

## Data Dictionary Codebook

12/12/2023 7:22pm

#	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, Required 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></table>	1	Yes				
1	Yes								

			<table><tr><td>0</td><td>No</td></tr></table>	0	No				
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								

## Data Dictionary Codebook

12/12/2023 7:23pm

#	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, Required Field Annotation: @READONLY										
7	[ nano_vi_ipp ]	IPP	text, Required										
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></table>	1	Caucasian	2	Black	3	Latino	4	Asian	5	Pacific Islander
1	Caucasian												
2	Black												
3	Latino												
4	Asian												
5	Pacific Islander												

			<table><tr><td>6</td><td>Other</td></tr></table>	6	Other		
6	Other						
12	<div>[ nano_vi_ethnicity_specify ]</div> <div>Show the field ONLY if: [nano_vi_ethnicity] = '6'</div>	Specify	text, Required				
13	<div>[ nano_vi_smoke ]</div>	Section Header: <i>Habits</i> Does the volunteer smoke or use tobacco 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						
14	<div>[ nano_vi_years_smoke ]</div> <div>Show the field ONLY if: [nano_vi_smoke] = '1'</div>	How many years of smoking ?	text (number, Min: 0, Max: 100), Required				
15	<div>[ nano_vi_cig_per_day ]</div> <div>Show the field ONLY if: [nano_vi_smoke] = '1'</div>	How many cigarettes per day ?	text (number, Min: 0, Max: 100), Required				
16	<div>[ nano_vi_alcohol ]</div>	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	<div>[ nano_vi_drink_per_week ]</div> <div>Show the field ONLY if: [nano_vi_alcohol] = '1'</div>	How many standard alcoholic drinks per week ?	text, Required				
18	<div>[ nano_vi_drug_consume ]</div>	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	<div>[ nano_vi_drugs_spec ]</div> <div>Show the field ONLY if: [nano_vi_drug_consume] = '1'</div>	Please specify drug(s)	text, Required				
20	<div>[ nano_vi_med_problem ]</div>	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	<div>[ nano_vi_med_condition ]</div>	Relevant medical condition	text				



22	[ nano_vi_med_condit ion_1 ]	Relevant medical condition	text
23	[ nano_vi_med_condit ion_2 ]	Relevant medical condition	text
24	[ nano_vi_med_condit ion_3 ]	Relevant medical condition	text
25	[ nano_vi_med_condit ion_4 ]	Relevant medical condition	text
26	[ nano_vi_med_condit ion_5 ]	Relevant medical condition	text
27	[ nano_vi_med_condit ion_6 ]	Relevant medical condition	text
28	[ nano_vi_table ]  Show the field ONL Y if: [nano_vi_med_probl em] = '1'	relevant medical condition day month year {nano_vi_med_condition} {nano_vi_med_condition_day} {nano_vi_med_condition_month} {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}	descriptive
29	[ nano_vi_table_2 ]  Show the field ONL Y if: [nano_vi_med_probl em] = '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}	descriptive

		{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}	
30	[ nano_vi_med_condit ion_day ]	day	text (integer, Min: 0, Max: 31)
31	[ nano_vi_med_condit ion_month ]	month	text (integer, Min: 0, Max: 12)
32	[ nano_vi_med_condit ion_year ]	year	text (integer, Min: 0000, Max: 2050)
33	[ nano_vi_med_condit ion_day_1 ]	day	text (integer, Min: 0, Max: 31)
34	[ nano_vi_med_condit ion_month_1 ]	month	text (integer, Min: 0, Max: 12)
35	[ nano_vi_med_condit ion_year_1 ]	year	text (integer, Min: 0000, Max: 2050)
36	[ nano_vi_med_condit ion_day_2 ]	day	text (integer, Min: 0, Max: 31)
37	[ nano_vi_med_condit ion_month_2 ]	month	text (integer, Min: 0, Max: 12)
38	[ nano_vi_med_condit ion_year_2 ]	year	text (integer, Min: 0, Max: 2050)
39	[ nano_vi_med_condit ion_day_3 ]	day	text (integer, Min: 0, Max: 31)
40	[ nano_vi_med_condit ion_month_3 ]	month	text (integer, Min: 0, Max: 12)
41	[ nano_vi_med_condit ion_year_3 ]	year	text (integer, Min: 0, Max: 2050)
42	[ nano_vi_med_condit ion_day_4 ]	day	text (integer, Min: 0, Max: 31)
43	[ nano_vi_med_condit ion_month_4 ]	month	text (integer, Min: 0, Max: 12)
44	[ nano_vi_med_condit ion_year_4 ]	year	text (integer, Min: 0, Max: 2050)
45	[ nano_vi_med_condit ion_day_5 ]	day	text (integer, Min: 0, Max: 31)

46	[ nano_vi_med_condit ion_month_5 ]	month	text (integer, Min: 0, Max: 12)
47	[ nano_vi_med_condit ion_year_5 ]	year	text (integer, Min: 0, Max: 2050)
48	[ nano_vi_med_condit ion_day_6 ]	day	text (integer, Min: 0, Max: 31)
49	[ nano_vi_med_condit ion_month_6 ]	month	text (integer, Min: 0, Max: 12)
50	[ nano_vi_med_condit ion_year_6 ]	year	text (integer, Min: 0, Max: 2050)
51	[ nano_vi_past_med_h is ]	Relevant past medical history	text
52	[ nano_vi_past_med_h is_1 ]	Relevant past medical history	text
53	[ nano_vi_past_med_h is_2 ]	Relevant past medical history	text
54	[ nano_vi_past_med_h is_3 ]	Relevant past medical history	text
55	[ nano_vi_past_med_h is_4 ]	Relevant past medical history	text
56	[ nano_vi_past_med_h is_5 ]	Relevant past medical history	text
57	[ nano_vi_past_med_h is_6 ]	Relevant past medical history	text
58	[ nano_vi_past_med_h is_day ]	day	text (integer, Min: 0, Max: 31)
59	[ nano_vi_past_med_h is_month ]	month	text (integer, Min: 0, Max: 12)
60	[ nano_vi_past_med_h is_year ]	year	text (integer, Min: 0, Max: 2050)
61	[ nano_vi_past_med_h is_day_1 ]	day	text (integer, Min: 0, Max: 31)
62	[ nano_vi_past_med_h is_month_1 ]	month	text (integer, Min: 0, Max: 12)
63	[ nano_vi_past_med_h is_year_1 ]	year	text (integer, Min: 0, Max: 2050)
64	[ nano_vi_past_med_h is_day_2 ]	day	text (integer, Min: 0, Max: 31)
65	[ nano_vi_past_med_h is_month_2 ]	month	text (integer, Min: 0, Max: 12)
66	[ nano_vi_past_med_h is_year_2 ]	year	text (integer, Min: 0, Max: 2050)
67	[ nano_vi_past_med_h is_day_3 ]	day	text (integer, Min: 0, Max: 31)
68	[ nano_vi_past_med_h is_month_3 ]	month	text (integer, Min: 0, Max: 12)

69	[ nano_vi_past_med_his_year_3 ]	year	text (integer, Min: 0, 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: 0, 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: 0, 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: 0, 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	[ volunteer_information_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)									
82	[ dep_name3 ]	Research physician	descriptive						
83	[ 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								
84	[ nano_ic_date_delivery ]	Date of information sheet delivery	text (datetime_dmy), Required						
85	[ 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								

86	[ nano_ic_date_signature ]	Date of informed consent signature	text (datetime_dmy), Required						
87	[ 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						
88	[ 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: <b>Medical History</b> (medical_history)									
89	[ dep_name4 ]  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						
90	[ nano_mh_consent_signed ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Section Header: <i>Verifying informations</i> 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								
91	[ nano_mh_consent_changed ]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1'	Changes in 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								
92	[ nano_mh_consent_changed_message ]  Show the field ONLY if: [nano_mh_consent_changed] = '1'	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						
93	[ nano_mh_abnormalities ]	Abnormalities/new medical event reported 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								
94	[ nano_mh_abnormalities_spec ]  Show the field ONLY if:	Specify	notes, Required						

	[nano_mh_abnormalities] = '1'								
95	<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 <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								
96	<div>[ nano_mh_fill_med ]</div> <div>Show the field ONLY if: [nano_mh_medication_changed] = '1'</div>	Please fill the medication form	descriptive						
97	<div>[ nano_mh_new_vac ]</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>	Any vaccination received 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								
98	<div>[ nano_mh_date_vac ]</div> <div>Show the field ONLY if: [nano_mh_new_vac] = '1'</div>	Date of vaccination	text (date_dmy), Required						
99	<div>[ nano_mh_postpone ]</div> <div>Show the field ONLY if: [nano_mh_new_vac] = '1'</div>	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						
100	<div>[ medical_history_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>Adverse Events</b> (adverse_events)									
101	<div>[ dep_name5 ]</div> <div>Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vac"</div>	Study nurse	descriptive						

	cination_arm_1" OR [event-name] = "2nd _vaccination_arm_1"						
102	[ nano_ae_date_visit ]	Date of visit	text (datetime_dmy), Required				
103	[ nano_ae_list ]	Section Header: <i>Updating reports</i> List of current AE reports to be updated	descriptive				
104	[ nano_sae_list ]	List of current SAE reports to be updated	descriptive				
105	[ 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						
106	[ nano_sae_definition ]		descriptive				
107	[ nano_sae_button ]  Show the field ONLY if: [nano_ae_new_ae] = '1'	Please fill a SAE form	descriptive				
108	[ nano_sae_new_pain ]  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"	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						
109	[ 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						
110	[ nano_sae_new_erythema ]  Show the field ONLY if:	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						

	[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"						
111	[ 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						
112	[ 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				
113	[ nano_sae_unsolicited_ae_inj ]  Show the field ONLY if: [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'	Section Header: <i>Unsolicited adverse event at injection site</i>  Is there any new unsolicited adverse event at injection site?	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						
114	[ nano_sae_button_3 ]  Show the field ONLY if: [nano_sae_unsolicited_ae_inj] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				
115	[ nano_sae_new_nausea ]	Section Header: <i>Solicited systemic adverse event</i>  New nausea/vomiting	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						



	Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'						
116	[ nano_sae_new_diarrhea ]  Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'	New diarrhea	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						
117	[ nano_sae_new_headache ]  Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'	New headache	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						
118	[ nano_sae_new_myalgia ]  Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'	New myalgia	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						
119	[ nano_sae_new_asthenia ]  Show the field ONLY if: [event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'	New asthenia	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						
120	[ nano_sae_new_tem_p ]  Show the field ONLY if:	New fever (Temp > or = 37.5°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						

	[event-name] <> '2nd_vaccination_arm_1' and [event-name] <> 'visit_11_arm_1' and [event-name] <> 'visit_12_arm_1'						
121	[ nano_sae_new_fever ]  Show the field ONLY if: [nano_sae_new_temp] = "1"	Axillary temperature	text (number, Min: 33, Max: 43), Required				
122	[ nano_sae_button_4 ]  Show the field ONLY if: [nano_sae_new_nausea] = '1' or [nano_sae_new_diarrhea] = '1' or [nano_sae_new_headache] = '1' or [nano_sae_new_myalgia] = '1' or [nano_sae_new_asthenia] = '1' or [nano_sae_new_temp] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				
123	[ nano_sae_unsolicited_sys_ae ]	Section Header: <i>Unsolicited systemic adverse event</i> Is there any new unsolicited systemic 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						
124	[ nano_sae_button_5 ]  Show the field ONLY if: [nano_sae_unsolicited_sys_ae] = "1"	Please fill a SAE form - Please fill a AE form	descriptive				
125	[ nano_ae_sun ]	Section Header: <i>Sun exposure</i> Has the participant been exposed to the sun since the last visit?(>=1h without clothing on the 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						
126	[ nano_sun_ld ]  Show the field ONLY if: [event-name] = "2nd_vaccination_arm_1"	! For LD participants, specify sun exposure since the first vaccination	descriptive				
127	[ nano_ae_sun_specify ]  Show the field ONLY if: [nano_ae_sun] = '1'	SpecifyDate - Type of exposure - Length of exposure - Suncream	notes				

128	[ <b>adverse_events_complete</b> ]	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)															
129	[ <b>dep_name6</b> ]  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												
130	[ <b>nano_cm_curr_medication</b> ]  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														
131	[ <b>nano_cm_fill_med</b> ]  Show the field ONLY if: [nano_cm_curr_medication] = "1"	Please fill the medication form	descriptive												
132	[ <b>nano_cm_contraceptive</b> ]  Show the field ONLY if: [event-name] = "screening_arm_1" and [screening_arm_1][nano_vi_gender] = '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														
133	[ <b>nano_cm_contraceptive_spec</b> ]  Show the field ONLY if: [nano_cm_contraceptive] = '1'	Please specify	radio, Required <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														

134	[ 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						
135	[ 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						
136	[ 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								
137	[ nano_sae_button_6 ]  Show the field ONLY if: [nano_sae_change_medication] = "1"	Please fill the medication form	descriptive						
138	[ 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								
139	[ nano_sae_vaccination_name ]  Show the field ONLY if: [nano_sae_vaccination] = '1'	Specify vaccine name	text, Required						
140	[ nano_sae_vaccination_date ]  Show the field ONLY if: [nano_sae_vaccination] = '1'	Date of vaccination	text (date_dmy), Required						
141	[ 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)							
142	<div>[ dep_name7 ]</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				
143	<div>[ nano_po_physical_exam_done ]</div> <div>Show the field ONLY if: [event-name] &lt;&gt; '2nd_vaccination_arm_1' and [event-name] &lt;&gt; "screening_arm_1" and [event-name] &lt;&gt; '1st_vaccination_arm_1'</div>	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						
144	<div>[ nano_po_physical_exam_done_why ]</div> <div>Show the field ONLY if: ([nano_po_physical_exam_done] = "0" and [event-name] &lt;&gt; "visit_3_phone_arm_1") or ([event-name] = "visit_3_phone_arm_1" and [nano_po_physical_exam_done] = "1")</div>	Specify why	text, Required				
145	<div>[ nano_po_height ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1'</div>	Body height <i>cm</i>	text (integer, Min: 0, Max: 220), Required				
146	<div>[ nano_po_weight ]</div> <div>Show the field ONLY if: ([event-name] = 'screening_arm_1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1') or ([nano_po_physical_exam_done] = '1' and [event-name] &lt;&gt; '2nd_vaccination_arm_1')</div>	Body weight <i>kg</i>	text (number, Min: 0, Max: 150), Required				

147	<div>[ nano_po_temperature ]</div> <div>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")</div>	Axillary temperature °C	text (number, Min: 33, Max: 42), Required				
148	<div>[ nano_po_heart_rate ]</div> <div>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")</div>	Heart rate bpm	text (integer, Min: 35, Max: 150), Required				
149	<div>[ nano_po_sys_blood_press ]</div> <div>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")</div>	Systolic blood pressure mmHg	text (integer, Min: 50, Max: 230), Required				
150	<div>[ nano_po_dia_blood_pressure ]</div> <div>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")</div>	Diastolic blood pressure mmHg	text (integer, Min: 20, Max: 150), Required				
151	<div>[ physical_observations_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></table>	0	Incomplete	1	Unverified
0	Incomplete						
1	Unverified						

2 Complete

**Instrument: Physical examination (physical\_examination)**

152	[ <b>dep_name16</b> ]  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				
153	[ <b>nano_pe_prevac_pe</b> ]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1' or [event-name] = '2nd_vaccination_arm_1'	Has a pre-vaccination physical examination been done ? (Mandatory on visit 2 and 6)	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	[ <b>nano_pe_prevac_pe_why</b> ]  Show the field ONLY if: [nano_pe_prevac_pe] = '0'	Specify why	text, Required				
155	[ <b>nano_pe_cardiovascular</b> ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"	Cardiovascular	notes, Required				
156	[ <b>nano_pe_respiratory</b> ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"	Respiratory	notes, Required				
157	[ <b>nano_pe_gastrointestinal</b> ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"	Gastro-intestinal	notes, Required				

	vent-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"								
158	[ nano_pe_dermatological ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"	Dermatological	notes, Required						
159	[ nano_pe_specify ]  Show the field ONLY if: [nano_po_physical_exam_done] = '1' or [event-name] = 'screening_arm_1' or [nano_pe_prevac_pe] = "1"	Other(s) : Specify	notes, Required						
160	[ physical_examination_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>Laboratory analyses</b> (laboratory_analyses)									
161	[ dep_name18 ]	Study nurse	descriptive						
162	[ nano_la_blood_sample_date_collect ]	Section Header: <i>Samples</i> Blood Sampling Date and Time	text (datetime_dmy), Required						
163	[ nano_la_blood_sample_routine ]  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 (CHUV) taken as per protocol ?	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								
164	[ nano_la_rt_no ]  Show the field ONLY if: [nano_la_blood_sample_routine] = '0'	Specify why	text, Required						



165	[ nano_la_blood_sample_research ]  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 (CLED) taken as per protocol ?	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						
166	[ nano_la_rs_no ]  Show the field ONLY if: [nano_la_blood_sample_research] = '0'	Specify why	text, Required				
167	[ nano_la_deviation ]  Show the field ONLY if: [nano_la_blood_sample_research] = '0'	If necessary, please fill the following forms  Please fill the minor protocol deviation form -  Please fill the major protocol deviation form	descriptive				
168	[ nano_la_poc_dengue ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_5_arm_1' or [event-name] = 'visit_9_arm_1' or [event-name] = "visit_11_arm_1" or [event-name] = 'visit_12_arm_1'	Section Header: <i>POC tests results</i>  Dengue rapid 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						
169	[ nano_la_poc_dengue_pos ]  Show the field ONLY if: [nano_la_poc_dengue] = '1' and [event-name] = 'screening_arm_1'	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
170	[ nano_la_poc_dengue_ns1 ]  Show the field ONLY if:	Specify : NS1 antigen	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						

	[nano_la_poc_dengue] = '1'						
171	[ nano_la_poc_dengue_igm]  Show the field ONLY if: [nano_la_poc_dengue] = '1'	Specify : IgM 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						
172	[ nano_la_poc_dengue_igg]  Show the field ONLY if: [nano_la_poc_dengue] = '1'	Specify : IgG 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						
173	[ nano_la_poc_sarscov2_antigen]  Show the field ONLY if: [event-name] = '1st_vaccination_arm_1' or [event-name] = '2nd_vaccination_arm_1'	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						
174	[ 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						
175	[ 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				
176	[ nano_la_poc_sarscov2_serology]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_5_	SARS-CoV-2 serology rapid 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						

	arm_1' or [event-name] = 'visit_9_arm_1' or [event-name] = "visit_11_arm_1" or [event-name] = 'visit_12_arm_1'										
177	[ 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								
178	[ 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	+++										
179	[ nano_la_uri_proteins ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	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	+++										
180	[ nano_la_uri_glucose ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	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	+++										
181	[ nano_la_poc_urine_failure ]  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'	Please repeat or, if clinically significant, directly complete the SCREEN FAILURE page	descriptive								

182	[ nano_la_uri_pregnancy ]  Show the field ONLY if: [nano_vi_gender] = '2' AND [event-name] = 'screening_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						
183	[ nano_la_uri_pregnancy ]  Show the field ONLY if: [nano_la_uri_pregnancy] = '1'	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
184	[ nano_la_hem_leukocytes ]  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'	Section Header: <i>Hematology</i>  Leukocytes <i>G/I - REF RANGE: 4 - 10</i>	text (number, Min: 0, Max: 100), Required				
185	[ nano_la_oor ]  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						
186	[ nano_la_oor_deviation ]  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"	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						

187	<div>[ nano_la_oor_deviat ion_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 <div><div>1Yes</div><div>0No</div></div>
188	<div>[ nano_la_hem_erythr ocythes ]</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
189	<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 <div><div>1Yes</div><div>0No</div></div>
190	<div>[ nano_la_oor_deviat ion_2 ]</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_2] = "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>
191	<div>[ nano_la_oor_deviat ion_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 <div><div>1Yes</div><div>0No</div></div>

192	[ nano_la_hem_hemoglobin ]  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'	Hemoglobin <i>g/l - REF RANGE: 133 - 177 (male) - 117 - 157 (female)</i>	text (number), Required				
193	[ nano_la_oor_3 ]  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						
194	[ nano_la_oor_deviation_3 ]  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"	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						
195	[ nano_la_oor_deviation_23 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_3] = "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						
196	[ nano_la_hem_hematocrit ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1'	Hematocrit <i>% - REF RANGE: 40 - 52 (male) - 35 - 47 (female)</i>	text (number), Required				

	OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
197	<div>[ nano_la_oor_4 ]</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						
198	<div>[ nano_la_oor_deviation_4 ]</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_4] = "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						
199	<div>[ nano_la_oor_deviation_24 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_4] = "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						
200	<div>[ nano_la_hem_mcv ]</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>	MCV (Mean corpuscular volume) <i>fl - REF RANGE: 81 - 99</i>	text (number), Required				
201	<div>[ nano_la_oor_5 ]</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						

	ent-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'						
202	[ nano_la_oor_deviation_5 ]  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"	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						
203	[ nano_la_oor_deviation_25 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_5] = "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						
204	[ nano_la_hem_mch ]  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'	MCH (Mean cell hemoglobin) <i>pg - REF RANGE: 27 - 34</i>	text (number, Min: 5, Max: 50), Required				
205	[ nano_la_oor_6 ]  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						
206	[ nano_la_oor_deviation_6 ]	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></table>	1	Yes		
1	Yes						



	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_6] = "1"	<table><tr><td>0</td><td>No</td></tr></table>	0	No		
0	No					
207	[ nano_la_oor_deviation_26 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_6] = "1"	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_hem_mchc ]  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'	MCHC (Mean corpuscular hemoglobin concentration) <i>g/l - REF RANGE: 310 - 360</i>   				

211	<div>[ nano_la_oor_deviat ion_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						
212	<div>[ nano_la_hem_platelts ]</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>	Platelets <i>G/I - REF RANGE: 150 - 350</i>	text (integer), Required				
213	<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						
214	<div>[ nano_la_oor_deviat ion_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						
215	<div>[ nano_la_oor_deviat ion_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						

216	<div>[ nano_la_hem_neutr o ]</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				
217	<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' 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						
218	<div>[ nano_la_oor_deviation_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						
219	<div>[ nano_la_oor_deviation_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						
220	<div>[ nano_la_hem_lymph o ]</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'</div>	Lymphocytes <i>G/I - REF RANGE: 1.5 - 4</i>	text (number), Required				

	OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'						
221	<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						
222	<div>[ nano_la_oor_deviation_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						
223	<div>[ nano_la_oor_deviation_30 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_10] = "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						
224	<div>[ nano_la_hem_mono ]</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>	Monocytes <i>G/I - REF RANGE: 0.2 - 0.8</i>	text (number), Required				
225	<div>[ nano_la_oor_11 ]</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						

	ent-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'						
226	[ nano_la_oor_deviation_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						
227	[ nano_la_oor_deviation_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						
228	[ 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				
229	[ nano_la_oor_12 ]  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						
230	[ nano_la_oor_deviation_12 ]	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required				

	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"		<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						
231	[ nano_la_oor_deviation_32 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_12] = "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						
232	[ nano_la_hem_baso ]  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'	Basophils <i>G/I - REF RANGE: 0.01 - 0.05</i>	text (number), Required				
233	[ nano_la_oor_13 ]  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						
234	[ nano_la_oor_deviation_13 ]  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_13] = "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						

235	<div>[ nano_la_oor_deviati ion_33 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_13] = "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						
236	<div>[ nano_la_bio_creatinine ]</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>Biochemistry</i>  Creatinine <i>μmol/ - REF RANGE: 62-106 (male) - 44 - 80 (female)</i>	text (integer), Required				
237	<div>[ nano_la_oor_14 ]</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						
238	<div>[ nano_la_oor_deviati ion_14 ]</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_14] = "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						
239	<div>[ nano_la_oor_deviati ion_34 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_14] = "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						

240	[ nano_la_bio_bilirubin ]  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'	Total bilirubin <i>μmol/l - REF RANGE: 0 - 21</i>	text (integer), Required				
241	[ nano_la_oor_19 ]  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						
242	[ nano_la_oor_deviation_19 ]  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"	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						
243	[ nano_la_oor_deviation_39 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_19] = "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						
244	[ nano_la_bio_c_reactant ]  Show the field ONLY if: [event-name] = 'screening_arm_1' OR [event-name] = 'visit_4_arm_1' OR [event-name] = 'visit_5_arm_1'	C reactive protein <i>mg/l - REF RANGE: &lt; 10</i>	text, Required				



	OR [event-name] = "visit_8_arm_1" or [event-name] = 'visit_9_arm_1'		
245	<div>[ nano_la_oor_20 ]</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>
246	<div>[ nano_la_oor_deviation_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>	Is it a deviation listed here or a clinically significant deviation from normal ranges?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
247	<div>[ nano_la_oor_deviation_40 ]</div> <div>Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_20] = "1"</div>	Is it a clinically significant deviation from normal ranges?	yesno, Required <div><div>1Yes</div><div>0No</div></div>
248	<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>	AST <i>UI/I - REF RANGE: 9 - 50</i>	text (integer), Required
249	<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>	Is this value out of range?	yesno, Required <div><div>1Yes</div><div>0No</div></div>

	ent-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'						
250	[ nano_la_oor_deviation_15 ]  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_15] = "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						
251	[ nano_la_oor_deviation_35 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_15] = "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						
252	[ nano_la_bio_alt ]  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'	ALT <i>UI/I - REF RANGE: 9 - 50</i>	text (integer), Required				
253	[ nano_la_oor_16 ]  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						
254	[ nano_la_oor_deviation_16 ]	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></table>	1	Yes		
1	Yes						

	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"	<table><tr><td>0</td><td>No</td></tr></table>	0	No		
0	No					
255	[ nano_la_oor_deviation_36 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_16] = "1"	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					
256	[ nano_la_bio_gct ]  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'	GGT <i>UI/I - REF RANGE: 6 - 42</i>  text (integer), Required				
257	[ 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'	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	[ 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"	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					

259	[ nano_la_oor_deviat ion_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						
260	[ 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				
261	[ 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						
262	[ nano_la_oor_deviat ion_17 ]  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"	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						
263	[ nano_la_oor_deviat ion_37 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' and [nano_la_oor_17] = "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						
264	[ nano_la_sero_aghs ]	Section Header: <i>Serologies</i>  AgHbs	radio, Required <table><tr><td>1</td><td>Positive</td></tr></table>	1	Positive		
1	Positive						

	Show the field ONLY if: [event-name] = 'screening_arm_1'		<table><tr><td>2</td><td>Negative</td></tr></table>	2	Negative		
2	Negative						
265	[ nano_la_sero_anti_hbc ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	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						
266	[ nano_la_sero_anti_hcv ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	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						
267	[ nano_la_sero_hiv ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	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						
268	[ nano_la_screen_failure ]  Show the field ONLY if: [nano_la_sero_aghs] = "1" OR [nano_la_sero_anti_hbc] = "1" OR [nano_la_sero_anti_hcv] = "1" OR [nano_la_sero_hiv] = "1"	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
269	[ nano_la_anti_nuclear ]  Show the field ONLY if: [event-name] = 'screening_arm_1' or [event-name] = "visit_11_arm_1"	Section Header: <i>Autoimmune reactions</i>  Anti-nuclear antibodies <i>Titer - REF RANGE &lt; 1/80</i>	text, Required				
270	[ nano_la_oor_21 ]  Show the field ONLY if: [event-name] = 'screening_arm_1' or [event-name] = "visit_11_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						
271	[ nano_la_oor_deviation_41 ]  Show the field ONLY if:	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						

	[event-name] = "visit_11_arm_1" and [nano_la_oor_21] = "1"						
272	<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						
273	<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>	Section Header: <i>Deviation from normal ranges</i> Research Physician	descriptive				
274	<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 Field Annotation: @HIDDEN				
275	<div>[ nano_la_not_enrolled ]</div> <div>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" o</div>	If an abnormal test result is deemed clinically significant it may be repeated to ensure it is not a single occurrence. If the test is repeated, please note the first value in the comment field below (the last value will be entered in the corresponding field above). If after evaluation, the participant CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				

r [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 [na

	no_la_oor_deviation_40] = "1") and [event-name] = "screening_arm_1"						
276	[ 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						
277	[ nano_la_comment_2 ]  Show the field ONLY if: [nano_la_comment] = '1'		notes				
278	[ 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	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 [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") and [event-name] <> "screening_arm_1"								
279	[ 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: <b>Contraception (contraception)</b>									
280	[ 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						
281	[ nano_sae_contraception ]  Show the field ONLY if:	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								

	[screening_arm_1][nano_vi_gender] = '2'												
282	[ nano_sae_contraception_specify ]  Show the field ONLY if: [nano_sae_contraception] = "1"	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												
283	[ nano_c_text_2 ]  Show the field ONLY if: [nano_sae_contraception_specify] = "a" OR [nano_sae_contraception_specify] = "b"	Update the medication form if needed	descriptive										
284	[ nano_c_text ]  Show the field ONLY if: [nano_sae_contraception] = "1"	Contraception has to be continued until Day 90.	descriptive										
285	[ nano_c_screen_failure ]  Show the field ONLY if: [nano_sae_contraception] = "0" AND [event-name] = '1st_vaccination_arm_1'	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										
286	[ nano_c_text_3 ]  Show the field ONLY if: [nano_sae_contraception] = "0" AND [screening_arm_1][nano_vi_gender] = "2" AND ([event-name] <> "1st_vaccination_arm_1" AND [event-name] <> 'screening_arm_1' AND [event-name] <> 'visit_12_arm_1')	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										
287	[ nano_sae_contraception_preg_test_date ]	Pregnancy test Date	text (date_dmy), Required										

	Show the field ONLY if: [screening_arm_1][nano_vi_gender] = '2' and [event-name] <> '1st_vaccination_arm_1' and [nano_sae_contraception] = '0'								
288	[ nano_sae_contraception_preg_test_result ]  Show the field ONLY if: [screening_arm_1][nano_vi_gender] = '2' and [event-name] <> '1st_vaccination_arm_1' and [nano_sae_contraception] = '0'	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								
289	[ nano_c_text_4 ]  Show the field ONLY if: [nano_sae_contraception_preg_test_result] = '1'	Please fill the the PREGNANCY form	descriptive						
290	[ 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)									
291	[ 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						
292	[ nano_e_text ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Pre-eligibility	descriptive						
293	[ nano_e_text_2 ]  Show the field ONLY if: [event-name] <> 'screening_arm_1' and [event-name] <> 'visi	Review of eligibility	descriptive						

	t_11_arm_1' and [event-name] <> 'visit_5_arm_1'						
294	[ 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						
295	[ nano_e_consent ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_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						
296	[ nano_e_able_willing ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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						
297	[ nano_e_failure ]  Show the field ONLY if: [nano_e_aged] = '0' or [nano_e_consent] = '0' or [nano_e_able_willing] = '0'	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				
298	[ nano_e_chronic ]  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>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						
299	[ nano_e_addiction ]  Show the field ONLY if:	Current alcohol abuse or drug addiction	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] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"						
300	[ nano_e_congenital ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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						
301	[ nano_e_hypersensitivity ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Known systemic hypersensitivity to any of the vaccine components (e.g. gold), or history of a life-threatening reaction to vaccines, or to a vaccine containing any of the same substances	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						
302	[ nano_e_trombo ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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						
303	[ nano_e_pregnancy ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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						
304	[ nano_e_other_clinical_trial ]  Show the field ONLY if:	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						

	[event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"						
305	[ nano_e_other_vaccine ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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 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						
306	[ nano_e_immuno ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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						
307	[ nano_e_vaccine_japanese_encephalitis ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Previous vaccination against Japanese encephalitis, Yellow Fever, or any dengue virus vaccine (monovalent or tetravalent) at any time in the past with either the trial vaccine or another vaccine based on history taking	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						
308	[ nano_e_flaviviruses ]  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 history of flavivirus (FV) infection (e.g. DENV, YF, WNV, JE, TBE), confirmed either clinically or serologically	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	[ nano_e_hiv ]  Show the field ONLY if: [event-name] = "screening_arm_1" OR [event-name] = "1st_vaccination_arm_1" OR	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						

	[event-name] = "2nd_vaccination_arm_1"						
310	<div>[ nano_e_travel_flavivirus ]</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>	Previous residence for more than 12months in, or travel in the last 30 days to flavivirus-endemic regions	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_high_risk_dengue_infec ]</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>	At high risk for dengue infection during the trial**Subjects travelling to countries/regions with high dengue endemic or epidemic activity	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						
312	<div>[ nano_e_linked_w_study ]</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>	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						
313	<div>[ nano_e_refusal ]</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>	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						
314	<div>[ nano_e_not_enrolled_2 ]</div> <div>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_thrombo] = '1' or [nano</div>	The volunteer CAN NOT BE ENROLLED in the trial, please complete the SCREEN FAILURE page	descriptive				

	_e_pregnancy] = '1' or [nano_e_other_clinical_trial] = '1' or [nano_e_other_vaccine] = '1' or [nano_e_immuno] = '1' or [nano_e_vaccine_jap_encephalitis] = '1' or [nano_e_flavivirus] = '1' or [nano_e_hiv] = '1' or [nano_e_travel_flavivirus] = '1' or [nano_e_high_risk_dengue_infection] = '1' or [nano_e_linked_w_study] = '1' or [nano_e_refusal] = '1') and [event-name] <> '2nd_vaccination_arm_1'		
315	[ nano_e_not_enrolled_5 ]  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_thrombo] = '1' or [nano_e_pregnancy] = '1' or [nano_e_other_clinical_trial] = '1' or [nano_e_other_vaccine] = '1' or [nano_e_immuno] = '1' or [nano_e_vaccine_jap_encephalitis] = '1' or [nano_e_flavivirus] = '1' or [nano_e_hiv] = '1' or [nano_e_travel_flavivirus] = '1' or [nano_e_high_risk_dengue_infection] = '1' or [nano_e_linked_w_study] = '1' or [nano_e_refusal] = '1') and [event-name] = '2nd_vaccination_arm_1'	The volunteer IS NOT ELIGIBLE anymore. Please complete the END OF TRIAL page.	descriptive
316	[ nano_e_text_3 ]  Show the field ONLY if: [event-name] = 'screening_arm_1'	Pre-eligibility	descriptive
317	[ nano_e_text_4 ]	Exclusion criteria at the time of vaccination	descriptive



	Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"								
318	[ nano_e_pre_date ]  Show the field ONLY if: [event-name] = "screening_arm_1"	Date of pre-eligibility verification	text (date_dmy), Required						
319	[ nano_e_pre ]  Show the field ONLY if: [event-name] = "screening_arm_1"	Is the volunteer pre-eligible for this trial?	radio, Required <table><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>	a	Yes	b	Volunteer is definitely not eligible	c	All data are NOT yet available and eligibility will be re-considered before vaccination.
a	Yes								
b	Volunteer is definitely not eligible								
c	All data are NOT yet available and eligibility will be re-considered before vaccination.								
320	[ 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						
321	[ nano_e_not_enrolled_3 ]  Show the field ONLY if: [nano_e_pre] = 'b'	Please complete the SCREEN FAILURE page	descriptive						
322	[ nano_e_temp_above_375 ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	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								
323	[ nano_e_other_disease ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" OR [event-name] = "2nd_vaccination_arm_1"	Does the patient have a moderate or severe acute disease* today ? *All vaccines can be administered to persons with a minor illness such as diarrhoea, mild upper respiratory infection with or without low-grade febrile illness, i.e. axillary temperature of 37.5°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								

324	[ nano_e_other_disease_specify ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1" and [nano_e_other_disease] = '1'	Specify	text, Required						
325	[ nano_e_temp_above_375_message ]  Show the field ONLY if: [nano_e_temp_above_375] = '1' or [nano_e_other_disease] = '1'	Vaccination is contraindicated today. Assess if the subject may be vaccinated at a later date, or complete the SCREEN FAILURE page	descriptive						
326	[ nano_e_final_eligibility ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"	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?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr><tr><td>2</td><td>Not applicable</td></tr></table>	1	Yes	0	No	2	Not applicable
1	Yes								
0	No								
2	Not applicable								
327	[ nano_e_final_eligibility_2 ]  Show the field ONLY if: [event-name] = "2nd_vaccination_arm_1"	For the subjects who were eligible at Visit 2, is the volunteer still eligible to continue with the trial?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr><tr><td>2</td><td>Not applicable</td></tr></table>	1	Yes	0	No	2	Not applicable
1	Yes								
0	No								
2	Not applicable								
328	[ nano_e_not_enrolled ]  Show the field ONLY if: [nano_e_final_eligibility] = '0' AND [event-name] <> 'screening_arm_1' AND [event-name] <> '1st_vaccination_arm_1'	Complete the END OF TRIAL FORM	descriptive						
329	[ nano_e_not_enrolled_6 ]  Show the field ONLY if: [nano_e_final_eligibility_2] = '0'	The volunteer IS NOT ELIGIBLE anymore. Complete the END OF TRIAL page.	descriptive						
330	[ 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?	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr><tr><td>2</td><td>Not applicable</td></tr></table>	1	Yes	0	No	2	Not applicable
1	Yes								
0	No								
2	Not applicable								

331	[ 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						
332	[ nano_e_proceed ]  Show the field ONLY if: [nano_e_final_eligibility] = '1' AND [nano_e_not_final_eligibility] = '1'	Proceed to vaccination	descriptive						
333	[ nano_e_proceed_2 ]  Show the field ONLY if: [nano_e_final_eligibility_2] = '1'	Proceed to vaccination n°2.	descriptive						
334	[ 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								
335	[ 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						
336	[ nano_e_button_end ]  Show the field ONLY if: [nano_e_still_eligible] = "0"	Complete the END OF TRIAL FORM	descriptive						
337	[ 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><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete
0	Incomplete								
1	Unverified								
2	Complete								

Instrument: Vaccine administration (vaccine_administration)							
338	[ dep_name11 ]	Research Physician	descriptive				
339	[ 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						
340	[ nano_va_been_vac_spec ]  Show the field ONLY if: [nano_va_been_vac] = '0'	Specify	text, Required				
341	[ nano_va_vac_batch_number ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Lot number	text, Required				
342	[ nano_va_vac_number ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Randomization number	text (integer), Required				
343	[ 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						
344	[ nano_va_vac_date ]  Show the field ONLY if: [nano_va_been_vac] = '1'	Date and Time of vaccination	text (datetime_dmy)				
345	[ 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						
346	[ 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						
347	[ nano_va_vac_problem_specify ]	Specify* <i>*No papule, IMP leakage from the needle...</i>	text				

	Show the field ONLY if: [nano_va_vac_problem] = "1"								
348	[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: <b>60 minutes post vaccination assessment</b> (minutes_post_vaccination_assessment)									
349	[dep_name12]	Study nurse - Refer to Research Physician if needed.	descriptive						
350	[nano_60_post_axillary]	Section Header: <i>Physical observation</i> Axillary temperature	text (number, Min: 33, Max: 43)						
351	[nano_60_post_heart]	Heart rate	text (integer, Min: 35, Max: 150)						
352	[nano_60_post_systolic]	Systolic blood pressure	text (integer, Min: 50, Max: 230)						
353	[nano_60_post_diastolic]	Diastolic blood pressure	text (integer, Min: 20, Max: 150)						
354	[nano_60_post_title_2]	Adverse events	descriptive						
355	[nano_60_post_sae]	Is there any serious 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								
356	[post_sae_def]		descriptive						
357	[nano_60_post_sae_y]  Show the field ONLY if: [nano_60_post_sae] = "1"	Please fill a SAE form	descriptive						
358	[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								
359	[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								
360	[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								
361	[nano_60_post_swelling]	Swelling	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						
362	[ 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] = '1' OR [nano_60_post_swelling] = '1'	Please fill a SAE form - Please fill a AE form	descriptive				
363	[ 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						
364	[ 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				
365	[ 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						
366	[ nano_60_post_nausea_2 ]	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						
367	[ 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						
368	[ nano_60_post_asthenia ]	Asthenia	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_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						
370	[ nano_60_post_fever ]	Fever (Temp > or = 37.5°C)	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_axillary_temp ]  Show the field ONLY if:	Axillary temperature	text				

	[nano_60_post_fever] = "1"								
372	[ nano_60_post_sae_y_3 ]  Show the field ONLY if: [nano_60_post_headache] = '1' or [nano_60_post_nausea] = '1' or [nano_60_post_nausea_2] = '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						
373	[ 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><tr><td>0</td><td>No</td></tr></table>	1	Yes	0	No		
1	Yes								
0	No								
374	[ nano_60_post_sae_y_5 ]  Show the field ONLY if: [nano_60_post_any_unsolicited_system] = '1'	Please fill a SAE form - Please fill a AE form	descriptive						
375	[ minutes_post_vaccination_assessment_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>Diary card</b> (diary_card)									
376	[ dep_name17 ]  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						
377	[ nano_d_collect ]  Show the field ONLY if: [event-name] = "visit_5_arm_1" OR [event-name] = "visit_9_arm_1"	Collect the diary card	descriptive						

