Current Data Access Group: **[No Assignment]** Switch

Data Dictionary Codebook

MaPs in ENL (PID: 16)

26/08/2025 14:57

Instruments

Instrument	Form Name	Events
Participant information	participant_information	visit_0_arm_1
Consent	consent	visit_0_arm_1
Screening1	screening1	visit_0_arm_1
Screening 2	screening_2	visit_1_arm_1
Randomisation/Enrolment	randomisationenrolment	visit_1_arm_1
Baseline Visit	baseline_visit	visit_1_arm_1
Laboratory test	laboratory_test	visit_0_arm_1 visit_1_arm_1 visit_2_arm_1 visit_3_arm_1 visit_4_arm_1 visit_5_arm_1 visit_6_arm_1 visit_7_arm_1 visit_8_arm_1 visit_9_arm_1 visit_10_arm_1 visit_11_arm_1 visit_12_arm_1 visit_13_arm_1 visit_14_arm_1 visit_15_arm_1 visit_16_arm_1 visit_17_arm_1 visit_18_arm_1 visit_19_arm_1
Follow up Visit	follow_up_visit	visit_2_arm_1 visit_3_arm_1 visit_4_arm_1 visit_5_arm_1 visit_6_arm_1 visit_7_arm_1 visit_8_arm_1 visit_9_arm_1 visit_10_arm_1 visit_11_arm_1 visit_12_arm_1 visit_13_arm_1 visit_14_arm_1 visit_15_arm_1 visit_16_arm_1 visit_17_arm_1 visit_18_arm_1 visit_19_arm_1

Adverse Events	adverse_events	visit_2_arm_1 visit_3_arm_1 visit_4_arm_1 visit_5_arm_1 visit_6_arm_1 visit_7_arm_1 visit_8_arm_1 visit_9_arm_1 visit_10_arm_1 visit_11_arm_1 visit_12_arm_1 visit_13_arm_1 visit_14_arm_1 visit_15_arm_1 visit_16_arm_1 visit_17_arm_1 visit_18_arm_1 visit_19_arm_1
Follow up termination or completion	follow_up_termination_or_completion	visit_4_arm_1 visit_6_arm_1 visit_8_arm_1 visit_10_arm_1 visit_12_arm_1 visit_14_arm_1 visit_16_arm_1 visit_19_arm_1
DLQI	dlqi	visit_1_arm_1 visit_10_arm_1 visit_16_arm_1 visit_19_arm_1
SF-36	sf36	visit_1_arm_1 visit_10_arm_1 visit_16_arm_1 visit_19_arm_1
EESS	eess	visit_0_arm_1 visit_2_arm_1 visit_3_arm_1 visit_4_arm_1 visit_5_arm_1 visit_6_arm_1 visit_7_arm_1 visit_8_arm_1 visit_9_arm_1 visit_10_arm_1 visit_11_arm_1 visit_12_arm_1 visit_13_arm_1 visit_14_arm_1 visit_15_arm_1 visit_16_arm_1 visit_17_arm_1 visit_18_arm_1 visit_19_arm_1

Events	
Event Name	**Unique event name**

Visit #0	visit_0_arm_1
Visit #1	visit_1_arm_1
Visit #2	visit_2_arm_1
Visit #3	visit_3_arm_1
Visit #4	visit_4_arm_1
Visit #5	visit_5_arm_1
Visit #6	visit_6_arm_1
Visit #7	visit_7_arm_1
Visit #8	visit_8_arm_1
Visit #9	visit_9_arm_1
Visit #10	visit_10_arm_1
Visit #11	visit_11_arm_1
Visit #12	visit_12_arm_1
Visit #13	visit_13_arm_1
Visit #14	visit_14_arm_1
Visit #15	visit_15_arm_1
Visit #16	visit_16_arm_1
Visit #17	visit_17_arm_1
Visit #18	visit_18_arm_1
Visit #19	visit_19_arm_1

#	Variable / Field Name	Field Label *Field Note*	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)
Instrument: Participant information (participant_information)			
1	screening_id	Screening ID	text
2	date_registration	Date of registration:	text (date_dmy)
3	patient_id	Participant hospital number:	text, Required, Identifier
4	centre	Centre:	radio 1, DBLM/Bangladesh 2, Anandaban Hospital/ Nepal 3, TLMI Delhi, (Barabanki)/ India 4, BLP (Mumbai)/India 5, ALERT/ Ethiopia 6, Dr. Soetomo Hospital/ Indonesia

