 1, is the volunteer still eligible to continue with the trial?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
334	<div>[ nano_e_final_eligibility_2 ]</div> <div>Show the field ONLY if: [event-name] = "2nd_vaccination_arm_1"</div>	For the subjects who were eligible at Visit 2, is the volunteer still eligible to continue with the trial?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
335	<div>[ nano_e_not_enrolled ]</div> <div>Show the field ONLY if: [nano_e_final_eligibility] = '0' AND [event-name] &lt;&gt; 'screening_arm_1' AND [event-name] &lt;&gt; '1st_vaccination_arm_1'</div>	Complete the END OF TRIAL FORM	descriptive				
336	<div>[ nano_e_not_enrolled_6 ]</div>	The volunteer IS NOT ELIGIBLE anymore. Complete the END OF TRIAL page.	descriptive				

	Show the field ONLY if: [nano_e_final_eligibility_2] = '0'						
337	[ nano_e_not_final_eligibility ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"	For the subjects who were not yet eligible at Visit 1, is the volunteer now eligible?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
338	[ nano_e_not_enrolled_4 ]  Show the field ONLY if: [nano_e_final_eligibility] = '0' OR [nano_e_not_final_eligibility] = '0'	The volunteer CAN NOT BE ENROLLED in the trial, please STOP and complete the SCREEN FAILURE page	descriptive				
339	[ nano_e_proceed ]  Show the field ONLY if: [nano_e_final_eligibility] = '1' AND [nano_e_not_final_eligibility] = '1'	Proceed to vaccination	descriptive				
340	[ nano_e_proceed_2 ]  Show the field ONLY if: [nano_e_final_eligibility_2] = '1'	Proceed to vaccination n°2.	descriptive				
341	[ nano_e_still_eligible ]  Show the field ONLY if: [event-name] <> "1st_vaccination_arm_1" AND [event-name] <> "screening_arm_1" and [event-name] <> "2nd_vaccination_arm_1"	Is the volunteer still eligible to continue with the trial ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
342	[ nano_e_prescription_form ]  Show the field ONLY if: [nano_e_still_eligible] = "1" and [event-name] = "visit_5_arm_1"	Go to Prescription form	descriptive				
343	[ nano_e_button_end ]  Show the field ONLY if: [nano_e_still_eligible] = "0"	Complete the END OF TRIAL FORM	descriptive				
344	[ eligibility_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr></table>	0	Incomplete	1	Unverified
0	Incomplete						
1	Unverified						

			2	Complete				
Instrument: Vaccine administration (vaccine_administration)								
345	[ dep_name11 ]	Research Physician	descriptive					
346	[ nano_va_been_vac ]	Has the volunteer been vaccinated ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>		1	Yes	0	No
1	Yes							
0	No							
347	[ nano_va_been_vac_spec ]  Show the field ONLY if: [nano_va_been_vac] = '0'	Specify	text, Required					
348	[ nano_va_vac_batch_number ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Lot number	text, Required					
349	[ nano_va_vac_number ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Randomization number	text (integer), Required					
350	[ nano_va_vac_dose ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Dose	radio <table><tr><td>LD</td><td>Low dose</td></tr><tr><td>HD</td><td>High dose</td></tr></table>		LD	Low dose	HD	High dose
LD	Low dose							
HD	High dose							
351	[ nano_va_vac_date ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Date and Time of vaccination	text (datetime_dmy)					
352	[ nano_va_vac_arm ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Injection site : arm (intradermal)	radio <table><tr><td>1</td><td>Left</td></tr><tr><td>2</td><td>Right</td></tr></table>		1	Left	2	Right
1	Left							
2	Right							
353	[ nano_va_vac_problem ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Any problem with the injection?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>		1	Yes	0	No
1	Yes							
0	No							
354	[ nano_va_vac_problem_specify ]  Show the field ONLY if: [nano_va_vac_problem] = "1"	Specify* *No papule, IMP leakage from the needle...	text					

355	[ vaccine_administration_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: 60 minutes post vaccination assessment (minutes_post_vaccination_assessment)									
356	[ dep_name12 ]	Study nurse - Refer to Research Physician if needed.	descriptive						
357	[ nano_60_post_axillary ]	Section Header: <i>Physical observation</i> Axillary temperature	text (number, Min: 33, Max: 43)						
358	[ nano_60_post_systolic ]	Systolic blood pressure	text (integer, Min: 50, Max: 230)						
359	[ nano_60_post_diastolic ]	Diastolic blood pressure	text (integer, Min: 20, Max: 150)						
360	[ nano_60_post_heart ]	Heart rate	text (integer, Min: 35, Max: 150)						
361	[ nano_60_post_title_2 ]	Adverse events	descriptive						
362	[ nano_60_post_sae ]	Is there any adverse event (SAE)?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
363	[ post_sae_def ]		descriptive (Attachment: Definition_Serious Adverse Event.pdf, Display format: Link)						
364	[ nano_60_post_sae_y ]  Show the field ONLY if: [nano_60_post_sae] = "1"	Please fill a SAE form	descriptive						
365	[ nano_60_post_pain ]	Section Header: <i>Solicited adverse event at injection site</i> Pain	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
366	[ nano_60_post_tenderness ]	Tenderness	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
367	[ nano_60_post_erythema ]	Erythema	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
368	[ nano_60_post_swelling ]	Swelling	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
369	[ nano_60_post_sae_y_2 ]  Show the field ONLY if: [nano_60_post_pain] = '1' OR [nano_60_post_tenderness] = '1' OR [nano_60_post_erythema]	Please fill a SAE form - Please fill a AE form	descriptive						

	a] = '1' OR [nano_60_post_swelling] = '1'						
370	[ nano_60_post_any_unsolicited ]	Section Header: <i>Unsolicited adverse event at injection site</i> Is there any unsolicited adverse event at injection site?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
371	[ nano_60_post_sae_y_4 ]  Show the field ONLY if: [nano_60_post_any_unsolicited] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				
372	[ nano_60_post_nausea ]	Section Header: <i>Solicited systemic adverse event</i> Nausea/vomiting	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
373	[ nano_60_post_diarrhea ]	Diarrhea	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
374	[ nano_60_post_headache ]	Headache	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
375	[ nano_60_post_asthenia ]	Fatigue	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
376	[ nano_60_post_myalgia ]	Myalgia	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
377	[ nano_60_post_fever ]	Fever	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
378	[ nano_60_post_axillary_temp ]  Show the field ONLY if: [nano_60_post_fever] = "1"	Axillary temperature	text				
379	[ nano_60_post_sae_y_3 ]  Show the field ONLY if: [nano_60_post_headache] = '1' or [nano_60_post_myalgia] = '1' or [nano_60_post_asthenia] = '1' or [nano_60_post_fever] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				
380	[ nano_60_post_any_unsolicited_system ]	Section Header: <i>Unsolicited systemic adverse event</i> Is there any unsolicited systemic adverse event?	yesno <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes		
1	Yes						

			<table><tr><td>0</td><td>No</td></tr></table>	0	No				
0	No								
381	<div>[ nano_60_post_sae_y_5 ]</div> <div>Show the field ONLY if: [nano_60_post_any_unsolicited_system] = '1'</div>	Please fill a SAE form - Please fill a AE form	descriptive						
382	<div>[ minutes_post_vaccination_assessment_complete ]</div>	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Diary card</b> (diary_card)									
383	<div>[ dep_name17 ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"</div>	Study nurse	descriptive						
384	<div>[ nano_d_collect ]</div> <div>Show the field ONLY if: [event-name] = "visit_5_arm_1" OR [event-name] = "visit_9_arm_1"</div>	Collect the diary card	descriptive						
385	<div>[ nano_d_diary_card_given ]</div> <div>Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"</div>	Diary card given to the subject	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
386	<div>[ nano_d_specify ]</div> <div>Show the field ONLY if: [nano_d_diary_card_given] = '0'</div>	Specify why	text						
387	<div>[ nano_d_diary_card_given_2 ]</div> <div>Show the field ONLY if: [event-name] = "2nd_vaccination_arm_1"</div>	Diary card n°2 given to the subject	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
388	<div>[ nano_d_specify_2 ]</div> <div>Show the field ONLY if: [nano_d_diary_card_given_2] = '0'</div>	Specify why	text						
389	<div>[ nano_d_thermometer_given ]</div>	Thermometer given to te subject	yesno <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes				
1	Yes								

	Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"		<table><tr><td>0</td><td>No</td></tr></table>	0	No				
0	No								
390	[ nano_d_ruler_given ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"	Ruler given to the subject	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
391	[ nano_d_text ]  Show the field ONLY if: [event-name] <> 'visit_5_arm_1' and [event-name] <> 'visit_9_arm_1'	Remind the subject to measure axillary temperature, erythema or swelling at the injection site, to record adverse events and to bring daily diary at next visit.	descriptive						
392	[ diary_card_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Protocol deviation</b> (protocol_deviation)									
393	[ dep_name13 ]  Show the field ONLY if: [event-name] <> "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Study nurse - Refer to the Research Physician if needed.	descriptive						
394	[ nano_e_protocol_deviation ]	Section Header: <i>Protocol deviation</i> Is there a protocol deviation ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
395	[ nano_pd_button ]  Show the field ONLY if: [nano_e_protocol_deviation] = "1"	Please fill the minor protocol deviation form	descriptive						
396	[ nano_pd_button_2 ]  Show the field ONLY if: [nano_e_protocol_deviation] = "1"	Please fill the major protocol deviation form	descriptive						
397	[ protocol_deviation_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Additional comment</b> (additionnal_comment)									
398	[ dep_name14 ]	Section Header: <i>Additional comment</i> Study Nurse	descriptive						

	Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"								
399	[ nano_ac_add_comment ]  Show the field ONLY if: [nano_ac_add_comment] = '1'	Any additional comment ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
400	[ nano_ac_add_comment_prec ]  Show the field ONLY if: [nano_ac_add_comment] = '1'	Specify	notes						
401	[ additionnal_comment_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

**Instrument: Compensation (compensation\_43a693)**

402	<div>[ nano_ac_chf ]</div> <div>Show the field ONLY if: [event-name]='1st_vaccination_arm_1' OR [event-name]='visit_4_arm_1' OR [event-name]='visit_5_arm_1' OR [event-name]='2nd_vaccination_arm_1' OR [event-name]='visit_8_arm_1' OR [event-name]='visit_9_arm_1' OR [event-name]='visit_11_arm_1' OR [event-name]='visit_12_arm_1'</div>	<div>Section Header: <i>Compensation</i></div> <div>Compensation given (100CHF) ?</div>	<div>yesno</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
403	<div>[ nano_ac_chf_date ]</div> <div>Show the field ONLY if: [nano_ac_chf] = '1'</div>	<div>Date</div>	<div>text (date_dmy)</div>						
404	<div>[ nano_ac_chf_reason ]</div> <div>Show the field ONLY if: [nano_ac_chf] = '0'</div>	<div>If no, why ?</div>	<div>text</div>						
405	<div>[ compensation_43a693_complete ]</div>	<div>Section Header: <i>Form Status</i></div> <div>Complete?</div>	<div>dropdown</div> <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

**Instrument: Next visit (next\_visit)**



406	[ dep_name15 ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Section Header: <i>Next Visit</i>  Study nurse	descriptive						
407	[ nano_nv_date_next_visit ]	Date of next visit	text (datetime_dmy)						
408	[ nano_nv_send_sms ]	Send the reminder by SMS ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
409	[ next_visit_complete ]	Section Header: <i>Form Status</i>  Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Adverse Event</b> (adverse_event)									
410	[ nano_ae_custom_record_id ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF						
411	[ nano_ae_number ]	Adverse Event Number	text, Required						
412	[ nano_ae_id ]	Inclusion ID	text, Required						
413	[ nano_ae_date_contained ]	Date of onset {nano_ae_date} {nano_ae_date_unknown}	descriptive						
414	[ nano_ae_date_unknown ]	Date unknown	checkbox <table><tr><td>1</td><td>nano_ae_date_unknown__1</td><td>Date unknown</td></tr></table>	1	nano_ae_date_unknown__1	Date unknown			
1	nano_ae_date_unknown__1	Date unknown							
415	[ nano_ae_date ]	Date of onset	text (date_dmy)						
416	[ nano_ae_term ]	Section Header: <i>Adverse Event Description</i>  AE term	text						
417	[ nano_ae_description ]	Adverse Event description	notes, Required						
418	[ nano_ae_sae ]	Is this a serious adverse event* ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
419	[ nano_ae_sae_definition ]		descriptive (Attachment: Definition_Serious Adverse Event.pdf, Display format: Link)						
420	[ nano_ae_sae_todo ]  Show the field ONLY if: [nano_ae_sae] = "1"	Please complete a SAE form and do not complete this AE form. SAE form	descriptive						
421	[ nano_ae_solicited ]	Which type of AE is it ?	radio, Required <table><tr><td>1</td><td>Solicited AE</td></tr><tr><td>2</td><td>Unsolicited AE related with an abnormal laboratory value</td></tr></table>	1	Solicited AE	2	Unsolicited AE related with an abnormal laboratory value		
1	Solicited AE								
2	Unsolicited AE related with an abnormal laboratory value								

			3Unsolicited AE																					
422	[ nano_ae_toxicity ]  Show the field ONLY if: [nano_ae_solicited] = "1"	FDA toxicity grading scale term	dropdown, Required <table><tr><td>1</td><td>Pain</td></tr><tr><td>2</td><td>Tenderness</td></tr><tr><td>3</td><td>Erythema/Redness</td></tr><tr><td>4</td><td>Induration/Swelling</td></tr><tr><td>5</td><td>Nausae/Vomiiting</td></tr><tr><td>6</td><td>Diarrhea</td></tr><tr><td>7</td><td>Headache</td></tr><tr><td>8</td><td>Fatigue</td></tr><tr><td>9</td><td>Myalgia</td></tr><tr><td>10</td><td>Fever</td></tr></table>		1	Pain	2	Tenderness	3	Erythema/Redness	4	Induration/Swelling	5	Nausae/Vomiiting	6	Diarrhea	7	Headache	8	Fatigue	9	Myalgia	10	Fever
1	Pain																							
2	Tenderness																							
3	Erythema/Redness																							
4	Induration/Swelling																							
5	Nausae/Vomiiting																							
6	Diarrhea																							
7	Headache																							
8	Fatigue																							
9	Myalgia																							
10	Fever																							
423	[ nano_ae_fda_tox_grade_2 ]  Show the field ONLY if: [nano_ae_solicited] = "1"	AE grade according to adapted FDA toxicity grading scale	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr></table>		1	Grade 1	2	Grade 2	3	Grade 3														
1	Grade 1																							
2	Grade 2																							
3	Grade 3																							
424	[ nano_ae_call_doctor ]  Show the field ONLY if: [nano_ae_solicited] = "2" OR [nano_ae_solicited] = "3" OR [nano_ae_fda_tox_grade_2] = "2" OR [nano_ae_fda_tox_grade_2] = "3"	Call the research physician. The study nurse can only complete AEs forms for solicited local grade 1 AEs.	descriptive																					
425	[ nano_ae_fda_tox_grade ]  Show the field ONLY if: [nano_ae_solicited] = "1"		descriptive (Attachment: naNO-COVID_FDA_adapted (4).pdf, Display format: Link)																					
426	[ nano_ae_ctcae_6 ]  Show the field ONLY if: [nano_ae_solicited] = "2"	AE grade according to adapted CTCAE v5.0	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr><tr><td>4</td><td>Grade 4</td></tr><tr><td>5</td><td>Grade 5</td></tr></table>		1	Grade 1	2	Grade 2	3	Grade 3	4	Grade 4	5	Grade 5										
1	Grade 1																							
2	Grade 2																							
3	Grade 3																							
4	Grade 4																							
5	Grade 5																							
427	[ nano_ae_ctcae_grade_v7 ]  Show the field ONLY if: [nano_ae_solicited] = "2"		descriptive (Attachment: naNO-COVID_CTCAE_adapted_lab (2).pdf, Display format: Link)																					
428	[ nano_ae_ctcae ]	CTCAE term for grading AE	text, Required <table><tr><td>BIOPORTAL:CTCAE</td><td>BIOPORTAL:CTCAE</td></tr></table>		BIOPORTAL:CTCAE	BIOPORTAL:CTCAE																		
BIOPORTAL:CTCAE	BIOPORTAL:CTCAE																							

	Show the field ONLY if: [nano_ae_solicited] = "3"												
429	[ nano_ae_spec_ctcae ]  Show the field ONLY if: [nano_ae_solicited] = "3"	If needed, please specify	text, Required										
430	[ nano_ae_ctcae_5 ]  Show the field ONLY if: [nano_ae_solicited] = "3"	AE grade according to CTCAE v5.0	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr><tr><td>4</td><td>Grade 4</td></tr><tr><td>5</td><td>Grade 5</td></tr></table>	1	Grade 1	2	Grade 2	3	Grade 3	4	Grade 4	5	Grade 5
1	Grade 1												
2	Grade 2												
3	Grade 3												
4	Grade 4												
5	Grade 5												
431	[ nano_p_ae_interest ]	Is this an adverse event of special interest ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
432	[ nano_aesi_def ]		descriptive (Attachment: Definition of Adverse Event of Special Interest.pdf, Display format: Link)										
433	[ nano_ae_sae_info ]  Show the field ONLY if: [nano_p_ae_interest] = "1" OR [nano_ae_ctcae_5] = "3" OR [nano_ae_ctcae_5]= "4" OR [nano_ae_ctcae_5]= "5"	Please complete a SAE form and do not complete this AE form. SAE form	descriptive										
434	[ nano_ae_causality ]	Causality to the study vaccine	radio, Required <table><tr><td>1</td><td>No relationship</td></tr><tr><td>2</td><td>Possible</td></tr><tr><td>3</td><td>Probable</td></tr><tr><td>4</td><td>Definite</td></tr></table>	1	No relationship	2	Possible	3	Probable	4	Definite		
1	No relationship												
2	Possible												
3	Probable												
4	Definite												
435	[ nano_ae_causality_2 ]		descriptive (Attachment: Guidelines for assessing the relationship of vaccine administration to an adverse event (2).pdf, Display format: Link)										
436	[ nano_ae_new_event ]	Already experienced this event prior to study enrollment?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known				
1	Yes												
2	No												
3	Not known												
437	[ nano_ae_comment_event ]  Show the field ONLY if:	Please comment	text, Required										

	[nano_ae_new_event] = "1"						
438	[ nano_ae_doses ]	Section Header: <i>IMP 1st vaccine dose +/- 2nd vaccine dose</i> Were one or two doses administred ?	radio, Required <table><tr><td>1</td><td>One</td></tr><tr><td>2</td><td>Two</td></tr></table>	1	One	2	Two
1	One						
2	Two						
439	[ nano_ae_random_number ]	Randomization number	text (integer), Required				
440	[ nano_ae_code_broken ]	Was the code broken ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
441	[ nano_ae_detail ] Show the field ONLY if: [nano_ae_code_broken] = "1"	Please detail the reason for unblinding, the person who proceeded to unblinding and the date.	notes, Required				
442	[ nano_ae_imp_name ]	Name of IMP : PepGNP-COVID / Base-GNP	descriptive				
443	[ nano_ae_dose ]	Dose	radio, Required <table><tr><td>1</td><td>Low dose (14.8 ug of gold nanoparticles +/- 2.5 nmol dengue peptides)</td></tr><tr><td>2</td><td>High dose (44.5 ug of gold nanoparticles +/- 7.5 nmol dengue peptides)</td></tr></table>	1	Low dose (14.8 ug of gold nanoparticles +/- 2.5 nmol dengue peptides)	2	High dose (44.5 ug of gold nanoparticles +/- 7.5 nmol dengue peptides)
1	Low dose (14.8 ug of gold nanoparticles +/- 2.5 nmol dengue peptides)						
2	High dose (44.5 ug of gold nanoparticles +/- 7.5 nmol dengue peptides)						
444	[ nano_ae_route ]	Route : Intradermal injection	descriptive				
445	[ nano_ae_date_administered ]	Administration date dose 1	text (date_dmy), Required				
446	[ nano_ae_date_administered_2 ] Show the field ONLY if: [nano_ae_doses] = "2"	Administration date dose 2	text (date_dmy), Required				
447	[ nano_ae_tests_performed ]	Section Header: <i>Action taken</i> Have some paraclinical tests been performed ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
448	[ nano_ae_test_lab ] Show the field ONLY if: [nano_ae_tests_performed] = "1"	Laboratory tests	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
449	[ nano_ae_test_radio ] Show the field ONLY if: [nano_ae_tests_performed] = "1"	Radiological exams	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
450	[ nano_ae_main_result ] Show the field ONLY if:	Please provide the main results of the exams performed	notes, Required				

	[nano_ae_tests_performed] = "1"																							
451	[ nano_ae_do_not_forget ]  Show the field ONLY if: [nano_ae_test_radio] = "1" OR [nano_ae_test_lab] = "1" OR [nano_ae_tests_performed] = "1"	Do not forget to collect complementary exam, remove identifying data, code them and register them as source documents.	descriptive																					
452	[ nano_ae_action_taken_imp ]	Which action(s) was/were taken with IMP ? (Several possible)	<table><tr><td colspan="3">checkbox, Required</td></tr><tr><td>a</td><td>nano_ae_action_taken_imp__a</td><td>No action</td></tr><tr><td>b</td><td>nano_ae_action_taken_imp__b</td><td>Dose not change</td></tr><tr><td>c</td><td>nano_ae_action_taken_imp__c</td><td>Dose reduce</td></tr><tr><td>d</td><td>nano_ae_action_taken_imp__d</td><td>Dose increase</td></tr><tr><td>e</td><td>nano_ae_action_taken_imp__e</td><td>Drug temporary interruption</td></tr><tr><td>f</td><td>nano_ae_action_taken_imp__f</td><td>Drug withdrawal</td></tr></table>	checkbox, Required			a	nano_ae_action_taken_imp__a	No action	b	nano_ae_action_taken_imp__b	Dose not change	c	nano_ae_action_taken_imp__c	Dose reduce	d	nano_ae_action_taken_imp__d	Dose increase	e	nano_ae_action_taken_imp__e	Drug temporary interruption	f	nano_ae_action_taken_imp__f	Drug withdrawal
checkbox, Required																								
a	nano_ae_action_taken_imp__a	No action																						
b	nano_ae_action_taken_imp__b	Dose not change																						
c	nano_ae_action_taken_imp__c	Dose reduce																						
d	nano_ae_action_taken_imp__d	Dose increase																						
e	nano_ae_action_taken_imp__e	Drug temporary interruption																						
f	nano_ae_action_taken_imp__f	Drug withdrawal																						
453	[ nano_ae_action_taken ]	Which action(s) was/were taken with the participant? (Several possible)	<table><tr><td colspan="3">checkbox, Required</td></tr><tr><td>7</td><td>nano_ae_action_taken__7</td><td>Medication treatment</td></tr><tr><td>8</td><td>nano_ae_action_taken__8</td><td>Non medication treatment</td></tr><tr><td>9</td><td>nano_ae_action_taken__9</td><td>Hospitalization</td></tr><tr><td>10</td><td>nano_ae_action_taken__10</td><td>No action</td></tr></table>	checkbox, Required			7	nano_ae_action_taken__7	Medication treatment	8	nano_ae_action_taken__8	Non medication treatment	9	nano_ae_action_taken__9	Hospitalization	10	nano_ae_action_taken__10	No action						
checkbox, Required																								
7	nano_ae_action_taken__7	Medication treatment																						
8	nano_ae_action_taken__8	Non medication treatment																						
9	nano_ae_action_taken__9	Hospitalization																						
10	nano_ae_action_taken__10	No action																						
454	[ nano_ae_specify ]  Show the field ONLY if: [nano_ae_action_taken (8)]	Specify	text, Required																					
455	[ nano_ae_text ]  Show the field ONLY if: [nano_ae_action_taken (7)]	Please fill the medication form	descriptive																					
456	[ nano_ae_reaction_reappear ]	Did the reaction reappear after the second dose of the vaccination ?	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	radio, Required		1	Yes	2	No	3	Not applicable													
radio, Required																								
1	Yes																							
2	No																							
3	Not applicable																							
457	[ nano_ae_text_sae ]  Show the field ONLY if:	Fill the SAE form	descriptive																					