378	[ nano_d_diary_card_given ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"	Diary card n°1 and participant 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								
379	[ nano_d_specify ]  Show the field ONLY if: [nano_d_diary_card_given] = '0'	Specify why	text						
380	[ nano_d_diary_card_given_2 ]  Show the field ONLY if: [event-name] = "2nd_vaccination_arm_1"	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								
381	[ nano_d_specify_2 ]  Show the field ONLY if: [nano_d_diary_card_given_2] = '0'	Specify why	text						
382	[ nano_d_thermometer_given ]  Show the field ONLY if: [event-name] = "1st_vaccination_arm_1"	Thermometer given to te 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								
383	[ nano_d_ruler_give n ]  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								
384	[ 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, to take photos if necessary and to bring daily diary at next visit.	descriptive						
385	[ 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: Protocol deviation (protocol_deviation)									



386	[ 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						
387	[ nano_e_protocol_deviation ]  Show the field ONLY if: [event-name] <> 'screening_arm_1'	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								
388	[ nano_pd_button ]  Show the field ONLY if: [nano_e_protocol_deviation] = "1"	Please fill the minor protocol deviation form	descriptive						
389	[ nano_pd_button_2 ]  Show the field ONLY if: [nano_e_protocol_deviation] = "1"	Please fill the major protocol deviation form	descriptive						
390	[ 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> (additional_comment)									
391	[ dep_name14 ]  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						
392	[ nano_ac_add_comment ]	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								
393	[ nano_ac_add_comment_prec ]  Show the field ONLY if:	Specify	notes						

	[nano_ac_add_comment] = '1'								
394	[ nano_ac_chf ]  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'	Compensation given (100CHF) ?	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_ac_chf_reason ]  Show the field ONLY if: [nano_ac_chf] = '0'	If no, why ?	text						
396	[ additional_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: <b>Next visit</b> (next_visit)									
397	[ 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"	Study nurse	descriptive						
398	[ nano_nv_date_next_visit ]	Date of next visit	text (datetime_dmy)						
399	[ 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								
400	[ 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>Screen Failure</b> (screen_failure)																											
401	[ nano_sf_date ]	Date of completion	text (date_dmy)																								
402	[ nano_sf_date_last_contact ]	Date of last contact	text (date_dmy)																								
403	[ nano_sf_specify ]	Specify reason for screen failure	<div>radio</div> <table border="1"> <tbody> <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, 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 vaccine in the 4 weeks following trial vaccination</td> </tr> </tbody> </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, 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 vaccine in the 4 weeks following trial vaccination
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			<table><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>Previous vaccination against Japanese encephalitis, Yellow Fever, or any dengue virus vaccine</td></tr><tr><td>o</td><td>Self-reported or documented history of flavivirus infection*, confirmed either clinically or serologically</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>q</td><td>Previous residence for more than 12months in, or travel in the last 30 days to flavivirus-endemic regions</td></tr><tr><td>r</td><td>At high risk for dengue infection during the trial</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>	m	Receipt of immunoglobulins, blood or blood-derived products in the past 3 months	n	Previous vaccination against Japanese encephalitis, Yellow Fever, or any dengue virus vaccine	o	Self-reported or documented history of flavivirus infection*, confirmed either clinically or serologically	p	Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C	q	Previous residence for more than 12months in, or travel in the last 30 days to flavivirus-endemic regions	r	At high risk for dengue infection during the trial	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
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v	Lost to follow up																								
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404	<div><div>[ nano_sf_specify_fa il ]</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</div></div>	Specify	text																						

	[nano_sf_specify] = "h" or [nano_sf_specify] = "j" or [nano_sf_specify] = "l" or [nano_sf_specify] = "m" or [nano_sf_specify] = "m" 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"								
405	[ nano_sf_comment_yn ]	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								
406	[ nano_sf_comment ]  Show the field ONLY if: [nano_sf_comment_yn] = "1"	Specify	text						
407	[ screen_failure_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>Unscheduled visit</b> (unscheduled_visit)									
408	[ nano_uv_reason ]	Section Header: <i>Reason of visit</i> 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								
409	[ nano_uv_reason_specify ]  Show the field ONLY if: [nano_uv_reason] = "c"	Specify	text						
410	[ nano_uv_number ]  Show the field ONLY if: [nano_uv_reason] = "a" or [nano_uv_reason] = "b"	Event number	text						
411	[ nano_uv_med_event ]	Section Header: <i>Medical history</i> Any relevant medical event since the last visit?	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						
412	[ nano_uv_event_med_specify ]  Show the field ONLY if: [nano_uv_med_event] = "1"	Specify	text				
413	[ nano_uv_event_med_date ]	Date	text (date_dmy)				
414	[ 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						
415	[ nano_uv_med_form ]  Show the field ONLY if: [nano_uv_med_change] = "1"	Please fill the medication form	descriptive				
416	[ 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						
417	[ nano_uv_vaccine_name ]  Show the field ONLY if: [nano_uv_vac] = "1"	Specify vaccine name	text				
418	[ nano_uv_vaccine_date ]	Date of vaccination	text (date_dmy)				
419	[ 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						
420	[ nano_uv_phy_exam_specify ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Specify why	text				
421	[ nano_uv_body_weight ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Section Header: <i>Physical observations</i> Body weight	text				
422	[ nano_uv_axillary_t ]	Axillary temperature	text				

	Show the field ONLY if: [nano_uv_physical_exam] = "1"		
423	[ nano_uv_heart_rate ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Heart rate	text
424	[ nano_uv_systolic_pressure ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Systolic blood pressure	text
425	[ nano_uv_diastolic_pressure ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Diastolic blood pressure	text
426	[ nano_uv_cardiovascular ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Section Header: <i>Physical examination</i> Cardiovascular	text
427	[ nano_uv_respiratory ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Respiratory	text
428	[ nano_uv_gastrointestinal ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Gastro-intestinal	text
429	[ nano_uv_dermatological ]  Show the field ONLY if: [nano_uv_physical_exam] = "1"	Dermatological	text
430	[ nano_uv_others ]  Show the field ONLY if:	Other(s) : Specify	text

	[nano_uv_physical_exam] = "1"						
431	[ nano_uv_paraclinical_perf]	Section Header: <i>Action taken</i> Have some paraclinical tests been performed ?	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						
432	[ nano_uv_para_specify]  Show the field ONLY if: [nano_uv_paraclinical_perf] = "1"	Specify	text				
433	[ nano_uv_laboratory_tests]  Show the field ONLY if: [nano_uv_paraclinical_perf] = "1"	Laboratory tests*	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						
434	[ nano_uv_radiological_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						
435	[ nano_uv_text]  Show the field ONLY if: [nano_uv_paraclinical_perf] = "1" or [nano_uv_radiological_exams] = "1" or [nano_uv_laboratory_tests] = "1"	* Do not forget to collect complementary exam, remove identifying data, code them and register them as source documents.	descriptive				
436	[ 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						
437	[ nano_uv_text_2]  Show the field ONLY if: [nano_uv_eligible] = "0"	Complete the END OF TRIAL FORM	descriptive				
438	[ nano_uv_date_next_visit]  Show the field ONLY if: [nano_uv_eligible] = "1"	Date of next visit	text (date_dmy)				
439	[ nano_uv_comment]	Section Header: <i>Additional comment</i> Any additional comment?	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								
440	[ nano_uv_comment_specify ]  Show the field ONLY if: [ nano_uv_comment ] = "1"	Specify	notes						
441	[ 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: <b>Prescription form</b> (prescription_form)									
442	[ nano_pf_title ]	FORMULAIRE DE PRESCRIPTION	descriptive						
443	[ nano_pf_nano_id ]	Screening ID	text Field Annotation: @DEFAULT='[record-name]' @READONLY						
444	[ nano_pf_nano_id_2 ]	Inclusion ID	text Field Annotation: @DEFAULT='[screening_arm_1][nano_vi_full_id]' @READONLY						
445	[ nano_pf_ipp ]	IPP	text Field Annotation: @DEFAULT='[screening_arm_1][nano_vi_ipp]' @READONLY						
446	[ 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)								
447	[ nano_pf_first_vacc ]		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								
448	[ nano_pf_date ]	Section Header: <i>1ère vaccination</i> Date d'administration souhaitée pour la première vaccination :	text (date_dmy)						
449	[ nano_pf_hour ]	Heure souhaitée pour la première vaccination :	text (time)						
450	[ nano_pf_name_date ]	Date de la demande pour la première vaccination	text (date_dmy)						
451	[ nano_pf_name ]	Nom du demandeur pour la première vaccination	text						
452	[ nano_pf_signature ]	Signature pour la première vaccination (Médecin)	descriptive						
453	[ 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								

454	[ 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)						
455	[ nano_pf_hour_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Heure souhaitée pour la deuxième vaccination :	text (time)						
456	[ 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)						
457	[ nano_pf_name_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Nom du demandeur pour la deuxième vaccination	text						
458	[ nano_pf_signature_2 ]  Show the field ONLY if: [nano_pf_first_vac] = "2"	Signature pour la deuxième vaccination (Médecin)	descriptive						
459	[ 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								
460	[ 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: <b>Pregnancy form</b> (pregnancy_form)									
461	[ 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'						
462	[ nano_pr_sponsor_name ]	Name of Sponsor	text Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'						

463	[ 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'				
464	[ nano_pr_pi_name ]	Name of Principal Investigator	text Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'				
465	[ nano_pr_pi_addresses ]	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'				
466	[ nano_pr_product_name ]	Investigational Medicinal Product Name	text Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"				
467	[ nano_pr_project_number ]	BASEC research project number (Swissethics)	text Field Annotation: @DEFAULT="2020-02258"				
468	[ nano_pr_notif_number ]	Notification n° (Swissmedic)	text				
469	[ nano_pr_yob ]	Section Header: <i>Maternal information</i> Year of birth	text (integer, Min: 1900, Max: 2100)				
470	[ nano_pr_height ]	Height	text (integer, Min: 100, Max: 220)				
471	[ nano_pr_weight ]	Weight	text (integer, Min: 25, Max: 170)				
472	[ nano_pr_contraception_met ]	Section Header: <i>Contraception</i> Method of contraception	text				
473	[ 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						
474	[ 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				
475	[ 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								
476	[ nano_pr_count_gest t]  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								
477	[ nano_pr_week_gestation]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 0	Gestation week	text (number)						
478	[ nano_pr_outcome]  Show the field ONLY if: [nano_pr_prev_pregn] = "1" and [nano_pr_count_gest] > 0	Outcome including any abnormalities	text						
479	[ 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)						
480	[ 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						
481	[ 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)						
482	[ 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						

483	[ nano_pr_concom_drug ]  Show the field ONLY if: [nano_pr_concom_drug] = "1"	Section Header: <i>Relevant medication</i> Any concomittant 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																
484	[ nano_pr_count_conc ]  Show the field ONLY if: [nano_pr_concom_drug] = "1"	How many concomittant 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><tr><td>4</td><td>4</td></tr><tr><td>5</td><td>5</td></tr></table>	1	1	2	2	3	3	4	4	5	5				
1	1																
2	2																
3	3																
4	4																
5	5																
485	[ nano_pr_med_name ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 0	Medication Name (Commercial name)	text														
486	[ nano_pr_med_int_name ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 0	Medication Name (International nonproprietary name)	text														
487	[ nano_pr_dose ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 0	Dose	text (integer, Min: 0, Max: 9999999)														
488	[ nano_pr_dose_unit ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 0	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																
489	[ nano_pr_med_frequency ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 0	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></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)
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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)																

			<table><tr><td>h</td><td>Other (specify)</td></tr></table>	h	Other (specify)																						
h	Other (specify)																										
490	<p>[ nano_pr_med_route ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 0</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)
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491	<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																								
492	<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)																								
493	<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	<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																										
494	<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)																								
495	<p>[ nano_pr_med_name_2 ]</p>	Medication Name (Commercial name)	text																								

	Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1																		
496	[ nano_pr_med_int_name_2 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	Medication Name (International nonproprietary name)	text																
497	[ nano_pr_dose_2 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	Dose	text (integer, Min: 0, Max: 9999999)																
498	[ nano_pr_dose_unit_2 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	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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499	[ nano_pr_med_frequency_2 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	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)																		
500	[ nano_pr_med_route_2 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 1	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></table>	a	Oral	b	Topical	c	Subcutaneous injection	d	Intravenous 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)								
501	<p>[ nano_pr_med_indication_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Indication(s) for use	text						
502	<p>[ nano_pr_med_start_date_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Start Date	text (date_dmy)						
503	<p>[ nano_pr_med_ongoing_2 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	Ongoing	<p>yesno</p> <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								
504	<p>[ nano_pr_med_end_date_2 ]</p> <p>Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 1</p>	End date	text (date_dmy)						
505	<p>[ nano_pr_med_name_3 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 2</p>	Medication Name (Commercial name)	text						
506	<p>[ nano_pr_med_int_name_3 ]</p> <p>Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] &gt; 2</p>	Medication Name (International nonproprietary name)	text						
507	[ nano_pr_dose_3 ]	Dose	text (integer, Min: 0, Max: 9999999)						



	Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2																								
508	[ 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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509	[ 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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g	PRN (ad needed)																								
h	Other (specify)																								
510	[ nano_pr_med_route_3 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2	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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511	[ 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																						
512	[ nano_pr_med_start_date_3 ]	Start Date	text (date_dmy)																						

	Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 2														
513	[ 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														
514	[ 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)												
515	[ 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												
516	[ nano_pr_med_int_name_4 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3	Medication Name (International nonproprietary name)	text												
517	[ 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)												
518	[ 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														

519	<div>[ nano_pr_med_freque ncy_4 ]</div> <div>Show the field ONLY if: [nano_pr_concom_d rug] = "1" and [nano _pr_count_conc] &gt; 3</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																								
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)																								
520	<div>[ nano_pr_med_route_ 4 ]</div> <div>Show the field ONLY if: [nano_pr_concom_d rug] = "1" and [nano _pr_count_conc] &gt; 3</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>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																								
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g	Nasal																								
h	Inhaled																								
i	Transdermal																								
j	Vaginal																								
k	Other (Specify)																								
521	<div>[ nano_pr_med_indica tion_4 ]</div> <div>Show the field ONLY if: [nano_pr_concom_d rug] = "1" and [nano _pr_count_conc] &gt; 3</div>	Indication(s) for use	text																						
522	<div>[ nano_pr_med_start_ date_4 ]</div> <div>Show the field ONLY if: [nano_pr_concom_d rug] = "1" and [nano _pr_count_conc] &gt; 3</div>	Start Date	text (date_dmy)																						
523	<div>[ nano_pr_med_ongoing_4 ]</div> <div>Show the field ONLY if: [nano_pr_concom_d rug] = "1" and [nano _pr_count_conc] &gt; 3</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																		
1	Yes																								
0	No																								
524	<div>[ nano_pr_med_end_da te_4 ]</div>	End date	text (date_dmy)																						

	Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 3																		
525	[ 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																
526	[ 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																
527	[ 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)																
528	[ 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				
a	Microgram																		
b	Miligram																		
c	Gram																		
d	Mililiter																		
e	Other (Specify)																		
f	Unknown																		
529	[ 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><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																		
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)																		
530	[ nano_pr_med_route_5 ]	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] > 4		<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)																						
531	[ nano_pr_med_indication_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Indication(s) for use	text																				
532	[ nano_pr_med_start_date_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	Start Date	text (date_dmy)																				
533	[ nano_pr_med_ongoing_5 ]  Show the field ONLY if: [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 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																						
534	[ nano_pr_med_end_date_5 ]  Show the field ONLY if: [nano_pr_med_ongoing] = '0' and [nano_pr_concom_drug] = "1" and [nano_pr_count_conc] > 4	End date	text (date_dmy)																				
535	[ nano_pr_tests_performed ]  Section Header: <i>Pregnancy informations</i> Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far?	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																						
536	[ nano_pr_specify ]  Show the field ONLY if:	Specify	text																				

	[nano_pr_tests_perf] = "1"								
537	[ nano_pr_delivery ]  Show the field ONLY if: [nano_pr_delivery] = "1"	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								
538	[ nano_pr_delivery_spec ]  Show the field ONLY if: [nano_pr_delivery] = "1"	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								
539	[ nano_pr_problems ]  Show the field ONLY if: [nano_pr_delivery] = "1"	Maternal complications 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								
540	[ nano_pr_problems_specify ]  Show the field ONLY if: [nano_pr_problems] = "1"	Specify	text						
541	[ nano_pr_abortion ]	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								
542	[ nano_pr_abortion_date ]  Show the field ONLY if: [nano_pr_delivery] = "1" or [nano_pr_abortion] = "1"	Date	text (date_dmy)						
543	[ nano_pr_abortion_week ]  Show the field ONLY if: [nano_pr_delivery] = "1" or [nano_pr_abortion] = "1"	At week	text (integer)						
544	[ nano_pr_abortion_specify ]  Show the field ONLY if: [nano_pr_abortion] = "1"	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								
545	[ nano_pr_specify_abnorm ]	Specify reason and any abnormalities (if known)	text (integer)						

	Show the field ONLY if: [nano_pr_abortion] = "1"																		
546	[ nano_pr_neonate ]	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																		
547	[ nano_pr_neonate_specify ]  Show the field ONLY if: [nano_pr_neonate] = "b" or [nano_pr_neonate] = "c"	Specify	text																
548	[ nano_pr_child_gender ]	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																		
549	[ nano_pr_child_height ]	Height	text (integer, Min: 0, Max: 70)																
550	[ nano_pr_child_weight ]	Weight	text (integer, Min: 0, Max: 7)																
551	[ nano_pr_child_head ]	Head circumference	text (integer, Min: 0, Max: 70)																
552	[ nano_pr_child_apgar_1 ]	Apgar score 1 min	text (integer, Min: 0, Max: 10)																
553	[ nano_pr_child_apgar_5 ]	Apgar score 5 min	text (integer, Min: 0, Max: 10)																
554	[ nano_pr_child_apgar_10 ]	Apgar score 10 min	text (integer, Min: 0, Max: 10)																
555	[ nano_pr_seriousness ]	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																		
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5	Persistent or significant disability/incapacity																		
6	Congenital anomaly/birth defect																		
7	Life-threatening																		
8	Other significant medical events																		
556	[ 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></table>	1	No relationship *	2	Unlikely *												
1	No relationship *																		
2	Unlikely *																		

			<table><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>	3	Possible *	4	Probable *	5	Definite *
3	Possible *								
4	Probable *								
5	Definite *								
557	[ nano_pr_comments ]	Section Header: <i>Additional informations</i> Comments	text						
558	[ nano_pr_investigat or_name ]	Section Header: <i>Investigator signature</i> Name of investigator	text						
559	[ nano_pr_approved_p i ]	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								
560	[ nano_pr_investigat or_date ]	Place, date and signature of investigator	text						
561	[ nano_pr_add_commen t ]	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								
562	[ nano_pr_text ]	All pregnancies must be reported to the Principal Investigator	descriptive						
563	[ nano_pr_add_commen ts ]  Show the field ONLY if: [nano_pr_add_com ment] = "1"	Specify	text						
564	[ nano_pr_pi_validat ion ]	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								
565	[ nano_pr_pi_name_2 ]	Name of PI	text Field Annotation: @DEFAULT="Prof Blaise Genton"						
566	[ nano_pr_pi_date ]	Place, date and signature of PI	text Field Annotation: @DEFAULT="Prof Blaise Genton"						
567	[ nano_pr_text_2 ]	All pregnancies must be reported immediately and within a maximum of 24 hours to the Sponsor	descriptive						
568	[ nano_pr_lock_repor t ]	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								
569	[ nano_pr_send_repor t_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								
570	[ pregnancy_form_com plete ]	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>End Of Trial / Early Termination</b> (end_of_trial_early_termination)																	
571	[ nano_end_date_completion ]	Date of completion	text (date_dmy)														
572	[ 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																
573	[ nano_end_date_last ]  Show the field ONLY if: [nano_end_trial_period]='0'	Date of last contact	text (date_dmy)														
574	[ 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																
575	[ nano_end_specify ]  Show the field ONLY if: [nano_end_reason]='b' or [nano_end_reason]='f' or [nano_end_reason]='g'	Specify	text														
576	[ 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														
577	[ 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																
578	[ nano_end_date_broken ]  Show the field ONLY if:	Date	text (date_dmy)														

	[nano_end_rando_broken]='1'														
579	[ nano_end_allocation ]  Show the field ONLY if: [nano_end_rando_broken]='1'	Allocation	radio <table border="1"> <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														
580	[ 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														
581	[ nano_end_add_comm_spec ]  Show the field ONLY if: [nano_end_additional_comm]='1'	Specify	text												
582	[ 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>															
583	[ nano_mf_med_name ]	Medication Name (Commercial name)	text												
584	[ nano_mf_med_int_name ]	Medication Name (International nonproprietary name)	text												
585	[ nano_mf_dose ]	Dose	text (number, Min: 0, Max: 9999999)												
586	[ 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
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b	Miligram														
c	Gram														
d	Mililiter														
e	Other (Specify)														
f	Unknown														
587	[ nano_mf_dose_unit_spec ]  Show the field ONLY if: [nano_mf_dose_unit] = "e"	Specify	text												
588	[ 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> </table>	a	Daily	b	Twice daily	c	Three times a day						
a	Daily														
b	Twice daily														
c	Three times a day														