5	name	Name:	text, Identifier
6	adress	Address:	text, Identifier
7	contact_inf	Contact information (telephone number):	text, Required, Identifier
8	date_of_birth	AGE: AGE CRITERIA 18 TO 60 YEARS at registration	text (number, Min: 18, Max: 60)
9	gender	Gender:	radio 1 Male 2 Female
10	participant_information_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Consent (consent)			
11	consent_date	Date:	text (date_dmy)
12	consent_1	Does the individual have all the inclusion criteria from Screening 1 or later screening?	yesno 1 Yes 0 No
13	consent_2 Show the field ONLY if: [consent_1] = '1'	Does the individual consent in continuing with the screening process? Does the individual consent with doing blood tests including serologies for HIV and Hepatitis B and C? Does the individual consent in taking a thorax RX?	yesno 1 Yes 0 No
14	consent_3 Show the field ONLY if: [consent_1] = '1' and [consent_2] = '1'	Has the individual given informed consent? Is the individual aware of the possibility of not being able to participate in the study? Is the individual willing to collaborate with data already collected?	yesno 1 Yes 0 No
15	consent_4 Show the field ONLY if: [consent_1] = '1' and [consent_2] = '1' and [consent_3] = '1'	Is the individual aware he or she can withdraw from the study at any time?	yesno 1 Yes 0 No
16	consent_5 Show the field ONLY if: [consent_1] = '1' and [consent_2] = '1' a	If you agree with the consent form for participation in Methotrexate and prednisolone In ENL study, please sign here.	file (signature)

	nd [consent_3] = '1' and [consent_4] = ' 1'		
17	consent_signed Show the field ONL Y if: [consent_1] = '1' an d [consent_2] = '1' a nd [consent_3] = '1' and [consent_4] = ' 1'	Please upload the consent form signed here.	file, Required, Identifier
18	consent_complet e	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Screening1 (screening1)			
19	screen1_date	Date:	text (date_dmy)
20	scr_enl	Does the individual have leprosy complicated by ENL?	yesno 1 Yes 0 No
21	scr_age	Is the individual between 18-60 years old?	yesno 1 Yes 0 No
22	scr_det_symp	Does the individual have deteriorating symptoms of ENL?	yesno 1 Yes 0 No
23	scr_lesions	Does the individual have 10 or more tender, papular or nodular ENL skin lesions?	yesno 1 Yes 0 No
24	scr_eess	Does the individual score at least 9 on ENLIST Erythema Nodosum Leprosum Severity Scale (EESS)?	yesno 1 Yes 0 No
25	scr_eess_score Show the field ONL Y if: [scr_eess] = '1'	Current EESS score:	text (number, Min: 9, Max: 30)
26	scr_enl_treat	Is the individual currently on ENL	yesno

		treatment?	1 Yes 0 No
27	scr_treat Show the field ONLY if: [scr_enl_treat] = '1'	Individual's ENL and treatment status:	radio 1 Acute ENL and Prednisolone up to 30mg per day or equivalent alternative corticosteroid dose 2 Recurrent/chronic ENL on Prednisolone 10-30mg (inclusive) per day or equivalent alternative corticosteroid dose 3 Recurrent/chronic ENL on Thalidomide or other non-steroidal anti-ENL medication 4 Recurrent/chronic ENL on a combination of prednisolone (up to 30 mg) and another non-steroidal anti-ENL medication (thalidomide, clofazimine,azathioprine, pentoxifylline, ciclosporin, minocycline)
28	scr_time	Was the individual first diagnosed with ENL more than 4 years before screening for this study?	yesno 1 Yes 0 No
29	scr_weight	Patient weight (Kg): *Participants must weigh more than 35Kg*	text (number, Min: 35)
30	scr_women_childbearing Show the field ONLY if: [gender]="2"	For women of child-bearing age, do you agree to use effective contraception? PLEASE MAKE SURE SURE PARTICIPANT UNDERSTANDS SHE MUST NOT BECOME PREGNANT.	yesno 1 Yes 0 No
31	scr_men_contr Show the field ONLY if: [gender]="1"	For men only, does the individual intend to have a child with his partner in the period of the study?	yesno 1 Yes 0 No
32	scr_women_breatfeeding Show the field ONLY if: [gender]="2"	If woman, Is the individual pregnant or brestfeeding?	yesno 1 Yes 0 No
33	scr_mtx	Did the individual take methotrexate by any route for the last 12 weeks?	yesno