	[nano_ae_action_taken (9)]																		
458	[ nano_ae_withdrawn ]  Show the field ONLY if: [nano_ae_withdrawn] = "1"	Withdrawn from the study because of this AE ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No												
1	Yes																		
0	No																		
459	[ nano_end_of_trial ]  Show the field ONLY if: [nano_ae_withdrawn] = "1"	Complete the END OF TRIAL FORM	descriptive																
460	[ nano_ae_outcome ]	Section Header: <i>Outcome</i> Outcome of the adverse event	radio, Required <table><tr><td>1</td><td>Resolved (for date, last day of symptoms)</td></tr><tr><td>2</td><td>Resolved with sequelae</td></tr><tr><td>3</td><td>Ongoing</td></tr><tr><td>4</td><td>Stabilisation</td></tr><tr><td>5</td><td>Improvement</td></tr><tr><td>6</td><td>Agravation</td></tr><tr><td>7</td><td>Fatal</td></tr><tr><td>8</td><td>Unknown</td></tr></table>	1	Resolved (for date, last day of symptoms)	2	Resolved with sequelae	3	Ongoing	4	Stabilisation	5	Improvement	6	Agravation	7	Fatal	8	Unknown
1	Resolved (for date, last day of symptoms)																		
2	Resolved with sequelae																		
3	Ongoing																		
4	Stabilisation																		
5	Improvement																		
6	Agravation																		
7	Fatal																		
8	Unknown																		
461	[ nano_ae_date_outcome ]	Date of the outcome evaluation	text (date_dmy)																
462	[ nano_ae_last_day_sympt ]  Show the field ONLY if: [nano_ae_outcome] = '1' or [nano_ae_outcome] = '2'	Date of resolution	text (date_dmy), Required																
463	[ nano_ae_death_date ]  Show the field ONLY if: [nano_ae_outcome] = '7'	Date of death	text (date_dmy), Required																
464	[ nano_ae_evolved ]	Has this AE evolved in a SAE/AESI/SUSAR ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No												
1	Yes																		
0	No																		
465	[ nano_ae_sae_number ]  Show the field ONLY if: [nano_ae_evolved] = "1"	Specify the SAE number related	text, Required																
466	[ nano_ae_text_sae_2 ]  Show the field ONLY if: [nano_ae_evolved] = "1"	Fill the SAE form	descriptive																
467	[ nano_ae_comment ]	Add comments	yesno, Required																

			<table border="1"> <tr> <td>1</td><td>Yes</td></tr> <tr> <td>0</td><td>No</td></tr> </table>	1	Yes	0	No																				
1	Yes																										
0	No																										
468	[ nano_ae_comments ] Show the field ONLY if: [nano_ae_comment] = "1"	Comments	notes, Required																								
469	[ adverse_event_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr> <td>0</td><td>Incomplete</td></tr> <tr> <td>1</td><td>Unverified</td></tr> <tr> <td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete																		
0	Incomplete																										
1	Unverified																										
2	Complete																										
<b>Instrument: Screen Failure (screen_failure)</b>																											
470	[ nano_sf_date ]	Date of screenfailure (if applicable)	text (date_dmy)																								
471	[ nano_sf_date_last_contact ]	Date of last contact	text (date_dmy)																								
472	[ nano_sf_specify ]	Specify reason for screen failure	radio <table border="1"> <tr> <td>a</td><td>Age &lt; 18 or &gt; 45 years</td></tr> <tr> <td>b</td><td>Written consent not provided/consent withdrawal</td></tr> <tr> <td>c</td><td>Not able/do not want to attend all scheduled visit/to comply with all study requirements</td></tr> <tr> <td>d</td><td>Chronic illness that might interfere with trial conduct</td></tr> <tr> <td>e</td><td>Current alcohol abuse or drug addiction (reported or suspected)</td></tr> <tr> <td>f</td><td>Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy</td></tr> <tr> <td>g</td><td>Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening reaction to vaccines</td></tr> <tr> <td>h</td><td>Thrombocytopenia or any coagulation disorder</td></tr> <tr> <td>i</td><td>Pregnancy or lactating</td></tr> <tr> <td>j</td><td>Non-use of an effective method of contraception from at least 4 weeks prior to the first vaccination</td></tr> <tr> <td>k</td><td>Participation in another clinical trial investigating a vaccine, drug, medical device or medical procedure in the 4 weeks preceding the first vaccination, or planned participation during the study period</td></tr> <tr> <td>l</td><td>Receipt of any vaccine in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received</td></tr> </table>	a	Age < 18 or > 45 years	b	Written consent not provided/consent withdrawal	c	Not able/do not want to attend all scheduled visit/to comply with all study requirements	d	Chronic illness that might interfere with trial conduct	e	Current alcohol abuse or drug addiction (reported or suspected)	f	Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy	g	Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening reaction to vaccines	h	Thrombocytopenia or any coagulation disorder	i	Pregnancy or lactating	j	Non-use of an effective method of contraception from at least 4 weeks prior to the first vaccination	k	Participation in another clinical trial investigating a vaccine, drug, medical device or medical procedure in the 4 weeks preceding the first vaccination, or planned participation during the study period	l	Receipt of any vaccine in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received
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			<table><tr><td></td><td>up to 2 weeks before first study vaccine) or planned receipt of any vaccine in the 4 weeks following trial vaccination</td></tr><tr><td>m</td><td>Receipt of immunoglobulins, blood or blood-derived products in the past 3 months</td></tr><tr><td>n</td><td>Positive SARS-CoV-2 test in the 4 weeks preceding the first trial vaccination</td></tr><tr><td>p</td><td>Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C</td></tr><tr><td>s</td><td>Identified as an Investigator or employee of the Investigator or study centre with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural or adopted child) of the Investigator or employee with direct involvement in the proposed study</td></tr><tr><td>t</td><td>Refusal to be informed in the event that relevant results concerning the participant's health are revealed.</td></tr><tr><td>u</td><td>Abnormal laboratory (blood/urine) value</td></tr><tr><td>v</td><td>Lost to follow up</td></tr><tr><td>w</td><td>Other</td></tr></table>		up to 2 weeks before first study vaccine) or planned receipt of any vaccine in the 4 weeks following trial vaccination	m	Receipt of immunoglobulins, blood or blood-derived products in the past 3 months	n	Positive SARS-CoV-2 test in the 4 weeks preceding the first trial vaccination	p	Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C	s	Identified as an Investigator or employee of the Investigator or study centre with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural or adopted child) of the Investigator or employee with direct involvement in the proposed study	t	Refusal to be informed in the event that relevant results concerning the participant's health are revealed.	u	Abnormal laboratory (blood/urine) value	v	Lost to follow up	w	Other
	up to 2 weeks before first study vaccine) or planned receipt of any vaccine in the 4 weeks following trial vaccination																				
m	Receipt of immunoglobulins, blood or blood-derived products in the past 3 months																				
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u	Abnormal laboratory (blood/urine) value																				
v	Lost to follow up																				
w	Other																				
473	<div>[ nano_sf_specify_fai1 ]</div> <div>Show the field ONLY if: [nano_sf_specify] = "c" or [nano_sf_specify] = "d" or [nano_sf_specify] = "f" or [nano_sf_specify] = "g" or [nano_sf_specify] = "h" or [nano_sf_specify] = "j" or [nano_sf_specify] = "l" or [nano_sf_specify] = "m" or [nano_sf_specify] = "n" or [nano_sf_specify] = "o" or [nano_sf_specify] = "p" or [nano_sf_specify] = "q" or [nano_sf_specify] = "r" or [nano_sf_specify] = "u" or [nano_sf_specify] = "v" or [nano_sf_specify] = "w"</div>	Specify	text																		
474	<div>[ nano_sf_comment_yn ]</div>	Any additional comment?	yesno																		



			<table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
475	<div>[ nano_sf_comment ]</div> <div>Show the field ONLY if: [nano_sf_comment_y n] = "1"</div>	Specify	notes						
476	<div>[ screen_failure_com plete ]</div>	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: <b>Unscheduled visit</b> (unscheduled_visit)									
477	<div>[ nano_uv_date_visit ]</div>	Section Header: <i>Reason of visit</i> Date of visit	text (date_dmy)						
478	<div>[ nano_uv_reason ]</div>	Reason of visit	radio <table><tr><td>a</td><td>New adverse event</td></tr><tr><td>b</td><td>Follow up of an adverse event</td></tr><tr><td>c</td><td>Other</td></tr></table>	a	New adverse event	b	Follow up of an adverse event	c	Other
a	New adverse event								
b	Follow up of an adverse event								
c	Other								
479	<div>[ nano_uv_reason_spec ify ]</div> <div>Show the field ONLY if: [nano_uv_reason] = "c"</div>	Specify	notes						
480	<div>[ nano_uv_number ]</div> <div>Show the field ONLY if: [nano_uv_reason] = "a" or [nano_uv_reason] = "b"</div>	Event number	sql <div>SELECT instance, value from redcap_data where project_id = 341 and field_name = 'nano_ae_number' and record = [record-name] order by value</div>						
481	<div>[ nano_uv_med_event ]</div>	Section Header: <i>Medical history</i> Any relevant medical event since the last visit ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
482	<div>[ nano_uv_event_med_s pecify ]</div> <div>Show the field ONLY if: [nano_uv_med_event] = "1"</div>	Specify	notes						
483	<div>[ nano_uv_new_ae ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; 'visit_11_arm_1' and [event-name] &lt;&gt; 'visit_12_arm_1'</div>	Is there any new adverse event ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
484	<div>[ nano_sae_button_7 ]</div> <div>Show the field ONLY if:</div>	Please fill a AE form	descriptive						

	[nano_uv_new_ae] = '1'						
485	[ nano_uv_new_sae ]	Is there any serious adverse event (SAE) since last visit?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
486	[ nano_sae_definition_2 ]		descriptive (Attachment: Definition_Serious Adverse Event.pdf, Display format: Link)				
487	[ nano_sae_button_8 ]  Show the field ONLY if: [nano_uv_new_sae] = '1'	Please fill a SAE form	descriptive				
488	[ nano_uv_med_change ]	Section Header: <i>Current medication</i> Is there any new or changed medication since the last visit?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
489	[ nano_uv_med_form ]  Show the field ONLY if: [nano_uv_med_change] = "1"	Please fill the medication form	descriptive				
490	[ nano_uv_vac ]	Is there any vaccination since the last visit?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
491	[ nano_uv_vaccine_name ]  Show the field ONLY if: [nano_uv_vac] = "1"	Specify vaccine name	text				
492	[ nano_uv_vaccine_date ]  Show the field ONLY if: [nano_uv_vac] = "1"	Date of vaccination	text (date_dmy)				
493	[ nano_uv_physical_exam ]	Section Header: <i>Physical exam</i> Has a physical examination been done ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
494	[ nano_uv_phy_exam_specify ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Specify why	text				
495	[ nano_uv_body_weight ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Section Header: <i>Physical observations</i> Body weight	text (integer, Min: 0, Max: 150)				
496	[ nano_uv_axillary_t ]	Axillary temperature	text (number_1dp, Min: 00, Max: 42)				

	Show the field ONLY if: [nano_uv_physical_exam] = "1"		
497	[ nano_uv_heart_rate ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Heart rate	text (integer, Min: 00, Max: 150)
498	[ nano_uv_systolic_pressure ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Systolic blood pressure	text (integer, Min: 00, Max: 230)
499	[ nano_uv_diastolic_pressure ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Diastolic blood pressure	text (integer, Min: 00, Max: 150)
500	[ nano_uv_cardiovascular ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Section Header: <i>Physical examination</i> Cardiovascular	notes
501	[ nano_uv_respiratory ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Respiratory	notes
502	[ nano_uv_gastrointestinal ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Gastro-intestinal	notes
503	[ nano_uv_dermatological ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Dermatological	notes
504	[ nano_uv_others ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Other(s) : Specify	notes

505	[ nano_uv_paraclinical_perf ]	Section Header: <i>Action taken</i> Have some paraclinical tests been performed ?	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>		1	Yes	0	No																																																																	
1	Yes																																																																								
0	No																																																																								
506	[ nano_uv_labo_tests ]  Show the field ONLY if: [ nano_uv_paraclinical_perf ] = "1"	Laboratory tests*	yesno <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>		1	Yes	0	No																																																																	
1	Yes																																																																								
0	No																																																																								
507	[ nano_uv_which_test ]  Show the field ONLY if: [ nano_uv_labo_tests ] = "1"	What test has been done ?	checkbox <table border="1"> <tr> <td>1</td> <td>nano_uv_which_test__1</td> <td>Hemoglobin</td> </tr> <tr> <td>2</td> <td>nano_uv_which_test__2</td> <td>Hematocrit</td> </tr> <tr> <td>3</td> <td>nano_uv_which_test__3</td> <td>Erythrocyte</td> </tr> <tr> <td>4</td> <td>nano_uv_which_test__4</td> <td>MCV (Mean corpuscular volume)</td> </tr> <tr> <td>5</td> <td>nano_uv_which_test__5</td> <td>MCH (Mean cell hemoglobin)</td> </tr> <tr> <td>6</td> <td>nano_uv_which_test__6</td> <td>MCHC (Mean corpuscular hemoglobin concentration)</td> </tr> <tr> <td>7</td> <td>nano_uv_which_test__7</td> <td>Platelets</td> </tr> <tr> <td>8</td> <td>nano_uv_which_test__8</td> <td>Leukocytes</td> </tr> <tr> <td>9</td> <td>nano_uv_which_test__9</td> <td>Neutrophils</td> </tr> <tr> <td>10</td> <td>nano_uv_which_test__10</td> <td>Lymphocytes</td> </tr> <tr> <td>11</td> <td>nano_uv_which_test__11</td> <td>Monocytes</td> </tr> <tr> <td>12</td> <td>nano_uv_which_test__12</td> <td>Eosinophils</td> </tr> <tr> <td>13</td> <td>nano_uv_which_test__13</td> <td>Basophils</td> </tr> <tr> <td>15</td> <td>nano_uv_which_test__15</td> <td>Creatinine</td> </tr> <tr> <td>16</td> <td>nano_uv_which_test__16</td> <td>AST</td> </tr> <tr> <td>17</td> <td>nano_uv_which_test__17</td> <td>ALT</td> </tr> <tr> <td>18</td> <td>nano_uv_which_test__18</td> <td>Alkaline phosphatase</td> </tr> <tr> <td>19</td> <td>nano_uv_which_test__19</td> <td>GGT</td> </tr> <tr> <td>20</td> <td>nano_uv_which_test__20</td> <td>Total bilirubin</td> </tr> <tr> <td>21</td> <td>nano_uv_which_test__21</td> <td>C reactive protein</td> </tr> <tr> <td>23</td> <td>nano_uv_which_test__23</td> <td>Urine dipstick</td> </tr> <tr> <td>24</td> <td>nano_uv_which_test__24</td> <td>Pregnancy test</td> </tr> <tr> <td>22</td> <td>nano_uv_which_test__22</td> <td>Other</td> </tr> </table>		1	nano_uv_which_test__1	Hemoglobin	2	nano_uv_which_test__2	Hematocrit	3	nano_uv_which_test__3	Erythrocyte	4	nano_uv_which_test__4	MCV (Mean corpuscular volume)	5	nano_uv_which_test__5	MCH (Mean cell hemoglobin)	6	nano_uv_which_test__6	MCHC (Mean corpuscular hemoglobin concentration)	7	nano_uv_which_test__7	Platelets	8	nano_uv_which_test__8	Leukocytes	9	nano_uv_which_test__9	Neutrophils	10	nano_uv_which_test__10	Lymphocytes	11	nano_uv_which_test__11	Monocytes	12	nano_uv_which_test__12	Eosinophils	13	nano_uv_which_test__13	Basophils	15	nano_uv_which_test__15	Creatinine	16	nano_uv_which_test__16	AST	17	nano_uv_which_test__17	ALT	18	nano_uv_which_test__18	Alkaline phosphatase	19	nano_uv_which_test__19	GGT	20	nano_uv_which_test__20	Total bilirubin	21	nano_uv_which_test__21	C reactive protein	23	nano_uv_which_test__23	Urine dipstick	24	nano_uv_which_test__24	Pregnancy test	22	nano_uv_which_test__22	Other
1	nano_uv_which_test__1	Hemoglobin																																																																							
2	nano_uv_which_test__2	Hematocrit																																																																							
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4	nano_uv_which_test__4	MCV (Mean corpuscular volume)																																																																							
5	nano_uv_which_test__5	MCH (Mean cell hemoglobin)																																																																							
6	nano_uv_which_test__6	MCHC (Mean corpuscular hemoglobin concentration)																																																																							
7	nano_uv_which_test__7	Platelets																																																																							
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9	nano_uv_which_test__9	Neutrophils																																																																							
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11	nano_uv_which_test__11	Monocytes																																																																							
12	nano_uv_which_test__12	Eosinophils																																																																							
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16	nano_uv_which_test__16	AST																																																																							
17	nano_uv_which_test__17	ALT																																																																							
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19	nano_uv_which_test__19	GGT																																																																							
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24	nano_uv_which_test__24	Pregnancy test																																																																							
22	nano_uv_which_test__22	Other																																																																							
508	[ nano_uv_leukocytes ]  Show the field ONLY if: [ nano_uv_which_test (8) ]	Leukocytes <i>G/I - REF RANGE: 4 - 10</i>	text																																																																						

509	[ nano_uv_oor ]  Show the field ONLY if: [nano_uv_which_test (8)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
510	[ nano_uv_oor_deviati on ]  Show the field ONLY if: [nano_uv_oor] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
511	[ nano_uv_erythrocyte s ]  Show the field ONLY if: [nano_uv_which_test (3)]	Erythrocytes <i>T/I - REF RANGE: 4.4 - 5.8 (Male) - 3.8 - 5.2 (Female)</i>	text				
512	[ nano_uv_oor_2 ]  Show the field ONLY if: [nano_uv_which_test (3)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
513	[ nano_uv_oor_deviati on_2 ]  Show the field ONLY if: [nano_uv_oor_2] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
514	[ nano_uv_hemoglobin ]  Show the field ONLY if: [nano_uv_which_test (1)]	Hemoglobin <i>g/l - REF RANGE: 133 - 177 (male) - 117 - 157 (female)</i>	text				
515	[ nano_uv_oor_3 ]  Show the field ONLY if: [nano_uv_which_test (1)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
516	[ nano_uv_oor_deviati on_3 ]  Show the field ONLY if: [nano_uv_oor_3] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
517	[ nano_uv_hematocrit ]  Show the field ONLY if: [nano_uv_which_test (2)]	Hematocrit <i>% - REF RANGE: 40 - 52 (male) - 35 - 47 (female)</i>	text				
518	[ nano_uv_oor_4 ]  Show the field ONLY if: [nano_uv_which_test (2)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

519	<div>[ nano_uv_oor_deviati on_4 ]</div> <div>Show the field ONLY if: [nano_uv_oor_4] = '1'</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
520	<div>[ nano_uv_mcv ]</div> <div>Show the field ONLY if: [nano_uv_which_test (4)]</div>	MCV (Mean corpuscular volume) <i>f/l - REF RANGE: 81 - 99</i>	text				
521	<div>[ nano_uv_oor_5 ]</div> <div>Show the field ONLY if: [nano_uv_which_test (4)]</div>	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
522	<div>[ nano_uv_oor_deviati on_5 ]</div> <div>Show the field ONLY if: [nano_uv_oor_5] = '1'</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
523	<div>[ nano_uv_mch ]</div> <div>Show the field ONLY if: [nano_uv_which_test (5)]</div>	MCH (Mean cell hemoglobin) <i>pg - REF RANGE: 27 - 34</i>	text				
524	<div>[ nano_uv_oor_6 ]</div> <div>Show the field ONLY if: [nano_uv_which_test (5)]</div>	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
525	<div>[ nano_uv_oor_deviati on_6 ]</div> <div>Show the field ONLY if: [nano_uv_oor_6] = '1'</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
526	<div>[ nano_uv_mchc ]</div> <div>Show the field ONLY if: [nano_uv_which_test (6)]</div>	MCHC (Mean corpuscular hemoglobin concentration) <i>g/l - REF RANGE: 310 - 360</i>	text				
527	<div>[ nano_uv_oor_7 ]</div> <div>Show the field ONLY if: [nano_uv_which_test (6)]</div>	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
528	<div>[ nano_uv_oor_deviati on_7 ]</div> <div>Show the field ONLY if: [nano_uv_oor_7] = '1'</div>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
529	<div>[ nano_uv_platelets ]</div>	Platelets <i>G/l - REF RANGE: 150 - 350</i>	text				

	Show the field ONLY if: [nano_uv_which_test (7)]						
530	[ nano_uv_oor_8 ]  Show the field ONLY if: [nano_uv_which_test (7)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
531	[ nano_uv_oor_deviati on_8 ]  Show the field ONLY if: [nano_uv_oor_8] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
532	[ nano_uv_neutrophils ]  Show the field ONLY if: [nano_uv_which_test (9)]	Neutrophils <i>G/I - REF RANGE: 1.8 - 7.5</i>	text				
533	[ nano_uv_oor_9 ]  Show the field ONLY if: [nano_uv_which_test (9)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
534	[ nano_uv_oor_deviati on_9 ]  Show the field ONLY if: [nano_uv_oor_9] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
535	[ nano_uv_lymphocytes ]  Show the field ONLY if: [nano_uv_which_test(10)]	Lymphocytes <i>G/I - REF RANGE: 1.5 - 4</i>	text				
536	[ nano_uv_oor_10 ]  Show the field ONLY if: [nano_uv_which_test(10)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
537	[ nano_uv_oor_deviati on_10 ]  Show the field ONLY if: [nano_uv_oor_10] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
538	[ nano_uv_monocytes ]  Show the field ONLY if: [nano_uv_which_test(11)]	Monocytes <i>G/I - REF RANGE: 0.2 - 0.8</i>	text				
539	[ nano_uv_oor_11 ]	Is this value out of range?	yesno				

	Show the field ONLY if: [nano_uv_which_test(11)]		<table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
540	[ nano_uv_oor_deviations_11 ]  Show the field ONLY if: [nano_uv_oor_11] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
541	[ nano_uv_eosinophils ]  Show the field ONLY if: [nano_uv_which_test(12)]	Eosinophils <i>G/I - REF RANGE: 0.05 - 0.5</i>	text				
542	[ nano_uv_oor_12 ]  Show the field ONLY if: [nano_uv_which_test(12)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
543	[ nano_uv_oor_deviations_12 ]  Show the field ONLY if: [nano_uv_oor_12] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
544	[ nano_uv_basophils ]  Show the field ONLY if: [nano_uv_which_test(13)]	Basophils <i>G/I - REF RANGE: 0.01 - 0.05</i>	text				
545	[ nano_uv_oor_13 ]  Show the field ONLY if: [nano_uv_which_test(13)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
546	[ nano_uv_oor_deviations_13 ]  Show the field ONLY if: [nano_uv_oor_13] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
547	[ nano_uv_creatinine ]  Show the field ONLY if: [nano_uv_which_test(15)]	Creatinine <i>μmol/ - REF RANGE: 62-106 (male) - 44 - 80 (female)</i>	text				
548	[ nano_uv_oor_14 ]  Show the field ONLY if: [nano_uv_which_test(15)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
549	[ nano_uv_oor_deviations_14 ]	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes		
1	Yes						



	Show the field ONLY if: [nano_uv_oor_14] = '1'		<table><tr><td>0</td><td>No</td></tr></table>	0	No		
0	No						
550	[ nano_uv_ast ]  Show the field ONLY if: [nano_uv_which_test(16)]	AST <i>UI/I - REF RANGE: 9 - 50</i>	text				
551	[ nano_uv_oor_15 ]  Show the field ONLY if: [nano_uv_which_test(16)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
552	[ nano_uv_oor_deviati on_15 ]  Show the field ONLY if: [nano_uv_oor_15] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
553	[ nano_uv_alt ]  Show the field ONLY if: [nano_uv_which_test(17)]	ALT <i>UI/I - REF RANGE: 9 - 50</i>	text				
554	[ nano_uv_oor_16 ]  Show the field ONLY if: [nano_uv_which_test(17)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
555	[ nano_uv_oor_deviati on_16 ]  Show the field ONLY if: [nano_uv_oor_16] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
556	[ nano_uv_alkaline ]  Show the field ONLY if: [nano_uv_which_test(18)]	Alkaline phosphatase <i>UI/I - REF RANGE: 36 - 120</i>	text				
557	[ nano_uv_oor_17 ]  Show the field ONLY if: [nano_uv_which_test(18)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
558	[ nano_uv_oor_deviati on_17 ]  Show the field ONLY if: [nano_uv_oor_17] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
559	[ nano_uv_ggt ]  Show the field ONLY if:	GGT <i>UI/I - REF RANGE: 6 - 42</i>	text				