			<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)																								
589	[ nano_mf_med_freque ncy_spec ]  Show the field ONLY if: [nano_mf_med_frequency] = "h"	Specify	text																						
590	[ 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>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)
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)																								
591	[ nano_mf_med_route_ spec ]  Show the field ONLY if: [nano_mf_med_route] = "k"	Specify	text																						
592	[ nano_mf_med_indica tion ]	Indication(s) for use	text																						
593	[ nano_mf_med_start_ date ]	Start Date	text (date_dmy)																						
594	[ 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																								
595	[ nano_mf_med_end_date ]  Show the field ONLY if: [nano_mf_med_ongoing] = '0'	End date	text (date_dmy)																						

596	[ 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																
597	[ nano_mf_med_ae_n ]  Show the field ONLY if: [ nano_mf_med_prescribed ] = '1'	AE number	text														
598	[ 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><tr><td>2</td><td>Complete</td></tr></table>	0	Incomplete	1	Unverified	2	Complete								
0	Incomplete																
1	Unverified																
2	Complete																
Instrument: <b>Screening and enrolment log</b> (screening_and_enrolment_log)																	
599	[ nano_sel_sr_id ]	Screening ID	text Field Annotation: @READONLY														
600	[ nano_sel_id ]	Inclusion ID	text Field Annotation: @READONLY														
601	[ nano_sel_date_icf ]	Date of ICF signature	text (datetime_dmy) Field Annotation: @READONLY														
602	[ nano_sel_date_screening ]	Date of screening	text (date_dmy) Field Annotation: @READONLY														
603	[ nano_sel_date_sf ]	Date of screenfailure (if applicable)	text (date_dmy) Field Annotation: @READONLY														
604	[ nano_sel_sf_specify ]	Specify reason for screen failure	radio <table><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 heaction to vaccines, or to a vaccine containing any of the same substances</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 heaction to vaccines, or to a vaccine containing any of the same substances
a	Age < 18 or > 45 years																
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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 vaccine in the 4 weeks following trial vaccination
m	Receipt of immunoglobulins, blood or blood-derived products in the past 3 months
n	Previous vaccination against Japanese encephalitis, Yellow Fever, or any dengue virus vaccine
o	Self-reported or documented history of flavivirus infection*, confirmed either clinically or serologically
p	Self-reported or documented seropositivity for human immunodeficiency virus (HIV), hepatitis B natural infection (HBcAb positive serology), or hepatitis C
q	Previous residence for more than 12 months in, or travel in the last 30 days to flavivirus-endemic regions
r	At high risk for dengue infection during the trial
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

			<table><tr><td></td><td>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> <div>Field Annotation: @READONLY</div>		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
	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												
605	[ nano_sel_vac ]	Vaccinated (1st dose)?	<div>yesno</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> <div>Field Annotation: @READONLY</div>	1	Yes	0	No						
1	Yes												
0	No												
606	[ nano_sel_reason_no_vac ]	If no, reason for non-eligiblity for dose 1	<div>text</div> <div>Field Annotation: @READONLY</div>										
607	[ nano_sel_date_v1 ]	Date of vaccination 1	<div>text (datetime_dmy)</div> <div>Field Annotation: @READONLY</div>										
608	[ nano_sel_vac_2 ]	Vaccinated (2nd dose)?	<div>yesno</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> <div>Field Annotation: @READONLY</div>	1	Yes	0	No						
1	Yes												
0	No												
609	[ nano_sel_reason_no_vac_2 ]	If no, reason for non-eligiblity for dose 2	<div>text</div> <div>Field Annotation: @READONLY</div>										
610	[ nano_sel_date_v2 ]	Date of vaccination 2	<div>text (datetime_dmy)</div> <div>Field Annotation: @READONLY</div>										
611	[ nano_sel_date_end_d ]	Date of end of trial :	<div>text (date_dmy)</div> <div>Field Annotation: @READONLY</div>										
612	[ nano_sel_date_end_6m ]	Did the volunteer complete the 6 months trial period ?	<div>yesno</div> <table><tr><td>1</td><td>Yes</td></tr><tr><td>0</td><td>No</td></tr></table> <div>Field Annotation: @READONLY</div>	1	Yes	0	No						
1	Yes												
0	No												
613	[ nano_sel_date_end_2 ]	If early termination, reason for end of trial :	<div>radio</div> <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></table>	a	Not eligible	b	Consent withdrawal	c	Lost to follow up	d	Death	e	Adverse Event
a	Not eligible												
b	Consent withdrawal												
c	Lost to follow up												
d	Death												
e	Adverse Event												

			<table border="1"> <tr> <td>f</td> <td>Violation of protocol</td> </tr> <tr> <td>g</td> <td>Other</td> </tr> </table> <p>Field Annotation: @READONLY</p>	f	Violation of protocol	g	Other		
f	Violation of protocol								
g	Other								
614	[ screening_and_enrollment_log_complete ]	Section Header: <i>Form Status</i> Complete?	<p>dropdown</p> <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: Compensation (compensation)</b>									
615	[ nano_comp_id ]	Inclusion ID	<p>text</p> <p>Field Annotation: @READONLY</p>						
616	[ nano_comp ]	1st vaccination Compensation received ?	<p>yesno</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table> <p>Field Annotation: @READONLY</p>	1	Yes	0	No		
1	Yes								
0	No								
617	[ nano_comp_reason ]	If no, reason	<p>text</p> <p>Field Annotation: @READONLY</p>						
618	[ nano_comp_2 ]	Visit 4 Compensation received ?	<p>yesno</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table> <p>Field Annotation: @READONLY</p>	1	Yes	0	No		
1	Yes								
0	No								
619	[ nano_comp_reason_2 ]	If no, reason	<p>text</p> <p>Field Annotation: @READONLY</p>						
620	[ nano_comp_3 ]	Visit 5 Compensation received ?	<p>yesno</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table> <p>Field Annotation: @READONLY</p>	1	Yes	0	No		
1	Yes								
0	No								
621	[ nano_comp_reason_3 ]	If no, reason	<p>text</p> <p>Field Annotation: @READONLY</p>						
622	[ nano_comp_4 ]	2nd vaccination Compensation received ?	<p>yesno</p> <table border="1"> <tr> <td>1</td> <td>Yes</td> </tr> <tr> <td>0</td> <td>No</td> </tr> </table> <p>Field Annotation: @READONLY</p>	1	Yes	0	No		
1	Yes								
0	No								
623	[ nano_comp_reason_4 ]	If no, reason	<p>text</p> <p>Field Annotation: @READONLY</p>						
624	[ nano_comp_5 ]	Visit 8 Compensation received ?	<p>yesno</p> <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								

			Field Annotation: @READONLY						
625	[ nano_comp_reason_5 ]	If no, reason	text Field Annotation: @READONLY						
626	[ 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								
627	[ nano_comp_reason_6 ]	If no, reason	text Field Annotation: @READONLY						
628	[ 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								
629	[ nano_comp_reason_7 ]	If no, reason	text Field Annotation: @READONLY						
630	[ nano_comp_8 ]	Visit 12 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								
631	[ nano_comp_reason_8 ]	If no, reason	text Field Annotation: @READONLY						
632	[ compensation_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

12/12/2023 7:24pm

#	Variable / Field Name	Field Label <i>Field Note</i>	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)																				
Instrument: <b>Adverse Event Form</b> (adverse_event_form)																							
1	[ record_id ]	Record id	text, Required Field Annotation: @HIDDEN-PDF																				
2	[ nano_ae_custom_record_id ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF																				
3	[ nano_ae_number ]	Adverse Event Number	text, Required																				
4	[ nano_ae_id ]	Inclusion ID	text, Required																				
5	[ nano_ae_date ]	Date of onset	text (date_dmy), Required																				
6	[ nano_ae_description ]	Section Header: <i>Adverse Event Description</i> Adverse Event description	notes, Required																				
7	[ 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																						
8	[ nano_ae_sae_definition ]		descriptive																				
9	[ 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																				
10	[ 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><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																						
11	[ 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/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	Nausae/Vomiting	6	Diarrhea	7	Headache	8	Fatigue	9	Myalgia	10	Fever
1	Pain																						
2	Tenderness																						
3	Erythema/Redness																						
4	Induration/Swelling																						
5	Nausae/Vomiting																						
6	Diarrhea																						
7	Headache																						
8	Fatigue																						
9	Myalgia																						
10	Fever																						
12	[ 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																						

13	<div>[ nano_ae_call_doctor ]</div> <div>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"</div>	Call the research physician. The study nurse can only complete AEs forms for solicited local grade 1 AEs.💎	descriptive										
14	<div>[ nano_ae_fda_tox_grade ]</div> <div>Show the field ONLY if: [nano_ae_solicited] = "1"</div>		descriptive										
15	<div>[ nano_ae_ctcae_6 ]</div> <div>Show the field ONLY if: [nano_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												
16	<div>[ nano_ae_ctcae_grade_v7 ]</div> <div>Show the field ONLY if: [nano_ae_solicited] = "2"</div>		descriptive										
17	<div>[ nano_ae_ctcae ]</div> <div>Show the field ONLY if: [nano_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												
18	<div>[ nano_ae_spec_ctcae ]</div> <div>Show the field ONLY if: [nano_ae_solicited] = "3"</div>	If needed, please specify	text, Required										
19	<div>[ nano_ae_ctcae_5 ]</div> <div>Show the field ONLY if: [nano_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												
20	<div>[ nano_p_ae_interest ]</div>	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												
21	<div>[ nano_aes_i_def ]</div>		descriptive										
22	<div>[ nano_ae_sae_info ]</div> <div>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"</div>	Please complete a SAE form and do not complete this AE form. SAE form	descriptive										
23	<div>[ nano_ae_causality ]</div>	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										
24	[ nano_ae_causality_2 ]		descriptive								
25	[ 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										
26	[ nano_ae_comment_event ]  Show the field ONLY if: [nano_ae_new_event] = "1"	Please comment	text, Required								
27	[ nano_ae_doses ]	Section Header: <i>IMP 1st vaccine dose et +/- second 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										
28	[ nano_ae_random_number ]	Randomization number	text (integer), Required								
29	[ 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										
30	[ 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								
31	[ nano_ae_imp_name ]	Name of IMP : PepGNP-DENGUE / Base-GNP	descriptive								
32	[ 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)										
33	[ nano_ae_route ]	Route : Intradermal injection	descriptive								
34	[ nano_ae_date_administered ]	Administration date	text (date_dmy), Required								
35	[ nano_ae_imp_name_2 ]  Show the field ONLY if: [nano_ae_doses] = "2"	Name of IMP : PepGNP-DENGUE / Base-GNP	descriptive								
36	[ nano_ae_dose_2 ]  Show the field ONLY if: [nano_ae_doses] = "2"	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)										
37	[ nano_ae_route_2 ]	Route : Intradermal injection	descriptive								

	Show the field ONLY if: [nano_ae_doses] = "2"																				
38	[ nano_ae_date_administrated_2 ]  Show the field ONLY if: [nano_ae_doses] = "2"	Administration date	text (date_dmy), Required																		
39	[ nano_ae_tests_performed ]  Show the field ONLY if: [nano_ae_doses] = "2"	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																				
40	[ nano_ae_test_labo ]  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																				
41	[ 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																				
42	[ nano_ae_main_result ]  Show the field ONLY if: [nano_ae_tests_performed] = "1"	Please provide the main results of the exams performed	notes, Required																		
43	[ nano_ae_do_not_forget ]  Show the field ONLY if: [nano_ae_test_radio] = "1" OR [nano_ae_test_labo] = "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																		
44	[ nano_ae_action_taken_imp ]	Which action(s) was/were taken with IMP ? (Several possible)	checkbox, Required <table><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 changed</td></tr><tr><td>c</td><td>nano_ae_action_taken_imp__c</td><td>Dose reduced</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 temporarily interrupted</td></tr><tr><td>f</td><td>nano_ae_action_taken_imp__f</td><td>Drug withdrawal</td></tr></table>	a	nano_ae_action_taken_imp__a	No action	b	nano_ae_action_taken_imp__b	Dose not changed	c	nano_ae_action_taken_imp__c	Dose reduced	d	nano_ae_action_taken_imp__d	Dose increase	e	nano_ae_action_taken_imp__e	Drug temporarily interrupted	f	nano_ae_action_taken_imp__f	Drug withdrawal
a	nano_ae_action_taken_imp__a	No action																			
b	nano_ae_action_taken_imp__b	Dose not changed																			
c	nano_ae_action_taken_imp__c	Dose reduced																			
d	nano_ae_action_taken_imp__d	Dose increase																			
e	nano_ae_action_taken_imp__e	Drug temporarily interrupted																			
f	nano_ae_action_taken_imp__f	Drug withdrawal																			
45	[ nano_ae_action_taken ]	Which action(s) was/were taken with the participant? (Several possible)	checkbox, Required <table><tr><td>7</td><td>nano_ae_action_taken__7</td><td>Medication treatments</td></tr><tr><td>8</td><td>nano_ae_action_taken__8</td><td>Non medication treatments</td></tr><tr><td>9</td><td>nano_ae_action_taken__9</td><td>Hospitalisation</td></tr><tr><td>10</td><td>nano_ae_action_taken__10</td><td>No action</td></tr></table>	7	nano_ae_action_taken__7	Medication treatments	8	nano_ae_action_taken__8	Non medication treatments	9	nano_ae_action_taken__9	Hospitalisation	10	nano_ae_action_taken__10	No action						
7	nano_ae_action_taken__7	Medication treatments																			
8	nano_ae_action_taken__8	Non medication treatments																			
9	nano_ae_action_taken__9	Hospitalisation																			
10	nano_ae_action_taken__10	No action																			
46	[ nano_ae_specify ]  Show the field ONLY if:	Specify	text, Required																		

	[nano_ae_action_taken (8)]																		
47	[ nano_ae_text ]  Show the field ONLY if: [nano_ae_action_taken (7)]	Please fill the medication form	descriptive																
48	[ nano_ae_reaction_abate ]	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																		
49	[ nano_ae_reaction_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																		
50	[ nano_ae_text_sae ]  Show the field ONLY if: [nano_ae_action_taken (9)]	Fill the SAE form	descriptive																
51	[ nano_ae_withdrawn ]	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																		
52	[ nano_end_of_trial ]  Show the field ONLY if: [nano_ae_withdrawn] = "1"	Complete the END OF TRIAL FORM	descriptive																
53	[ 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																		
54	[ nano_ae_last_day_sympt ]  Show the field ONLY if: [nano_ae_outcome] = '2' or [nano_ae_outcome] = '1' or [nano_ae_outcome] = '7'	Date	text (date_dmy), Required																
55	[ 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																		
56	[ nano_ae_sae_number ]  Show the field ONLY if: [nano_ae_evolved] = "1"	Specify the SAE number related	text, Required																

57	[ nano_ae_text_sae_2 ] Show the field ONLY if: [nano_ae_evolved] = "1"	Fill the SAE form	descriptive						
58	[ 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								
59	[ nano_ae_comments ] Show the field ONLY if: [nano_ae_comment] = "1"	Comments	text, Required						
60	[ nano_ae_name_investigator ]	Section Header: <i>Investigator signature</i> Name of investigator	text, Required						
61	[ nano_ae_sign_date ]	Date	text (date_dmy), Required						
62	[ nano_ae_signature ]	Signature of investigator	file (signature), Required						
63	[ adverse_event_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: Serious Adverse Event Form (serious_adverse_event_form)</b>									
64	[ nano_sae_sae_number ]	SAE number	text, Required						
65	[ nano_sae_custom_record_id ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF						
66	[ 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'						
67	[ nano_sae_sponsor_name ]	Name of Sponsor	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'						
68	[ nano_sae_sponsor_address ]	Address of Sponsor	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = '4 & 5 Dunmore Court Wootton Road, Abingdon, Oxfordshire, England, OX13 6BH'						
69	[ nano_sae_pi_name ]	Name of Principal Investigator	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'						
70	[ nano_sae_product_name ]	Investigational Medicinal Product Name	text, Required Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"						
71	[ nano_sae_pi_address ]	Adress of Principal Investigator	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Unisanté, Département Formation, recherche et innovation Polyclinique de médecine tropicale, voyages et vaccinations Rue du Bugnon 44 1011 Lausanne, Suisse Blaise.genton@unisante.ch M :+41 79 556 58 68'						

72	[ nano_sae_project_number ]	BASEC research project number (Swissethics)	text, Required Field Annotation: @DEFAULT="2020-02258"																					
73	[ nano_sae_notif_number ]	Notification n° (Swissmedic)	text, Required Field Annotation: @DEFAULT="2021DR1042"																					
74	[ nano_sae_id ]	Section Header: <i>SAE information</i> Inclusion ID	text, Required Custom alignment: RH																					
75	[ nano_sae_dob ]	Year of birth	text (integer), Required Custom alignment: RH																					
76	[ nano_sae_sex ]	Sex	radio, Required <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table> Custom alignment: RH	1	Male	2	Female																	
1	Male																							
2	Female																							
77	[ nano_sae_ethnicity ]	Ethnicity (Several possible)	checkbox, Required <table><tr><td>1</td><td>nano_sae_ethnicity__1</td><td>Caucasian</td></tr><tr><td>2</td><td>nano_sae_ethnicity__2</td><td>Asian</td></tr><tr><td>3</td><td>nano_sae_ethnicity__3</td><td>Black</td></tr><tr><td>4</td><td>nano_sae_ethnicity__4</td><td>Carribean</td></tr><tr><td>5</td><td>nano_sae_ethnicity__5</td><td>Indian</td></tr><tr><td>6</td><td>nano_sae_ethnicity__6</td><td>Arab</td></tr><tr><td>7</td><td>nano_sae_ethnicity__7</td><td>Other</td></tr></table>	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
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																						
78	[ nano_sae_ethnicity_specify ]  Show the field ONLY if: [nano_sae_ethnicity(7)] = '1'	Specify	text, Required																					
79	[ nano_sae_ae_date ]	AE onset date	text (date_dmy), Required																					
80	[ nano_sae_ae_awareness ]	AE awareness date	text (date_dmy), Required																					
81	[ nano_sae_ae_evolution ]	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																							
82	[ nano_sae_ae_number ]  Show the field ONLY if: [nano_sae_ae_evolution] = "1"	Specify AE number	text, Required																					
83	[ 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																					
84	[ nano_sae_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><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																							
85	[ nano_sae_fda_toxicity ]  Show the field ONLY if:	FDA toxicity grading scale term	dropdown, Required <table><tr><td>1</td><td>Pain</td></tr></table>	1	Pain																			
1	Pain																							

	[nano_sae_ae_solicited] = "1"		<table><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/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>	2	Tenderness	3	Erythema/Redness	4	Induration/Swelling	5	Nausae/Vomiting	6	Diarrhea	7	Headache	8	Fatigue	9	Myalgia	10	Fever
2	Tenderness																				
3	Erythema/Redness																				
4	Induration/Swelling																				
5	Nausae/Vomiting																				
6	Diarrhea																				
7	Headache																				
8	Fatigue																				
9	Myalgia																				
10	Fever																				
86	[ nano_sae_fda_tox_grade_2 ]  Show the field ONLY if: [nano_sae_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																				
87	[ nano_sae_fda_tox_grade ]  Show the field ONLY if: [nano_sae_ae_solicited] = "1"		descriptive Field Annotation: @HIDDEN-PDF																		
88	[ nano_sae_labo_ctcae_term ]  Show the field ONLY if: [nano_sae_ae_solicited] = "2"	AE term	text, Required																		
89	[ nano_sae_ctcae_grade_v6 ]  Show the field ONLY if: [nano_sae_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																				
90	[ nano_sae_ctcae_grade_v7 ]  Show the field ONLY if: [nano_sae_ae_solicited] = "2"		descriptive Field Annotation: @HIDDEN-PDF																		
91	[ nano_sae_ctcae_grade ]  Show the field ONLY if: [nano_sae_ae_solicited] = "3"	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																				
92	[ nano_sae_spec_ctcae ]  Show the field ONLY if: [nano_sae_ae_solicited] = "3"	If needed, please specify	text, Required																		
93	[ nano_sae_ctcae_grade_v5 ]  Show the field ONLY if: [nano_sae_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></table>	1	Grade 1	2	Grade 2	3	Grade 3												
1	Grade 1																				
2	Grade 2																				
3	Grade 3																				