			1 Yes 0 No
34	scr_hypersensitivity	Does the individual have hypersensitivity to methotrexate?	yesno 1 Yes 0 No
35	scr_contra_2	Does the individual have a recognised contraindication?	yesno 1 Yes 0 No
36	scr_contraind Show the field ONLY if: [scr_contra_2] = '1'	If yes, which one?	text
37	scr_t1r	Is the individual currently diagnosed with Type 1 reaction?	yesno 1 Yes 0 No
38	scr_luciosphen	Is the individual currently diagnosed Lucio's phenomenon?	yesno 1 Yes 0 No
39	scr_tb	Does the individual have evidence of tuberculosis?	yesno 1 Yes 0 No
40	scr_pf	Does the individual have evidence of pulmonary fibrosis?	yesno 1 Yes 0 No
41	scr_chroniclivr	Does the individual have a history of chronic liver disease?	yesno 1 Yes 0 No
42	scr_alcohol_hx	Does the individual have a history of excessive alcohol intake?	yesno 1 Yes 0 No
43	scr_ilicit_drugs	Does the individual have a history of illicit substance consumption?	yesno 1 Yes 0 No
44	scr_severe_infe	Does the individual have severe inter-	yesno

	ction	current infections?	1 Yes 0 No
45	scr_infection1 Show the field ONLY if: [scr_severe_infection] = '1'	If yes, please describe.	text
46	scr_dm_severe	Does the individual have severe uncontrolled diabetes?	yesno 1 Yes 0 No
47	scr_peptic_ulcer	Does the individual have active peptic ulcer?	yesno 1 Yes 0 No
48	scr_malignancy	Does the individual have untreated malignancy?	yesno 1 Yes 0 No
49	scr_attendancy	Is the individual able to attend regularly for assessment and continuing treatment?	yesno 1 Yes 0 No
50	scr_att_1 Show the field ONLY if: [scr_attendancy] = '0'	If no, please describe why.	text
51	scr_participat	Does the individual agree to participate?	yesno 1 Yes 0 No
52	screening1_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Screening 2 (screening_2)			
53	screen_date	Date:	text (date_dmy)
54	screen_round scr_round	Screening round: *How many times the participant was screening? Is this the first time? Write the number of times in the box.*	text

55	screening_2_2	Does the individual have haemoglobin less than 10 g/dL?	yesno, Required 1 Yes 0 No
56	screening_2_3	Does the individual have white blood cells less than 3.0 x109 cells/l?	yesno, Required 1 Yes 0 No
57	screening_2_4	Does the individual have neutrophils less than 1.5x109/l?	yesno, Required 1 Yes 0 No
58	screening_2_5	Does the individual have platelets less than 100X109/l?	yesno, Required 1 Yes 0 No
59	screening_2_6	Does the individual have AST or ALT less than 2 times the upper limit of normal range?	yesno, Required 1 Yes 0 No
60	screening_2_7	Does the individual have total bilirubin less than > 2times the upper limit of the normal range AND normal liver function enzymes ?	yesno, Required 1 Yes 0 No
61	screening_2_8	Does the individual have Hypoalbuminemia less than 3.5g/dl?	yesno, Required 1 Yes 0 No
62	scr_hiv	Does the individual have a positive serology for HIV?	yesno 1 Yes 0 No
63	scr_hepb	Does the individual have a positive serology for Hepatitis B?	yesno 1 Yes 0 No
64	scr_hepc	Does the individual have a positive serology for hepatitis C?	yesno 1 Yes 0 No
65	screening_2_9	Does this individual qualify for enrolment?	yesno, Required 1 Yes 0 No

66	scrrening_2_9_1 Show the field ONLY if: [screening_2_9] = '0'	If NO, and if in future one or more of the above criteria change then should the individual be screened again?	yesno 1 Yes 0 No
67	screening_2_9_2 Show the field ONLY if: [screening_2_9] = '1'	Does this individual agree to enrolment in the study?	yesno 1 Yes 0 No
68	screening_2_10 Show the field ONLY if: [screening_2_9_2] = '1'	Did the individual have enough time to consider the study?	yesno, Required 1 Yes 0 No
69	screening_2_11 Show the field ONLY if: [screening_2_9_2] = '1'	Does the individual understand the risks and benefits of participating in this study?	yesno 1 Yes 0 No
70	scr_2_12	If the participant can't be recruited at the moment, please specify why:	text
71	screening_2_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Randomisation/Enrolment (randomisationenrolment)			
72	enroll_date	Date:	text (date_dmy)
73	enrollment1	Has the individual given informed consent?	yesno 1 Yes 0 No
74	enrollment2	Has the individual received the Participant Information Sheet (PIS)?	yesno 1 Yes 0 No
75	enrollment3	Did the individual have enough time to consider the study?	yesno 1 Yes 0 No
76	enroll_3_1	Did he or she understand the risks and	yesno