	[nano_uv_which_test(19)]										
560	[ nano_uv_oor_18 ]  Show the field ONLY if: [nano_uv_which_test(19)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
561	[ nano_uv_oor_deviati on_18 ]  Show the field ONLY if: [nano_uv_oor_18] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
562	[ nano_uv_bilirubin ]  Show the field ONLY if: [nano_uv_which_test(20)]	Total bilirubin <i>μmol/l - REF RANGE: 0 - 21</i>	text								
563	[ nano_uv_oor_19 ]  Show the field ONLY if: [nano_uv_which_test(20)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
564	[ nano_uv_oor_deviati on_19 ]  Show the field ONLY if: [nano_uv_oor_19] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
565	[ nano_uv_creativeprotein ]  Show the field ONLY if: [nano_uv_which_test(21)]	C reactive protein <i>mg/l - REF RANGE: &lt; 10</i>	text								
566	[ nano_uv_oor_20 ]  Show the field ONLY if: [nano_uv_which_test(21)]	Is this value out of range?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
567	[ nano_uv_oor_deviati on_20 ]  Show the field ONLY if: [nano_uv_oor_20] = '1'	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
568	[ nano_uv_hematuria ]  Show the field ONLY if: [nano_uv_which_test(23)]	Hematuria	radio <table><tr><td>a</td><td>0</td></tr><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	a	0	b	+	c	++	d	+++
a	0										
b	+										
c	++										
d	+++										
569	[ nano_uv_proteins ]  Show the field ONLY if:	Proteins in urine	radio <table><tr><td>a</td><td>0</td></tr></table>	a	0						
a	0										

	[nano_uv_which_test(23)]		<table><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	b	+	c	++	d	+++		
b	+										
c	++										
d	+++										
570	[ nano_uv_glucose ] Show the field ONLY if: [nano_uv_which_test(23)]	Glucose in urine	radio <table><tr><td>a</td><td>0</td></tr><tr><td>b</td><td>+</td></tr><tr><td>c</td><td>++</td></tr><tr><td>d</td><td>+++</td></tr></table>	a	0	b	+	c	++	d	+++
a	0										
b	+										
c	++										
d	+++										
571	[ nano_uv_pregnancy ] Show the field ONLY if: [nano_uv_which_test(24)]	Pregnancy test result	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
572	[ nano_uv_other ] Show the field ONLY if: [nano_uv_which_test(22)]	Other, specify	text								
573	[ nano_uv_radio_exams ] Show the field ONLY if: [nano_uv_paraclinical_perf] = "1"	Radiological exams*	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
574	[ nano_uv_other_exams ] Show the field ONLY if: [nano_uv_paraclinical_perf] = "1"	Other exam	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
575	[ nano_uv_para_specify ] Show the field ONLY if: [nano_uv_other_exams] = "1" OR [nano_uv_radio_exams] = "1"	Specify	text								
576	[ nano_uv_text ] Show the field ONLY if: [nano_uv_paraclinical_perf] = "1" or [nano_uv_radio_exams] = "1" or [nano_uv_labo_tests] = "1"	* Do not forget to collect complementary exam, remove identifying data, code them and register them as source documents.	descriptive								
577	[ nano_uv_eligible ]	Section Header: <i>Continuation of trial - Review of eligibility</i> Is the volunteer still eligible to continue with the trial ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
578	[ nano_uv_text_2 ]	Complete the END OF TRIAL FORM	descriptive								

	Show the field ONLY if: [nano_uv_eligible] = "0"								
579	[ nano_uv_date_protocol_deviation ]  Show the field ONLY if: [nano_uv_eligible] = "1"	Date of next visit	text (date_dmy)						
580	[ nano_uv_comment ]	Section Header: <i>Additional comment</i> Any additional comment?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
581	[ nano_uv_comment_specify ]  Show the field ONLY if: [nano_uv_comment] = "1"	Specify	notes						
582	[ unscheduled_visit_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: Prescription form (prescription_form)									
583	[ nano_pf_title ]	FORMULAIRE DE PRESCRIPTION	descriptive						
584	[ nano_pf_nano_id ]	Screening ID	text Field Annotation: @DEFAULT='[record-name]' @READONLY						
585	[ nano_pf_nano_id_2 ]	Inclusion ID	text Field Annotation: @DEFAULT='[screening_arm_1][nano_vi_full_id]' @READONLY						
586	[ nano_pf_ipp ]	IPP	text Field Annotation: @DEFAULT='[screening_arm_1][nano_vi_ipp]' @READONLY						
587	[ nano_pf_dose ]		radio <table><tr><td>1</td><td>Low dose (vera / placebo)</td></tr><tr><td>2</td><td>High dose (vera/placebo)</td></tr></table>	1	Low dose (vera / placebo)	2	High dose (vera/placebo)		
1	Low dose (vera / placebo)								
2	High dose (vera/placebo)								
588	[ nano_pf_first_vac ]		radio <table><tr><td>1</td><td>1ère vaccination</td></tr><tr><td>2</td><td>2ème vaccination</td></tr></table>	1	1ère vaccination	2	2ème vaccination		
1	1ère vaccination								
2	2ème vaccination								
589	[ nano_pf_date ]	Section Header: <i>1ère vaccination</i> Date d'administration souhaitée pour la première vaccination :	text (date_dmy)						
590	[ nano_pf_hour ]	Heure souhaitée pour la première vaccination :	text (time)						
591	[ nano_pf_name_date ]	Date de la demande pour la première vaccination	text (date_dmy)						

592	[ nano_pf_name ]	Nom du demandeur pour la première vaccination	text						
593	[ nano_pf_signature ]	Signature pour la première vaccination	file (signature)						
594	[ nano_pf_send ]	Envoi de la demande pour la première vaccination par mail à la pharmacie ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
595	[ nano_pf_date_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Section Header: 2 <sup>e</sup> vaccination Date d'administration souhaitée pour la deuxième vaccination :	text (date_dmy)						
596	[ nano_pf_hour_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Heure souhaitée pour la deuxième vaccination :	text (time)						
597	[ nano_pf_name_date_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Date de la demande pour la deuxième vaccination	text (date_dmy)						
598	[ nano_pf_name_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Nom du demandeur pour la deuxième vaccination	text						
599	[ nano_pf_signature_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Signature pour la deuxième vaccination	file (signature)						
600	[ nano_pf_send_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Envoi de la demande pour la deuxième vaccination par mail à la pharmacie ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
601	[ prescription_form_complete ]	Section Header: Form Status Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								
Instrument: Pregnancy form (pregnancy_form)									
602	[ nano_pr_title ]	Title of research project	notes Custom alignment: RH Field Annotation: @DEFAULT = 'naNO-DENGUE: A Phase-I study of a nanoparticle-based peptide vaccine against Dengue virus'						

603	[ nano_pr_sponsor_name ]	Name of Sponsor	text Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'				
604	[ nano_pr_sponsor_address ]	Adress of Sponsor	notes Custom alignment: RH Field Annotation: @DEFAULT = '4 & 5 Dunmore Court Wootton Road, Abingdon, Oxfordshire, England, OX13 6BH'				
605	[ nano_pr_pi_name ]	Name of Principal Investigator	text Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'				
606	[ nano_pr_pi_address ]	Adress of Principal Investigator	notes Custom alignment: RH Field Annotation: @DEFAULT = 'Unisanté, Département Formation, recherche et innovation Policlinique de médecine tropicale, voyages et vaccinations Rue du Bugnon 44 1011 Lausanne, Suisse Blaise.genton@unisante.ch M :+41 79 556 58 68'				
607	[ nano_pr_product_name ]	Investigational Medicinal Product Name	text Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"				
608	[ nano_pr_project_number ]	BASEC research project number (Swissethics)	text Field Annotation: @DEFAULT="2020-02258"				
609	[ nano_pr_notif_number ]	Notification n° (Swissmedic)	text				
610	[ nano_pr_yob ]	Section Header: <i>Maternal information</i> Year of birth	text (integer, Min: 1900, Max: 2100)				
611	[ nano_pr_height ]	Height	text (integer, Min: 100, Max: 220)				
612	[ nano_pr_weight ]	Weight	text (integer, Min: 25, Max: 170)				
613	[ nano_pr_contraception_met ]	Section Header: <i>Contraception</i> Method of contraception	text				
614	[ nano_pr_contra_used ]	Contraception used as instructed	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						
615	[ nano_pr_risk ]	Section Header: <i>Medical history</i> Patient past history (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy e.g. alcohol, smoking, other substance consumption, hypertension, eclampsia, diabetes including gestational, infections during pregnancy, environmental or occupational exposure that may pose a risk factor).	text				
616	[ nano_pr_prev_pregn ]	Previous pregnancies (including abortion or stillbirth)	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No
1	Yes						
0	No						

617	[ nano_pr_count_gest ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1"	How many gestation ?	dropdown <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr></table>	1	1	2	2	3	3
1	1								
2	2								
3	3								
618	[ nano_pr_week_gestation ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 0	Gestation week	text (number)						
619	[ nano_pr_outcome ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 0	Outcome including any abnormalities	text						
620	[ nano_pr_week_gestation_2 ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 1	Gestation week	text (number)						
621	[ nano_pr_outcome_2 ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 1	Outcome including any abnormalities	text						
622	[ nano_pr_week_gestation_3 ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 2	Gestation week	text (number)						
623	[ nano_pr_outcome_3 ]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 2	Outcome including any abnormalities	text						
624	[ nano_pr_concom_drug ]	Section Header: <i>Relevant medication</i> Any concomitant drug(s)?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
625	[ nano_pr_count_conc ]  Show the field ONLY if: [nano_pr_concom_drug] = "1"	How many concomitant drug(s) ?	dropdown <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr></table>	1	1	2	2	3	3
1	1								
2	2								
3	3								

			<table><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table>	4	4	5	5												
4	4																		
5	5																		
626	<div>[ nano_pr_med_name ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Medication Name (Commercial name)	text																
627	<div>[ nano_pr_med_int_name ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Medication Name (International nonproprietary name)	text																
628	<div>[ nano_pr_dose ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Dose	text (integer, Min: 0, Max: 9999999)																
629	<div>[ nano_pr_dose_unit ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Dose unit	radio <table><tr><td>a</td><td>Microgram</td></tr><tr><td>b</td><td>Miligram</td></tr><tr><td>c</td><td>Gram</td></tr><tr><td>d</td><td>Mililiter</td></tr><tr><td>e</td><td>Other (Specify)</td></tr><tr><td>f</td><td>Unknown</td></tr></table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown				
a	Microgram																		
b	Miligram																		
c	Gram																		
d	Mililiter																		
e	Other (Specify)																		
f	Unknown																		
630	<div>[ nano_pr_med_frequency ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Frequency	radio <table><tr><td>a</td><td>Daily</td></tr><tr><td>b</td><td>Twice daily</td></tr><tr><td>c</td><td>Three times a day</td></tr><tr><td>d</td><td>Four times a day</td></tr><tr><td>e</td><td>4-6 hours</td></tr><tr><td>f</td><td>6-8 hours</td></tr><tr><td>g</td><td>PRN (ad needed)</td></tr><tr><td>h</td><td>Other (specify)</td></tr></table>	a	Daily	b	Twice daily	c	Three times a day	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (ad needed)	h	Other (specify)
a	Daily																		
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g	PRN (ad needed)																		
h	Other (specify)																		
631	<div>[ nano_pr_med_route ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</div>	Route	radio <table><tr><td>a</td><td>Oral</td></tr><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intraveinous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr></table>	a	Oral	b	Topical	c	Subcutaneous injection	d	Intraveinous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled
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			<table><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	i	Transdermal	j	Vaginal	k	Other (Specify)
i	Transdermal								
j	Vaginal								
k	Other (Specify)								
632	<p>[ nano_pr_med_indication ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</p>	Indication(s) for use	text						
633	<p>[ nano_pr_med_start_date ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</p>	Start Date	text (date_dmy)						
634	<p>[ nano_pr_med_ongoing ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</p>	Ongoing	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
635	<p>[ nano_pr_med_end_date ]</p> <p>Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</p>	End date	text (date_dmy)						
636	<p>[ nano_pr_med_name_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Medication Name (Commercial name)	text						
637	<p>[ nano_pr_med_int_name_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Medication Name (International nonproprietary name)	text						
638	<p>[ nano_pr_dose_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Dose	text (integer, Min: 0, Max: 9999999)						

639	<div>[ nano_pr_dose_unit_2 ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</div>	Dose unit	radio <table><tr><td>a</td><td>Microgram</td></tr><tr><td>b</td><td>Miligram</td></tr><tr><td>c</td><td>Gram</td></tr><tr><td>d</td><td>Mililiter</td></tr><tr><td>e</td><td>Other (Specify)</td></tr><tr><td>f</td><td>Unknown</td></tr></table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown										
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640	<div>[ nano_pr_med_frequency_2 ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</div>	Frequency	radio <table><tr><td>a</td><td>Daily</td></tr><tr><td>b</td><td>Twice daily</td></tr><tr><td>c</td><td>Three times a day</td></tr><tr><td>d</td><td>Four times a day</td></tr><tr><td>e</td><td>4-6 hours</td></tr><tr><td>f</td><td>6-8 hours</td></tr><tr><td>g</td><td>PRN (ad needed)</td></tr><tr><td>h</td><td>Other (specify)</td></tr></table>	a	Daily	b	Twice daily	c	Three times a day	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (ad needed)	h	Other (specify)						
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h	Other (specify)																								
641	<div>[ nano_pr_med_route_2 ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</div>	Route	radio <table><tr><td>a</td><td>Oral</td></tr><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intraveinous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	a	Oral	b	Topical	c	Subcutaneous injection	d	Intraveinous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled	i	Transdermal	j	Vaginal	k	Other (Specify)
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642	<div>[ nano_pr_med_indication_2 ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</div>	Indication(s) for use	text																						
643	<div>[ nano_pr_med_start_date_2 ]</div> <div>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</div>	Start Date	text (date_dmy)																						
644	<div>[ nano_pr_med_ongoing_2 ]</div> <div>Show the field ONLY if:</div>	Ongoing	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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	[nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1																		
645	[ nano_pr_med_end_date_2 ]  Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	End date	text (date_dmy)																
646	[ nano_pr_med_name_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Medication Name (Commercial name)	text																
647	[ nano_pr_med_int_name_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Medication Name (International nonproprietary name)	text																
648	[ nano_pr_dose_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Dose	text (integer, Min: 0, Max: 9999999)																
649	[ nano_pr_dose_unit_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Dose unit	radio <table><tr><td>a</td><td>Microgram</td></tr><tr><td>b</td><td>Miligram</td></tr><tr><td>c</td><td>Gram</td></tr><tr><td>d</td><td>Mililiter</td></tr><tr><td>e</td><td>Other (Specify)</td></tr><tr><td>f</td><td>Unknown</td></tr></table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown				
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650	[ nano_pr_med_frequency_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Frequency	radio <table><tr><td>a</td><td>Daily</td></tr><tr><td>b</td><td>Twice daily</td></tr><tr><td>c</td><td>Three times a day</td></tr><tr><td>d</td><td>Four times a day</td></tr><tr><td>e</td><td>4-6 hours</td></tr><tr><td>f</td><td>6-8 hours</td></tr><tr><td>g</td><td>PRN (ad needed)</td></tr><tr><td>h</td><td>Other (specify)</td></tr></table>	a	Daily	b	Twice daily	c	Three times a day	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (ad needed)	h	Other (specify)
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651	[ nano_pr_med_route_3 ]	Route	radio <table><tr><td>a</td><td>Oral</td></tr></table>	a	Oral														
a	Oral																		

	Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2		<table><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intravenous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	b	Topical	c	Subcutaneous injection	d	Intravenous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled	i	Transdermal	j	Vaginal	k	Other (Specify)
b	Topical																						
c	Subcutaneous injection																						
d	Intravenous injection																						
e	Intramuscular injection																						
f	Rectal																						
g	Nasal																						
h	Inhaled																						
i	Transdermal																						
j	Vaginal																						
k	Other (Specify)																						
652	[ nano_pr_med_indication_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Indication(s) for use	text																				
653	[ nano_pr_med_start_date_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Start Date	text (date_dmy)																				
654	[ nano_pr_med_ongoing_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	Ongoing	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																
1	Yes																						
0	No																						
655	[ nano_pr_med_end_date_3 ]  Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	End date	text (date_dmy)																				
656	[ nano_pr_med_name_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Medication Name (Commercial name)	text																				
657	[ nano_pr_med_int_name_4 ]  Show the field ONLY if:	Medication Name (International nonproprietary name)	text																				

	[nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3																								
658	[ nano_pr_dose_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Dose	text (integer, Min: 0, Max: 9999999)																						
659	[ nano_pr_dose_unit_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Dose unit	radio <table><tr><td>a</td><td>Microgram</td></tr><tr><td>b</td><td>Miligram</td></tr><tr><td>c</td><td>Gram</td></tr><tr><td>d</td><td>Mililiter</td></tr><tr><td>e</td><td>Other (Specify)</td></tr><tr><td>f</td><td>Unknown</td></tr></table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown										
a	Microgram																								
b	Miligram																								
c	Gram																								
d	Mililiter																								
e	Other (Specify)																								
f	Unknown																								
660	[ nano_pr_med_frequency_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Frequency	radio <table><tr><td>a</td><td>Daily</td></tr><tr><td>b</td><td>Twice daily</td></tr><tr><td>c</td><td>Three times a day</td></tr><tr><td>d</td><td>Four times a day</td></tr><tr><td>e</td><td>4-6 hours</td></tr><tr><td>f</td><td>6-8 hours</td></tr><tr><td>g</td><td>PRN (ad needed)</td></tr><tr><td>h</td><td>Other (specify)</td></tr></table>	a	Daily	b	Twice daily	c	Three times a day	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (ad needed)	h	Other (specify)						
a	Daily																								
b	Twice daily																								
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f	6-8 hours																								
g	PRN (ad needed)																								
h	Other (specify)																								
661	[ nano_pr_med_route_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Route	radio <table><tr><td>a</td><td>Oral</td></tr><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intravenous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	a	Oral	b	Topical	c	Subcutaneous injection	d	Intravenous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled	i	Transdermal	j	Vaginal	k	Other (Specify)
a	Oral																								
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i	Transdermal																								
j	Vaginal																								
k	Other (Specify)																								
662	[ nano_pr_med_indication_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Indication(s) for use	text																						
663	[ nano_pr_med_start_date_4 ]	Start Date	text (date_dmy)																						

	Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3														
664	[ nano_pr_med_ongoing_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Ongoing	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
665	[ nano_pr_med_end_date_4 ]  Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	End date	text (date_dmy)												
666	[ nano_pr_med_name_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Medication Name (Commercial name)	text												
667	[ nano_pr_med_int_name_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Medication Name (International nonproprietary name)	text												
668	[ nano_pr_dose_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Dose	text (integer, Min: 0, Max: 9999999)												
669	[ nano_pr_dose_unit_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Dose unit	radio <table><tr><td>a</td><td>Microgram</td></tr><tr><td>b</td><td>Miligram</td></tr><tr><td>c</td><td>Gram</td></tr><tr><td>d</td><td>Mililiter</td></tr><tr><td>e</td><td>Other (Specify)</td></tr><tr><td>f</td><td>Unknown</td></tr></table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown
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b	Miligram														
c	Gram														
d	Mililiter														
e	Other (Specify)														
f	Unknown														
670	[ nano_pr_med_frequency_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Frequency	radio <table><tr><td>a</td><td>Daily</td></tr><tr><td>b</td><td>Twice daily</td></tr><tr><td>c</td><td>Three times a day</td></tr></table>	a	Daily	b	Twice daily	c	Three times a day						
a	Daily														
b	Twice daily														
c	Three times a day														

	count_conc] > 4		<table><tr><td>d</td><td>Four times a day</td></tr><tr><td>e</td><td>4-6 hours</td></tr><tr><td>f</td><td>6-8 hours</td></tr><tr><td>g</td><td>PRN (ad needed)</td></tr><tr><td>h</td><td>Other (specify)</td></tr></table>	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (ad needed)	h	Other (specify)														
d	Four times a day																										
e	4-6 hours																										
f	6-8 hours																										
g	PRN (ad needed)																										
h	Other (specify)																										
671	<p>[ nano_pr_med_route_5 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 4</p>	Route	<table><tr><td colspan="2">radio</td></tr><tr><td>a</td><td>Oral</td></tr><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intravenous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	radio		a	Oral	b	Topical	c	Subcutaneous injection	d	Intravenous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled	i	Transdermal	j	Vaginal	k	Other (Specify)
radio																											
a	Oral																										
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g	Nasal																										
h	Inhaled																										
i	Transdermal																										
j	Vaginal																										
k	Other (Specify)																										
672	<p>[ nano_pr_med_indication_5 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 4</p>	Indication(s) for use	text																								
673	<p>[ nano_pr_med_start_date_5 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 4</p>	Start Date	text (date_dmy)																								
674	<p>[ nano_pr_med_ongoing_5 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 4</p>	Ongoing	<table><tr><td colspan="2">yesno</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	yesno		1	Yes	0	No																		
yesno																											
1	Yes																										
0	No																										
675	<p>[ nano_pr_med_end_date_5 ]</p> <p>Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 4</p>	End date	text (date_dmy)																								
676	[ nano_pr_tests_perf ]	Section Header: <i>Pregnancy informations</i>	<table><tr><td colspan="2">yesno</td></tr><tr><td>1</td><td>Yes</td></tr></table>	yesno		1	Yes																				
yesno																											
1	Yes																										

		Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far?	<table><tr><td>0</td><td>No</td></tr></table>	0	No				
0	No								
677	<p>[ nano_pr_specify ]</p> <p>Show the field ONLY if: [nano_pr_tests_perf] = "1"</p>	Specify	text						
678	<p>[ nano_pr_delivery ]</p>	Delivery	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
679	<p>[ nano_pr_delivery_spec ]</p> <p>Show the field ONLY if: [nano_pr_delivery] = "1"</p>	Specify	radio <table><tr><td>1</td><td>Normal</td></tr><tr><td>2</td><td>Forceps/Ventouse</td></tr><tr><td>3</td><td>Caesarean section</td></tr></table>	1	Normal	2	Forceps/Ventouse	3	Caesarean section
1	Normal								
2	Forceps/Ventouse								
3	Caesarean section								
680	<p>[ nano_pr_problems ]</p> <p>Show the field ONLY if: [nano_pr_delivery] = "1"</p>	Maternal complicatons or problems related to birth	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
681	<p>[ nano_pr_problems_specify ]</p> <p>Show the field ONLY if: [nano_pr_problems] = "1"</p>	Specify	text						
682	<p>[ nano_pr_abortion ]</p>	Abortion	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
683	<p>[ nano_pr_abortion_date ]</p> <p>Show the field ONLY if: [nano_pr_delivery] = "1" or [nano_pr_abortion] = "1"</p>	Date	text (date_dmy)						
684	<p>[ nano_pr_abortion_week ]</p> <p>Show the field ONLY if: [nano_pr_delivery] = "1" or [nano_pr_abortion] = "1"</p>	At week	text (integer)						
685	<p>[ nano_pr_abortion_specify ]</p> <p>Show the field ONLY if: [nano_pr_abortion] = "1"</p>	Specify	radio <table><tr><td>1</td><td>Therapeutic</td></tr><tr><td>2</td><td>Planned</td></tr><tr><td>3</td><td>Spontaneous</td></tr></table>	1	Therapeutic	2	Planned	3	Spontaneous
1	Therapeutic								
2	Planned								
3	Spontaneous								