			<table><tr><td>4</td><td>Grade 4</td></tr><tr><td>5</td><td>Grade 5</td></tr></table>	4	Grade 4	5	Grade 5								
4	Grade 4														
5	Grade 5														
94	[ nano_sae_yes_no ]	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														
95	[ nano_sae_type ]  Show the field ONLY if: [nano_sae_yes_no] = "1"	Check SAE (seriousness definition)	radio, Required <table><tr><td>a</td><td>Death</td></tr><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>	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)	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)
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)														
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)														
96	[ 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														
97	[ nano_sae_aesi_def ]		descriptive Field Annotation: @HIDDEN-PDF												
98	[ 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														
99	[ 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														
100	[ nano_sae_random_number ]	Randomisation number	text (integer), Required												
101	[ 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														
102	[ 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												
103	[ nano_sae_imp_name ]	Name of IMP : PepGNP-DENGUE or vehicle-GNP	descriptive												
104	[ nano_sae_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)														
105	[ nano_sae_route ]	Route : Intradermal injection	descriptive												

106	[ nano_sae_date_admini stred ]	Administration date	text (date_dmy), Required									
107	[ nano_sae_imp_name_2 ]  Show the field ONLY if: [nano_sae_doses] = "2"	Name of IMP : PepGNP-DENGUE or vehicle-GNP	descriptive									
108	[ nano_sae_dose_2 ]  Show the field ONLY if: [nano_sae_doses] = "2"	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)											
109	[ nano_sae_route_2 ]  Show the field ONLY if: [nano_sae_doses] = "2"	Route : Intradermal injection	descriptive									
110	[ nano_sae_date_admini stred_2 ]  Show the field ONLY if: [nano_sae_doses] = "2"	Administration date	text (date_dmy), Required									
111	[ nano_sae_causality ]	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											
112	[ nano_sae_causality_d ef ]		descriptive Field Annotation: @HIDDEN-PDF									
113	[ 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									
114	[ nano_sae_disease ]	Disease / Intervention /Allergy	text									
115	[ nano_sae_date_diseas e ]	Start date	text									
116	[ nano_sae_disease_ong oing ]	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											
117	[ nano_sae_disease_sto p ]	Stop date	text									

118	[ nano_sae_disease_1 ]	Disease / Intervention /Allergy	text												
119	[ nano_sae_date_diseas e_1 ]	Start date	text												
120	[ nano_sae_disease_ong oing_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														
121	[ nano_sae_disease_sto p_1 ]	Stop date	text												
122	[ nano_sae_disease_2 ]	Disease / Intervention /Allergy	text												
123	[ nano_sae_date_diseas e_2 ]	Start date	text												
124	[ nano_sae_disease_ong oing_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														
125	[ nano_sae_disease_sto p_2 ]	Stop date	text												
126	[ nano_sae_disease_3 ]	Disease / Intervention /Allergy	text												
127	[ nano_sae_date_diseas e_3 ]	Start date	text												
128	[ 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														
129	[ nano_sae_disease_sto p_3 ]	Stop date	text												
130	[ nano_sae_disease_4 ]	Disease / Intervention /Allergy	text												
131	[ nano_sae_date_diseas e_4 ]	Start date	text												
132	[ 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														
133	[ nano_sae_disease_sto p_4 ]	Stop date	text												
134	[ 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														
135	[ 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														
136	[ nano_sae_med_name ]  Show the field ONLY if:	Medication Name (Commercial name)	text, Required												

	[nano_sae_drug] ="1" and [nano_sae_conc_count] > 0																		
137	[ nano_sae_med_name_in ter ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 0	Medication Name (International nonproprietary name)	text, Required																
138	[ nano_sae_med_dose ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 0	Dose	text (number), Required																
139	[ nano_sae_med_dose_unit ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 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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140	[ nano_sae_med_dose_spec ]  Show the field ONLY if: [nano_sae_med_dose_unit] = "5"	Specify	text, Required																
141	[ nano_sae_med_dose_freq ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 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)
1	Daily																		
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142	[ nano_sae_med_freq_spec ]  Show the field ONLY if: [nano_sae_med_dose_freq] = "8"	Specify	text, Required																
143	[ nano_sae_med_route ]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 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><tr><td>6</td><td>Rectal</td></tr><tr><td>7</td><td>Nasal</td></tr></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal		
1	Oral																		
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			<table><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>	8	Inhaled	9	Transdermal	10	Vaginal	11	Other (Specify)
8	Inhaled										
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10	Vaginal										
11	Other (Specify)										
144	<div>[ nano_sae_med_route_spec ]</div> <div>Show the field ONLY if: [nano_sae_med_route] = "11"</div>	Specify	text, Required								
145	<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								
146	<div>[ nano_sae_med_start ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</div>	Start Date	text (date_dmy), Required								
147	<div>[ nano_sae_med_ongoing ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 0</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				
1	Yes										
0	No										
148	<div>[ nano_sae_med_end_date ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing] = "0" and [nano_sae_conc_count] &gt; 0</div>	End date	text (date_dmy), Required								
149	<div>[ nano_sae_med_name_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</div>	Medication Name (Commercial name)	text, Required								
150	<div>[ nano_sae_med_name_inter_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</div>	Medication Name (International nonproprietary name)	text, Required								
151	<div>[ nano_sae_med_dose_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 1</div>	Dose	text (number, Min: 0, Max: 9999999), Required								
152	<div>[ nano_sae_med_dose_unit_1 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count]</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></table>	1	Microgram	2	Miligram	3	Gram		
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	nt] > 1		<table><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>	4	Mililiter	5	Other (Specify)	6	Unknown																
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153	[ nano_sae_med_dose_spec_1]  Show the field ONLY if: [nano_sae_med_dose_unit_1] = "5"	Specify	text, Required																						
154	[ nano_sae_med_dose_freq_1]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 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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155	[ nano_sae_med_freq_spec_1]  Show the field ONLY if: [nano_sae_med_dose_freq_1] = "8"	Specify	text, Required																						
156	[ nano_sae_med_route_1]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 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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157	[ nano_sae_med_route_spec_1]  Show the field ONLY if: [nano_sae_med_route_1] = "11"	Specify	text, Required																						
158	[ nano_sae_med_use_1]  Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] > 1	Indication(s) for use	text, Required																						
159	[ nano_sae_med_start_1]  Show the field ONLY if:	Start Date	text (date_dmy), Required																						

	[ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 1														
160	[ nano_sae_med_ongoing _1 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 1	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														
161	[ nano_sae_med_end_dat e_1 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" A ND [ nano_sae_med_on going_1 ] = "0" and [ nan o_sae_conc_count] > 1	End date	text (date_dmy), Required												
162	[ nano_sae_med_name_2 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 2	Medication Name (Commercial name)	text, Required												
163	[ nano_sae_med_name_in ter_2 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 2	Medication Name (International nonproprietary name)	text, Required												
164	[ nano_sae_med_dose_2 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 2	Dose	text (integer, Min: 0, Max: 9999999), Required												
165	[ nano_sae_med_dose_un it_2 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 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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166	[ nano_sae_med_dose_sp ec_2 ]  Show the field ONLY if: [ nano_sae_med_dose_u nit_2 ] = "5"	Specify	text, Required												
167	[ nano_sae_med_dose_fr eq_2 ]  Show the field ONLY if: [ nano_sae_drug ] ="1" a nd [ nano_sae_conc_cou nt] > 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></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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168	<div>[ nano_sae_med_freq_spec_2 ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_freq_2] = "8"</div>	Specify	text, Required																						
169	<div>[ nano_sae_med_route_2 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_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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170	<div>[ nano_sae_med_route_spec_2 ]</div> <div>Show the field ONLY if: [nano_sae_med_route_2] = "11"</div>	Specify	text, Required																						
171	<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																						
172	<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																						
173	<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																								
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174	<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																						
175	<div>[ nano_sae_med_name_3 ]</div> <div>Show the field ONLY if:</div>	Medication Name (Commercial name)	text, Required																						



	[nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 3																		
176	[ nano_sae_med_name_in ter_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 3	Medication Name (International nonproprietary name)	text, Required																
177	[ nano_sae_med_dose_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 3	Dose	text (number, Min: 0, Max: 9999999), Required																
178	[ nano_sae_med_dose_un it_3 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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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181	[ nano_sae_med_freq_sp ec_3 ]  Show the field ONLY if: [nano_sae_med_dose_f req_3] = "8"	Specify	text, Required																
182	[ nano_sae_med_route_ 3 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 3	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></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal	7	Nasal		
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183	<div>[ nano_sae_med_route_spec_3 ]</div> <div>Show the field ONLY if: [nano_sae_med_route_3] = "11"</div>	Specify	text, Required								
184	<div>[ nano_sae_med_use_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Indication(s) for use	text, Required								
185	<div>[ nano_sae_med_start_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</div>	Start Date	text (date_dmy), Required								
186	<div>[ nano_sae_med_ongoing_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 3</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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0	No										
187	<div>[ nano_sae_med_end_date_3 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing_3] = "0" and [nano_sae_conc_count] &gt; 3</div>	End date	text (date_dmy), Required								
188	<div>[ nano_sae_med_name_4 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 4</div>	Medication Name (Commercial name)	text, Required								
189	<div>[ nano_sae_med_name_inter_4 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 4</div>	Medication Name (International nonproprietary name)	text, Required								
190	<div>[ nano_sae_med_dose_4 ]</div> <div>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 4</div>	Dose	text (number, Min: 0, Max: 9999999), Required								
191	<div>[ nano_sae_med_dose_unit_4 ]</div> <div>Show the field ONLY if:</div>	Dose unit	<div>radio, Required</div> <table><tr><td>1</td><td>Microgram</td></tr><tr><td>2</td><td>Miligram</td></tr></table>	1	Microgram	2	Miligram				
1	Microgram										
2	Miligram										

	[nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 4		<table><tr><td>3</td><td>Gram</td></tr><tr><td>4</td><td>Milliliter</td></tr><tr><td>5</td><td>Other (Specify)</td></tr><tr><td>6</td><td>Unknown</td></tr></table>	3	Gram	4	Milliliter	5	Other (Specify)	6	Unknown														
3	Gram																								
4	Milliliter																								
5	Other (Specify)																								
6	Unknown																								
192	[ nano_sae_med_dose_sp ec_4 ]  Show the field ONLY if: [nano_sae_med_dose_u nit_4] = "5"	Specify	text, Required																						
193	[ nano_sae_med_dose_fr eq_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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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8	Other (specify)																								
194	[ nano_sae_med_freq_sp ec_4 ]  Show the field ONLY if: [nano_sae_med_dose_f req_4] = "8"	Specify	text, Required																						
195	[ nano_sae_med_route_ 4 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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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196	[ nano_sae_med_route_s pec_4 ]  Show the field ONLY if: [nano_sae_med_route_ 4] = "11"	Specify	text, Required																						
197	[ nano_sae_med_use_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 4	Indication(s) for use	text, Required																						
198	[ nano_sae_med_start_ 4 ]	Start Date	text (date_dmy), Required																						

	Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 4														
199	[ nano_sae_med_ongoing_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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														
200	[ nano_sae_med_end_dat e_4 ]  Show the field ONLY if: [nano_sae_drug] ="1" A ND [nano_sae_med_on going_4] = "0" and [nan o_sae_conc_count] > 4	End date	text (date_dmy), Required												
201	[ nano_sae_med_name_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 5	Medication Name (Commercial name)	text, Required												
202	[ nano_sae_med_name_in ter_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 5	Medication Name (International nonproprietary name)	text, Required												
203	[ nano_sae_med_dose_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 5	Dose	text (number, Min: 0, Max: 9999999), Required												
204	[ nano_sae_med_dose_un it_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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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205	[ nano_sae_med_dose_sp ec_5 ]  Show the field ONLY if: [nano_sae_med_dose_u nit_5] = "5"	Specify	text, Required												
206	[ nano_sae_med_dose_fr eq_5 ]  Show the field ONLY if: [nano_sae_drug] ="1" a nd [nano_sae_conc_cou nt] > 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></table>	1	Daily	2	Twice daily	3	Three times a day	4	Four times a day	5	4-6 hours		
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8	Other (specify)																								
207	<p>[ nano_sae_med_freq_spec_5 ]</p> <p>Show the field ONLY if: [nano_sae_med_dose_freq_5] = "8"</p>	Specify	text, Required																						
208	<p>[ nano_sae_med_route_5 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 5</p>	Route	<p>radio, Required</p> <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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209	<p>[ nano_sae_med_route_spec_5 ]</p> <p>Show the field ONLY if: [nano_sae_med_route_5] = "11"</p>	Specify	text, Required																						
210	<p>[ nano_sae_med_use_5 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 5</p>	Indication(s) for use	text, Required																						
211	<p>[ nano_sae_med_start_5 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 5</p>	Start Date	text (date_dmy), Required																						
212	<p>[ nano_sae_med_ongoing_5 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" and [nano_sae_conc_count] &gt; 5</p>	Ongoing	<p>yesno, Required</p> <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	<p>[ nano_sae_med_end_date_5 ]</p> <p>Show the field ONLY if: [nano_sae_drug] ="1" AND [nano_sae_med_ongoing_5] = "0" and [nano_sae_conc_count] &gt; 5</p>	End date	text (date_dmy), Required																						

214	[ nano_sae_test_performed ]	Section Header: <i>Relevant paraclinic tests</i> Have some paraclinical tests/procedures been performed ?	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																				
215	[ nano_sae_lab_tests ] Show the field ONLY if: [nano_sae_test_performed] = "1"	Laboratory tests	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																				
216	[ nano_sae_radio_tests ] Show the field ONLY if: [nano_sae_test_performed] = "1"	Radiological exams	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																				
217	[ nano_sae_relevant_procedure ] 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																				
218	[ nano_sae_specify ] Show the field ONLY if: [nano_sae_relevant_procedure] = "1"	Specify	text, Required																		
219	[ 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																		
220	[ nano_sae_text ] Show the field ONLY if: [nano_sae_relevant_procedure] = "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																		
221	[ 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 not change</td></tr> <tr><td>c</td><td>nano_sae_action_taken_imp__c</td><td>Dose reduction</td></tr> <tr><td>d</td><td>nano_sae_action_taken_imp__d</td><td>Dose increase</td></tr> <tr><td>e</td><td>nano_sae_action_taken_imp__e</td><td>Drug temporary interruption</td></tr> <tr><td>f</td><td>nano_sae_action_taken_imp__f</td><td>Drug withdrawal</td></tr> </table>	a	nano_sae_action_taken_imp__a	No action	b	nano_sae_action_taken_imp__b	Dose not change	c	nano_sae_action_taken_imp__c	Dose reduction	d	nano_sae_action_taken_imp__d	Dose increase	e	nano_sae_action_taken_imp__e	Drug temporary interruption	f	nano_sae_action_taken_imp__f	Drug withdrawal
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f	nano_sae_action_taken_imp__f	Drug withdrawal																			
222	[ nano_sae_action_taken_imp_sp ] Show the field ONLY if:	Specify	text, Required																		

	[nano_sae_action_taken_imp(c)] = '1' or [nano_sae_action_taken_imp(d)] = '1' or [nano_sae_action_taken_imp(e)] = '1'																						
223	[ nano_sae_action_taken ]  Show the field ONLY if: [nano_sae_action_taken(h)] = '1'	Which action(s) was/were taken with the participant ? (Several possible)	<table><tr><td colspan="3">checkbox, Required</td></tr><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>	checkbox, Required			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								
checkbox, Required																							
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224	[ nano_sae_action_taken_spec ]  Show the field ONLY if: [nano_sae_action_taken(h)] = '1'	Specify	text, Required																				
225	[ nano_sae_count ]  Show the field ONLY if: [nano_sae_action_taken(g)] = '1'	How many medication ?	<table><tr><td colspan="2">dropdown, Required</td></tr><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>	dropdown, Required		1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9
dropdown, Required																							
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8	8																						
9	9																						
226	[ nano_sae_action_med_name ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 0	Medication Name (Commercial name)	text, Required																				
227	[ nano_sae_action_med_name_inter ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 0	Medication Name (International nonproprietary name)	text, Required																				
228	[ nano_sae_action_med_dose ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 0	Dose	text (number, Min: 0, Max: 9999999), Required																				
229	[ nano_sae_action_med_unit ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 0	Dose unit	<table><tr><td colspan="2">radio, Required</td></tr><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></table>	radio, Required		1	Microgram	2	Miligram	3	Gram	4	Mililiter										
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230	<div>[ nano_sae_action_med_unit_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit] = "5"</div>	Specify	text, Required																						
231	<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	<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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232	<div>[ nano_sae_action_med_freq_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq] = "8"</div>	Specify	text, Required																						
233	<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	<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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234	<div>[ nano_sae_action_med_route_spec ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route] = "11"</div>	Specify	text, Required																						
235	<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																						
236	<div>[ nano_sae_action_med_ongoing ]</div> <div>Show the field ONLY if:</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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	[nano_sae_action_taken (g)] and [nano_sae_cou nt] > 0																		
237	[ nano_sae_action_med_end ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 0 and [nano_sae_a ction_med_ongoing] = "0"	End date	text (date_dmy), Required																
238	[ nano_sae_action_med_name_1 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 1	Medication Name (Commercial name)	text, Required																
239	[ nano_sae_action_med_name_inter_1 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 1	Medication Name (International nonproprietary name)	text, Required																
240	[ nano_sae_action_med_dose_1 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 1	Dose	text (number, Min: 0, Max: 9999999), Required																
241	[ nano_sae_action_med_unit_1 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 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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244	<div>[ nano_sae_med_action_freq_spec_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_freq_1] = "8"</div>	Specify	text, Required																							
245	<div>[ nano_sae_action_med_route_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &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><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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246	<div>[ nano_sae_med_action_route_spec_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_1] = "11"</div>	Specify	text, Required																							
247	<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																							
248	<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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249	<div>[ nano_sae_action_med_end_1 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 1 and [nano_sae_action_med_ongoing_1] = "0"</div>	End date	text (date_dmy), Required																							
250	<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																							
251	<div>[ nano_sae_action_med_name_inter_2 ]</div> <div>Show the field ONLY if:</div>	Medication Name (International nonproprietary name)	text, Required																							

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252	[ nano_sae_action_med_dose_2 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 2	Dose	text (number, Min: 0, Max: 9999999), Required																						
253	[ nano_sae_action_med_unit_2 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 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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258	<div>[ nano_sae_med_action_route_spec_2 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_2] = "11"</div>	Specify	text, Required												
259	<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												
260	<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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261	<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												
262	<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												
263	<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												
264	<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												
265	<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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269	<div>[ nano_sae_action_med_route_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_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)
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271	<div>[ nano_sae_action_med_date_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 3</div>	Start Date	text (date_dmy), Required																						
272	<div>[ nano_sae_action_med_ongoing_3 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 3</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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275	[ 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																
276	[ nano_sae_action_med_dose_4 ]  Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] > 4	Dose	text (number, Min: 0, Max: 9999999), Required																
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292	[ nano_sae_med_action_ freq_spec_5 ]  Show the field ONLY if: [nano_sae_action_med_ freq_5] = "8"	Specify	text, Required																						
293	[ nano_sae_action_med_ route_5 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 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><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																								
2	Topical																								
3	Subcutaneous injection																								
4	Intravenous injection																								
5	Intramuscular injection																								
6	Rectal																								
7	Nasal																								
8	Inhaled																								
9	Transdermal																								
10	Vaginal																								
11	Other (Specify)																								
294	[ nano_sae_med_action_ route_spec_5 ]  Show the field ONLY if: [nano_sae_action_med_ route_5] = "11"	Specify	text, Required																						



295	<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												
296	<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								
1	Yes														
0	No														
297	<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_action_med_ongoing_5] = "0"</div>	End date	text (date_dmy), Required												
298	<div>[ nano_sae_action_med_name_6 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 6</div>	Medication Name (Commercial name)	text, Required												
299	<div>[ nano_sae_action_med_name_inter_6 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 6</div>	Medication Name (International nonproprietary name)	text, Required												
300	<div>[ nano_sae_action_med_dose_6 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 6</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
301	<div>[ nano_sae_action_med_unit_6 ]</div> <div>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &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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2	Miligram														
3	Gram														
4	Mililiter														
5	Other (Specify)														
6	Unknown														
302	<div>[ nano_sae_action_med_unit_spec_6 ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_6] = "5"</div>	Specify	text, Required												
303	<div>[ nano_sae_action_med_freq_6 ]</div> <div>Show the field ONLY if:</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr></table>	1	Daily	2	Twice daily								
1	Daily														
2	Twice daily														

	[nano_sae_action_taken (g)] and [nano_sae_cou nt] > 6		<table><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>	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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7	PRN (ad needed)																								
8	Other (specify)																								
304	[ nano_sae_med_action_freq_spec_6 ]  Show the field ONLY if: [nano_sae_action_med_freq_6] = "8"	Specify	text, Required																						
305	[ nano_sae_action_med_route_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 6	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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306	[ nano_sae_med_action_route_spec_6 ]  Show the field ONLY if: [nano_sae_action_med_route_6] = "11"	Specify	text, Required																						
307	[ nano_sae_action_med_date_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 6	Start Date	text (date_dmy), Required																						
308	[ nano_sae_action_med_ongoing_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 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																								
309	[ nano_sae_action_med_end_6 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_cou nt] > 6 and [nano_sae_a ction_med_ongoing_6] = "0"	End date	text (date_dmy), Required																						
310	[ nano_sae_action_med_name_7 ]	Medication Name (Commercial name)	text, Required																						

	Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7																		
311	[ 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																
312	[ 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																
313	[ nano_sae_action_med_unit_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 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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314	[ nano_sae_action_med_unit_spec_7 ]  Show the field ONLY if: [nano_sae_action_med_unit_7] = "5"	Specify	text, Required																
315	[ nano_sae_action_med_freq_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	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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7	PRN (ad needed)																		
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316	[ nano_sae_med_action_freq_spec_7 ]  Show the field ONLY if: [nano_sae_action_med_freq_7] = "8"	Specify	text, Required																
317	[ nano_sae_action_med_route_7 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 7	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)												
318	<p>[ nano_sae_med_action_route_spec_7 ]</p> <p>Show the field ONLY if: [nano_sae_action_med_route_7] = "11"</p>	Specify	text, Required										
319	<p>[ nano_sae_action_med_date_7 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 7</p>	Start Date	text (date_dmy), Required										
320	<p>[ nano_sae_action_med_ongoing_7 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 7</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												
321	<p>[ nano_sae_action_med_end_7 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 7 and [nano_sae_action_med_ongoing_7] = "0"</p>	End date	text (date_dmy), Required										
322	<p>[ nano_sae_action_med_name_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</p>	Medication Name (Commercial name)	text, Required										
323	<p>[ nano_sae_action_med_name_inter_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</p>	Medication Name (International nonproprietary name)	text, Required										
324	<p>[ nano_sae_action_med_dose_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</p>	Dose	text (number, Min: 0, Max: 9999999), Required										
325	<p>[ nano_sae_action_med_unit_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken(g)] and [nano_sae_count] &gt; 8</p>	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></table>	1	Microgram	2	Miligram	3	Gram				
1	Microgram												
2	Miligram												
3	Gram												

			<table><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>	4	Mililiter	5	Other (Specify)	6	Unknown																
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5	Other (Specify)																								
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326	<p>[ nano_sae_action_med_unit_spec_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_med_unit_8] = "5"</p>	Specify	text, Required																						
327	<p>[ nano_sae_action_med_freq_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 8</p>	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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8	Other (specify)																								
328	<p>[ nano_sae_med_action_freq_spec_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_med_freq_8] = "8"</p>	Specify	text, Required																						
329	<p>[ nano_sae_action_med_route_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 8</p>	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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10	Vaginal																								
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330	<p>[ nano_sae_med_action_route_spec_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_med_route_8] = "11"</p>	Specify	text, Required																						
331	<p>[ nano_sae_action_med_date_8 ]</p> <p>Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] &gt; 8</p>	Start Date	text (date_dmy), Required																						
332	<p>[ nano_sae_action_med_ongoing_8 ]</p>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes																				
1	Yes																								

	Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8		<table><tr><td>0</td><td>No</td></tr></table>	0	No														
0	No																		
333	[ nano_sae_action_med_end_8 ]  Show the field ONLY if: [nano_sae_action_taken (g)] and [nano_sae_count] > 8 and [nano_sae_action_med_ongoing_8] = "0"	End date	text (date_dmy), Required																
334	[ nano_sae_react_abate ]	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																		
335	[ 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																		
336	[ 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
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6	Agravation																		
7	Fatal																		
8	Unknown																		
337	[ 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																
338	[ nano_sae_outcome_specify ]  Show the field ONLY if: [nano_sae_outcome] = '8'	Specify	text, Required																
339	[ 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																		
340	[ nano_sae_autopsy_report ]  Show the field ONLY if:	Autopsy report available	radio, Required <table><tr><td>1</td><td>Yes</td></tr><tr><td>2</td><td>No</td></tr></table>	1	Yes	2	No												
1	Yes																		
2	No																		

	[nano_sae_autopsy] = '1'		3 Not known
341	[ 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
342	[ nano_sae_doc_sent ]	Source document sent ?	yesno, Required 1 Yes 0 No
343	[ nano_sae_doc_spec ] Show the field ONLY if: [nano_sae_doc_sent] = "1"	Specify	text, Required
344	[ nano_sae_investigator_name ]	Section Header: <i>Investigator Signature</i> Name of investigator	text, Required
345	[ nano_sae_inv_sign_date ]	Date	text (date_dmy), Required
346	[ nano_sae_investigator_sign ]	Signature of investigator	file (signature), Required
347	[ nano_sae_send_report ]	Send the report to the PI for modification/validation	yesno, Required 1 Yes 0 No Field Annotation: @HIDDEN-PDF
348	[ nano_sae_approved ]	Section Header: <i>SAE report PI evaluation</i> SAE report approved by PI	yesno, Required 1 Yes 0 No Field Annotation: @HIDE_BY_ROLE=PI
349	[ nano_sae_add_comment ]	Additional comment	yesno, Required 1 Yes 0 No Field Annotation: @HIDE_BY_ROLE=PI
350	[ 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
351	[ nano_sae_pi_name_botom ]	Name of PI	text, Required Field Annotation: @HIDE_BY_ROLE=PI
352	[ nano_sae_pi_sign_date ]	Date	text (date_dmy), Required Field Annotation: @HIDE_BY_ROLE=PI
353	[ nano_sae_sign_pi ]	Signature of PI	file (signature), Required Field Annotation: @HIDE_BY_ROLE=PI
354	[ 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
355	[ nano_sae_pdf ]	Generated PDF that will be sent to sponsor	file, Required Field Annotation: @HIDE_BY_ROLE=PI

			@HIDDEN-PDF @HIDDEN																				
356	[ 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																						
357	[ 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: <b>Adverse Event Form Followup</b> (adverse_event_form_followup)																							
358	[ nano_ae_custom_record_id_fup ]	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF																				
359	[ nano_ae_number_fup ]	Adverse Event Number	text, Required																				
360	[ nano_ae_id_fup ]	Inclusion ID	text, Required																				
361	[ nano_ae_date_fup ]	Date of onset	text (date_dmy), Required																				
362	[ nano_ae_description_fup ]	Section Header: <i>Adverse Event Description</i> Adverse Event description	notes, Required																				
363	[ nano_ae_sae_fup ]	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																						
364	[ nano_ae_sae_definition_fup ]		descriptive																				
365	[ nano_ae_sae_todo_fup ]  Show the field ONLY if: [nano_ae_sae_fup] = "1"	Please complete a SAE form and do not complete this AE form. SAE form	descriptive																				
366	[ nano_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																						
367	[ nano_ae_toxicity_fup ]  Show the field ONLY if: [nano_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																						



368	<div>[ nano_ae_fda_tox_grade_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "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												
369	<div>[ nano_ae_call_doctor_2 ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "2" OR [nano_ae_solicited_fup] = "3" OR [nano_ae_fda_tox_grade_2_fup] = "2" OR [nano_ae_fda_tox_grade_2_fup] = "3"</div>	Call the research physician. The study nurse can only complete AEs forms for solicited local grade 1 AE.	descriptive										
370	<div>[ nano_ae_fda_tox_grade_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "1"</div>		descriptive										
371	<div>[ nano_ae_ctcae_6_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "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												
372	<div>[ nano_ae_ctcae_grade_v7_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "2"</div>		descriptive										
373	<div>[ nano_ae_ctcae_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "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												
374	<div>[ nano_ae_spec_ctcae_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "3"</div>	If needed, please specify	text, Required										
375	<div>[ nano_ae_ctcae_5_fup ]</div> <div>Show the field ONLY if: [nano_ae_solicited_fup] = "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												
376	<div>[ nano_p_ae_interest_fup ]</div>	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												
377	<div>[ nano_aes_i_def_fup ]</div>		descriptive										

378	[ nano_ae_sae_info_fup ]  Show the field ONLY if: [nano_p_ae_interest_fup] = "1" OR [nano_ae_ctcae_5_fup] = "3" OR [nano_ae_ctcae_5_fup] = "4" OR [nano_ae_ctcae_5_fup] = "5"	Please complete a SAE form and do not complete this AE form. SAE form	descriptive								
379	[ nano_ae_causality_fup ]	Causality to the study vaccine	radio, Required <table border="1"> <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										
380	[ nano_ae_causality_fup_2 ]		descriptive								
381	[ nano_ae_new_event_fup ]	Already experienced this event prior to study enrollment?	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										
382	[ nano_ae_comment_event_fup ]  Show the field ONLY if: [nano_ae_new_event_fup] = "1"	Please comment	text, Required								
383	[ nano_ae_doses_fup ]	Section Header: <i>IMP 1st vaccine dose et +/- second vaccine dose</i>  Were one or two doses administered ?	radio, Required <table border="1"> <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										
384	[ nano_ae_random_number_fup ]	Randomization number	text (integer), Required								
385	[ nano_ae_code_broken_fup ]	Was the code broken ?	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										
386	[ nano_ae_detail_fup ]  Show the field ONLY if: [nano_ae_code_broken_fup] = "1"	Please detail the reason for unblinding, the person who proceeded to unblinding and the date.	text, Required								
387	[ nano_ae_imp_name_fup ]	Name of IMP : PepGNP-DENGUE / Base-GNP	descriptive								
388	[ nano_ae_dose_fup ]	Dose	radio, Required <table border="1"> <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)										
389	[ nano_ae_route_fup ]	Route : Intradermal injection	descriptive								
390	[ nano_ae_date_administered_fup ]	Administration date	text (date_dmy), Required								

391	<div>[ nano_ae_imp_name_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_doses_fup] = "2"</div>	Name of IMP : PepGNP-DENGUE / Base-GNP	descriptive										
392	<div>[ nano_ae_dose_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_doses_fup] = "2"</div>	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)												
393	<div>[ nano_ae_route_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_doses_fup] = "2"</div>	Route : Intradermal injection	descriptive										
394	<div>[ nano_ae_date_administrated_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_doses_fup] = "2"</div>	Administration date	text (date_dmy), Required										
395	<div>[ nano_ae_tests_performed_fup ]</div>	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												
396	<div>[ nano_ae_test_labofup ]</div> <div>Show the field ONLY if: [nano_ae_tests_performed_fup] = "1"</div>	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												
397	<div>[ nano_ae_test_radio_fup ]</div> <div>Show the field ONLY if: [nano_ae_tests_performed_fup] = "1"</div>	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												
398	<div>[ nano_ae_main_result_fup ]</div> <div>Show the field ONLY if: [nano_ae_tests_performed_fup] = "1"</div>	Please provide the main results of the exams performed	notes, Required										
399	<div>[ nano_ae_do_not_forget_fup ]</div> <div>Show the field ONLY if: [nano_ae_test_radio_fup] = "1" OR [nano_ae_test_labofup] = "1" OR [nano_ae_tests_performed_fup] = "1"</div>	Do not forget to collect complementary exam, remove identifying data, code them and register them as source documents.	descriptive										
400	<div>[ nano_ae_action_taken_imp_fup ]</div>	Which action(s) was/were taken with IMP ? (Several possible)	checkbox, Required <table><tr><td>a</td><td>nano_ae_action_taken_imp_fup__a</td><td>No action taken</td></tr><tr><td>b</td><td>nano_ae_action_taken_imp_fup__b</td><td>Does not characterize the IMP</td></tr><tr><td>c</td><td>nano_ae_action_taken_imp_fup__c</td><td>Does not reduce the risk</td></tr></table>		a	nano_ae_action_taken_imp_fup__a	No action taken	b	nano_ae_action_taken_imp_fup__b	Does not characterize the IMP	c	nano_ae_action_taken_imp_fup__c	Does not reduce the risk
a	nano_ae_action_taken_imp_fup__a	No action taken											
b	nano_ae_action_taken_imp_fup__b	Does not characterize the IMP											
c	nano_ae_action_taken_imp_fup__c	Does not reduce the risk											

			<table><tr><td>d</td><td>nano_ae_action_taken_imp_fup___d</td><td>Dose increased</td></tr><tr><td>e</td><td>nano_ae_action_taken_imp_fup___e</td><td>Drug treatment interrupted</td></tr><tr><td>f</td><td>nano_ae_action_taken_imp_fup___f</td><td>Drug withdrawn</td></tr></table>	d	nano_ae_action_taken_imp_fup___d	Dose increased	e	nano_ae_action_taken_imp_fup___e	Drug treatment interrupted	f	nano_ae_action_taken_imp_fup___f	Drug withdrawn						
d	nano_ae_action_taken_imp_fup___d	Dose increased																
e	nano_ae_action_taken_imp_fup___e	Drug treatment interrupted																
f	nano_ae_action_taken_imp_fup___f	Drug withdrawn																
401	[ nano_ae_action_taken_fup ]	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_fup___7</td><td>Medical treatment</td></tr><tr><td>8</td><td>nano_ae_action_taken_fup___8</td><td>Non medical treatment</td></tr><tr><td>9</td><td>nano_ae_action_taken_fup___9</td><td>Hospitalization</td></tr><tr><td>10</td><td>nano_ae_action_taken_fup___10</td><td>No action</td></tr></table>	checkbox, Required			7	nano_ae_action_taken_fup___7	Medical treatment	8	nano_ae_action_taken_fup___8	Non medical treatment	9	nano_ae_action_taken_fup___9	Hospitalization	10	nano_ae_action_taken_fup___10	No action
checkbox, Required																		
7	nano_ae_action_taken_fup___7	Medical treatment																
8	nano_ae_action_taken_fup___8	Non medical treatment																
9	nano_ae_action_taken_fup___9	Hospitalization																
10	nano_ae_action_taken_fup___10	No action																
402	[ nano_ae_specify_fup ]  Show the field ONLY if: [nano_ae_action_taken_fup(8)]	Specify	text, Required															
403	[ nano_ae_text_fup ]  Show the field ONLY if: [nano_ae_action_taken_fup(7)]	Please fill the medication form	descriptive															
404	[ nano_ae_reaction_abate_fup ]	Did the reaction abate after stopping 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																	
405	[ nano_ae_reaction_reappear_fup ]	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																	
406	[ nano_ae_text_sae_fup ]  Show the field ONLY if: [nano_ae_action_taken_fup(9)]	Fill the SAE form	descriptive															
407	[ nano_ae_withdrawn_fup ]	Withdrawn from the study because of this AE ?	<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																	
408	[ nano_end_of_trial_fup ]  Show the field ONLY if: [nano_ae_withdrawn_fup] = "1"	Complete the END OF TRIAL FORM	descriptive															
409	[ nano_ae_outcome_fup ]	Section Header: <i>Outcome</i>  Outcome of the adverse event	<table><tr><td colspan="2">radio, Required</td></tr><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></table>	radio, Required		1	Resolved (for date, last day of symptoms)	2	Resolved with sequelae	3	Ongoing							
radio, Required																		
1	Resolved (for date, last day of symptoms)																	
2	Resolved with sequelae																	
3	Ongoing																	

			<table><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>	4	Stabilisation	5	Improvement	6	Agravation	7	Fatal	8	Unknown
4	Stabilisation												
5	Improvement												
6	Agravation												
7	Fatal												
8	Unknown												
410	<div>[ nano_ae_last_day_sympt_fup ]</div> <div>Show the field ONLY if: [nano_ae_outcome_fup] = '2' or [nano_ae_outcome_fup] = '1' or [nano_ae_outcome_fup] = '7'</div>	Last day of the symptoms	text (date_dmy), Required										
411	<div>[ nano_ae_evolved_fup ]</div>	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												
412	<div>[ nano_ae_sae_number_fup ]</div> <div>Show the field ONLY if: [nano_ae_evolved_fup] = "1"</div>	Specify the SAE number related	text, Required										
413	<div>[ nano_ae_text_sae_2_fup ]</div> <div>Show the field ONLY if: [nano_ae_evolved_fup] = "1"</div>	Fill the SAE form	descriptive										
414	<div>[ nano_ae_comment_fup ]</div>	Add comments	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												
415	<div>[ nano_ae_comments_fup ]</div> <div>Show the field ONLY if: [nano_ae_comment_fup] = "1"</div>	Comments	text, Required										
416	<div>[ nano_ae_name_investigator_fup ]</div>	Section Header: <i>Investigator signature</i> Name of investigator	text, Required										
417	<div>[ nano_ae_sign_date_fup ]</div>	Date	text (date_dmy), Required										
418	<div>[ nano_ae_signature_fup ]</div>	Signature of investigator	file (signature), Required										
419	<div>[ adverse_event_form_followup_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>Serious Adverse Event Form Followup</b> (serious_adverse_event_form_followup)													
420	<div>[ nano_sae_sae_number_fup ]</div>	SAE number	text, Required										
421	<div>[ nano_sae_custom_record_id_fup ]</div>	Custom record id	text, Required Field Annotation: @HIDDEN @HIDDEN-PDF										

422	[ 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'																					
423	[ nano_sae_sponsor_name_fup ]	Name of Sponsor	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Emergex Vaccines Holding Limited'																					
424	[ 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'																					
425	[ nano_sae_pi_name_fup ]	Name of Principal Investigator	text, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Prof. Blaise Genton'																					
426	[ nano_sae_product_name_fup ]	Investigational Medicinal Product Name	text, Required Field Annotation: @DEFAULT="PepGNP-DENGUE vaccine"																					
427	[ nano_sae_pi_address_fup ]	Adress of Principal Investigator	notes, Required Custom alignment: RH Field Annotation: @DEFAULT = 'Unisanté, Département Formation, recherche et innovation Polyclinique de médecine tropicale, voyages et vaccinations Rue du Bugnon 44 1011 Lausanne, Suisse Blaise.genton@unisante.ch M :+41 79 556 58 68'																					
428	[ nano_sae_project_number_fup ]	BASEC research project number (Swissethics)	text, Required Field Annotation: @DEFAULT="2020-02258"																					
429	[ nano_sae_notif_number_fup ]	Notification n° (Swissmedic)	text, Required Field Annotation: @DEFAULT="2021DR1042"																					
430	[ nano_sae_id_fup ]	Section Header: <i>SAE information</i> Inclusion ID	text, Required Custom alignment: RH																					
431	[ nano_sae_dob_fup ]	Year of birth	text (integer), Required Custom alignment: RH																					
432	[ nano_sae_sex_fup ]	Sex	radio, Required <table><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr></table> Custom alignment: RH	1	Male	2	Female																	
1	Male																							
2	Female																							
433	[ nano_sae_ethnicity_fup ]	Ethnicity (Several possible)	checkbox, Required <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><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>	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	5	nano_sae_ethnicity_fup__5	Indian	6	nano_sae_ethnicity_fup__6	Arab	7	nano_sae_ethnicity_fup__7	Other
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																						
5	nano_sae_ethnicity_fup__5	Indian																						
6	nano_sae_ethnicity_fup__6	Arab																						
7	nano_sae_ethnicity_fup__7	Other																						

434	<div>[ nano_sae_ethnicity_specify_fup ]</div> <div>Show the field ONLY if: [nano_sae_ethnicity_fup(7)] = '1'</div>	Specify	text, Required																				
435	<div>[ nano_sae_ae_date_fup ]</div>	AE onset date	text (date_dmy), Required																				
436	<div>[ nano_sae_ae_awareness_fup ]</div>	AE awareness date	text (date_dmy), Required																				
437	<div>[ nano_sae_ae_evolution_fup ]</div>	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																						
438	<div>[ nano_sae_ae_number_fup ]</div> <div>Show the field ONLY if: [nano_sae_ae_evolution_fup] = "1"</div>	Specify AE number	text, Required																				
439	<div>[ nano_sae_ae_description_fup ]</div>	Section Header: <i>General</i> Describe the AE and the connection to project procedures (including relevant test/lab data)	notes, Required																				
440	<div>[ nano_sae_ae_solicited_fup ]</div>	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																						
441	<div>[ nano_sae_fda_toxicity_fup ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited_fup] = "1"</div>	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																						
442	<div>[ nano_sae_fda_tox_grade_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited_fup] = "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																						
443	<div>[ nano_sae_fda_tox_grade_fup ]</div> <div>Show the field ONLY if: [nano_sae_ae_solicited_fup] = "1"</div>		descriptive Field Annotation: @HIDDEN-PDF																				
444	<div>[ nano_sae_labo_ctcae_term_fup ]</div> <div>Show the field ONLY if:</div>	AE term	text, Required																				