		benefits of participating in this study?	1, Yes 0, No
77	enrollment5	Was a witness present during the consent process? Please sign here. (witness)	file (signature)
78	enrollment6	RANDOMISATION NUMBER: (enrolment number) This is the number in the participant box. Remember to check the package list and note down the screening ID number on it.	text
79	randomisationenrolment_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: Baseline Visit (baseline_visit)			
80	base_date	Assessment at baseline Date:	text (date_dmy)
81	base_researcher	Assessment done by:	text
82	base_enl_episode	Is this the first episode of ENL the participant has ever had?	yesno 1, Yes 0, No
83	base_enl_episode_time Show the field ONLY if: [base_enl_episode] = '1'	If yes: How long has he/she had symptoms of ENL (in days)?	text
84	base_enl_prev_episode Show the field ONLY if: [base_enl_episode] = '0'	If no: How long ago was the last ENL episode (in months): Last episode is the episode before the current one.The participant must have been without medication for ENL.	text
85	base_last_treat Show the field ONLY if: [base_enl_episode]	When did the last ENL episode treatment end: Last episode before the current flare.	text (date_dmy)

	= '0'		
86	base_enl_months	How many months of ENL reactions in total?	text
87	base_enl_duration Show the field ONLY if: [base_enl_episode] = '0'	Duration of this ENL flare (in days): Worsening of symptoms	text (number)
88	base_date_1enl Show the field ONLY if: [base_enl_episode] = '0'	Date of first ENL episode?	text (date_dmy)
89	base_date_current_enl	Date of current ENL episode?	text (date_dmy)
90	base_classif	The individual has: Acute ENL is defined as occurring if a patient has either a first episode of ENL less than 24 weeks duration or experiences a second or subsequent episode of ENL which lasts less than 24 weeks and occurs 84 days (ie 12 weeks) or more after stopping treatment for ENL. Recurrent ENL is defined as occurring if a patient experienced a second or subsequent episode of ENL occurring between 28 and 84 days of stopping treatment for ENL. Chronic ENL is defined as occurring for more than 24 weeks during which a patient has required ENL treatment either continuously or where any treatment free period had been 27 days or less.	radio 1 Acute ENL 2 Recurent/ Chronic ENL
91	base_ridleyjopling	Classification (Ridley- Jopling):	radio 1 Borderline Lepromatous (BL) 2 Lepromatous Leprosy (LL)
92	base_bi	Mean Bacterial Index at time of diagnosis:	radio 0 0 1 1 2 2 3 3 4 4

			5 | 5 6 | 6 7 | Missing or not done
93	base_bi2 Show the field ONLY if: [base_bi] = '0' or [base_bi] = '1' or [base_bi] = '2' or [base_bi] = '3' or [base_bi] = '4' or [base_bi] = '5' or [base_bi] = '6'	Date of BI at diagnosis (if available):	text (date_dmy)
94	base_bi3	Most recent mean bacterial Index:	radio 0 | 0 1 | 1 2 | 2 3 | 3 4 | 4 5 | 5 6 | 6 7 | Missing or not done
95	base_bi4 Show the field ONLY if: [base_bi3] = '0' or [base_bi3] = '1' or [base_bi3] = '2' or [base_bi3] = '3' or [base_bi3] = '4' or [base_bi3] = '5' or [base_bi3] = '6'	Date of most recent BI (if available):	text (date_dmy)
96	base_mdt_status	Current MDT status:	radio 1 | On MDT 2 | Not on MDT
97	base_mdt_date Show the field ONLY if: [base_mdt_status] = '1'	MDT start date:	text (date_dmy)