686	<div>[ nano_pr_specify_abnormal ]</div> <div>Show the field ONLY if: [nano_pr_abortion] = "1"</div>	Specify reason and any abnormalities (if known)	text (integer)																
687	<div>[ nano_pr_neonate ]</div>	Section Header: <i>Child informations</i> Neonate	radio <table><tr><td>a</td><td>Normal</td></tr><tr><td>b</td><td>Abnormal</td></tr><tr><td>c</td><td>Stillbirth</td></tr></table>	a	Normal	b	Abnormal	c	Stillbirth										
a	Normal																		
b	Abnormal																		
c	Stillbirth																		
688	<div>[ nano_pr_neonate_specify ]</div> <div>Show the field ONLY if: [nano_pr_neonate] = "b" or [nano_pr_neonate] = "c"</div>	Specify	text																
689	<div>[ nano_pr_child_gender ]</div>	Gender	radio <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table>	1	Male	2	Female												
1	Male																		
2	Female																		
690	<div>[ nano_pr_child_height ]</div>	Height	text (integer, Min: 0, Max: 70)																
691	<div>[ nano_pr_child_weight ]</div>	Weight	text (integer, Min: 0, Max: 7)																
692	<div>[ nano_pr_child_head ]</div>	Head circumference	text (integer, Min: 0, Max: 70)																
693	<div>[ nano_pr_child_apgar_1 ]</div>	Apgar score 1 min	text (integer, Min: 0, Max: 10)																
694	<div>[ nano_pr_child_apgar_5 ]</div>	Apgar score 5 min	text (integer, Min: 0, Max: 10)																
695	<div>[ nano_pr_child_apgar_10 ]</div>	Apgar score 10 min	text (integer, Min: 0, Max: 10)																
696	<div>[ nano_pr_seriousness ]</div>	Section Header: <i>Assessment of pregnancy outcome</i> Seriousness criteria	radio <table><tr><td>1</td><td>Non serious</td></tr><tr><td>2</td><td>Mother died</td></tr><tr><td>3</td><td>Stillbirth/ Neonate died</td></tr><tr><td>4</td><td>Hospitalisation</td></tr><tr><td>5</td><td>Persistent or significant disability/incapacity</td></tr><tr><td>6</td><td>Congenital anomaly/birth defect</td></tr><tr><td>7</td><td>Life-threatening</td></tr><tr><td>8</td><td>Other significant medical events</td></tr></table>	1	Non serious	2	Mother died	3	Stillbirth/ Neonate died	4	Hospitalisation	5	Persistent or significant disability/incapacity	6	Congenital anomaly/birth defect	7	Life-threatening	8	Other significant medical events
1	Non serious																		
2	Mother died																		
3	Stillbirth/ Neonate died																		
4	Hospitalisation																		
5	Persistent or significant disability/incapacity																		
6	Congenital anomaly/birth defect																		
7	Life-threatening																		
8	Other significant medical events																		

697	[ nano_pr_causality ]	Assessment of causality with study IMP	radio <table><tr><td>1</td><td>No relationship *</td></tr><tr><td>2</td><td>Unlikely *</td></tr><tr><td>3</td><td>Possible *</td></tr><tr><td>4</td><td>Probable *</td></tr><tr><td>5</td><td>Definite *</td></tr></table>	1	No relationship *	2	Unlikely *	3	Possible *	4	Probable *	5	Definite *
1	No relationship *												
2	Unlikely *												
3	Possible *												
4	Probable *												
5	Definite *												
698	[ nano_pr_comments ]	Section Header: <i>Additional informations</i> Comments	text										
699	[ nano_pr_investigator_name ]	Section Header: <i>Investigator signature</i> Name of investigator	text										
700	[ nano_pr_approved_pi ]	Section Header: <i>Pregnancy report PI evaluation</i> Pregnancy report approved by PI	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
701	[ nano_pr_investigator_date ]	Place, date and signature of investigator	text										
702	[ nano_pr_add_comment ]	Additionnal comment	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
703	[ nano_pr_text ]	All pregnancies must be reported to the Principal Investigator	descriptive										
704	[ nano_pr_add_comments ]  Show the field ONLY if: [nano_pr_add_comment] = "1"	Specify	text										
705	[ nano_pr_pi_validation ]	Send the report to the PI for modification/validation	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
706	[ nano_pr_pi_name_2 ]	Name of PI	text Field Annotation: @DEFAULT="Prof Blaise Genton"										
707	[ nano_pr_pi_date ]	Place, date and signature of PI	text Field Annotation: @DEFAULT="Prof Blaise Genton"										
708	[ nano_pr_text_2 ]	All pregnancies must be reported immediately and within a maximum of 24 hours to the Sponsor	descriptive										
709	[ nano_pr_lock_report ]	Lock the report	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
710	[ nano_pr_send_report_sponsor ]	Send the PDF report to the Sponsor	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
711	[ pregnancy_form_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr></table>	0	Incomplete								
0	Incomplete												

			<table><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	1	Unverified	2	Complete										
1	Unverified																
2	Complete																
Instrument: End Of Trial / Early Termination (end_of_trial_early_termination)																	
712	[ nano_end_date_completion ]	Date of end of trial	text (date_dmy)														
713	[ nano_end_trial_period ]	Did the volunteer complete the 6 months trial period ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
714	[ nano_end_date_last ]  Show the field ONLY if: [nano_end_trial_period]='0'	Date of last contact	text (date_dmy)														
715	[ nano_end_reason ]  Show the field ONLY if: [nano_end_trial_period]='0'	Specify reason for early termination	radio <table><tr><td>a</td><td>Not eligible</td></tr><tr><td>b</td><td>Consent withdrawal</td></tr><tr><td>c</td><td>Lost to follow up</td></tr><tr><td>d</td><td>Death</td></tr><tr><td>e</td><td>Adverse Event</td></tr><tr><td>f</td><td>Violation of protocol</td></tr><tr><td>g</td><td>Other</td></tr></table>	a	Not eligible	b	Consent withdrawal	c	Lost to follow up	d	Death	e	Adverse Event	f	Violation of protocol	g	Other
a	Not eligible																
b	Consent withdrawal																
c	Lost to follow up																
d	Death																
e	Adverse Event																
f	Violation of protocol																
g	Other																
716	[ nano_end_specify ]  Show the field ONLY if: [nano_end_reason]='b' or [nano_end_reason]='f' or [nano_end_reason]='g'	Specify	text														
717	[ nano_end_fill_ae_form ]  Show the field ONLY if: [nano_end_reason]='d' or [nano_end_reason]='e'	Please fill a SAE form - Please fill a AE form	descriptive														
718	[ nano_end_randomization_broken ]	Has the randomization code been broken ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
719	[ nano_end_date_broken ]  Show the field ONLY if: [nano_end_randomization_broken]='1'	Date	text (date_dmy)														
720	[ nano_end_allocation ]  Show the field ONLY if:	Allocation	radio <table><tr><td>1</td><td>Vaccine vera</td></tr><tr><td>2</td><td>Vehicle control</td></tr></table>	1	Vaccine vera	2	Vehicle control										
1	Vaccine vera																
2	Vehicle control																

	[nano_end_rando_broken]='1'																		
721	[ nano_end_additional_comm ]	Any additional comment?	yesno <table border="1"> <tr> <td>1</td><td>Yes</td></tr> <tr> <td>0</td><td>No</td></tr> </table>	1	Yes	0	No												
1	Yes																		
0	No																		
722	[ nano_end_add_comm_spec ]  Show the field ONLY if: [nano_end_additional_comm]='1'	Specify	text																
723	[ end_of_trial_early_termination_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr> <td>0</td><td>Incomplete</td></tr> <tr> <td>1</td><td>Unverified</td></tr> <tr> <td>2</td><td>Complete</td></tr> </table>	0	Incomplete	1	Unverified	2	Complete										
0	Incomplete																		
1	Unverified																		
2	Complete																		
<b>Instrument: Medication Form (medication_form)</b>																			
724	[ nano_mf_med_name ]	Medication Name (Commercial name)	text																
725	[ nano_mf_med_int_name ]	Medication Name (International nonproprietary name)	text																
726	[ nano_mf_dose ]	Dose	text (number, Min: 0, Max: 9999999)																
727	[ nano_mf_dose_unit ]	Dose unit	radio <table border="1"> <tr> <td>a</td><td>Microgram</td></tr> <tr> <td>b</td><td>Miligram</td></tr> <tr> <td>c</td><td>Gram</td></tr> <tr> <td>d</td><td>Mililiter</td></tr> <tr> <td>e</td><td>Other (Specify)</td></tr> <tr> <td>f</td><td>Unknown</td></tr> </table>	a	Microgram	b	Miligram	c	Gram	d	Mililiter	e	Other (Specify)	f	Unknown				
a	Microgram																		
b	Miligram																		
c	Gram																		
d	Mililiter																		
e	Other (Specify)																		
f	Unknown																		
728	[ nano_mf_specify ]  Show the field ONLY if: [nano_mf_dose_unit] = "e"	Specify	text																
729	[ nano_mf_med_frequency ]	Frequency	radio <table border="1"> <tr> <td>a</td><td>Daily</td></tr> <tr> <td>b</td><td>Twice daily</td></tr> <tr> <td>c</td><td>Three times a day</td></tr> <tr> <td>d</td><td>Four times a day</td></tr> <tr> <td>e</td><td>4-6 hours</td></tr> <tr> <td>f</td><td>6-8 hours</td></tr> <tr> <td>g</td><td>PRN (as needed)</td></tr> <tr> <td>h</td><td>Other (specify)</td></tr> </table>	a	Daily	b	Twice daily	c	Three times a day	d	Four times a day	e	4-6 hours	f	6-8 hours	g	PRN (as needed)	h	Other (specify)
a	Daily																		
b	Twice daily																		
c	Three times a day																		
d	Four times a day																		
e	4-6 hours																		
f	6-8 hours																		
g	PRN (as needed)																		
h	Other (specify)																		

730	[ nano_mf_specify_2 ]  Show the field ONLY if: [nano_mf_med_frequency] = "h"	Specify	text																						
731	[ nano_mf_med_route ]	Route	radio <table><tr><td>a</td><td>Oral</td></tr><tr><td>b</td><td>Topical</td></tr><tr><td>c</td><td>Subcutaneous injection</td></tr><tr><td>d</td><td>Intravenous injection</td></tr><tr><td>e</td><td>Intramuscular injection</td></tr><tr><td>f</td><td>Rectal</td></tr><tr><td>g</td><td>Nasal</td></tr><tr><td>h</td><td>Inhaled</td></tr><tr><td>i</td><td>Transdermal</td></tr><tr><td>j</td><td>Vaginal</td></tr><tr><td>k</td><td>Other (Specify)</td></tr></table>	a	Oral	b	Topical	c	Subcutaneous injection	d	Intravenous injection	e	Intramuscular injection	f	Rectal	g	Nasal	h	Inhaled	i	Transdermal	j	Vaginal	k	Other (Specify)
a	Oral																								
b	Topical																								
c	Subcutaneous injection																								
d	Intravenous injection																								
e	Intramuscular injection																								
f	Rectal																								
g	Nasal																								
h	Inhaled																								
i	Transdermal																								
j	Vaginal																								
k	Other (Specify)																								
732	[ nano_mf_specify_3 ]  Show the field ONLY if: [nano_mf_med_route] = "k"	Specify	text																						
733	[ nano_mf_med_indication ]	Indication(s) for use	text																						
734	[ nano_mf_med_start_date ]	Start Date	text (date_dmy)																						
735	[ nano_mf_med_ongoing ]	Ongoing	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
1	Yes																								
0	No																								
736	[ nano_mf_med_end_date ]  Show the field ONLY if: [nano_mf_med_ongoing] = '0'	End date	text (date_dmy)																						
737	[ nano_mf_med_prescribed ]	Was this medication prescribed for an AE ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
1	Yes																								
0	No																								
738	[ nano_mf_med_ae_n ]  Show the field ONLY if: [nano_mf_med_prescribed] = '1'	AE number	sql <table><tr><td colspan="2">SELECT instance, value from redcap_data where project_id = 341 and field_name = 'nano_ae_number' and record = [record-name] order by value</td></tr></table>	SELECT instance, value from redcap_data where project_id = 341 and field_name = 'nano_ae_number' and record = [record-name] order by value																					
SELECT instance, value from redcap_data where project_id = 341 and field_name = 'nano_ae_number' and record = [record-name] order by value																									
739	[ medication_form_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr></table>	0	Incomplete	1	Unverified																		
0	Incomplete																								
1	Unverified																								

2 Complete

**Instrument: Screening and enrolment log (screening\_and\_enrolment\_log)**

740	[ nano_sel_sr_id ]	Screening ID	text Field Annotation: @READONLY																										
741	[ nano_sel_id ]	Inclusion ID	text Field Annotation: @READONLY																										
742	[ nano_sel_date_icf ]	Date of ICF signature	text (datetime_dmy) Field Annotation: @READONLY																										
743	[ nano_sel_date_screening ]	Date of screening	text (date_dmy) Field Annotation: @READONLY																										
744	[ nano_sel_date_sf ]	Date of screenfailure (if applicable)	text (date_dmy) Field Annotation: @READONLY																										
745	[ nano_sel_sf_specify ]	Specify reason for screen failure	<table><tr><td colspan="2">radio</td></tr><tr><td>a</td><td>Age &lt; 18 or &gt; 45 years</td></tr><tr><td>b</td><td>Written consent not provided/consent withdrawal</td></tr><tr><td>c</td><td>Not able/do not want to attend all scheduled visit/to comply with all study requirments</td></tr><tr><td>d</td><td>Chronic illness that might interfere with trial conduct</td></tr><tr><td>e</td><td>Current alcohol abuse or drug addiction (reported or suspected)</td></tr><tr><td>f</td><td>Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy</td></tr><tr><td>g</td><td>Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening heaction to vaccines, or to a vaccine containing any of the same substances</td></tr><tr><td>h</td><td>Thrombocytopenia or any coagulation disorder</td></tr><tr><td>i</td><td>Pregnancy or lactating</td></tr><tr><td>j</td><td>Non-use of an effective method of contraception from at least 4 weeks prior to the first vaccination</td></tr><tr><td>k</td><td>Participation in another clinical trial investigating a vaccine, drug, medical device or medical procedure in the 4 weeks preceding the first vaccination, or planned participation during the study period</td></tr><tr><td>l</td><td>Receipt of any vaccine in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received up to 2 weeks before study vaccines) or planned receipt of any</td></tr></table>	radio		a	Age < 18 or > 45 years	b	Written consent not provided/consent withdrawal	c	Not able/do not want to attend all scheduled visit/to comply with all study requirments	d	Chronic illness that might interfere with trial conduct	e	Current alcohol abuse or drug addiction (reported or suspected)	f	Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy	g	Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening heaction to vaccines, or to a vaccine containing any of the same substances	h	Thrombocytopenia or any coagulation disorder	i	Pregnancy or lactating	j	Non-use of an effective method of contraception from at least 4 weeks prior to the first vaccination	k	Participation in another clinical trial investigating a vaccine, drug, medical device or medical procedure in the 4 weeks preceding the first vaccination, or planned participation during the study period	l	Receipt of any vaccine in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received up to 2 weeks before study vaccines) or planned receipt of any
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l	Receipt of any vaccine in the 4 weeks preceding the trial vaccination (excepting influenza vaccination, which may be received up to 2 weeks before study vaccines) or planned receipt of any																												

			<div>vaccine in the 4 weeks following trial vaccination</div> <div>m Receipt of immunoglobulins, blood or blood-derived products in the past 3 months</div> <div>n Previous vaccination against Japanese encephalitis, Yellow Fever, or any dengue virus vaccine</div> <div>o Self-reported or documented history of flavivirus infection*, confirmed either clinically or serologically</div> <div>p Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C</div> <div>q Previous residence for more than 12months in, or travel in the last 30 days to flavivirus-endemic regions</div> <div>r At high risk for dengue infection during the trial</div> <div>s Identified as an Investigator or employee of the Investigator or study centre with direct involvement in the proposed study, or identified as an immediate family member (i.e., parent, spouse, natural or adopted child) of the Investigator or employee with direct involvement in the proposed study</div> <div>t Refusal to be informed in the event that relevant results concerning the participant's health are revealed.</div> <div>u Abnormal laboratory (blood/urine) value</div> <div>v Lost to follow up</div> <div>w Other</div> <div>Field Annotation: @READONLY</div>
746	[ nano_sel_vac ]	Vaccinated (1st dose)?	<div>yesno</div> <div> <div>1 Yes</div> <div>0 No</div> </div> <div>Field Annotation: @READONLY</div>
747	[ nano_sel_reason_no_vac ]	If no, reason for non-eligibility for dose 1	<div>text</div> <div>Field Annotation: @READONLY</div>
748	[ nano_sel_date_v1 ]	Date of vaccination 1	<div>text (datetime_dmy)</div> <div>Field Annotation: @READONLY</div>
749	[ nano_sel_vac_2 ]	Vaccinated (2nd dose)?	<div>yesno</div> <div> <div>1 Yes</div> <div>0 No</div> </div>

			Field Annotation: @READONLY														
750	[ nano_sel_reason_no_vac_2 ]	If no, reason for non-eligibility for dose 2	text Field Annotation: @READONLY														
751	[ nano_sel_date_v2 ]	Date of vaccination 2	text (datetime_dmy) Field Annotation: @READONLY														
752	[ nano_sel_date_end ]	Date of end of trial :	text (date_dmy) Field Annotation: @READONLY														
753	[ nano_sel_date_end_6m ]	Did the volunteer complete the 6 months trial period ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No										
1	Yes																
0	No																
754	[ nano_sel_date_end_2 ]	If early termination, reason for end of trial :	radio <table><tr><td>a</td><td>Not eligible</td></tr><tr><td>b</td><td>Consent withdrawal</td></tr><tr><td>c</td><td>Lost to follow up</td></tr><tr><td>d</td><td>Death</td></tr><tr><td>e</td><td>Adverse Event</td></tr><tr><td>f</td><td>Violation of protocol</td></tr><tr><td>g</td><td>Other</td></tr></table> Field Annotation: @READONLY	a	Not eligible	b	Consent withdrawal	c	Lost to follow up	d	Death	e	Adverse Event	f	Violation of protocol	g	Other
a	Not eligible																
b	Consent withdrawal																
c	Lost to follow up																
d	Death																
e	Adverse Event																
f	Violation of protocol																
g	Other																
755	[ screening_and_enrolment_log_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																
Instrument: <b>Compensation log</b> (compensation_log)																	
756	[ nano_comp_id ]	Inclusion ID	text Field Annotation: @READONLY														
757	[ nano_comp ]	1st vaccination Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No										
1	Yes																
0	No																
758	[ nano_comp_chf_date ]	Date	text (date_dmy) Field Annotation: @READONLY														
759	[ nano_comp_reason ]	If no, reason	text Field Annotation: @READONLY														
760	[ nano_comp_2 ]	Visit 4 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No										
1	Yes																
0	No																
761	[ nano_comp_chf_date_2 ]	Date	text (date_dmy) Field Annotation: @READONLY														



762	[ nano_comp_reason_2 ]	If no, reason	text Field Annotation: @READONLY				
763	[ nano_comp_3 ]	Visit 5 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No
1	Yes						
0	No						
764	[ nano_comp_chf_date_3 ]	Date	text (date_dmy) Field Annotation: @READONLY				
765	[ nano_comp_reason_3 ]	If no, reason	text Field Annotation: @READONLY				
766	[ nano_comp_4 ]	2nd vaccination Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No
1	Yes						
0	No						
767	[ nano_comp_chf_date_4 ]	Date	text (date_dmy) Field Annotation: @READONLY				
768	[ nano_comp_reason_4 ]	If no, reason	text Field Annotation: @READONLY				
769	[ nano_comp_5 ]	Visit 8 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No
1	Yes						
0	No						
770	[ nano_comp_chf_date_5 ]	Date	text (date_dmy) Field Annotation: @READONLY				
771	[ nano_comp_reason_5 ]	If no, reason	text Field Annotation: @READONLY				
772	[ nano_comp_6 ]	Visit 9 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No
1	Yes						
0	No						
773	[ nano_comp_chf_date_6 ]	Date	text (date_dmy) Field Annotation: @READONLY				
774	[ nano_comp_reason_6 ]	If no, reason	text Field Annotation: @READONLY				
775	[ nano_comp_7 ]	Visit 11 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	1	Yes	0	No
1	Yes						
0	No						
776	[ nano_comp_chf_date_7 ]	Date	text (date_dmy) Field Annotation: @READONLY				
777	[ nano_comp_reason_7 ]	If no, reason	text Field Annotation: @READONLY				
778	[ nano_comp_8 ]	Visit 12 Compensation received ?	yesno <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes		
1	Yes						

			<table><tr><td>0</td><td>No</td></tr></table> Field Annotation: @READONLY	0	No				
0	No								
779	[ nano_comp_chf_date_8 ]	Date	text (date_dmy) Field Annotation: @READONLY						
780	[ nano_comp_reason_8 ]	If no, reason	text Field Annotation: @READONLY						
781	[ compensation_log_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

## Data Dictionary Codebook

**naNO-COVID - Pharmacovigilance (PID: 342)**

01/10/2024 9:10am

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)				
Instrument: <b>Serious Adverse Event Form</b> (serious_adverse_event_form)							
1	[ record_id ]	Record id	text, Required Field Annotation: @HIDDEN-PDF				
2	[ nano_sae_sae_number ]	SAE number	text, Required				
3	[ nano_sae_custom_reco rd_id ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF				
4	[ nano_sae_title ]	Title of research project	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'naNO-DENGUE: A Phase-I study of a nanoparticle-based peptide vaccine against Dengue virus'				
5	[ nano_sae_sponsor_nam e ]	Name of Sponsor	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'				
6	[ nano_sae_sponsor_adr ess ]	Address of Sponsor	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = '4 & 5 Dunmore Court Wootton Road, Abingdon, Oxfordshire, England, OX13 6BH'				
7	[ nano_sae_pi_name ]	Name of Principal Investigator	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'				
8	[ nano_sae_product_nam e ]	Investigational Medicinal Product Name	text, Required Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"				
9	[ nano_sae_pi_adress ]	Adress of Principal Investigator	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Unisanté, Département Formation, recherche et innovation Policlinique de médecine tropicale, voyages et vaccinations Rue du Bugnon 44 1011 Lausanne, Suisse Blaise.genton@unisante.ch M :+41 79 556 58 68'				
10	[ nano_sae_project_num ber ]	BASEC research project number (Swissethics)	text, Required Field Annotation: @DEFAULT="2020-02258"				
11	[ nano_sae_notif_numbe r ]	Notification n° (Swissmedic)	text, Required Field Annotation: @DEFAULT="2021DR1042"				
12	[ nano_sae_id ]	Section Header: <i>SAE information</i> Inclusion ID	text, Required Custom alignment: RH				
13	[ nano_sae_dob ]	Year of birth	text (integer), Required Custom alignment: RH				
14	[ nano_sae_sex ]	Sex	radio, Required <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table>	1	Male	2	Female
1	Male						
2	Female						

			Custom alignment: RH		
15	[ nano_sae_ethnicity ]	Ethnicity (Several possible)	checkbox, Required		
			1	nano_sae_ethnicity__1	Caucasian
			2	nano_sae_ethnicity__2	Asian
			3	nano_sae_ethnicity__3	Black
			4	nano_sae_ethnicity__4	Carribean
			5	nano_sae_ethnicity__5	Indian
			6	nano_sae_ethnicity__6	Arab
			7	nano_sae_ethnicity__7	Other
16	[ nano_sae_ethnicity_specify ]  Show the field ONLY if: [nano_sae_ethnicity(7)] = '1'	Specify	text, Required		
17	[ nano_sae_date_containner ]	Date of onset {nano_sae_ae_date} {nano_sae_date_unknown}	descriptive		
18	[ nano_sae_ae_date ]	AE onset date	text (date_dmy)		
19	[ nano_sae_date_unknownn ]	Date unknown	checkbox		
			1	nano_sae_date_unknown__1	Date unknown
20	[ nano_sae_ae_awareness ]	AE awareness date	text (date_dmy), Required		
21	[ nano_sae_ae_evolutionn ]	Does this SAE form report the evolution of a previously reported AE ?	yesno, Required		
			1	Yes	
			0	No	
22	[ nano_sae_ae_number ]  Show the field ONLY if: [nano_sae_ae_evolutionn] = "1"	Specify AE number	text, Required		
23	[ nano_sae_ae_description ]	Section Header: <i>General</i>  Describe the AE and the connection to project procedures (including relevant test/lab data)	notes, Required		
24	[ nano_sae_ae_solicited ]	Which type of AE is it ?	radio, Required		
			1	Solicited AE	
			2	Unsolicited AE related with an abnormal laboratory value	
			3	Unsolicited AE	
25	[ nano_sae_fda_toxicity ]  Show the field ONLY if: [nano_sae_ae_solicited] = "1"	FDA toxicity grading scale term	dropdown, Required		
			1	Pain	
			2	Tenderness	
			3	Erythema/Redness	
			4	Induration/Swelling	
			5	Nausae/Vomiiting	
			6	Diarrhea	
			7	Headache	
			8	Fatigue	