	[nano_sae_ae_solicited_fup] = "2"														
445	[ 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 <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														
446	[ nano_sae_ctcae_grade_v7_fup ]  Show the field ONLY if: [nano_sae_ae_solicited_fup] = "2"		descriptive Field Annotation: @HIDDEN-PDF												
447	[ nano_sae_ctcae_grade_fup ]  Show the field ONLY if: [nano_sae_ae_solicited_fup] = "3"	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														
448	[ nano_sae_spec_ctcae_fup ]  Show the field ONLY if: [nano_sae_ae_solicited_fup] = "3"	If needed, please specify	text, Required												
449	[ 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 <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														
450	[ nano_sae_yes_no_fup ]	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														
451	[ nano_sae_type_fup ]  Show the field ONLY if: [nano_sae_yes_no_fup] = "1"	Check SAE (seriousness definition)	radio, Required <table><tr><td>a</td><td>Death</td></tr><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>	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)	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)
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)														
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)														
452	[ 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														



453	[ nano_sae_aes_i_def_fup ]		descriptive Field Annotation: @HIDDEN-PDF				
454	[ 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						
455	[ 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						
456	[ nano_sae_random_number_fup ]	Randomisation number	text (integer), Required				
457	[ 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						
458	[ 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				
459	[ nano_sae_imp_name_fup ]	Name of IMP : PepGNP-DENGUE or vehicle-GNP	descriptive				
460	[ nano_sae_dose_fup ]	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)						
461	[ nano_sae_route_fup ]	Route : Intradermal injection	descriptive				
462	[ nano_sae_date_administred_fup ]	Administration date	text (date_dmy), Required				
463	[ nano_sae_imp_name_2_fup ] Show the field ONLY if: [nano_sae_doses_fup] = "2"	Name of IMP : PepGNP-DENGUE or vehicle-GNP	descriptive				
464	[ 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 (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)						
465	[ nano_sae_route_2_fup ] Show the field ONLY if: [nano_sae_doses_fup] = "2"	Route : Intradermal injection	descriptive				
466	[ nano_sae_date_administred_2_fup ] Show the field ONLY if:	Administration date	text (date_dmy), Required				

	[nano_sae_doses_fup] = "2"										
467	[ nano_sae_causality_fup ]	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										
468	[ nano_sae_causality_def_fup ]		descriptive Field Annotation: @HIDDEN-PDF								
469	[ nano_sae_table_fup ]	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								
470	[ nano_sae_disease_fup ]	Disease / Intervention /Allergy	text								
471	[ nano_sae_date_disease_fup ]	Start date	text								
472	[ nano_sae_disease_ongoing_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										
473	[ nano_sae_disease_stop_fup ]	Stop date	text								
474	[ nano_sae_disease_1_fup ]	Disease / Intervention /Allergy	text								
475	[ nano_sae_date_disease_1_fup ]	Start date	text								
476	[ 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										
477	[ nano_sae_disease_stop_1_fup ]	Stop date	text								
478	[ nano_sae_disease_2_fup ]	Disease / Intervention /Allergy	text								
479	[ nano_sae_date_disease_2_fup ]	Start date	text								

480	[ 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														
481	[ nano_sae_disease_stop_2_fup ]	Stop date	text												
482	[ nano_sae_disease_3_fup ]	Disease / Intervention /Allergy	text												
483	[ nano_sae_date_disease_3_fup ]	Start date	text												
484	[ 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														
485	[ nano_sae_disease_stop_3_fup ]	Stop date	text												
486	[ nano_sae_disease_4_fup ]	Disease / Intervention /Allergy	text												
487	[ nano_sae_date_disease_4_fup ]	Start date	text												
488	[ 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														
489	[ nano_sae_disease_stop_4_fup ]	Stop date	text												
490	[ 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														
491	[ 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														
492	[ nano_sae_med_name_fup ]  Show the field ONLY if: [ nano_sae_drug_fup ] = "1" and [ nano_sae_conc_count_fup ] > 0	Medication Name (Commercial name)	text, Required												
493	[ nano_sae_med_name_inter_fup ]  Show the field ONLY if: [ nano_sae_drug_fup ] = "1" and [ nano_sae_conc_count_fup ] > 0	Medication Name (International nonproprietary name)	text, Required												
494	[ nano_sae_med_dose_fup ]  Show the field ONLY if:	Dose	text (number), Required												

	[ nano_sae_drug_fup ] ="1" and [ nano_sae_co nc_count_fup ] > 0																								
495	[ nano_sae_med_dose_un it_fup ]  Show the field ONLY if: [ nano_sae_drug_fup ] ="1" and [ nano_sae_co nc_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										
1	Microgram																								
2	Miligram																								
3	Gram																								
4	Mililiter																								
5	Other (Specify)																								
6	Unknown																								
496	[ nano_sae_med_dose_sp ec_fup ]  Show the field ONLY if: [ nano_sae_med_dose_u nit_fup ] = "5"	Specify	text, Required																						
497	[ nano_sae_med_dose_fr eq_fup ]  Show the field ONLY if: [ nano_sae_drug_fup ] ="1" and [ nano_sae_co nc_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)						
1	Daily																								
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7	PRN (ad needed)																								
8	Other (specify)																								
498	[ nano_sae_med_freq_sp ec_fup ]  Show the field ONLY if: [ nano_sae_med_dose_f req_fup ] = "8"	Specify	text, Required																						
499	[ nano_sae_med_route_f up ]  Show the field ONLY if: [ nano_sae_drug_fup ] ="1" and [ nano_sae_co nc_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><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																								
2	Topical																								
3	Subcutaneous injection																								
4	Intravenous injection																								
5	Intramuscular injection																								
6	Rectal																								
7	Nasal																								
8	Inhaled																								
9	Transdermal																								
10	Vaginal																								
11	Other (Specify)																								
500	[ nano_sae_med_route_s pec_fup ]  Show the field ONLY if: [ nano_sae_med_route_f up ] = "11"	Specify	text, Required																						

501	<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												
502	<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												
503	<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								
1	Yes														
0	No														
504	<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												
505	<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												
506	<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												
507	<div>[ nano_sae_med_dose_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 1</div>	Dose	text (number, Min: 0, Max: 9999999), Required												
508	<div>[ nano_sae_med_dose_unit_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &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														
2	Miligram														
3	Gram														
4	Mililiter														
5	Other (Specify)														
6	Unknown														
509	<div>[ nano_sae_med_dose_spec_1_fup ]</div>	Specify	text, Required												

	Show the field ONLY if: [nano_sae_med_dose_u nit_1_fup] = "5"																								
510	[ nano_sae_med_dose_fr eq_1_fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_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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511	[ nano_sae_med_freq_sp ec_1_fup ]  Show the field ONLY if: [nano_sae_med_dose_f req_1_fup] = "8"	Specify	text, Required																						
512	[ nano_sae_med_route_1 _fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_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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513	[ nano_sae_med_route_s pec_1_fup ]  Show the field ONLY if: [nano_sae_med_route_ 1_fup] = "11"	Specify	text, Required																						
514	[ nano_sae_med_use_1_f up ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 1	Indication(s) for use	text, Required																						
515	[ nano_sae_med_start_1 _fup ]  Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_co nc_count_fup] > 1	Start Date	text (date_dmy), Required																						
516	[ nano_sae_med_ongoing _1_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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	[nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 1		<table><tr><td>0</td><td>No</td></tr></table>	0	No														
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517	[ nano_sae_med_end_date_1_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_1_fup] = "0" and [nano_sae_conc_count_fup] > 1	End date	text (date_dmy), Required																
518	[ nano_sae_med_name_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	Medication Name (Commercial name)	text, Required																
519	[ nano_sae_med_name_inter_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	Medication Name (International nonproprietary name)	text, Required																
520	[ nano_sae_med_dose_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	Dose	text (integer, Min: 0, Max: 9999999), Required																
521	[ nano_sae_med_dose_unit_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 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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523	[ nano_sae_med_dose_freq_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_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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525	[ nano_sae_med_route_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_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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526	[ nano_sae_med_route_spec_2_fup ]  Show the field ONLY if: [nano_sae_med_route_2_fup] = "11"	Specify	text, Required																							
527	[ nano_sae_med_use_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	Indication(s) for use	text, Required																							
528	[ nano_sae_med_start_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	Start Date	text (date_dmy), Required																							
529	[ nano_sae_med_ongoing_2_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 2	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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530	[ 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																							
531	[ nano_sae_med_name_3_fup ]  Show the field ONLY if:	Medication Name (Commercial name)	text, Required																							



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532	[ nano_sae_med_name_inter_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 3	Medication Name (International nonproprietary name)	text, Required																
533	[ nano_sae_med_dose_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 3	Dose	text (number, Min: 0, Max: 9999999), Required																
534	[ nano_sae_med_dose_unit_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_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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538	[ nano_sae_med_route_3_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_count_fup] > 3	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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539	<p>[ nano_sae_med_route_spec_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_med_route_3_fup] = "11"</p>	Specify	text, Required										
540	<p>[ nano_sae_med_use_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 3</p>	Indication(s) for use	text, Required										
541	<p>[ nano_sae_med_start_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 3</p>	Start Date	text (date_dmy), Required										
542	<p>[ nano_sae_med_ongoing_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 3</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						
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543	<p>[ nano_sae_med_end_date_3_fup ]</p> <p>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</p>	End date	text (date_dmy), Required										
544	<p>[ nano_sae_med_name_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Medication Name (Commercial name)	text, Required										
545	<p>[ nano_sae_med_name_inter_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Medication Name (International nonproprietary name)	text, Required										
546	<p>[ nano_sae_med_dose_4_fup ]</p> <p>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &gt; 4</p>	Dose	text (number, Min: 0, Max: 9999999), Required										

547	<div>[ nano_sae_med_dose_unit_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_count_fup] &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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548	<div>[ nano_sae_med_dose_spec_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_med_dose_unit_4_fup] = "5"</div>	Specify	text, Required																						
549	<div>[ nano_sae_med_dose_freq_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_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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551	<div>[ nano_sae_med_route_4_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" and [nano_sae_conc_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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553	<div>[ nano_sae_med_use_4_fup ]</div> <div>Show the field ONLY if:</div>	Indication(s) for use	text, Required																						

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555	[ nano_sae_med_ongoing_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 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								
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556	[ nano_sae_med_end_date_4_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" AND [nano_sae_med_ongoing_4_fup] = "0" and [nano_sae_conc_count_fup] > 4	End date	text (date_dmy), Required												
557	[ nano_sae_med_name_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5	Medication Name (Commercial name)	text, Required												
558	[ nano_sae_med_name_inter_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5	Medication Name (International nonproprietary name)	text, Required												
559	[ nano_sae_med_dose_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 5	Dose	text (number, Min: 0, Max: 9999999), Required												
560	[ nano_sae_med_dose_unit_5_fup ]  Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] > 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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561	[ nano_sae_med_dose_spec_5_fup ]  Show the field ONLY if: [nano_sae_med_dose_unit_5_fup] = "5"	Specify	text, Required												

562	<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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563	<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																						
564	<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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565	<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																						
566	<div>[ nano_sae_med_use_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 5</div>	Indication(s) for use	text, Required																						
567	<div>[ nano_sae_med_start_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &gt; 5</div>	Start Date	text (date_dmy), Required																						
568	<div>[ nano_sae_med_ongoing_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] = "1" and [nano_sae_conc_count_fup] &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																		
1	Yes																								
0	No																								

569	<div>[ nano_sae_med_end_date_5_fup ]</div> <div>Show the field ONLY if: [nano_sae_drug_fup] ="1" AND [nano_sae_med_ongoing_5_fup] = "0" and [nano_sae_conc_count_fup] &gt; 5</div>	End date	text (date_dmy), Required													
570	<div>[ nano_sae_test_performed_med_fup ]</div>	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															
571	<div>[ nano_sae_lab_tests_fup ]</div> <div>Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"</div>	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															
572	<div>[ nano_sae_radio_tests_fup ]</div> <div>Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"</div>	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															
573	<div>[ nano_sae_relevant_procedure_fup ]</div> <div>Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"</div>	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															
574	<div>[ nano_sae_specify_fup ]</div> <div>Show the field ONLY if: [nano_sae_relevant_procedure_fup] = "1"</div>	Specify	text, Required													
575	<div>[ nano_sae_main_result_fup ]</div> <div>Show the field ONLY if: [nano_sae_test_performed_med_fup] = "1"</div>	Please provide the main results of the exams performed	notes, Required													
576	<div>[ nano_sae_text_fup ]</div> <div>Show the field ONLY if: [nano_sae_relevant_procedure_fup] = "1" OR [nano_sae_radio_tests_fup] = "1" OR [nano_sae_lab_tests_fup] = "1"</div>	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													
577	<div>[ nano_sae_action_taken_imp_fup ]</div>	Section Header: <i>Actions taken and outcome</i> Which action(s) was/were taken with IMP ? (Several possible)	checkbox, Required <table><tr><td>a</td><td>nano_sae_action_taken_imp_fup__a</td><td>No</td></tr><tr><td>b</td><td>nano_sae_action_taken_imp_fup__b</td><td>Do ch</td></tr><tr><td>c</td><td>nano_sae_action_taken_imp_fup__c</td><td>Do re</td></tr><tr><td>d</td><td>nano_sae_action_taken_imp_fup__d</td><td>Do inc</td></tr></table>		a	nano_sae_action_taken_imp_fup__a	No	b	nano_sae_action_taken_imp_fup__b	Do ch	c	nano_sae_action_taken_imp_fup__c	Do re	d	nano_sae_action_taken_imp_fup__d	Do inc
a	nano_sae_action_taken_imp_fup__a	No														
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c	nano_sae_action_taken_imp_fup__c	Do re														
d	nano_sae_action_taken_imp_fup__d	Do inc														

			<table><tr><td>e</td><td>nano_sae_action_taken_imp_fup__e</td><td>Drug treatment intervention</td></tr><tr><td>f</td><td>nano_sae_action_taken_imp_fup__f</td><td>Drug withdrawal</td></tr></table>	e	nano_sae_action_taken_imp_fup__e	Drug treatment intervention	f	nano_sae_action_taken_imp_fup__f	Drug withdrawal														
e	nano_sae_action_taken_imp_fup__e	Drug treatment intervention																					
f	nano_sae_action_taken_imp_fup__f	Drug withdrawal																					
578	[ nano_sae_action_taken_imp_sp_fup ]  Show the field ONLY if: [nano_sae_action_taken_imp_fup(c)] = '1' or [nano_sae_action_taken_imp_fup(d)] = '1' or [nano_sae_action_taken_imp_fup(e)] = '1'	Specify	text, Required																				
579	[ nano_sae_action_taken_fup ]	Which action(s) was/were taken with the participant ? (Several possible)	<table><tr><td colspan="3">checkbox, Required</td></tr><tr><td>f</td><td>nano_sae_action_taken_fup__f</td><td>No action</td></tr><tr><td>g</td><td>nano_sae_action_taken_fup__g</td><td>Medication treatment</td></tr><tr><td>h</td><td>nano_sae_action_taken_fup__h</td><td>Non medication treatment</td></tr></table>	checkbox, Required			f	nano_sae_action_taken_fup__f	No action	g	nano_sae_action_taken_fup__g	Medication treatment	h	nano_sae_action_taken_fup__h	Non medication treatment								
checkbox, Required																							
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h	nano_sae_action_taken_fup__h	Non medication treatment																					
580	[ nano_sae_action_taken_spec_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(h)] = '1'	Specify	text, Required																				
581	[ nano_sae_count_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] = '1'	How many medication ?	<table><tr><td colspan="2">dropdown, Required</td></tr><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>	dropdown, Required		1	1	2	2	3	3	4	4	5	5	6	6	7	7	8	8	9	9
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7	7																						
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582	[ nano_sae_action_med_name_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0	Medication Name (Commercial name)	text, Required																				
583	[ 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																				
584	[ nano_sae_action_med_dose_fup ]  Show the field ONLY if:	Dose	text (number, Min: 0, Max: 9999999), Required																				

	[nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 0																								
585	[ 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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586	[ nano_sae_action_med_unit_spec_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_fup] = "5"	Specify	text, Required																						
587	[ 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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588	[ nano_sae_action_med_freq_spec_fup ]  Show the field ONLY if: [nano_sae_action_med_freq_fup] = "8"	Specify	text, Required																						
589	[ 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><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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590	[ nano_sae_action_med_route_spec_fup ]  Show the field ONLY if: [nano_sae_action_med_route_fup] = "11"	Specify	text, Required																						



591	<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												
592	<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														
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593	<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												
594	<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												
595	<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												
596	<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												
597	<div>[ nano_sae_action_med_unit_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &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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598	<div>[ nano_sae_action_med_unit_spec_1_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_1_fup] = "5"</div>	Specify	text, Required												
599	<div>[ nano_sae_action_med_freq_1_fup ]</div> <div>Show the field ONLY if:</div>	Frequency	radio, Required <table><tr><td>1</td><td>Daily</td></tr><tr><td>2</td><td>Twice daily</td></tr></table>	1	Daily	2	Twice daily								
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	[ nano_sae_action_taken_fup(g) ] and [ nano_sae_count_fup ] > 1		<table><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>	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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601	[ 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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602	[ nano_sae_med_action_route_spec_1_fup ]  Show the field ONLY if: [ nano_sae_action_med_route_1_fup ] = "11"	Specify	text, Required																						
603	[ 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																						
604	[ nano_sae_action_med_ongoing_1_fup ]  Show the field ONLY if: [ nano_sae_action_taken_fup(g) ] and [ nano_sae_count_fup ] > 1	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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605	[ nano_sae_action_med_end_1_fup ]  Show the field ONLY if: [ nano_sae_action_taken_fup(g) ] and [ nano_sae_count_fup ] > 1 and [ nano_sae_action_med_ongoing_1_fup ] = "0"	End date	text (date_dmy), Required																						
606	[ nano_sae_action_med_name_2_fup ]	Medication Name (Commercial name)	text, Required																						

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607	[ nano_sae_action_med_name_inter_2_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 2	Medication Name (International nonproprietary name)	text, Required																
608	[ nano_sae_action_med_dose_2_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 2	Dose	text (number, Min: 0, Max: 9999999), Required																
609	[ nano_sae_action_med_unit_2_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 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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610	[ nano_sae_action_med_unit_spec_2_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_2_fup] = "5"	Specify	text, Required																
611	[ nano_sae_action_med_freq_2_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_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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612	[ nano_sae_med_action_freq_spec_2_fup ]  Show the field ONLY if: [nano_sae_action_med_freq_2_fup] = "8"	Specify	text, Required																
613	[ nano_sae_action_med_route_2_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_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></table>	1	Oral	2	Topical	3	Subcutaneous injection	4	Intravenous injection	5	Intramuscular injection	6	Rectal				
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614	<p>[ nano_sae_med_action_route_spec_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_med_route_2_fup] = "11"</p>	Specify	text, Required										
615	<p>[ nano_sae_action_med_date_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</p>	Start Date	text (date_dmy), Required										
616	<p>[ nano_sae_action_med_ongoing_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2</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						
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0	No												
617	<p>[ nano_sae_action_med_end_2_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 2 and [nano_sae_action_med_ongoing_2_fup] = "0"</p>	End date	text (date_dmy), Required										
618	<p>[ nano_sae_action_med_name_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</p>	Medication Name (Commercial name)	text, Required										
619	<p>[ nano_sae_action_med_name_inter_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</p>	Medication Name (International nonproprietary name)	text, Required										
620	<p>[ nano_sae_action_med_dose_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</p>	Dose	text (number, Min: 0, Max: 9999999), Required										
621	<p>[ nano_sae_action_med_unit_3_fup ]</p> <p>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 3</p>	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></table>	1	Microgram	2	Miligram	3	Gram				
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622	<div>[ nano_sae_action_med_unit_spec_3_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_unit_3_fup] = "5"</div>	Specify	text, Required																						
623	<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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625	<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><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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628	<div>[ nano_sae_action_med_ongoing_3_fup ]</div>	Ongoing	yesno, Required <table><tr><td>1</td><td>Yes</td></tr></table>	1	Yes																				
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629	[ nano_sae_action_med_end_3_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 3 and [nano_sae_action_med_ongoing_3_fup] = "0"	End date	text (date_dmy), Required																
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631	[ nano_sae_action_med_name_inter_4_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 4	Medication Name (International nonproprietary name)	text, Required																
632	[ nano_sae_action_med_dose_4_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 4	Dose	text (number, Min: 0, Max: 9999999), Required																
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637	<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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643	<div>[ nano_sae_action_med_name_inter_5_fup ]</div> <div>Show the field ONLY if:</div>	Medication Name (International nonproprietary name)	text, Required																							

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644	[ nano_sae_action_med_dose_5_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 5	Dose	text (number, Min: 0, Max: 9999999), Required																						
645	[ nano_sae_action_med_unit_5_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 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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655	<div>[ nano_sae_action_med_name_inter_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Medication Name (International nonproprietary name)	text, Required												
656	<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												
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662	<div>[ nano_sae_med_action_route_spec_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_med_route_6_fup] = "11"</div>	Specify	text, Required																						
663	<div>[ nano_sae_action_med_date_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</div>	Start Date	text (date_dmy), Required																						
664	<div>[ nano_sae_action_med_ongoing_6_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 6</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																								
665	<div>[ nano_sae_action_med_end_6_fup ]</div> <div>Show the field ONLY if:</div>	End date	text (date_dmy), Required																						