98	base_enl_treat	Is the participant on ENL treatment:	yesno 1 Yes 0 No
99	base_yes_enl_treat Show the field ONLY if: [base_enl_treat] = '1'	If yes: When was it started:	text (date_dmy)
100	base_no_enl_treat Show the field ONLY if: [base_enl_treat] = '0'	If no: When was it stopped:	text (date_dmy)
101	base_enl_treat_pred Show the field ONLY if: [base_enl_treat] = '1'	How long has the participant been on prednisolone (in days)?	text (number)
102	base_pred_cur_dose Show the field ONLY if: [base_enl_treat] = '1'	What is the current daily dose of prednisolone in (0-30)mg?	text (number, Min: 0, Max: 30)
103	base_pred_dose_taken Show the field ONLY if: [base_enl_treat] = '1'	When was the last dose taken? Date:	text (date_dmy)
104	base_hist_dm	Section Header: *Medical History* Diabetes	radio (Matrix) 0 NO 1 YES
105	base_hist_ht	Hypertension	radio (Matrix) 0 NO 1 YES
106	base_hist_tb	Tuberculosis (past)	radio (Matrix)

			0 NO 1 YES
107	base_hist_cpox	History of chicken pox	radio (Matrix) 0 NO 1 YES
108	base_hist_alcohol	Alcohol intake	radio (Matrix) 0 NO 1 YES
109	base_hist_other	If any other medical history, please specify:	text
110	base_analgesia	Section Header: *Current medication:* Analgesia	radio (Matrix) 0 NO 1 YES
111	base_antiinflammatory	anti-inflammatory medication	radio (Matrix) 0 NO 1 YES
112	base_antibiotic	Antibiotics	radio (Matrix) 0 NO 1 YES
113	base_hypertensive	Antihypertensive medication	radio (Matrix) 0 NO 1 YES
114	base_antifungal	Anti-fungal medication	radio (Matrix) 0 NO 1 YES
115	base_dm	Diabetic control medication	radio (Matrix) 0 NO 1 YES
116	base_opht	Ophthalmological medication	radio (Matrix) 0 NO 1 YES
117	base_psychiatric	Psychiatric medication	radio (Matrix) 0 NO 1 YES

118	base_other_medication	Other medication	radio (Matrix) 0 NO 1 YES
119	base_generic_drugs	If yes to any of the above please specify each drug with generic name.	text
120	base_alergies	Known allergies:	yesno 1 Yes 0 No
121	base_alergies_spe Show the field ONLY if: [base_alergies] = '1'	If yes, please specify:	text
122	base_contraindication	Is the participant on any contra-indication: DAPSONE, SULFONAMIDE ANTIBIOTICS, TRIMETHOPRIM	yesno, Required 1 Yes 0 No
123	base_woman_childb Show the field ONLY if: [gender]="2"	Women: Child-bearing capacity:	yesno, Required 1 Yes 0 No
124	base_period Show the field ONLY if: [base_woman_childb] = '1'	Date of last period (menstruation):	text (date_dmy)
125	base_contracept Show the field ONLY if: [base_woman_childb] = '1' and [gender] = '2'	Contraception used or planning to use: REMIND THE PARTICIPANT SHE MUST NOT BECOME PREGNANT AND NEEDS TO USE EFFECTIVE CONTRACEPTIVE METHODS, PREFEBABLY TWO METHODS.	text
126	base_fev	Section Header: *BASELINE QUESTIONNAIRE Ask the patient about the following conditions:* Fevers	radio (Matrix) 0 NO 1 YES
127	base_cut_infec	Cutaneous (including nails) fungal infections	radio (Matrix) 0 NO

			1 YES
128	base_infect	Infections	radio (Matrix) 0 NO 1 YES
129	base_infect_ulcers	Infected ulcers	radio (Matrix) 0 NO 1 YES
130	base_recent_tb	Recent tuberculosis diagnosis	radio (Matrix) 0 NO 1 YES
131	base_sweats	Night sweats	radio (Matrix) 0 NO 1 YES
132	base_nausea	Nausea	radio (Matrix) 0 NO 1 YES
133	base_jaundice	Jaundice	radio (Matrix) 0 NO 1 YES
134	base_dyspepsia	Dyspepsia	radio (Matrix) 0 NO 1 YES
135	base_gast_pain	Gastric pain requiring antacid	radio (Matrix) 0 NO 1 YES
136	base_gast_bleed	Gastrointestinal bleeding/ Melena	radio (Matrix) 0 NO 1 YES
137	base_vomiting	Vomiting	radio (Matrix) 0 NO 1 YES
138	base_diarrhoea	Diarrhoea	radio (Matrix) 0 NO