			<table><tr><td>9</td><td>Myalgia</td></tr><tr><td>10</td><td>Fever</td></tr></table>	9	Myalgia	10	Fever						
9	Myalgia												
10	Fever												
26	<div>[ nano_sae_fda_tox_grade_2 ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "1"</div>	AE grade according to adapted FDA toxicity grading scale	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr></table>	1	Grade 1	2	Grade 2	3	Grade 3				
1	Grade 1												
2	Grade 2												
3	Grade 3												
27	<div>[ nano_sae_fda_tox_grade ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "1"</div>		descriptive (Attachment: naNO-COVID_FDA_adapted.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF										
28	<div>[ nano_sae_labour_ctcae_term ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "2"</div>	AE term	text, Required										
29	<div>[ nano_sae_ctcae_grade_v6 ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "2"</div>	AE grade according to adapted CTCAE v5.0	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr><tr><td>4</td><td>Grade 4</td></tr><tr><td>5</td><td>Grade 5</td></tr></table>	1	Grade 1	2	Grade 2	3	Grade 3	4	Grade 4	5	Grade 5
1	Grade 1												
2	Grade 2												
3	Grade 3												
4	Grade 4												
5	Grade 5												
30	<div>[ nano_sae_ctcae_grade_v7 ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "2"</div>		descriptive (Attachment: naNO-COVID_CTCAE_adapted_lab.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF										
31	<div>[ nano_sae_ctcae_grade ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "3"</div>	CTCAE term for grading AE	text, Required <table><tr><td>BIOPORTAL:CTCAE</td><td>BIOPORTAL:CTCAE</td></tr></table>	BIOPORTAL:CTCAE	BIOPORTAL:CTCAE								
BIOPORTAL:CTCAE	BIOPORTAL:CTCAE												
32	<div>[ nano_sae_spec_ctcae ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "3"</div>	If needed, please specify	text, Required										
33	<div>[ nano_sae_ctcae_grade_v5 ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited] = "3"</div>	AE grade according to CTCAE v5.0	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr><tr><td>3</td><td>Grade 3</td></tr><tr><td>4</td><td>Grade 4</td></tr><tr><td>5</td><td>Grade 5</td></tr></table>	1	Grade 1	2	Grade 2	3	Grade 3	4	Grade 4	5	Grade 5
1	Grade 1												
2	Grade 2												
3	Grade 3												
4	Grade 4												
5	Grade 5												
34	<div>[ nano_sae_yes_no ]</div>	Is this a serious adverse event ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
35	<div>[ nano_sae_type ]</div> <div>Show the field ONLY if:</div>	Check SAE (seriousness definition)	radio, Required <table><tr><td>a</td><td>Death</td></tr></table>	a	Death								
a	Death												

	[ nano_sae_yes_no ] = "1"		<table><tr><td>b</td><td>Life-threatening event</td></tr><tr><td>c</td><td>Important medical event (i.e. jeopardises the patient or may require an intervention to prevent death or life threatening event)</td></tr><tr><td>d</td><td>Persistent or significant disability or incapacity</td></tr><tr><td>e</td><td>Hospitalisation or prolongation of an existing hospitalisation</td></tr><tr><td>f</td><td>Congenital anomaly or birth defect (in offspring of the subject)</td></tr></table>	b	Life-threatening event	c	Important medical event (i.e. jeopardises the patient or may require an intervention to prevent death or life threatening event)	d	Persistent or significant disability or incapacity	e	Hospitalisation or prolongation of an existing hospitalisation	f	Congenital anomaly or birth defect (in offspring of the subject)
b	Life-threatening event												
c	Important medical event (i.e. jeopardises the patient or may require an intervention to prevent death or life threatening event)												
d	Persistent or significant disability or incapacity												
e	Hospitalisation or prolongation of an existing hospitalisation												
f	Congenital anomaly or birth defect (in offspring of the subject)												
36	[ nano_sae_interest ]	Is this an adverse event of special interest ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
37	[ nano_sae_aes_i_def ]		descriptive (Attachment: Definition of Adverse Event of Special Interest.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF										
38	[ nano_sae_unexpected_ae ]	Was this an unexpected AE ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
39	[ nano_sae_doses ]	Section Header: <i>IMP</i> Were one or two doses administred ?	radio, Required <table><tr><td>1</td><td>One</td></tr><tr><td>2</td><td>Two</td></tr></table>	1	One	2	Two						
1	One												
2	Two												
40	[ nano_sae_random_number ]	Randomisation number	text (integer), Required										
41	[ nano_sae_code_broken ]	Was the code broken ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
42	[ nano_sae_detail ]  Show the field ONLY if: [ nano_sae_code_broken ] = "1"	Please detail the reason for unblinding, the person who proceeded to unblinding and the date.	notes, Required										
43	[ nano_sae_imp_name ]	Name of IMP : PepGNP-Covid19 or vehicle-GNP	descriptive										
44	[ nano_sae_dose ]	Dose	radio, Required <table><tr><td>1</td><td>Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)</td></tr><tr><td>2</td><td>High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)</td></tr></table>	1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)	2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)						
1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)												
2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)												
45	[ nano_sae_route ]	Route : Intradermal injection	descriptive										
46	[ nano_sae_date_administered ]	Administration date dose 1	text (date_dmy), Required										
47	[ nano_sae_date_administered_2 ]  Show the field ONLY if: [ nano_sae_doses ] = "2"	Administration date dose 2	text (date_dmy), Required										
48	[ nano_sae_causality ]	Section Header: <i>AE Causality</i>	radio, Required										

		Causality of event to intervention	<table><tr><td>1</td><td>No relationship</td></tr><tr><td>2</td><td>Possible</td></tr><tr><td>3</td><td>Probable</td></tr><tr><td>4</td><td>Definite</td></tr></table>	1	No relationship	2	Possible	3	Probable	4	Definite
1	No relationship										
2	Possible										
3	Probable										
4	Definite										
49	[ nano_sae_causality_def ]		descriptive (Attachment: Guidelines for assessing the relationship of vaccine administration to an adverse event.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF								
50	[ nano_sae_table ]	Section Header: <i>Relevant medical history</i> Disease / Intervention /Allergy Start date Ongoing Stop date {nano_sae_disease} {nano_sae_date_disease} {nano_sae_disease_ongoing} {nano_sae_disease_stop} {nano_sae_disease_1} {nano_sae_date_disease_1} {nano_sae_disease_ongoing_1} {nano_sae_disease_stop_1} {nano_sae_disease_2} {nano_sae_date_disease_2} {nano_sae_disease_ongoing_2} {nano_sae_disease_stop_2} {nano_sae_disease_3} {nano_sae_date_disease_3} {nano_sae_disease_ongoing_3} {nano_sae_disease_stop_3} {nano_sae_disease_4} {nano_sae_date_disease_4} {nano_sae_disease_ongoing_4} {nano_sae_disease_stop_4}	descriptive								
51	[ nano_sae_disease ]	Disease / Intervention /Allergy	text								
52	[ nano_sae_date_disease ]	Start date	text								
53	[ nano_sae_disease_ongoing ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
54	[ nano_sae_disease_stop ]	Stop date	text								
55	[ nano_sae_disease_1 ]	Disease / Intervention /Allergy	text								
56	[ nano_sae_date_disease_1 ]	Start date	text								
57	[ nano_sae_disease_ongoing_1 ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
58	[ nano_sae_disease_stop_1 ]	Stop date	text								
59	[ nano_sae_disease_2 ]	Disease / Intervention /Allergy	text								
60	[ nano_sae_date_disease_2 ]	Start date	text								
61	[ nano_sae_disease_ongoing_2 ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
62	[ nano_sae_disease_stop_2 ]	Stop date	text								
63	[ nano_sae_disease_3 ]	Disease / Intervention /Allergy	text								

64	[ nano_sae_date_diseas e_3 ]	Start date	text												
65	[ nano_sae_disease_ong oing_3 ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
66	[ nano_sae_disease_sto p_3 ]	Stop date	text												
67	[ nano_sae_disease_4 ]	Disease / Intervention /Allergy	text												
68	[ nano_sae_date_diseas e_4 ]	Start date	text												
69	[ nano_sae_disease_ong oing_4 ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
70	[ nano_sae_disease_sto p_4 ]	Stop date	text												
71	[ nano_sae_drug ]	Section Header: <i>Concomitant medications</i> Concomitant drug(s) (exclude those to treat event)	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
72	[ nano_sae_conc_count ]  Show the field ONLY if: [nano_sae_drug] ="1"	How many concomitant drug ?	dropdown, Required <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr><tr><td>6</td><td>6</td></tr></table>	1	1	2	2	3	3	4	4	5	5	6	6
1	1														
2	2														
3	3														
4	4														
5	5														
6	6														
73	[ nano_sae_med_name ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 0	Medication Name (Commercial name)	text, Required												
74	[ nano_sae_med_name_in ter ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 0	Medication Name (International nonproprietary name)	text, Required												
75	[ nano_sae_med_dose ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 0	Dose	text (number), Required												



76	<div>[ nano_sae_med_dose_unit ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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2	Miligram																								
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5	Other (Specify)																								
6	Unknown																								
77	<div>[ nano_sae_med_dose_spec ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_unit] = "5"</div>	Specify	text, Required																						
78	<div>[ nano_sae_med_dose_freq ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
1	Daily																								
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8	Other (specify)																								
79	<div>[ nano_sae_med_freq_spec ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq] = "8"</div>	Specify	text, Required																						
80	<div>[ nano_sae_med_route ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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9	Transdermal																								
10	Vaginal																								
11	Other (Specify)																								
81	<div>[ nano_sae_med_route_spec ]</div> <div>Show the field ONLY if: [nano_sae_med_route] = "11"</div>	Specify	text, Required																						
82	<div>[ nano_sae_med_use ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</div>	Indication(s) for use	text, Required																						

	[nt] > 0														
83	<div>[ nano_sae_med_start ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 0</div>	Start Date	text (date_dmy), Required												
84	<div>[ nano_sae_med_ongoi ng ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 0</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
85	<div>[ nano_sae_med_end_dat e ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" A ND [nano_sae_med_on going] = "0" and [nano_ sae_conc_count] &gt; 0</div>	End date	text (date_dmy), Required												
86	<div>[ nano_sae_med_name_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 1</div>	Medication Name (Commercial name)	text, Required												
87	<div>[ nano_sae_med_name_in ter_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 1</div>	Medication Name (International nonproprietary name)	text, Required												
88	<div>[ nano_sae_med_dose_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 1</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
89	<div>[ nano_sae_med_dose_un it_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 1</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
1	Microgram														
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90	<div>[ nano_sae_med_dose_sp ec_1 ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_u nit_1] = "5"</div>	Specify	text, Required												
91	<div>[ nano_sae_med_dose_fr eq_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] &gt; 1</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day						
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92	<p>[ nano_sae_med_freq_spec_1 ]</p> <p>Show the field ONLY if: [nano_sae_med_dose_freq_1] = "8"</p>	Specify	text, Required																								
93	<p>[ nano_sae_med_route_1 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</p>	Route	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	radio, Required		1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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94	<p>[ nano_sae_med_route_spec_1 ]</p> <p>Show the field ONLY if: [nano_sae_med_route_1] = "11"</p>	Specify	text, Required																								
95	<p>[ nano_sae_med_use_1 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</p>	Indication(s) for use	text, Required																								
96	<p>[ nano_sae_med_start_1 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</p>	Start Date	text (date_dmy), Required																								
97	<p>[ nano_sae_med_ongoing_1 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</p>	Ongoing	<table><tr><td colspan="2">yesno, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	yesno, Required		1	Yes	0	No																		
yesno, Required																											
1	Yes																										
0	No																										
98	<p>[ nano_sae_med_end_date_1 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_on</p>	End date	text (date_dmy), Required																								

	going_1] = "0" and [nano_sae_conc_count] > 1																		
99	[ nano_sae_med_name_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Medication Name (Commercial name)	text, Required																
100	[ nano_sae_med_name_inter_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Medication Name (International nonproprietary name)	text, Required																
101	[ nano_sae_med_dose_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Dose	text (integer, Min: 0, Max: 9999999), Required																
102	[ nano_sae_med_dose_unit_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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103	[ nano_sae_med_dose_spec_2 ]  Show the field ONLY if: [nano_sae_med_dose_unit_2] = "5"	Specify	text, Required																
104	[ nano_sae_med_dose_freq_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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105	[ nano_sae_med_freq_spec_2 ]  Show the field ONLY if: [nano_sae_med_dose_freq_2] = "8"	Specify	text, Required																
106	[ nano_sae_med_route_2 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 2	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection								
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11	Other (Specify)																
107	<div>[ nano_sae_med_route_spec_2 ]</div> <div>Show the field ONLY if: [nano_sae_med_route_2] = "11"</div>	Specify	text, Required														
108	<div>[ nano_sae_med_use_2 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 2</div>	Indication(s) for use	text, Required														
109	<div>[ nano_sae_med_start_2 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 2</div>	Start Date	text (date_dmy), Required														
110	<div>[ nano_sae_med_ongoing_2 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 2</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
111	<div>[ nano_sae_med_end_date_2 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing_2] = "0" and [nano_sae_conc_count] &gt; 2</div>	End date	text (date_dmy), Required														
112	<div>[ nano_sae_med_name_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Medication Name (Commercial name)	text, Required														
113	<div>[ nano_sae_med_name_inter_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Medication Name (International nonproprietary name)	text, Required														
114	<div>[ nano_sae_med_dose_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Dose	text (number, Min: 0, Max: 9999999), Required														

115	<div>[ nano_sae_med_dose_unit_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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2	Miligram																								
3	Gram																								
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6	Unknown																								
116	<div>[ nano_sae_med_dose_spec_3 ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_unit_3] = "5"</div>	Specify	text, Required																						
117	<div>[ nano_sae_med_dose_freq_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
1	Daily																								
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118	<div>[ nano_sae_med_freq_spec_3 ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq_3] = "8"</div>	Specify	text, Required																						
119	<div>[ nano_sae_med_route_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
1	Oral																								
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120	<div>[ nano_sae_med_route_spec_3 ]</div> <div>Show the field ONLY if: [nano_sae_med_route_3] = "11"</div>	Specify	text, Required																						
121	<div>[ nano_sae_med_use_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count]</div>	Indication(s) for use	text, Required																						

	[ nano_sae_med_start_3 ]														
122	[ nano_sae_med_start_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 3	Start Date	text (date_dmy), Required												
123	[ nano_sae_med_ongoing_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 3	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
124	[ nano_sae_med_end_date_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing_3] = "0" and [nano_sae_conc_count] > 3	End date	text (date_dmy), Required												
125	[ nano_sae_med_name_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Medication Name (Commercial name)	text, Required												
126	[ nano_sae_med_name_inter_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Medication Name (International nonproprietary name)	text, Required												
127	[ nano_sae_med_dose_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Dose	text (number, Min: 0, Max: 9999999), Required												
128	[ nano_sae_med_dose_unit_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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5	Other (Specify)														
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129	[ nano_sae_med_dose_spec_4 ]  Show the field ONLY if: [nano_sae_med_dose_unit_4] = "5"	Specify	text, Required												
130	[ nano_sae_med_dose_freq_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day						
1	Daily														
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	nt] > 4		<table><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)												
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131	[ nano_sae_med_freq_spec_4 ]  Show the field ONLY if: [nano_sae_med_dose_freq_4] = "8"	Specify	text, Required																						
132	[ nano_sae_med_route_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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133	[ nano_sae_med_route_spec_4 ]  Show the field ONLY if: [nano_sae_med_route_4] = "11"	Specify	text, Required																						
134	[ nano_sae_med_use_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Indication(s) for use	text, Required																						
135	[ nano_sae_med_start_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Start Date	text (date_dmy), Required																						
136	[ nano_sae_med_ongoing_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 4	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
1	Yes																								
0	No																								
137	[ nano_sae_med_end_date_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_on	End date	text (date_dmy), Required																						



	going_4] = "0" and [nano_sae_conc_count] > 4																		
138	[ nano_sae_med_name_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Medication Name (Commercial name)	text, Required																
139	[ nano_sae_med_name_inter_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Medication Name (International nonproprietary name)	text, Required																
140	[ nano_sae_med_dose_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Dose	text (number, Min: 0, Max: 9999999), Required																
141	[ nano_sae_med_dose_unit_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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142	[ nano_sae_med_dose_spec_5 ]  Show the field ONLY if: [nano_sae_med_dose_unit_5] = "5"	Specify	text, Required																
143	[ nano_sae_med_dose_freq_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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144	[ nano_sae_med_freq_spec_5 ]  Show the field ONLY if: [nano_sae_med_dose_freq_5] = "8"	Specify	text, Required																
145	[ nano_sae_med_route_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection								
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9	Transdermal																
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146	[ nano_sae_med_route_spec_5 ]  Show the field ONLY if: [nano_sae_med_route_5] = "11"	Specify	text, Required														
147	[ nano_sae_med_use_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Indication(s) for use	text, Required														
148	[ nano_sae_med_start_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Start Date	text (date_dmy), Required														
149	[ nano_sae_med_ongoing_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 5	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
1	Yes																
0	No																
150	[ nano_sae_med_end_date_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing_5] = "0" and [nano_sae_conc_count] > 5	End date	text (date_dmy), Required														
151	[ nano_sae_test_performed ]	Section Header: <i>Relevant paraclinic tests</i>  Have some paraclinical tests/procedures been performed ?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known								
1	Yes																
2	No																
3	Not known																
152	[ nano_sae_lab_tests ]  Show the field ONLY if: [nano_sae_test_performed] = "1"	Laboratory tests	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known								
1	Yes																
2	No																
3	Not known																
153	[ nano_sae_radio_tests ]  Show the field ONLY if: [nano_sae_test_performed] = "1"	Radiological exams	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known								
1	Yes																
2	No																
3	Not known																

154	[ nano_sae_relevant_proced ]  Show the field ONLY if: [nano_sae_test_performed] = "1"	Other relevant diagnostic procedure(s)*	radio, Required <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>2</td> <td>No</td> </tr> <tr> <td>3</td> <td>Not known</td> </tr> </table>	1	Yes	2	No	3	Not known												
1	Yes																				
2	No																				
3	Not known																				
155	[ nano_sae_specify ]  Show the field ONLY if: [nano_sae_relevant_proced] = "1"	Specify	text, Required																		
156	[ nano_sae_main_result ]  Show the field ONLY if: [nano_sae_test_performed] = "1"	Please provide the main results of the exams performed	notes, Required																		
157	[ nano_sae_text ]  Show the field ONLY if: [nano_sae_relevant_proced] = "1" OR [nano_sae_radio_tests] = "1" OR [nano_sae_lab_tests] = "1"	Do not forget to collect complementary exam, remove identifying data, code them, register them as source documents and send them to the PI in a separate email.	descriptive Field Annotation: @HIDDEN-PDF																		
158	[ nano_sae_action_taken_imp ]	Section Header: <i>Actions taken and outcome</i>  Which action(s) was/were taken with IMP ? (Several possible)	checkbox, Required <table border="1"> <tr> <td>a</td> <td>nano_sae_action_taken_imp__a</td> <td>No action</td> </tr> <tr> <td>b</td> <td>nano_sae_action_taken_imp__b</td> <td>Dose no change</td> </tr> <tr> <td>c</td> <td>nano_sae_action_taken_imp__c</td> <td>Dose reduced</td> </tr> <tr> <td>d</td> <td>nano_sae_action_taken_imp__d</td> <td>Dose increased</td> </tr> <tr> <td>e</td> <td>nano_sae_action_taken_imp__e</td> <td>Drug tempor interrupt</td> </tr> <tr> <td>f</td> <td>nano_sae_action_taken_imp__f</td> <td>Drug withdraw</td> </tr> </table>	a	nano_sae_action_taken_imp__a	No action	b	nano_sae_action_taken_imp__b	Dose no change	c	nano_sae_action_taken_imp__c	Dose reduced	d	nano_sae_action_taken_imp__d	Dose increased	e	nano_sae_action_taken_imp__e	Drug tempor interrupt	f	nano_sae_action_taken_imp__f	Drug withdraw
a	nano_sae_action_taken_imp__a	No action																			
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f	nano_sae_action_taken_imp__f	Drug withdraw																			
159	[ nano_sae_action_taken_imp_sp ]  Show the field ONLY if: [nano_sae_action_taken_imp(c)] = '1' or [nano_sae_action_taken_imp(d)] = '1' or [nano_sae_action_taken_imp(e)] = '1'	Specify	text, Required																		
160	[ nano_sae_action_taken ]	Which action(s) was/were taken with the participant ? (Several possible)	checkbox, Required <table border="1"> <tr> <td>f</td> <td>nano_sae_action_taken__f</td> <td>No action</td> </tr> <tr> <td>g</td> <td>nano_sae_action_taken__g</td> <td>Medication treatments</td> </tr> <tr> <td>h</td> <td>nano_sae_action_taken__h</td> <td>Non medication treatments</td> </tr> </table>	f	nano_sae_action_taken__f	No action	g	nano_sae_action_taken__g	Medication treatments	h	nano_sae_action_taken__h	Non medication treatments									
f	nano_sae_action_taken__f	No action																			
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161	[ nano_sae_action_taken_spec ]  Show the field ONLY if:	Specify	text, Required																		

	[nano_sae_action_taken(h)] = '1'																				
162	<div>[ nano_sae_count ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] = '1'</div>	How many medication ?	dropdown, Required <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr><tr><td>6</td><td>6</td></tr><tr><td>7</td><td>7</td></tr><tr><td>8</td><td>8</td></tr><tr><td>9</td><td>9</td></tr></table>	1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9
1	1																				
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8	8																				
9	9																				
163	<div>[ nano_sae_action_med_name ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 0</div>	Medication Name (Commercial name)	text, Required																		
164	<div>[ nano_sae_action_med_name_inter ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 0</div>	Medication Name (International nonproprietary name)	text, Required																		
165	<div>[ nano_sae_action_med_dose ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 0</div>	Dose	text (number, Min: 0, Max: 9999999), Required																		
166	<div>[ nano_sae_action_med_unit ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 0</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown						
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167	<div>[ nano_sae_action_med_unit_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit] = "5"</div>	Specify	text, Required																		
168	<div>[ nano_sae_action_med_freq ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 0</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours								
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169	<div>[ nano_sae_action_med_freq_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq] = "8"</div>	Specify	text, Required																						
170	<div>[ nano_sae_action_med_route ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 0</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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171	<div>[ nano_sae_action_med_route_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route] = "11"</div>	Specify	text, Required																						
172	<div>[ nano_sae_action_med_date ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 0</div>	Start Date	text (date_dmy), Required																						
173	<div>[ nano_sae_action_med_ongoing ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 0</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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174	<div>[ nano_sae_action_med_end ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 0 and [nano_sae_action_med_ongoing] = "0"</div>	End date	text (date_dmy), Required																						
175	<div>[ nano_sae_action_med_name_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 1</div>	Medication Name (Commercial name)	text, Required																						