	[nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 6 and [nano_sae_action_med_ongoing_6_fup] = "0"																		
666	[ 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																
667	[ 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																
668	[ 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																
669	[ 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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670	[ nano_sae_action_med_unit_spec_7_fup ]  Show the field ONLY if: [nano_sae_action_med_unit_7_fup] = "5"	Specify	text, Required																
671	[ nano_sae_action_med_freq_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	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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672	[ nano_sae_med_action_freq_spec_7_fup ]  Show the field ONLY if: [nano_sae_action_med_freq_7_fup] = "8"	Specify	text, Required																
673	[ nano_sae_action_med_route_7_fup ]	Route	radio, Required																

	Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7		<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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675	[ nano_sae_action_med_date_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 7	Start Date	text (date_dmy), Required																						
676	[ nano_sae_action_med_ongoing_7_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 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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678	[ nano_sae_action_med_name_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	Medication Name (Commercial name)	text, Required																						
679	[ nano_sae_action_med_name_inter_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	Medication Name (International nonproprietary name)	text, Required																						
680	[ nano_sae_action_med_dose_8_fup ]  Show the field ONLY if:	Dose	text (number, Min: 0, Max: 9999999), Required																						

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683	[ nano_sae_action_med_freq_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	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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684	[ nano_sae_med_action_freq_spec_8_fup ]  Show the field ONLY if: [nano_sae_action_med_freq_8_fup] = "8"	Specify	text, Required																						
685	[ nano_sae_action_med_route_8_fup ]  Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] > 8	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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686	[ nano_sae_med_action_route_spec_8_fup ]  Show the field ONLY if: [nano_sae_action_med_route_8_fup] = "11"	Specify	text, Required																						

687	<div>[ nano_sae_action_med_date_8_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</div>	Start Date	text (date_dmy), Required																
688	<div>[ nano_sae_action_med_ongoing_8_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8</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																		
689	<div>[ nano_sae_action_med_end_8_fup ]</div> <div>Show the field ONLY if: [nano_sae_action_taken_fup(g)] and [nano_sae_count_fup] &gt; 8 and [nano_sae_action_med_ongoing_8_fup] = "0"</div>	End date	text (date_dmy), Required																
690	<div>[ nano_sae_react_abate_fup ]</div>	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																		
691	<div>[ nano_sae_react_reappear_fup ]</div>	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																		
692	<div>[ nano_sae_outcome_fup ]</div>	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
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693	<div>[ nano_sae_outcome_date_fup ]</div> <div>Show the field ONLY if: [nano_sae_outcome_fup] = '2' or [nano_sae_outcome_fup] = '1' or [nano_sae_outcome_fup] = '7'</div>	Date	text (date_dmy), Required																
694	<div>[ nano_sae_outcome_specify_fup ]</div> <div>Show the field ONLY if: [nano_sae_outcome_fup] = '8'</div>	Specify	text, Required																

695	<div>[ nano_sae_autopsy_fup ]</div> <div>Show the field ONLY if: [nano_sae_outcome_fup] = '7'</div>	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								
696	<div>[ nano_sae_autopsy_report_fup ]</div> <div>Show the field ONLY if: [nano_sae_autopsy_fup] = '1'</div>	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								
697	<div>[ nano_sae_text_2_fup ]</div> <div>Show the field ONLY if: [nano_sae_autopsy_report_fup] = '1'</div>	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						
698	<div>[ nano_sae_doc_sent_fup ]</div>	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								
699	<div>[ nano_sae_doc_spec_fup ]</div> <div>Show the field ONLY if: [nano_sae_doc_sent_fup] = "1"</div>	Specify	text, Required						
700	<div>[ nano_sae_investigator_name_fup ]</div>	Section Header: <i>Investigator Signature</i> Name of investigator	text, Required						
701	<div>[ nano_sae_inv_sign_date_fup ]</div>	Date	text (date_dmy), Required						
702	<div>[ nano_sae_investigator_sign_fup ]</div>	Signature of investigator	file (signature), Required						
703	<div>[ nano_sae_send_report_fup ]</div>	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								
704	<div>[ nano_sae_approved_fup ]</div>	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								
705	<div>[ nano_sae_add_comment_fup ]</div>	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								
706	<div>[ nano_sae_comment_specify_fup ]</div> <div>Show the field ONLY if: [nano_sae_add_comment_fup] = "1" or [nano_sae_add_comment_fup] = "1"</div>	Specify	text, Required Field Annotation: @HIDE_BY_ROLE=PI						

707	[ nano_sae_pi_name_bot tom_fup ]	Name of PI	text, Required Field Annotation: @HIDE_BY_ROLE=PI																
708	[ nano_sae_pi_sign_date_fup ]	Date	text (date_dmy), Required Field Annotation: @HIDE_BY_ROLE=PI																
709	[ nano_sae_sign_pi_fup ]	Signature of PI	file (signature), Required Field Annotation: @HIDE_BY_ROLE=PI																
710	[ nano_sae_text_3_fup ]	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																
711	[ nano_sae_pdf_fup ]	Generated PDF that will be sent to sponsor	file, Required Field Annotation: @HIDE_BY_ROLE=PI @HIDDEN-PDF @HIDDEN																
712	[ nano_sae_send_sponsor_fup ]	Send the PDF report to the Sponsor	yesno, Required <table border="1"> <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																		
713	[ serious_adverse_event_form_followup_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: Major Protocol Deviation Form (major_protocol_deviation_form)</b>																			
714	[ nano_p_screening_id ]	Section Header: <i>General informations</i> Screening ID	text, Required																
715	[ nano_p_number ]	Protocol deviation/violation number	text, Required																
716	[ nano_p_date ]	Date of the event	text (date_dmy), Required																
717	[ nano_p_date_intern ]	Date of its discovery by research personnel	text (date_dmy), Required																
718	[ nano_p_ae ]	Did the deviation/violation resulted 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																		
719	[ nano_p_date_report ]	Date of the report	text (date_dmy), Required																
720	[ nano_p_type ]	Section Header: <i>Event details</i> Deviation type	radio, Required <table border="1"> <tr> <td>a</td> <td>Consent Procedures</td> </tr> <tr> <td>b</td> <td>Inclusion/Exclusion Criteria</td> </tr> <tr> <td>c</td> <td>Concomitant Medication/Therapy</td> </tr> <tr> <td>d</td> <td>Laboratory Assessments/Procedures</td> </tr> <tr> <td>e</td> <td>Adverse Event Reporting</td> </tr> <tr> <td>f</td> <td>Randomization Procedures/Study Drug Dosing</td> </tr> <tr> <td>g</td> <td>Visit Schedule/Interval</td> </tr> <tr> <td>h</td> <td>Other</td> </tr> </table>	a	Consent Procedures	b	Inclusion/Exclusion Criteria	c	Concomitant Medication/Therapy	d	Laboratory Assessments/Procedures	e	Adverse Event Reporting	f	Randomization Procedures/Study Drug Dosing	g	Visit Schedule/Interval	h	Other
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f	Randomization Procedures/Study Drug Dosing																		
g	Visit Schedule/Interval																		
h	Other																		
721	[ nano_p_deviation_category ]  Show the field ONLY if: [ nano_p_type ] = "a"	Choose category of deviation	radio, Required <table border="1"> <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														
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722	[ nano_p_deviation_category_2 ]	Choose category of deviation	radio, Required																



	Show the field ONLY if: [nano_p_type] = "b"		<table><tr><td>a</td><td>Medical history not completed prior to vaccination</td></tr><tr><td>b</td><td>Concomitant medications 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>Dengue rapid test missed</td></tr><tr><td>e</td><td>COVID rapid test missed</td></tr><tr><td>f</td><td>Urinary protein/blood/glucose completely missed</td></tr><tr><td>g</td><td>Temperature not taken / not recorded prior to vaccination</td></tr><tr><td>h</td><td>Pregnancy test missed at screening and before vaccination</td></tr><tr><td>i</td><td>Contacting patient on day 1 or day 22 for telephone interview completely missed</td></tr></table>	a	Medical history not completed prior to vaccination	b	Concomitant medications not completed prior to vaccination	c	One or more aspects of physical exam completely missed	d	Dengue rapid test missed	e	COVID rapid test missed	f	Urinary protein/blood/glucose completely missed	g	Temperature not taken / not recorded prior to vaccination	h	Pregnancy test missed at screening and before vaccination	i	Contacting patient on day 1 or day 22 for telephone interview completely missed
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723	[ nano_p_deviation_cat_3 ]  Show the field ONLY if: [nano_p_type] = "c"	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														
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724	[ nano_p_deviation_cat_4 ]  Show the field ONLY if: [nano_p_type] = "d"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Incorrect dose given to patient, either first dose (D0) or second dose (D21)</td></tr><tr><td>b</td><td>Absence of monitoring after vaccination for adverse reactions</td></tr><tr><td>c</td><td>Second dose missed</td></tr></table>	a	Incorrect dose given to patient, either first dose (D0) or second dose (D21)	b	Absence of monitoring after vaccination for adverse reactions	c	Second dose missed												
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b	Absence of monitoring after vaccination for adverse reactions																				
c	Second dose missed																				
725	[ nano_p_deviation_cat_5 ]  Show the field ONLY if: [nano_p_type] = "e"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Any of the HIV, HBV, HCV tests not done</td></tr><tr><td>b</td><td>All haematology tests missed prior to vaccination</td></tr><tr><td>c</td><td>All biochemistry tests missed prior to vaccination</td></tr><tr><td>d</td><td>Participant is inadvertently unblinded</td></tr></table>	a	Any of the HIV, HBV, HCV tests not done	b	All haematology tests missed prior to vaccination	c	All biochemistry tests missed prior to vaccination	d	Participant is inadvertently unblinded										
a	Any of the HIV, HBV, HCV tests not done																				
b	All haematology tests missed prior to vaccination																				
c	All biochemistry tests missed prior to vaccination																				
d	Participant is inadvertently unblinded																				
726	[ nano_p_deviation_cat_7 ]  Show the field ONLY if: [nano_p_type] = "f"	Choose category of deviation	radio, Required <table><tr><td>a</td><td>Participant is inadvertently unblinded</td></tr></table>	a	Participant is inadvertently unblinded																
a	Participant is inadvertently unblinded																				
727	[ nano_p_text ]  Show the field ONLY if: [nano_p_deviation_cat_7] = "a"	Corrective action : continue to follow usual trial, report case in study safety and trial reports	descriptive																		
728	[ nano_p_deviation_cat_6 ]  Show the field ONLY if: [nano_p_type] = "g"	Choose category of deviation	radio, Required <table><tr><td>10</td><td>AE reported &gt;14 days late</td></tr><tr><td>AESI</td><td>SAE or SUSAR not reported</td></tr></table>	10	AE reported >14 days late	AESI	SAE or SUSAR not reported														
10	AE reported >14 days late																				
AESI	SAE or SUSAR not reported																				
729	[ nano_p_specify ]  Show the field ONLY if:	Specify	text, Required																		

	[nano_p_type] = "h"																				
730	[ nano_p_description ]	Describe the protocol deviation/violation	notes, Required																		
731	[ nano_p_reason ]	Please explain the reason for the deviation/violation:	notes, Required																		
732	[ 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																				
733	[ 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																				
734	[ nano_p_deviation_step_taken ]	Describe the steps taken to avoid recurrence of the deviation/violation	notes, Required																		
735	[ nano_p_name_investigator ]	Section Header: <i>Investigator signature</i> Name of investigator	text, Required																		
736	[ nano_p_date_2 ]	Date	text (datetime_dmy), Required																		
737	[ nano_p_sign_2 ]	Signature of investigator	file (signature), Required																		
738	[ 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																				
739	[ nano_p_pdf ]	Generated pdf	file, Required Field Annotation: @HIDDEN @HIDDEN-PDF																		
740	[ 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>																					
741	[ nano_mp_screening_id ]	Section Header: <i>General informations</i> Screening ID	text, Required																		
742	[ nano_mp_number ]	Protocol deviation number	text, Required																		
743	[ nano_mp_date ]	Date of the event	text (date_dmy), Required																		
744	[ nano_mp_date_discovered ]	Date of its discovery by research personnel	text (date_dmy), Required																		
745	[ nano_mp_date_report ]	Date of the report	text (date_dmy), Required																		
746	[ nano_mp_deviation ]	Section Header: <i>Event details</i> Deviation type	radio, Required <table border="1"> <tr><td>a</td><td>Consent Procedures</td></tr> <tr><td>b</td><td>Study Procedures</td></tr> <tr><td>c</td><td>Pharmacy</td></tr> <tr><td>d</td><td>Dosing</td></tr> <tr><td>e</td><td>Laboratory tests</td></tr> <tr><td>f</td><td>Data monitoring</td></tr> <tr><td>g</td><td>Randomization procedures</td></tr> <tr><td>h</td><td>Adverse Event Reporting</td></tr> <tr><td>i</td><td>Other</td></tr> </table>	a	Consent Procedures	b	Study Procedures	c	Pharmacy	d	Dosing	e	Laboratory tests	f	Data monitoring	g	Randomization procedures	h	Adverse Event Reporting	i	Other
a	Consent Procedures																				
b	Study Procedures																				
c	Pharmacy																				
d	Dosing																				
e	Laboratory tests																				
f	Data monitoring																				
g	Randomization procedures																				
h	Adverse Event Reporting																				
i	Other																				
747	[ nano_mp_deviation_category ]	Choose category of deviation	radio, Required																		

	Show the field ONLY if: [nano_mp_deviation] = "a"		<table><tr><td>a</td><td>Incorrect version of Informed Consent Form signed</td></tr><tr><td>b</td><td>Other</td></tr></table>	a	Incorrect version of Informed Consent Form signed	b	Other														
a	Incorrect version of Informed Consent Form signed																				
b	Other																				
748	[ nano_mp_text ]  Show the field ONLY if: [nano_mp_deviation_cat] = "a"	Corrective action: note in ISF / patient folder and ask patient to sign current version at next study visit	descriptive																		
749	[ nano_mp_deviation_cat_2 ]  Show the field ONLY if: [nano_mp_deviation] = "b"	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>Medical history incomplete</td></tr><tr><td>b</td><td>Concomitant medications 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>HLA typing missed</td></tr><tr><td>f</td><td>Temperature not taken / not recorded</td></tr><tr><td>g</td><td>Delayed day 1 or day 22 telephone interview</td></tr><tr><td>h</td><td>Other</td></tr></table>	radio, Required		a	Medical history incomplete	b	Concomitant medications missed	c	One or more aspects of physical exam missed	d	Urinary protein/blood/glucose missed	e	HLA typing missed	f	Temperature not taken / not recorded	g	Delayed day 1 or day 22 telephone interview	h	Other
radio, Required																					
a	Medical history incomplete																				
b	Concomitant medications missed																				
c	One or more aspects of physical exam missed																				
d	Urinary protein/blood/glucose missed																				
e	HLA typing missed																				
f	Temperature not taken / not recorded																				
g	Delayed day 1 or day 22 telephone interview																				
h	Other																				
750	[ nano_mp_text_2 ]  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"	Corrective action: complete/perform prior to vaccination	descriptive																		
751	[ nano_mp_text_3 ]  Show the field ONLY if: [nano_mp_deviation_cat_2] = "e"	Corrective action: perform from the blood of a later visit	descriptive																		
752	[ nano_mp_deviation_cat_3 ]  Show the field ONLY if: [nano_mp_deviation] = "c"	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>Other</td></tr></table>	radio, Required		a	Other														
radio, Required																					
a	Other																				
753	[ nano_mp_deviation_cat_8 ]  Show the field ONLY if: [nano_mp_deviation] = "d"	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>Second dose administered beyond the 2 days window</td></tr><tr><td>b</td><td>&lt; 60 min monitoring after vaccination for adverse reactions</td></tr><tr><td>c</td><td>Other</td></tr></table>	radio, Required		a	Second dose administered beyond the 2 days window	b	< 60 min monitoring after vaccination for adverse reactions	c	Other										
radio, Required																					
a	Second dose administered beyond the 2 days window																				
b	< 60 min monitoring after vaccination for adverse reactions																				
c	Other																				
754	[ nano_mp_text_4 ]  Show the field ONLY if: [nano_mp_deviation_cat_8] = "a"	Corrective action : continue to follow up for safety and try to recruit another patient to meet the numbers required for robust data	descriptive																		
755	[ nano_mp_deviation_cat_4 ]  Show the field ONLY if: [nano_mp_deviation] = "e"	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>One or more haematology tests missed</td></tr><tr><td>b</td><td>One or more biochemistry tests</td></tr></table>	radio, Required		a	One or more haematology tests missed	b	One or more biochemistry tests												
radio, Required																					
a	One or more haematology tests missed																				
b	One or more biochemistry tests																				

			<table><tr><td></td><td>missed</td></tr><tr><td>c</td><td>Exploratory bloods (PBMC / Serum) not taken</td></tr><tr><td>d</td><td>Secondary immunogenicity tests (Anti-Denv IgG, CD8 and Activation Markers) missed</td></tr><tr><td>e</td><td>Exploratory immunogenicity tests (Ig assay and T &amp; B Cell responses) missed</td></tr><tr><td>f</td><td>Other</td></tr></table>		missed	c	Exploratory bloods (PBMC / Serum) not taken	d	Secondary immunogenicity tests (Anti-Denv IgG, CD8 and Activation Markers) missed	e	Exploratory immunogenicity tests (Ig assay and T & B Cell responses) missed	f	Other
	missed												
c	Exploratory bloods (PBMC / Serum) not taken												
d	Secondary immunogenicity tests (Anti-Denv IgG, CD8 and Activation Markers) missed												
e	Exploratory immunogenicity tests (Ig assay and T & B Cell responses) missed												
f	Other												
756	<p>[ nano_mp_text_5 ]</p> <p>Show the field ONLY if: [nano_mp_deviation_cat_4] = "a" OR [nano_mp_deviation_cat_4] = "b"</p>	Corrective action: complete/perform prior to vaccination	descriptive										
757	<p>[ nano_mp_text_6 ]</p> <p>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"</p>	Corrective action : to be recorded and follow up, follow protocol provided instructions for next blood draw and testing	descriptive										
758	<p>[ nano_mp_deviation_cat_5 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "f"</p>	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><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>	radio, Required		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
radio, Required													
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												
759	<p>[ nano_mp_text_7 ]</p> <p>Show the field ONLY if: [nano_mp_deviation_cat_5] = "a"</p>	Corrective action : follow up with patient / medical records / lab where applicable to complete prior to patient's last visit	descriptive										
760	<p>[ nano_mp_text_8 ]</p> <p>Show the field ONLY if: [nano_mp_deviation_cat_5] = "b" OR [nano_mp_deviation_cat_5] = "c"</p>	Corrective action : monitor to raise with site staff and ensure completed	descriptive										
761	<p>[ nano_mp_deviation_cat_6 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "g"</p>	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>Other</td></tr></table>	radio, Required		a	Other						
radio, Required													
a	Other												
762	<p>[ nano_mp_deviation_cat_7 ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "h"</p>	Choose category of deviation	<table><tr><td colspan="2">radio, Required</td></tr><tr><td>a</td><td>AE reported &lt; 14 days late</td></tr><tr><td>b</td><td>Other</td></tr></table>	radio, Required		a	AE reported < 14 days late	b	Other				
radio, Required													
a	AE reported < 14 days late												
b	Other												
763	<p>[ nano_mp_specify ]</p> <p>Show the field ONLY if: [nano_mp_deviation] = "i" OR [nano mp deviat</p>	Specify	text, Required										

	ion_cat] = "b" OR [nano_mp_deviation_cat_2] = "h" OR [nano_mp_deviation_cat_3] = "a" OR [nano_mp_deviation_cat_8] = "c" OR [nano_mp_deviation_cat_4] = "f" OR [nano_mp_deviation_cat_5] = "d" OR [nano_mp_deviation_cat_6] = "a" OR [nano_mp_deviation_cat_7] = "b"								
764	[ nano_mp_description ]	Describe the protocol deviation	notes, Required						
765	[ nano_mp_reason ]	Please explain the reason for the deviation	notes, Required						
766	[ 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								
767	[ 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								
768	[ nano_mp_avoid_recurrence ]	Describe the steps taken to avoid recurrence of the deviation	notes, Required						
769	[ nano_mp_pi_name ]	Section Header: <i>Investigator signature</i> Name of investigator	text, Required						
770	[ nano_mp_pi_date ]	Date	text (datetime_dmy), Required						
771	[ nano_mp_pi_sign ]	Signature of investigator	file (signature), Required						
772	[ 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								