176	<div>[ nano_sae_action_med_name_inter_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] &gt; 1</div>	Medication Name (International nonproprietary name)	text, Required																		
177	<div>[ nano_sae_action_med_dose_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] &gt; 1</div>	Dose	text (number, Min: 0, Max: 9999999), Required																		
178	<div>[ nano_sae_action_med_unit_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] &gt; 1</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown						
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180	<div>[ nano_sae_action_med_freq_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] &gt; 1</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)		
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182	<div>[ nano_sae_action_med_route_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] &gt; 1</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal
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184	<div>[ nano_sae_action_med_date_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 1</div>	Start Date	text (date_dmy), Required												
185	<div>[ nano_sae_action_med_ongoing_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 1</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
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187	<div>[ nano_sae_action_med_name_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Medication Name (Commercial name)	text, Required												
188	<div>[ nano_sae_action_med_name_inter_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Medication Name (International nonproprietary name)	text, Required												
189	<div>[ nano_sae_action_med_dose_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
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192	<div>[ nano_sae_action_med_freq_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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194	<div>[ nano_sae_action_med_route_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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196	<div>[ nano_sae_action_med_date_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Start Date	text (date_dmy), Required																						
197	<div>[ nano_sae_action_med_ongoing_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 2</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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198	<div>[ nano_sae_action_med_end_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 2 and [nano_sae_action_med_ongoing_2] = "0"</div>	End date	text (date_dmy), Required																
199	<div>[ nano_sae_action_med_name_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 3</div>	Medication Name (Commercial name)	text, Required																
200	<div>[ nano_sae_action_med_name_inter_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 3</div>	Medication Name (International nonproprietary name)	text, Required																
201	<div>[ nano_sae_action_med_dose_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 3</div>	Dose	text (number, Min: 0, Max: 9999999), Required																
202	<div>[ nano_sae_action_med_unit_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 3</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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211	[ nano_sae_action_med_name_4 ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 4	Medication Name (Commercial name)	text, Required																						
212	[ nano_sae_action_med_name_inter_4 ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 4	Medication Name (International nonproprietary name)	text, Required																						

213	<div>[ nano_sae_action_med_dose_4 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 4</div>	Dose	text (number, Min: 0, Max: 9999999), Required																						
214	<div>[ nano_sae_action_med_unit_4 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 4</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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8	Other (specify)																								
217	<div>[ nano_sae_med_action_freq_spec_4 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_4] = "8"</div>	Specify	text, Required																						
218	<div>[ nano_sae_action_med_route_4 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 4</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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219	<div>[ nano_sae_med_action_route_spec_4 ]</div> <div>Show the field ONLY if:</div>	Specify	text, Required																						

	[nano_sae_action_med_route_4] = "11"														
220	[ nano_sae_action_med_date_4 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 4	Start Date	text (date_dmy), Required												
221	[ nano_sae_action_med_ongoing_4 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 4	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
222	[ nano_sae_action_med_end_4 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 4 and [nano_sae_action_med_ongoing_4] = "0"	End date	text (date_dmy), Required												
223	[ nano_sae_action_med_name_5 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 5	Medication Name (Commercial name)	text, Required												
224	[ nano_sae_action_med_name_inter_5 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 5	Medication Name (International nonproprietary name)	text, Required												
225	[ nano_sae_action_med_dose_5 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 5	Dose	text (number, Min: 0, Max: 9999999), Required												
226	[ nano_sae_action_med_unit_5 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 5	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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227	[ nano_sae_action_med_unit_spec_5 ]  Show the field ONLY if: [nano_sae_action_med_unit_5] = "5"	Specify	text, Required												

228	<div>[ nano_sae_action_med_freq_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 5</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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229	<div>[ nano_sae_med_action_freq_spec_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_5] = "8"</div>	Specify	text, Required																						
230	<div>[ nano_sae_action_med_route_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 5</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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231	<div>[ nano_sae_med_action_route_spec_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_5] = "11"</div>	Specify	text, Required																						
232	<div>[ nano_sae_action_med_date_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 5</div>	Start Date	text (date_dmy), Required																						
233	<div>[ nano_sae_action_med_ongoing_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 5</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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234	<div>[ nano_sae_action_med_end_5 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 5 and [nano_sae_a</div>	End date	text (date_dmy), Required																						

	ction_med_ongoing_5] = "0"																		
235	[ nano_sae_action_med_name_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Medication Name (Commercial name)	text, Required																
236	[ nano_sae_action_med_name_inter_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Medication Name (International nonproprietary name)	text, Required																
237	[ nano_sae_action_med_dose_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Dose	text (number, Min: 0, Max: 9999999), Required																
238	[ nano_sae_action_med_unit_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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240	[ nano_sae_action_med_freq_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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241	[ nano_sae_med_action_freq_spec_6 ]  Show the field ONLY if: [nano_sae_action_med_freq_6] = "8"	Specify	text, Required																
242	[ nano_sae_action_med_route_6 ]  Show the field ONLY if:	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr></table>	1	Oral	2	Topical												
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	[nano_sae_action_taken (g)] and [nano_sae_count] > 6		<table><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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243	[ nano_sae_med_action_route_spec_6 ]  Show the field ONLY if: [nano_sae_action_med_route_6] = "11"	Specify	text, Required																		
244	[ nano_sae_action_med_date_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Start Date	text (date_dmy), Required																		
245	[ nano_sae_action_med_ongoing_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No														
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246	[ nano_sae_action_med_end_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 6 and [nano_sae_action_med_ongoing_6] = "0"	End date	text (date_dmy), Required																		
247	[ nano_sae_action_med_name_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	Medication Name (Commercial name)	text, Required																		
248	[ nano_sae_action_med_name_inter_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	Medication Name (International nonproprietary name)	text, Required																		
249	[ nano_sae_action_med_dose_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	Dose	text (number, Min: 0, Max: 9999999), Required																		

250	<div>[ nano_sae_action_med_unit_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 7</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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251	<div>[ nano_sae_action_med_unit_spec_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_7] = "5"</div>	Specify	text, Required																						
252	<div>[ nano_sae_action_med_freq_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 7</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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253	<div>[ nano_sae_med_action_freq_spec_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_7] = "8"</div>	Specify	text, Required																						
254	<div>[ nano_sae_action_med_route_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 7</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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255	<div>[ nano_sae_med_action_route_spec_7 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_7] = "11"</div>	Specify	text, Required																						
256	<div>[ nano_sae_action_med_date_7 ]</div> <div>Show the field ONLY if:</div>	Start Date	text (date_dmy), Required																						



	[nano_sae_action_taken (g)] and [nano_sae_count] > 7														
257	[ nano_sae_action_med_ongoing_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
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258	[ nano_sae_action_med_end_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7 and [nano_sae_action_med_ongoing_7] = "0"	End date	text (date_dmy), Required												
259	[ nano_sae_action_med_name_8 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8	Medication Name (Commercial name)	text, Required												
260	[ nano_sae_action_med_name_inter_8 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8	Medication Name (International nonproprietary name)	text, Required												
261	[ nano_sae_action_med_dose_8 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8	Dose	text (number, Min: 0, Max: 9999999), Required												
262	[ nano_sae_action_med_unit_8 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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266	<div>[ nano_sae_action_med_route_8 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</div>	Route	<div>radio, Required</div> <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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267	<div>[ nano_sae_med_action_route_spec_8 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_8] = "11"</div>	Specify	text, Required																						
268	<div>[ nano_sae_action_med_date_8 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</div>	Start Date	text (date_dmy), Required																						
269	<div>[ nano_sae_action_med_ongoing_8 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</div>	Ongoing	<div>yesno, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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271	<div>[ nano_sae_react_abate ]</div>	Did the reaction abate after stopping the vaccination ?	<div>radio, Required</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No																		
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			<table><tr><td>3</td><td>Not applicable</td></tr></table>	3	Not applicable														
3	Not applicable																		
272	[ nano_sae_react_reappear ]	Did the reaction reappear after the second dose of the vaccination ?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Yes	2	No	3	Not applicable										
1	Yes																		
2	No																		
3	Not applicable																		
273	[ nano_sae_outcome ]	Issue of event	radio, Required <table><tr><td>1</td><td>Resolved (for date, last day of symptoms)</td></tr><tr><td>2</td><td>Resolved with sequelae</td></tr><tr><td>3</td><td>Ongoing</td></tr><tr><td>4</td><td>Stabilisation</td></tr><tr><td>5</td><td>Improvement</td></tr><tr><td>6</td><td>Agravation</td></tr><tr><td>7</td><td>Fatal</td></tr><tr><td>8</td><td>Unknown</td></tr></table>	1	Resolved (for date, last day of symptoms)	2	Resolved with sequelae	3	Ongoing	4	Stabilisation	5	Improvement	6	Agravation	7	Fatal	8	Unknown
1	Resolved (for date, last day of symptoms)																		
2	Resolved with sequelae																		
3	Ongoing																		
4	Stabilisation																		
5	Improvement																		
6	Agravation																		
7	Fatal																		
8	Unknown																		
274	[ nano_sae_outcome_date ]  Show the field ONLY if: [nano_sae_outcome] = '2' or [nano_sae_outcome] = '1' or [nano_sae_outcome] = '7'	Date	text (date_dmy), Required																
275	[ nano_sae_outcome_spec ]  Show the field ONLY if: [nano_sae_outcome] = '8'	Specify	text, Required																
276	[ nano_sae_autopsy ]  Show the field ONLY if: [nano_sae_outcome] = '7'	Autopsy performed	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known										
1	Yes																		
2	No																		
3	Not known																		
277	[ nano_sae_autopsy_report ]  Show the field ONLY if: [nano_sae_autopsy] = '1'	Autopsy report available	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known										
1	Yes																		
2	No																		
3	Not known																		
278	[ nano_sae_text_2 ]  Show the field ONLY if: [nano_sae_autopsy_report] = '1'	Do not forget to collect the report, remove identifying data, code it, register it as source documents and send it to the PI in a separate email.	descriptive Field Annotation: @HIDDEN-PDF																
279	[ nano_sae_doc_sent ]	Source document sent ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No												
1	Yes																		
0	No																		
280	[ nano_sae_doc_spec ]  Show the field ONLY if: [nano_sae_doc_sent] = "1"	Specify	text, Required																

281	[ nano_sae_investigator_name ]	Section Header: <i>Investigator Signature</i> Name of investigator	text, Required						
282	[ nano_sae_inv_sign_date ]	Date	text (date_dmy), Required						
283	[ nano_sae_investigator_sign ]	Signature of investigator	file (signature), Required						
284	[ nano_sae_send_report ]	Send the report to the PI for modification/validation	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDDEN-PDF	1	Yes	0	No		
1	Yes								
0	No								
285	[ nano_sae_approved ]	Section Header: <i>SAE report PI evaluation</i> SAE report approved by PI	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDE_BY_ROLE=PI	1	Yes	0	No		
1	Yes								
0	No								
286	[ nano_sae_add_comment ]	Additionnal comment	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDE_BY_ROLE=PI	1	Yes	0	No		
1	Yes								
0	No								
287	[ nano_sae_comment_specify ]  Show the field ONLY if: [nano_sae_add_comment] = "1" or [nano_sae_add_comment] = "1"	Specify	text, Required Field Annotation: @HIDE_BY_ROLE=PI						
288	[ nano_sae_pi_name_botom ]	Name of PI	text, Required Field Annotation: @HIDE_BY_ROLE=PI						
289	[ nano_sae_pi_sign_date ]	Date	text (date_dmy), Required Field Annotation: @HIDE_BY_ROLE=PI						
290	[ nano_sae_sign_pi ]	Signature of PI	file (signature), Required Field Annotation: @HIDE_BY_ROLE=PI						
291	[ nano_sae_text_3 ]	All SAE and AESI must be reported immediately and within a maximum of 24 hours to the Sponsor	descriptive Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF						
292	[ nano_sae_pdf ]	Generated PDF that will be sent to sponsor	file, Required Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF @HIDDEN						
293	[ nano_sae_send_sponsor ]	Send the PDF report to the Sponsor	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF	1	Yes	0	No		
1	Yes								
0	No								
294	[ serious_adverse_event_form_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Instrument: **Serious Adverse Event Form Followup** (serious\_adverse\_event\_form\_followup)

295	[ nano_sae_sae_number_fup ]	SAE number	text, Required														
296	[ nano_sae_custom_record_id_fup ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF														
297	[ nano_sae_title_fup ]	Title of research project	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'naNO-DENGUE: A Phase-I study of a nanoparticle-based peptide vaccine against Dengue virus'														
298	[ nano_sae_sponsor_name_fup ]	Name of Sponsor	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'														
299	[ nano_sae_sponsor_address_fup ]	Address of Sponsor	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = '4 & 5 Dunmore Court Wootton Road, Abingdon, Oxfordshire, England, OX13 6BH'														
300	[ nano_sae_pi_name_fup ]	Name of Principal Investigator	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'														
301	[ nano_sae_product_name_fup ]	Investigational Medicinal Product Name	text, Required Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"														
302	[ nano_sae_pi_address_fup ]	Adress of Principal Investigator	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Unisanté, Département Formation, recherche et innovation Policlinique de médecine tropicale, voyages et vaccinations Rue du Bugnon 44 1011 Lausanne, Suisse Blaise.genton@unisanté.ch M :+41 79 556 58 68'														
303	[ nano_sae_project_number_fup ]	BASEC research project number (Swissethics)	text, Required Field Annotation: @DEFAULT="2020-02258"														
304	[ nano_sae_notif_number_fup ]	Notification n° (Swissmedic)	text, Required Field Annotation: @DEFAULT="2021DR1042"														
305	[ nano_sae_id_fup ]	Section Header: <i>SAE information</i> Inclusion ID	text, Required Custom alignment: RH														
306	[ nano_sae_dob_fup ]	Year of birth	text (integer), Required Custom alignment: RH														
307	[ nano_sae_sex_fup ]	Sex	<div>radio, Required</div> <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table> <div>Custom alignment: RH</div>			1	Male	2	Female								
1	Male																
2	Female																
308	[ nano_sae_ethnicity_fup ]	Ethnicity (Several possible)	<div>checkbox, Required</div> <table><tr><td>1</td><td>nano_sae_ethnicity_fup__1</td><td>Caucasian</td></tr><tr><td>2</td><td>nano_sae_ethnicity_fup__2</td><td>Asian</td></tr><tr><td>3</td><td>nano_sae_ethnicity_fup__3</td><td>Black</td></tr><tr><td>4</td><td>nano_sae_ethnicity_fup__4</td><td>Carribean</td></tr></table>			1	nano_sae_ethnicity_fup__1	Caucasian	2	nano_sae_ethnicity_fup__2	Asian	3	nano_sae_ethnicity_fup__3	Black	4	nano_sae_ethnicity_fup__4	Carribean
1	nano_sae_ethnicity_fup__1	Caucasian															
2	nano_sae_ethnicity_fup__2	Asian															
3	nano_sae_ethnicity_fup__3	Black															
4	nano_sae_ethnicity_fup__4	Carribean															

			<table><tr><td>5</td><td>nano_sae_ethnicity_fup__5</td><td>Indian</td></tr><tr><td>6</td><td>nano_sae_ethnicity_fup__6</td><td>Arab</td></tr><tr><td>7</td><td>nano_sae_ethnicity_fup__7</td><td>Other</td></tr></table>	5	nano_sae_ethnicity_fup__5	Indian	6	nano_sae_ethnicity_fup__6	Arab	7	nano_sae_ethnicity_fup__7	Other											
5	nano_sae_ethnicity_fup__5	Indian																					
6	nano_sae_ethnicity_fup__6	Arab																					
7	nano_sae_ethnicity_fup__7	Other																					
309	[ nano_sae_ethnicity_specify_fup ]  Show the field ONLY if: [nano_sae_ethnicity_fup(7)] = '1'	Specify	text, Required																				
310	[ nano_sae_date_contain_fup ]	Date of onset {nano_sae_ae_date_fup} {nano_sae_date_unknown_fup}	descriptive																				
311	[ nano_sae_ae_date_fup ]	AE onset date	text (date_dmy)																				
312	[ nano_sae_date_unknown_fup ]	Date unknown	checkbox <table><tr><td>1</td><td>nano_sae_date_unknown_fup__1</td><td>Date unknown</td></tr></table>	1	nano_sae_date_unknown_fup__1	Date unknown																	
1	nano_sae_date_unknown_fup__1	Date unknown																					
313	[ nano_sae_ae_awareness_fup ]	AE awareness date	text (date_dmy), Required																				
314	[ nano_sae_ae_evolution_fup ]	Does this SAE form report the evolution of a previously reported AE ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																
1	Yes																						
0	No																						
315	[ nano_sae_ae_number_fup ]  Show the field ONLY if: [nano_sae_ae_evolution_fup] = "1"	Specify AE number	text, Required																				
316	[ nano_sae_ae_description_fup ]	Section Header: <i>General</i>  Describe the AE and the connection to project procedures (including relevant test/lab data)	notes, Required																				
317	[ nano_sae_ae_solicited_fup ]	Which type of AE is it ?	radio, Required <table><tr><td>1</td><td>Solicited AE</td></tr><tr><td>2</td><td>Unsolicited AE related with an abnormal laboratory value</td></tr><tr><td>3</td><td>Unsolicited AE</td></tr></table>	1	Solicited AE	2	Unsolicited AE related with an abnormal laboratory value	3	Unsolicited AE														
1	Solicited AE																						
2	Unsolicited AE related with an abnormal laboratory value																						
3	Unsolicited AE																						
318	[ nano_sae_fda_toxicity_fup ]  Show the field ONLY if: [nano_sae_ae_solicited_fup] = "1"	FDA toxicity grading scale term	dropdown, Required <table><tr><td>1</td><td>Pain</td></tr><tr><td>2</td><td>Tenderness</td></tr><tr><td>3</td><td>Erythema/Redness</td></tr><tr><td>4</td><td>Induration/Swelling</td></tr><tr><td>5</td><td>Nausea/Vomiting</td></tr><tr><td>6</td><td>Diarrhea</td></tr><tr><td>7</td><td>Headache</td></tr><tr><td>8</td><td>Fatigue</td></tr><tr><td>9</td><td>Myalgia</td></tr><tr><td>10</td><td>Fever</td></tr></table>	1	Pain	2	Tenderness	3	Erythema/Redness	4	Induration/Swelling	5	Nausea/Vomiting	6	Diarrhea	7	Headache	8	Fatigue	9	Myalgia	10	Fever
1	Pain																						
2	Tenderness																						
3	Erythema/Redness																						
4	Induration/Swelling																						
5	Nausea/Vomiting																						
6	Diarrhea																						
7	Headache																						
8	Fatigue																						
9	Myalgia																						
10	Fever																						
319	[ nano_sae_fda_tox_grade_2_fup ]  Show the field ONLY if:	AE grade according to adapted FDA toxicity grading scale	radio, Required <table><tr><td>1</td><td>Grade 1</td></tr><tr><td>2</td><td>Grade 2</td></tr></table>	1	Grade 1	2	Grade 2																
1	Grade 1																						
2	Grade 2																						

	[nano_sae_ae_solicited_fup] = "1"		3 Grade 3
320	[ nano_sae_fda_tox_grade_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "1"		descriptive (Attachment: naNO-COVID_FDA_adapted.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF
321	[ nano_sae_laboe_ctcae_term_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "2"	AE term	text, Required
322	[ nano_sae_ctcae_grade_v6_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "2"	AE grade according to adapted CTCAE v5.0	radio, Required 1 Grade 1 2 Grade 2 3 Grade 3 4 Grade 4 5 Grade 5
323	[ nano_sae_ctcae_grade_v7_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "2"		descriptive (Attachment: naNO-COVID_CTCAE_adapted_lab.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF
324	[ nano_sae_ctcae_grade_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "3"	CTCAE term for grading AE	text, Required BIOPORTAL:CTCAE BIOPORTAL:CTCAE
325	[ nano_sae_spec_ctcae_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "3"	If needed, please specify	text, Required
326	[ nano_sae_ctcae_grade_v5_fup ] Show the field ONLY if: [nano_sae_ae_solicited_fup] = "3"	AE grade according to CTCAE v5.0	radio, Required 1 Grade 1 2 Grade 2 3 Grade 3 4 Grade 4 5 Grade 5
327	[ nano_sae_yes_no_fup ]	Is this a serious adverse event ?	yesno, Required 1 Yes 0 No
328	[ nano_sae_type_fup ] Show the field ONLY if: [nano_sae_yes_no_fup] = "1"	Check SAE (seriousness definition)	radio, Required a Death b Life-threatening event c Important medical event (i.e. jeopardises the patient or may require an intervention to prevent death or life threatening event)

			<table><tr><td>d</td><td>Persistent or significant disability or incapacity</td></tr><tr><td>e</td><td>Hospitalisation or prolongation of an existing hospitalisation</td></tr><tr><td>f</td><td>Congenital anomaly or birth defect (in offspring of the subject)</td></tr></table>	d	Persistent or significant disability or incapacity	e	Hospitalisation or prolongation of an existing hospitalisation	f	Congenital anomaly or birth defect (in offspring of the subject)
d	Persistent or significant disability or incapacity								
e	Hospitalisation or prolongation of an existing hospitalisation								
f	Congenital anomaly or birth defect (in offspring of the subject)								
329	[ nano_sae_interest_fup ]	Is this an adverse event of special interest ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
330	[ nano_sae_aes_i_def_fup ]		descriptive (Attachment: Definition of Adverse Event of Special Interest.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF						
331	[ nano_sae_unexpected_ae_fup ]	Was this an unexpected AE ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
332	[ nano_sae_doses_fup ]	Section Header: <i>IMP</i> Were one or two doses administred ?	radio, Required <table><tr><td>1</td><td>One</td></tr><tr><td>2</td><td>Two</td></tr></table>	1	One	2	Two		
1	One								
2	Two								
333	[ nano_sae_random_number_fup ]	Randomisation number	text (integer), Required						
334	[ nano_sae_code_broken_fup ]	Was the code broken ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
335	[ nano_sae_detail_fup ] Show the field ONLY if: [ nano_sae_code_broken_fup ] = "1"	Please detail the reason for unblinding, the person who proceeded to unblinding and the date.	notes, Required						
336	[ nano_sae_imp_name_fup ]	Name of IMP : PepGNP-Covid19 or vehicle-GNP	descriptive						
337	[ nano_sae_dose_fup ]	Dose	radio, Required <table><tr><td>1</td><td>Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)</td></tr><tr><td>2</td><td>High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)</td></tr></table>	1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)	2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)		
1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)								
2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)								
338	[ nano_sae_route_fup ]	Route : Intradermal injection	descriptive						
339	[ nano_sae_date_administered_fup ]	Administration date	text (date_dmy), Required						
340	[ nano_sae_imp_name_2_fup ] Show the field ONLY if: [ nano_sae_doses_fup ] = "2"	Name of IMP : PepGNP-Covid19 or vehicle-GNP	descriptive						
341	[ nano_sae_dose_2_fup ] Show the field ONLY if: [ nano_sae_doses_fup ] = "2"	Dose	radio, Required <table><tr><td>1</td><td>Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)</td></tr></table>	1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)				
1	Low dose (12.8 ug of gold nanoparticles +/- 2.5 nmol SARSCoV2 peptides)								



			<table><tr><td>2</td><td>High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)</td></tr></table>	2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)						
2	High dose (38.3 ug of gold nanoparticles +/- 7.5 nmol SARSCoV2 peptides)										
342	<p>[ nano_sae_route_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_doses_fup] = "2"</p>	Route : Intradermal injection	descriptive								
343	<p>[ nano_sae_date_administered_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_doses_fup] = "2"</p>	Administration date	text (date_dmy), Required								
344	<p>[ nano_sae_causality_fup ]</p>	Section Header: <i>AE Causality</i> Causality of event to intervention	radio, Required <table><tr><td>1</td><td>No relationship</td></tr><tr><td>2</td><td>Possible</td></tr><tr><td>3</td><td>Probable</td></tr><tr><td>4</td><td>Definite</td></tr></table>	1	No relationship	2	Possible	3	Probable	4	Definite
1	No relationship										
2	Possible										
3	Probable										
4	Definite										
345	<p>[ nano_sae_causality_def_fup ]</p>		descriptive (Attachment: Guidelines for assessing the relationship of vaccine administration to an adverse event.pdf, Display format: Link) Field Annotation: @HIDDEN-PDF								
346	<p>[ nano_sae_table_fup ]</p>	Section Header: <i>Relevant medical history</i> Disease / Intervention /Allergy Start date Ongoing Stop date {nano_sae_disease_fup} {nano_sae_date_disease_fup} {nano_sae_disease_ongoing_fup} {nano_sae_disease_stop_fup} {nano_sae_disease_1_fup} {nano_sae_date_disease_1_fup} {nano_sae_disease_ongoing_1_fup} {nano_sae_disease_stop_1_fup} {nano_sae_disease_2_fup} {nano_sae_date_disease_2_fup} {nano_sae_disease_ongoing_2_fup} {nano_sae_disease_stop_2_fup} {nano_sae_disease_3_fup} {nano_sae_date_disease_3_fup} {nano_sae_disease_ongoing_3_fup} {nano_sae_disease_stop_3_fup} {nano_sae_disease_4_fup} {nano_sae_date_disease_4_fup} {nano_sae_disease_ongoing_4_fup} {nano_sae_disease_stop_4_fup}	descriptive								
347	<p>[ nano_sae_disease_fup ]</p>	Disease / Intervention /Allergy	text								
348	<p>[ nano_sae_date_disease_fup ]</p>	Start date	text								
349	<p>[ nano_sae_disease_ongoing_fup ]</p>	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No				
1	Yes										
0	No										
350	<p>[ nano_sae_disease_stop_fup ]</p>	Stop date	text								

351	[ nano_sae_disease_1_fup ]	Disease / Intervention /Allergy	text												
352	[ nano_sae_date_disease_1_fup ]	Start date	text												
353	[ nano_sae_disease_ongoing_1_fup ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
354	[ nano_sae_disease_stop_1_fup ]	Stop date	text												
355	[ nano_sae_disease_2_fup ]	Disease / Intervention /Allergy	text												
356	[ nano_sae_date_disease_2_fup ]	Start date	text												
357	[ nano_sae_disease_ongoing_2_fup ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
358	[ nano_sae_disease_stop_2_fup ]	Stop date	text												
359	[ nano_sae_disease_3_fup ]	Disease / Intervention /Allergy	text												
360	[ nano_sae_date_disease_3_fup ]	Start date	text												
361	[ nano_sae_disease_ongoing_3_fup ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
362	[ nano_sae_disease_stop_3_fup ]	Stop date	text												
363	[ nano_sae_disease_4_fup ]	Disease / Intervention /Allergy	text												
364	[ nano_sae_date_disease_4_fup ]	Start date	text												
365	[ nano_sae_disease_ongoing_4_fup ]	Ongoing ?	yesno <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
366	[ nano_sae_disease_stop_4_fup ]	Stop date	text												
367	[ nano_sae_drug_fup ]	Section Header: <i>Concomitant medications</i> Concomitant drug(s) (exclude those to treat event)	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
368	[ nano_sae_conc_count_fup ]  Show the field ONLY if: [ nano_sae_drug_fup ] ="1"	How many concomitant drug ?	dropdown, Required <table><tr><td>1</td><td>1</td></tr><tr><td>2</td><td>2</td></tr><tr><td>3</td><td>3</td></tr><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr><tr><td>6</td><td>6</td></tr></table>	1	1	2	2	3	3	4	4	5	5	6	6
1	1														
2	2														
3	3														
4	4														
5	5														
6	6														

369	<div>[ nano_sae_med_name_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Medication Name (Commercial name)	text, Required																
370	<div>[ nano_sae_med_name_int_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Medication Name (International nonproprietary name)	text, Required																
371	<div>[ nano_sae_med_dose_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Dose	text (number), Required																
372	<div>[ nano_sae_med_dose_unit_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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373	<div>[ nano_sae_med_dose_spec_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_unit_fup] = "5"</div>	Specify	text, Required																
374	<div>[ nano_sae_med_dose_freq_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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375	<div>[ nano_sae_med_freq_spec_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq_fup] = "8"</div>	Specify	text, Required																
376	<div>[ nano_sae_med_route_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_count_count_fup] &gt; 0</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection								
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377	<div>[ nano_sae_med_route_spec_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_route_fup] = "11"</div>	Specify	text, Required														
378	<div>[ nano_sae_med_use_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 0</div>	Indication(s) for use	text, Required														
379	<div>[ nano_sae_med_start_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 0</div>	Start Date	text (date_dmy), Required														
380	<div>[ nano_sae_med_ongoing_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 0</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No										
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381	<div>[ nano_sae_med_end_date_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_fup] = "0" and [nano_sae_conc_count_fup] &gt; 0</div>	End date	text (date_dmy), Required														
382	<div>[ nano_sae_med_name_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 1</div>	Medication Name (Commercial name)	text, Required														
383	<div>[ nano_sae_med_name_inter_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 1</div>	Medication Name (International nonproprietary name)	text, Required														
384	<div>[ nano_sae_med_dose_1_fup ]</div> <div>Show the field ONLY if:</div>	Dose	text (number, Min: 0, Max: 9999999), Required														

	[nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 1																								
385	[ nano_sae_med_dose_unit_1_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 1	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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386	[ nano_sae_med_dose_spec_1_fup ]  Show the field ONLY if: [nano_sae_med_dose_unit_1_fup] = "5"	Specify	text, Required																						
387	[ nano_sae_med_dose_freq_1_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 1	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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388	[ nano_sae_med_freq_spec_1_fup ]  Show the field ONLY if: [nano_sae_med_dose_freq_1_fup] = "8"	Specify	text, Required																						
389	[ nano_sae_med_route_1_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 1	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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390	[ nano_sae_med_route_spec_1_fup ]  Show the field ONLY if: [nano_sae_med_route_1_fup] = "11"	Specify	text, Required																						

391	<div>[ nano_sae_med_use_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 1</div>	Indication(s) for use	text, Required												
392	<div>[ nano_sae_med_start_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 1</div>	Start Date	text (date_dmy), Required												
393	<div>[ nano_sae_med_ongoing_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 1</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
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394	<div>[ nano_sae_med_end_date_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_1_fup] = "0" and [nano_sae_conc_count_fup] &gt; 1</div>	End date	text (date_dmy), Required												
395	<div>[ nano_sae_med_name_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 2</div>	Medication Name (Commercial name)	text, Required												
396	<div>[ nano_sae_med_name_inter_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 2</div>	Medication Name (International nonproprietary name)	text, Required												
397	<div>[ nano_sae_med_dose_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 2</div>	Dose	text (integer, Min: 0, Max: 9999999), Required												
398	<div>[ nano_sae_med_dose_unit_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 2</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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399	<div>[ nano_sae_med_dose_spec_2_fup ]</div>	Specify	text, Required												

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400	[ nano_sae_med_dose_fr eq_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 2	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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401	[ nano_sae_med_freq_sp ec_2_fup ]  Show the field ONLY if: [nano_sae_med_dose_f req_2_fup] = "8"	Specify	text, Required																						
402	[ nano_sae_med_route_2 _fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 2	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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403	[ nano_sae_med_route_s pec_2_fup ]  Show the field ONLY if: [nano_sae_med_route_ 2_fup] = "11"	Specify	text, Required																						
404	[ nano_sae_med_use_2_f up ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 2	Indication(s) for use	text, Required																						
405	[ nano_sae_med_start_2 _fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 2	Start Date	text (date_dmy), Required																						
406	[ nano_sae_med_ongoing _2_fup ]  Show the field ONLY if:	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes																				
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407	[ nano_sae_med_end_date_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_2_fup] = "0" and [nano_sae_conc_count_fup] > 2	End date	text (date_dmy), Required																
408	[ nano_sae_med_name_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 3	Medication Name (Commercial name)	text, Required																
409	[ nano_sae_med_name_inter_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 3	Medication Name (International nonproprietary name)	text, Required																
410	[ nano_sae_med_dose_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 3	Dose	text (number, Min: 0, Max: 9999999), Required																
411	[ nano_sae_med_dose_unit_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 3	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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414	<div>[ nano_sae_med_freq_spec_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq_3_fup] = "8"</div>	Specify	text, Required																							
415	<div>[ nano_sae_med_route_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 3</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>		1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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417	<div>[ nano_sae_med_use_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 3</div>	Indication(s) for use	text, Required																							
418	<div>[ nano_sae_med_start_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 3</div>	Start Date	text (date_dmy), Required																							
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420	<div>[ nano_sae_med_end_date_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_3_fup] = "0" and [nano_sae_conc_count_fup] &gt; 3</div>	End date	text (date_dmy), Required																							
421	<div>[ nano_sae_med_name_4_fup ]</div> <div>Show the field ONLY if:</div>	Medication Name (Commercial name)	text, Required																							

	[nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4																		
422	[ nano_sae_med_name_inter_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4	Medication Name (International nonproprietary name)	text, Required																
423	[ nano_sae_med_dose_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4	Dose	text (number, Min: 0, Max: 9999999), Required																
424	[ nano_sae_med_dose_unit_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
1	Microgram																		
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5	Other (Specify)																		
6	Unknown																		
425	[ nano_sae_med_dose_spec_4_fup ]  Show the field ONLY if: [nano_sae_med_dose_unit_4_fup] = "5"	Specify	text, Required																
426	[ nano_sae_med_dose_freq_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
1	Daily																		
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427	[ nano_sae_med_freq_spec_4_fup ]  Show the field ONLY if: [nano_sae_med_dose_freq_4_fup] = "8"	Specify	text, Required																
428	[ nano_sae_med_route_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 4	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal				
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			<table><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
7	Nasal												
8	Inhaled												
9	Transdermal												
10	Vaginal												
11	Other (Specify)												
429	<p>[ nano_sae_med_route_spec_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_med_route_4_fup] = "11"</p>	Specify	text, Required										
430	<p>[ nano_sae_med_use_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Indication(s) for use	text, Required										
431	<p>[ nano_sae_med_start_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Start Date	text (date_dmy), Required										
432	<p>[ nano_sae_med_ongoing_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No						
1	Yes												
0	No												
433	<p>[ nano_sae_med_end_date_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" AND [nano_sae_med_ongoing_4_fup] = "0" and [nano_sae_conc_count_fup] &gt; 4</p>	End date	text (date_dmy), Required										
434	<p>[ nano_sae_med_name_5_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</p>	Medication Name (Commercial name)	text, Required										
435	<p>[ nano_sae_med_name_inter_5_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</p>	Medication Name (International nonproprietary name)	text, Required										
436	<p>[ nano_sae_med_dose_5_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</p>	Dose	text (number, Min: 0, Max: 9999999), Required										

437	<div>[ nano_sae_med_dose_unit_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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438	<div>[ nano_sae_med_dose_spec_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_unit_5_fup] = "5"</div>	Specify	text, Required																						
439	<div>[ nano_sae_med_dose_freq_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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440	<div>[ nano_sae_med_freq_spec_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq_5_fup] = "8"</div>	Specify	text, Required																						
441	<div>[ nano_sae_med_route_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 5</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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11	Other (Specify)																								
442	<div>[ nano_sae_med_route_spec_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_route_5_fup] = "11"</div>	Specify	text, Required																						
443	<div>[ nano_sae_med_use_5_fup ]</div> <div>Show the field ONLY if:</div>	Indication(s) for use	text, Required																						

	[nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5								
444	[ nano_sae_med_start_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5	Start Date	text (date_dmy), Required						
445	[ nano_sae_med_ongoing_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
446	[ nano_sae_med_end_date_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_5_fup] = "0" and [nano_sae_conc_count_fup] > 5	End date	text (date_dmy), Required						
447	[ nano_sae_test_performed_med_fup ]	Section Header: <i>Relevant paraclinic tests</i>  Have some paraclinical tests/procedures been performed ?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known
1	Yes								
2	No								
3	Not known								
448	[ nano_sae_lab_tests_fup ]  Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"	Laboratory tests	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known
1	Yes								
2	No								
3	Not known								
449	[ nano_sae_radio_tests_fup ]  Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"	Radiological exams	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known
1	Yes								
2	No								
3	Not known								
450	[ nano_sae_relevant_procedure_fup ]  Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"	Other relevant diagnostic procedure(s)*	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	1	Yes	2	No	3	Not known
1	Yes								
2	No								
3	Not known								
451	[ nano_sae_specify_fup ]  Show the field ONLY if: [nano_sae_relevant_procedure_fup] = "1"	Specify	text, Required						
452	[ nano_sae_main_result_fup ]  Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"	Please provide the main results of the exams performed	notes, Required						
453	[ nano_sae_text_fup ]	Do not forget to collect complementary exam, remove identifying data, code them, register them	descriptive Field Annotation: @HIDDEN-PDF						

	Show the field ONLY if: [nano_sae_relevant_proced_fup] = "1" OR [nano_sae_radio_tests_fup] = "1" OR [nano_sae_lab_tests_fup] = "1"	as source documents and send them to the PI in a separate email.	
454	[ nano_sae_action_taken_imp_fup ]   <		

	Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0																		
460	[ nano_sae_action_med_name_inter_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Medication Name (International nonproprietary name)	text, Required																
461	[ nano_sae_action_med_dose_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Dose	text (number, Min: 0, Max: 9999999), Required																
462	[ nano_sae_action_med_unit_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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463	[ nano_sae_action_med_unit_spec_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_fup] = "5"	Specify	text, Required																
464	[ nano_sae_action_med_freq_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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465	[ nano_sae_action_med_freq_spec_fup ]  Show the field ONLY if: [nano_sae_action_med_freq_fup] = "8"	Specify	text, Required																
466	[ nano_sae_action_med_route_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection						
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6	Rectal														
7	Nasal														
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10	Vaginal														
11	Other (Specify)														
467	<div>[ nano_sae_action_med_route_spec_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_fup] = "11"</div>	Specify	text, Required												
468	<div>[ nano_sae_action_med_date_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 0</div>	Start Date	text (date_dmy), Required												
469	<div>[ nano_sae_action_med_ongoing_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 0</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
470	<div>[ nano_sae_action_med_end_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 0 and [nano_sae_action_med_ongoing_fup] = "0"</div>	End date	text (date_dmy), Required												
471	<div>[ nano_sae_action_med_name_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 1</div>	Medication Name (Commercial name)	text, Required												
472	<div>[ nano_sae_action_med_name_inter_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 1</div>	Medication Name (International nonproprietary name)	text, Required												
473	<div>[ nano_sae_action_med_dose_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 1</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
474	<div>[ nano_sae_action_med_unit_1_fup ]</div> <div>Show the field ONLY if:</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr></table>	1	Microgram	2	Miligram								
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475	[ nano_sae_action_med_unit_spec_1_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_1_fup] = "5"	Specify	text, Required																						
476	[ nano_sae_action_med_freq_1_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 1	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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478	[ nano_sae_action_med_route_1_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 1	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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479	[ nano_sae_med_action_route_spec_1_fup ]  Show the field ONLY if: [nano_sae_action_med_route_1_fup] = "11"	Specify	text, Required																						
480	[ nano_sae_action_med_date_1_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 1	Start Date	text (date_dmy), Required																						

481	<div>[ nano_sae_action_med_ongoing_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 1</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
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482	<div>[ nano_sae_action_med_end_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 1 and [nano_sae_action_med_ongoing_1_fup] = "0"</div>	End date	text (date_dmy), Required												
483	<div>[ nano_sae_action_med_name_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</div>	Medication Name (Commercial name)	text, Required												
484	<div>[ nano_sae_action_med_name_inter_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</div>	Medication Name (International nonproprietary name)	text, Required												
485	<div>[ nano_sae_action_med_dose_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
486	<div>[ nano_sae_action_med_unit_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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487	<div>[ nano_sae_action_med_unit_spec_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_2_fup] = "5"</div>	Specify	text, Required												
488	<div>[ nano_sae_action_med_freq_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours
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497	<div>[ nano_sae_action_med_dose_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</div>	Dose	text (number, Min: 0, Max: 9999999), Required																		
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500	<div>[ nano_sae_action_med_freq_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)		
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502	<div>[ nano_sae_action_med_route_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal
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508	<div>[ nano_sae_action_med_name_inter_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 4</div>	Medication Name (International nonproprietary name)	text, Required												
509	<div>[ nano_sae_action_med_dose_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 4</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
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512	<div>[ nano_sae_action_med_freq_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 4</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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514	<div>[ nano_sae_action_med_route_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 4</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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530	[ nano_sae_action_med_end_5_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 5 and [nano_sae_action_med_ongoing_5_fup] = "0"	End date	text (date_dmy), Required																						
531	[ nano_sae_action_med_name_6_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6	Medication Name (Commercial name)	text, Required																						
532	[ nano_sae_action_med_name_inter_6_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6	Medication Name (International nonproprietary name)	text, Required																						



533	<div>[ nano_sae_action_med_dose_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Dose	text (number, Min: 0, Max: 9999999), Required																						
534	<div>[ nano_sae_action_med_unit_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown										
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535	<div>[ nano_sae_action_med_unit_spec_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_6_fup] = "5"</div>	Specify	text, Required																						
536	<div>[ nano_sae_action_med_freq_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
1	Daily																								
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8	Other (specify)																								
537	<div>[ nano_sae_med_action_freq_spec_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_6_fup] = "8"</div>	Specify	text, Required																						
538	<div>[ nano_sae_action_med_route_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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539	<div>[ nano_sae_med_action_route_spec_6_fup ]</div> <div>Show the field ONLY if:</div>	Specify	text, Required																						

	[nano_sae_action_med_route_6_fup] = "11"														
540	[ nano_sae_action_med_date_6_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6	Start Date	text (date_dmy), Required												
541	[ nano_sae_action_med_ongoing_6_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No								
1	Yes														
0	No														
542	[ nano_sae_action_med_end_6_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6 and [nano_sae_action_med_ongoing_6_fup] = "0"	End date	text (date_dmy), Required												
543	[ nano_sae_action_med_name_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	Medication Name (Commercial name)	text, Required												
544	[ nano_sae_action_med_name_inter_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	Medication Name (International nonproprietary name)	text, Required												
545	[ nano_sae_action_med_dose_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	Dose	text (number, Min: 0, Max: 9999999), Required												
546	[ nano_sae_action_med_unit_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	Dose unit	radio, Required <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown
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547	[ nano_sae_action_med_unit_spec_7_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_7_fup] = "5"	Specify	text, Required												

548	<div>[ nano_sae_action_med_freq_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 7</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)						
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549	<div>[ nano_sae_med_action_freq_spec_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_7_fup] = "8"</div>	Specify	text, Required																						
550	<div>[ nano_sae_action_med_route_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 7</div>	Route	radio, Required <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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551	<div>[ nano_sae_med_action_route_spec_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_7_fup] = "11"</div>	Specify	text, Required																						
552	<div>[ nano_sae_action_med_date_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 7</div>	Start Date	text (date_dmy), Required																						
553	<div>[ nano_sae_action_med_ongoing_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 7</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No																		
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554	<div>[ nano_sae_action_med_end_7_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 7 and [nan</div>	End date	text (date_dmy), Required																						

	<div>o_sae_action_med_ongoing_7_fup] = "0"</div>																		
555	<div><div>[ nano_sae_action_med_name_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div></div>	Medication Name (Commercial name)	text, Required																
556	<div><div>[ nano_sae_action_med_name_inter_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div></div>	Medication Name (International nonproprietary name)	text, Required																
557	<div><div>[ nano_sae_action_med_dose_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div></div>	Dose	text (number, Min: 0, Max: 9999999), Required																
558	<div><div>[ nano_sae_action_med_unit_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div></div>	Dose unit	<div>radio, Required</div> <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Mililiter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	1	Microgram	2	Miligram	3	Gram	4	Mililiter	5	Other (Specify)	6	Unknown				
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559	<div><div>[ nano_sae_action_med_unit_spec_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_med_unit_8_fup] = "5"</div></div>	Specify	text, Required																
560	<div><div>[ nano_sae_action_med_freq_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div></div>	Frequency	<div>radio, Required</div> <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr><tr><td>3</td><td>Three times a day</td></tr><tr><td>4</td><td>Four times a day</td></tr><tr><td>5</td><td>4-6 hours</td></tr><tr><td>6</td><td>6-8 hours</td></tr><tr><td>7</td><td>PRN (ad needed)</td></tr><tr><td>8</td><td>Other (specify)</td></tr></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours	6	6-8 hours	7	PRN (ad needed)	8	Other (specify)
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561	<div><div>[ nano_sae_med_action_freq_spec_8_fup ]</div><div>Show the field ONLY if: [nano_sae_action_med_freq_8_fup] = "8"</div></div>	Specify	text, Required																
562	<div><div>[ nano_sae_action_med_route_8_fup ]</div><div>Show the field ONLY if:</div></div>	Route	<div>radio, Required</div> <table><tr><td>1</td><td>Oral</td></tr><tr><td>2</td><td>Topical</td></tr></table>	1	Oral	2	Topical												
1	Oral																		
2	Topical																		

	[nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8		<table><tr><td>3</td><td>Subcutaneous injection</td></tr><tr><td>4</td><td>Intravenous injection</td></tr><tr><td>5</td><td>Intramuscular injection</td></tr><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr><tr><td>8</td><td>Inhaled</td></tr><tr><td>9</td><td>Transdermal</td></tr><tr><td>10</td><td>Vaginal</td></tr><tr><td>11</td><td>Other (Specify)</td></tr></table>	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
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11	Other (Specify)																				
563	[ nano_sae_med_action_route_spec_8_fup ]  Show the field ONLY if: [nano_sae_action_med_route_8_fup] = "11"	Specify	text, Required																		
564	[ nano_sae_action_med_date_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	Start Date	text (date_dmy), Required																		
565	[ nano_sae_action_med_ongoing_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No														
1	Yes																				
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566	[ nano_sae_action_med_end_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8 and [nano_sae_action_med_ongoing_8_fup] = "0"	End date	text (date_dmy), Required																		
567	[ nano_sae_react_abate_fup ]	Did the reaction abate after stopping the vaccination ?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Yes	2	No	3	Not applicable												
1	Yes																				
2	No																				
3	Not applicable																				
568	[ nano_sae_react_reappear_fup ]	Did the reaction reappear after the second dose of the vaccination ?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not applicable</td></tr></table>	1	Yes	2	No	3	Not applicable												
1	Yes																				
2	No																				
3	Not applicable																				
569	[ nano_sae_outcome_fup ]	Issue of event	radio, Required <table><tr><td>1</td><td>Resolved (for date, last day of symptoms)</td></tr><tr><td>2</td><td>Resolved with sequelae</td></tr><tr><td>3</td><td>Ongoing</td></tr><tr><td>4</td><td>Stabilisation</td></tr><tr><td>5</td><td>Improvement</td></tr></table>	1	Resolved (for date, last day of symptoms)	2	Resolved with sequelae	3	Ongoing	4	Stabilisation	5	Improvement								
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			<table><tr><td>6</td><td>Agravation</td></tr><tr><td>7</td><td>Fatal</td></tr><tr><td>8</td><td>Unknown</td></tr></table>	6	Agravation	7	Fatal	8	Unknown		
6	Agravation										
7	Fatal										
8	Unknown										
570	<p>[ nano_sae_outcome_date_fup ]</p> <p>Show the field ONLY if: [nano_sae_outcome_fup] = '2' or [nano_sae_outcome_fup] = '1' or [nano_sae_outcome_fup] = '7'</p>	Date	text (date_dmy), Required								
571	<p>[ nano_sae_outcome_spec_fup ]</p> <p>Show the field ONLY if: [nano_sae_outcome_fup] = '8'</p>	Specify	text, Required								
572	<p>[ nano_sae_autopsy_fup ]</p> <p>Show the field ONLY if: [nano_sae_outcome_fup] = '7'</p>	Autopsy performed	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	radio, Required		1	Yes	2	No	3	Not known
radio, Required											
1	Yes										
2	No										
3	Not known										
573	<p>[ nano_sae_autopsy_report_fup ]</p> <p>Show the field ONLY if: [nano_sae_autopsy_fup] = '1'</p>	Autopsy report available	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr><tr><td>3</td><td>Not known</td></tr></table>	radio, Required		1	Yes	2	No	3	Not known
radio, Required											
1	Yes										
2	No										
3	Not known										
574	<p>[ nano_sae_text_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_autopsy_report_fup] = '1'</p>	Do not forget to collect the report, remove identifying data, code it, register it as source documents and send it to the PI in a separate email.	descriptive Field Annotation: @HIDDEN-PDF								
575	<p>[ nano_sae_doc_sent_fup ]</p>	Source document sent ?	<table><tr><td colspan="2">yesno, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	yesno, Required		1	Yes	0	No		
yesno, Required											
1	Yes										
0	No										
576	<p>[ nano_sae_doc_spec_fup ]</p> <p>Show the field ONLY if: [nano_sae_doc_sent_fup] = "1"</p>	Specify	text, Required								
577	<p>[ nano_sae_investigator_name_fup ]</p>	Section Header: <i>Investigator Signature</i> Name of investigator	text, Required								
578	<p>[ nano_sae_inv_sign_date_fup ]</p>	Date	text (date_dmy), Required								
579	<p>[ nano_sae_investigator_sign_fup ]</p>	Signature of investigator	file (signature), Required								
580	<p>[ nano_sae_send_report_fup ]</p>	Send the report to the PI for modification/validation	<table><tr><td colspan="2">yesno, Required</td></tr><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> Field Annotation: @HIDDEN-PDF	yesno, Required		1	Yes	0	No		
yesno, Required											
1	Yes										
0	No										
581	<p>[ nano_sae_approved_fup ]</p>	Section Header: <i>SAE report PI evaluation</i> SAE report approved by PI	<table><tr><td colspan="2">yesno, Required</td></tr><tr><td>1</td><td>Yes</td></tr></table>	yesno, Required		1	Yes				
yesno, Required											
1	Yes										

			<div>0 No</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
582	[ nano_sae_add_comment_fup ]	Additionnal comment	<div>yesno, Required</div> <div>1 Yes</div> <div>0 No</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
583	[ nano_sae_comment_specify_fup ] Show the field ONLY if: [nano_sae_add_comment_fup] = "1" or [nano_sae_add_comment_fup] = "1"	Specify	<div>text, Required</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
584	[ nano_sae_pi_name_botom_fup ]	Name of PI	<div>text, Required</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
585	[ nano_sae_pi_sign_date_fup ]	Date	<div>text (date_dmy), Required</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
586	[ nano_sae_sign_pi_fup ]	Signature of PI	<div>file (signature), Required</div> <div>Field Annotation: @HIDE_BY_ROLE=PI</div>
587	[ nano_sae_text_3_fup ]	All SAE and AESI must be reported immediately and within a maximum of 24 hours to the Sponsor	<div>descriptive</div> <div>Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF</div>
588	[ nano_sae_pdf_fup ]	Generated PDF that will be sent to sponsor	<div>file, Required</div> <div>Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF @HIDDEN</div>
589	[ nano_sae_send_sponsor_fup ]	Send the PDF report to the Sponsor	<div>yesno, Required</div> <div>1 Yes</div> <div>0 No</div> <div>Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF</div>
590	[ serious_adverse_event_form_followup_complete ]	Section Header: <i>Form Status</i> Complete?	<div>dropdown</div> <div>0 Incomplete</div> <div>1 Unverified</div> <div>2 Complete</div>
<b>Instrument: Major Protocol Deviation Form (major_protocol_deviation_form)</b>			
591	[ nano_p_screening_id ]	Section Header: <i>General informations</i> Screening ID	<div>text, Required</div>
592	[ nano_p_number ]	Protocol deviation/violation number	<div>text, Required</div>
593	[ nano_p_date ]	Date of the event	<div>text (date_dmy), Required</div>
594	[ nano_p_date_intern ]	Date of its discovery by research personnel	<div>text (date_dmy), Required</div>
595	[ nano_p_date_report ]	Date of the report	<div>text (date_dmy), Required</div>
596	[ nano_p_type ]	Section Header: <i>Event details</i> Deviation type	<div>radio, Required</div> <div>a Informed Consent</div> <div>b Eligibility Criteria</div> <div>c Study Procedures - Screening</div> <div>d Study Procedures - Study visits</div>

			<table><tr><td>e</td><td>Study Procedures - Laboratory Tests</td></tr><tr><td>f</td><td>Withdrawal/Discontinuation from study</td></tr><tr><td>g</td><td>Storage conditions not met</td></tr><tr><td>h</td><td>Incorrect study treatment /administration /dose</td></tr><tr><td>i</td><td>Excluded medication or vaccine</td></tr><tr><td>j</td><td>Randomisation</td></tr><tr><td>k</td><td>Blinding procedures</td></tr><tr><td>l</td><td>Safety reporting</td></tr><tr><td>m</td><td>Other</td></tr></table>	e	Study Procedures - Laboratory Tests	f	Withdrawal/Discontinuation from study	g	Storage conditions not met	h	Incorrect study treatment /administration /dose	i	Excluded medication or vaccine	j	Randomisation	k	Blinding procedures	l	Safety reporting	m	Other
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f	Withdrawal/Discontinuation from study																				
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i	Excluded medication or vaccine																				
j	Randomisation																				
k	Blinding procedures																				
l	Safety reporting																				
m	Other																				
597	<div>[ nano_p_deviation_cat ]</div> <div>Show the field ONLY if: [nano_p_type] = "a"</div>	Choose category of deviation	<div>radio, Required</div> <table><tr><td>1</td><td>Informed Consent Form not signed prior to any study procedure</td></tr></table>	1	Informed Consent Form not signed prior to any study procedure																
1	Informed Consent Form not signed prior to any study procedure																				
598	<div>[ nano_p_text_sponsor ]</div> <div>Show the field ONLY if: [nano_p_deviation_cat] = '1'</div>	Report to sponsor immediately.	descriptive																		
599	<div>[ nano_p_deviation_cat_1 ]</div> <div>Show the field ONLY if: [nano_p_type] = 'b'</div>	Choose category of deviation	<div>radio</div> <table><tr><td>a</td><td>Eligibility criteria not met</td></tr></table>	a	Eligibility criteria not met																
a	Eligibility criteria not met																				
600	<div>[ nano_p_text_cat_1 ]</div> <div>Show the field ONLY if: [nano_p_deviation_cat_1] = 'a'</div>	Refer to section 7.1 in the protocol for detailed inclusion/exclusion criterias.	descriptive																		
601	<div>[ nano_p_deviation_cat_2 ]</div> <div>Show the field ONLY if: [nano_p_type] = "c"</div>	Choose category of deviation	<div>radio, Required</div> <table><tr><td>a</td><td>Medical history not completed prior to vaccination</td></tr><tr><td>b</td><td>Concomitant medications information not completed prior to vaccination</td></tr><tr><td>c</td><td>One or more aspects of physical exam completely missed</td></tr><tr><td>d</td><td>Urinary protein/blood/glucose completely missed</td></tr><tr><td>e</td><td>Pregnancy test missed at screening and before vaccination</td></tr></table>	a	Medical history not completed prior to vaccination	b	Concomitant medications information not completed prior to vaccination	c	One or more aspects of physical exam completely missed	d	Urinary protein/blood/glucose completely missed	e	Pregnancy test missed at screening and before vaccination								
a	Medical history not completed prior to vaccination																				
b	Concomitant medications information not completed prior to vaccination																				
c	One or more aspects of physical exam completely missed																				
d	Urinary protein/blood/glucose completely missed																				
e	Pregnancy test missed at screening and before vaccination																				
602	<div>[ nano_p_deviation_cat_d ]</div> <div>Show the field ONLY if: [nano_p_type] = 'd'</div>	Choose category of deviation	<div>radio</div> <table><tr><td>a</td><td>Vaccination study visits (visit 2 &amp; 6) missed over and above the tolerance window</td></tr><tr><td>b</td><td>Participant Lost to follow up (LTFU)</td></tr><tr><td>c</td><td>Pregnancy Test missed at Vaccination 1 and/or 2</td></tr><tr><td>d</td><td>Body temperature not taken/ not recorded prior to vaccination</td></tr><tr><td>e</td><td>COVID PCR/rapid test not done prior to vaccinations</td></tr></table>	a	Vaccination study visits (visit 2 & 6) missed over and above the tolerance window	b	Participant Lost to follow up (LTFU)	c	Pregnancy Test missed at Vaccination 1 and/or 2	d	Body temperature not taken/ not recorded prior to vaccination	e	COVID PCR/rapid test not done prior to vaccinations								
a	Vaccination study visits (visit 2 & 6) missed over and above the tolerance window																				
b	Participant Lost to follow up (LTFU)																				
c	Pregnancy Test missed at Vaccination 1 and/or 2																				
d	Body temperature not taken/ not recorded prior to vaccination																				
e	COVID PCR/rapid test not done prior to vaccinations																				



603	[ nano_p_deviation_text_d2 ]  Show the field ONLY if: [ nano_p_deviation_cat_d ] = 'c'	If uncertain continuous contraception was adhered to, follow up with participant to come back into clinic (or take test at home) to confirm not pregnant.	descriptive										
604	[ nano_p_deviation_cat_e ]  Show the field ONLY if: [ nano_p_type ] = 'e'	Choose category of deviation	radio <table><tr><td>a</td><td>All haematology tests completely missed</td></tr><tr><td>b</td><td>All biochemistry tests completely missed</td></tr></table>	a	All haematology tests completely missed	b	All biochemistry tests completely missed						
a	All haematology tests completely missed												
b	All biochemistry tests completely missed												
605	[ nano_p_deviation_cat_f ]  Show the field ONLY if: [ nano_p_type ] = 'f'	Choose category of deviation	radio <table><tr><td>a</td><td>Participant not withdrawn/discontinued from study after developing withdrawal criteria</td></tr></table>	a	Participant not withdrawn/discontinued from study after developing withdrawal criteria								
a	Participant not withdrawn/discontinued from study after developing withdrawal criteria												
606	[ nano_p_deviation_cat_3 ]  Show the field ONLY if: [ nano_p_type ] = "g"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Storage of IMP and GNP at control less than -20°C</td></tr><tr><td>b</td><td>Prepared syringe kept at room temperature &gt;4 hours</td></tr></table>	a	Storage of IMP and GNP at control less than -20°C	b	Prepared syringe kept at room temperature >4 hours						
a	Storage of IMP and GNP at control less than -20°C												
b	Prepared syringe kept at room temperature >4 hours												
607	[ nano_p_deviation_cat_4 ]  Show the field ONLY if: [ nano_p_type ] = "h"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Incorrect dose given to patient - first dose (D0)</td></tr><tr><td>b</td><td>Incorrect dose given to patient - second dose (D21)</td></tr><tr><td>c</td><td>Missed second dose</td></tr><tr><td>d</td><td>Incorrect site or route of injection</td></tr><tr><td>e</td><td>No monitoring after vaccination for adverse reactions</td></tr></table>	a	Incorrect dose given to patient - first dose (D0)	b	Incorrect dose given to patient - second dose (D21)	c	Missed second dose	d	Incorrect site or route of injection	e	No monitoring after vaccination for adverse reactions
a	Incorrect dose given to patient - first dose (D0)												
b	Incorrect dose given to patient - second dose (D21)												
c	Missed second dose												
d	Incorrect site or route of injection												
e	No monitoring after vaccination for adverse reactions												
608	[ nano_p_deviation_cat_i ]  Show the field ONLY if: [ nano_p_type ] = 'i'	Choose category of deviation	radio <table><tr><td>a</td><td>Vaccinations excluded (including vaccination against COVID) by the protocol received 28 days prior or after PepGNP-Covid 19 injection</td></tr></table>	a	Vaccinations excluded (including vaccination against COVID) by the protocol received 28 days prior or after PepGNP-Covid 19 injection								
a	Vaccinations excluded (including vaccination against COVID) by the protocol received 28 days prior or after PepGNP-Covid 19 injection												
609	[ nano_p_deviation_text_i ]  Show the field ONLY if: [ nano_p_deviation_cat_i ] = 'a'	For influenza, this period is reduced to 14 days (2 weeks) preceding the IMP and 28 days afterward	descriptive										
610	[ nano_p_deviation_cat_j ]  Show the field ONLY if: [ nano_p_type ] = 'j'	Choose category of deviation	radio <table><tr><td>a</td><td>Randomisation not performed</td></tr></table>	a	Randomisation not performed								
a	Randomisation not performed												
611	[ nano_p_deviation_cat_7 ]  Show the field ONLY if: [ nano_p_type ] = "k"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Participant is inadvertently unblinded</td></tr><tr><td>b</td><td>Investigator/ Nurse inadvertently unblinded</td></tr></table>	a	Participant is inadvertently unblinded	b	Investigator/ Nurse inadvertently unblinded						
a	Participant is inadvertently unblinded												
b	Investigator/ Nurse inadvertently unblinded												
612	[ nano_p_text ]  Show the field ONLY if: [ nano_p_deviation_cat_7 ] = "a" OR [ nano_p_deviation_cat_7 ] = "b"	Corrective action : continue to follow usual trial, report case in study safety and trial reports.	descriptive										

613	[ nano_p_deviation_cat_6 ] Show the field ONLY if: [ nano_p_type ] = "l"	Choose category of deviation	radio, Required <table border="1"> <tr> <td>a</td> <td>SAE/AE not reported</td> </tr> <tr> <td>b</td> <td>Safety assessment not done at all</td> </tr> <tr> <td>c</td> <td>Reporting deadlines not followed</td> </tr> </table>	a	SAE/AE not reported	b	Safety assessment not done at all	c	Reporting deadlines not followed		
a	SAE/AE not reported										
b	Safety assessment not done at all										
c	Reporting deadlines not followed										
614	[ nano_p_specify ] Show the field ONLY if: [ nano_p_type ] = "m"	Specify	text, Required								
615	[ nano_p_description ]	Describe the protocol deviation/violation	notes, Required								
616	[ nano_p_reason ]	Please explain the reason for the deviation/violation:	notes, Required								
617	[ nano_p_result_ae ]	Did the deviation result in adverse event ?	yesno, Required <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
618	[ nano_p_continuation ]	Did the participant continue the study ?	yesno, Required <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
619	[ nano_p_deviation_step_taken ]	Describe the steps taken to avoid recurrence of the deviation/violation	notes, Required								
620	[ nano_p_name_investigator ]	Section Header: <i>Investigator signature</i> Name of investigator	text, Required								
621	[ nano_p_date_2 ]	Date	text (datetime_dmy), Required								
622	[ nano_p_sign_2 ]	Signature of investigator	file (signature), Required								
623	[ nano_p_send_report ]	Send the report to the PI and the Sponsor ?	yesno, Required <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table>	1	Yes	0	No				
1	Yes										
0	No										
624	[ nano_p_pdf ]	Generated pdf	file, Required Field Annotation: @HIDDEN @HIDDEN-PDF								
625	[ major_protocol_deviation_form_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table border="1"> <tr> <td>0</td> <td>Incomplete</td> </tr> <tr> <td>1</td> <td>Unverified</td> </tr> <tr> <td>2</td> <td>Complete</td> </tr> </table>	0	Incomplete	1	Unverified	2	Complete		
0	Incomplete										
1	Unverified										
2	Complete										
<b>Instrument: Minor Protocol Deviation Form (minor_protocol_deviation_form)</b>											
626	[ nano_mp_screening_id ]	Section Header: <i>General informations</i> Screening ID	text, Required								
627	[ nano_mp_number ]	Protocol deviation number	text, Required								
628	[ nano_mp_date ]	Date of the event	text (date_dmy), Required								
629	[ nano_mp_date_discovered ]	Date of its discovery by research personnel	text (date_dmy), Required								
630	[ nano_mp_date_report ]	Date of the report	text (date_dmy), Required								
631	[ nano_mp_deviation ]	Section Header: <i>Event details</i> Deviation type	radio, Required <table border="1"> <tr> <td>a</td> <td>Informed consent</td> </tr> <tr> <td>b</td> <td>Study Procedures - Screening</td> </tr> <tr> <td>c</td> <td>Study Procedures - Study visits</td> </tr> <tr> <td>d</td> <td>Study Procedures - Laboratory Tests</td> </tr> </table>	a	Informed consent	b	Study Procedures - Screening	c	Study Procedures - Study visits	d	Study Procedures - Laboratory Tests
a	Informed consent										
b	Study Procedures - Screening										
c	Study Procedures - Study visits										
d	Study Procedures - Laboratory Tests										

			<table border="1"> <tr> <td>e</td><td>Incorrect study treatment /administration /dose</td></tr> <tr> <td>f</td><td>Data monitoring</td></tr> <tr> <td>i</td><td>Other</td></tr> </table>	e	Incorrect study treatment /administration /dose	f	Data monitoring	i	Other								
e	Incorrect study treatment /administration /dose																
f	Data monitoring																
i	Other																
632	<p>[ nano_mp_deviation_cat ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "a"</p>	Choose category of deviation	<p>radio, Required</p> <table border="1"> <tr> <td>a</td><td>Incorrect version of Informed Consent signed</td></tr> <tr> <td>b</td><td>Other</td></tr> </table>	a	Incorrect version of Informed Consent signed	b	Other										
a	Incorrect version of Informed Consent signed																
b	Other																
633	<p>[ nano_mp_text ]</p> <p>Show the field ONLY if: [nano_mp_deviation_cat] = "a"</p>	Corrective action: note in ISF / patient folder and ask patient to sign current version at next study visit	descriptive														
634	<p>[ nano_mp_deviation_cat_2 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "b"</p>	Choose category of deviation	<p>radio, Required</p> <table border="1"> <tr> <td>a</td><td>Medical history incomplete</td></tr> <tr> <td>b</td><td>Concomitant medications information missed</td></tr> <tr> <td>c</td><td>One or more aspects of physical exam missed</td></tr> <tr> <td>d</td><td>Urinary protein/blood/glucose missed</td></tr> <tr> <td>e</td><td>Other</td></tr> </table>	a	Medical history incomplete	b	Concomitant medications information missed	c	One or more aspects of physical exam missed	d	Urinary protein/blood/glucose missed	e	Other				
a	Medical history incomplete																
b	Concomitant medications information missed																
c	One or more aspects of physical exam missed																
d	Urinary protein/blood/glucose missed																
e	Other																
635	<p>[ nano_mp_text_2 ]</p> <p>Show the field ONLY if: [nano_mp_deviation_cat_2] = "a" OR [nano_mp_deviation_cat_2] = "b" OR [nano_mp_deviation_cat_2] = "c" OR [nano_mp_deviation_cat_2] = "d"</p>	Corrective action: complete/perform prior to vaccination. Major protocol deviation if not complete/perform at all.	descriptive														
636	<p>[ nano_mp_deviation_cat_3 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "c"</p>	Choose category of deviation	<p>radio, Required</p> <table border="1"> <tr> <td>a</td><td>Study visits (excluding visit 2 &amp; 6) missed over and above the tolerance window</td></tr> <tr> <td>b</td><td>Other</td></tr> </table>	a	Study visits (excluding visit 2 & 6) missed over and above the tolerance window	b	Other										
a	Study visits (excluding visit 2 & 6) missed over and above the tolerance window																
b	Other																
637	<p>[ nano_mp_deviation_cat_4 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "d"</p>	Choose category of deviation	<p>radio, Required</p> <table border="1"> <tr> <td>a</td><td>One or more haematology tests missed</td></tr> <tr> <td>b</td><td>One or more biochemistry tests missed</td></tr> <tr> <td>c</td><td>Samples for immunogenicity studies (PBMC / Serum) not taken</td></tr> <tr> <td>d</td><td>One or more secondary immunogenicity tests missed (Anti-SARS-CoV-2 IgG, CD8 and Activation Markers)</td></tr> <tr> <td>e</td><td>One or more exploratory immunogenicity missed (Ig assay and T &amp; B Cell responses)</td></tr> <tr> <td>f</td><td>HLA Typing missed</td></tr> <tr> <td>g</td><td>Other</td></tr> </table>	a	One or more haematology tests missed	b	One or more biochemistry tests missed	c	Samples for immunogenicity studies (PBMC / Serum) not taken	d	One or more secondary immunogenicity tests missed (Anti-SARS-CoV-2 IgG, CD8 and Activation Markers)	e	One or more exploratory immunogenicity missed (Ig assay and T & B Cell responses)	f	HLA Typing missed	g	Other
a	One or more haematology tests missed																
b	One or more biochemistry tests missed																
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d	One or more secondary immunogenicity tests missed (Anti-SARS-CoV-2 IgG, CD8 and Activation Markers)																
e	One or more exploratory immunogenicity missed (Ig assay and T & B Cell responses)																
f	HLA Typing missed																
g	Other																

638	<div>[ nano_mp_text_5 ]</div> <div>Show the field ONLY if: [nano_mp_deviation_cat_4] = "a" OR [nano_mp_deviation_cat_4] = "b"</div>	Corrective action: complete/perform prior to vaccination. Major protocol deviation if not complete/perform at all.	descriptive								
639	<div>[ nano_mp_text_6 ]</div> <div>Show the field ONLY if: [nano_mp_deviation_cat_4] = "c" OR [nano_mp_deviation_cat_4] = "d" OR [nano_mp_deviation_cat_4] = "e"</div>	Corrective action : to be recorded and follow up. Follow protocol provided instructions for next blood draw and testing.	descriptive								
640	<div>[ nano_mp_deviation_cat_8 ]</div> <div>Show the field ONLY if: [nano_mp_deviation] = 'e'</div>	Choose category of deviation	<div>radio</div> <table><tr><td>a</td><td>&lt; 60 min monitoring after vaccination for adverse reactions</td></tr><tr><td>b</td><td>Other</td></tr></table>	a	< 60 min monitoring after vaccination for adverse reactions	b	Other				
a	< 60 min monitoring after vaccination for adverse reactions										
b	Other										
641	<div>[ nano_mp_text_10 ]</div> <div>Show the field ONLY if: [nano_mp_deviation_cat_8] = 'a'</div>	Major if completely missed otherwise minor.	descriptive								
642	<div>[ nano_mp_deviation_cat_5 ]</div> <div>Show the field ONLY if: [nano_mp_deviation] = "f"</div>	Choose category of deviation	<div>radio, Required</div> <table><tr><td>a</td><td>CRFs have incomplete information for test results</td></tr><tr><td>b</td><td>Date / time not entered for preparation of dose</td></tr><tr><td>c</td><td>Date / time not entered for administration of dose</td></tr><tr><td>d</td><td>Other</td></tr></table>	a	CRFs have incomplete information for test results	b	Date / time not entered for preparation of dose	c	Date / time not entered for administration of dose	d	Other
a	CRFs have incomplete information for test results										
b	Date / time not entered for preparation of dose										
c	Date / time not entered for administration of dose										
d	Other										
643	<div>[ nano_mp_text_7 ]</div> <div>Show the field ONLY if: [nano_mp_deviation_cat_5] = "a"</div>	Corrective action : follow up with patient / medical records / lab where applicable to complete prior to patient's last visit	descriptive								
644	<div>[ nano_mp_text_8 ]</div> <div>Show the field ONLY if: [nano_mp_deviation_cat_5] = "b" OR [nano_mp_deviation_cat_5] = "c"</div>	Corrective action : monitor to raise with site staff and ensure completed	descriptive								
645	<div>[ nano_mp_specify ]</div> <div>Show the field ONLY if: [nano_mp_deviation] = "g" OR [nano_mp_deviation_cat] = "b" OR [nano_mp_deviation_cat_2] = "e" OR [nano_mp_deviation_cat_3] = "b" OR [nano_mp_deviation_cat_8] = "b" OR [nano_mp_deviation_cat_4] = "g" OR [nano_mp_deviation_cat_5] = "d" OR [nano_mp_deviation] = "i"</div>	Specify	notes, Required								
646	<div>[ nano_mp_description ]</div>	Describe the protocol deviation	notes, Required								
647	<div>[ nano_mp_reason ]</div>	Please explain the reason for the deviation	notes, Required								

648	[ nano_mp_result_ae ]	Did the deviation result in adverse event ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
649	[ nano_mp_continue_study ]	Did the participant continue the study ?	yesno, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
650	[ nano_mp_avoid_recurrence ]	Describe the steps taken to avoid recurrence of the deviation	notes, Required						
651	[ nano_mp_pi_name ]	Section Header: <i>Investigator signature</i> Name of investigator	text, Required						
652	[ nano_mp_pi_date ]	Date	text (datetime_dmy), Required						
653	[ nano_mp_pi_sign ]	Signature of investigator	file (signature), Required						
654	[ minor_protocol_deviation_form_complete ]	Section Header: <i>Form Status</i> Complete?	dropdown <table><tr><td>0</td><td>Incomplete</td></tr><tr><td>1</td><td>Unverified</td></tr><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								