			1 YES
139	base_ulcers_mouth	Ulcers in the mouth	radio (Matrix) 0 NO 1 YES
140	base_moon_face	Moon face	radio (Matrix) 0 NO 1 YES
141	base_anorexia	Anorexia	radio (Matrix) 0 NO 1 YES
142	base_weight_lost	Weight lost >5kg in 3 months	radio (Matrix) 0 NO 1 YES
143	base_weight_gain	Weight gain	radio (Matrix) 0 NO 1 YES
144	base_nocturia	Nocturia, polyuria, polydipsia	radio (Matrix) 0 NO 1 YES
145	base_ht	Hypertension BP> 160/90 on 2 separate readings at least 1week apart	radio (Matrix) 0 NO 1 YES
146	base_other_rashes	Other rashes	radio (Matrix) 0 NO 1 YES
147	base_hair_loss	Hair loss	radio (Matrix) 0 NO 1 YES
148	base_pruritus	Pruritus	radio (Matrix) 0 NO 1 YES
149	base_acne	Acne	radio (Matrix) 0 NO

			1 YES
150	base_periph_oedema	Peripheral oedema	radio (Matrix) 0 NO 1 YES
151	base_short_breath	Shortness of breath	radio (Matrix) 0 NO 1 YES
152	base_chronic_cough	Chronic cough	radio (Matrix) 0 NO 1 YES
153	base_chest_pain	Chest pain	radio (Matrix) 0 NO 1 YES
154	base_easy_bruising	Easy bruising/Haematoma	radio (Matrix) 0 NO 1 YES
155	base_dizziness	Dizziness	radio (Matrix) 0 NO 1 YES
156	base_headaches	Headaches	radio (Matrix) 0 NO 1 YES
157	base_convulsions	Convulsions	radio (Matrix) 0 NO 1 YES
158	base_psychosis	Psychosis or other mental health problems	radio (Matrix) 0 NO 1 YES
159	base_recent_fractures	Recent fractures	radio (Matrix) 0 NO 1 YES
160	base_menorrhagia	Menorrhagia	radio (Matrix) 0 NO

			1 YES
161	base_amenorrhagia	Amenorrhea	radio (Matrix) 0 NO 1 YES
162	base_glaucoma	Corner Glaucoma	radio (Matrix) 0 NO 1 YES
163	base_corneal_ulcer	Corneal ulcer	radio (Matrix) 0 NO 1 YES
164	base_cataract	Cataract	radio (Matrix) 0 NO 1 YES
165	base_quest_other_symp	Any other symptoms:	text
166	base_temp	Section Header: *EXAMINATION AT REGISTRATION Baseline Physical Examination Day 1* Temperature oC:	text (number)
167	base_pulse	Pulse (b/min)	text (number)
168	base_bp	Blood Pressure (systolic/ diastolic)	text
169	base_weight	Weight (kg)	text (number, Min: 35), Required
170	base_height	Height (cm)	text
171	base_mouth	Section Header: *GENERAL EXAMINATION* Mouth:	radio 1 Normal 2 Abnormal 3 Not examined
172	base_mouth1 Show the field ONLY if: [base_mouth] = '2'	If abnormal, please specify:	text
173	base_lungs	Lungs:	radio 1 Normal 2 Abnormal 3 Not examined
174	base_lungs1	If abnormal, please specify:	text

	Show the field ONLY if: [base_lungs] = '2'		
175	base_heart	Heart:	radio 1 Normal 2 Abnormal 3 Not examined
176	base_heart1 Show the field ONLY if: [base_heart] = '2'	If abnormal, please specify:	text
177	base_abdomen	Abdomen:	radio 1 Normal 2 Abnormal 3 Not examined
178	base_abdomen1 Show the field ONLY if: [base_abdomen] = '2'	If abnormal, please specify:	text
179	base_orchitis Show the field ONLY if: [gender] = '1'	Does the patient have Orchitis? For men only	yesno 1 Yes 0 No
180	base_redeye	Does the patient have painful or red eyes?	yesno 1 Yes 0 No
181	base_neuritis	Section Header: *LEPROSY EXAMINATION* Is there any signs and symptoms of neuritis (recent = less than 6 months)?	yesno 1 Yes 0 No
182	base_neuritis2 Show the field ONLY if: [base_neuritis] = '1'	If yes which one and where?	text
183	base_vmt_st	Is there any alteration in the VMT/ST assessment?	yesno 1 Yes 0 No

184	base_vmt_st2 Show the field ONLY if: [base_vmt_st] = '1'	If any abnormality, specify:	text
185	baseline_photo	If you like to upload a picture or a file please do it here:	descriptive
186	base_hiv	Section Header: *INVESTIGATIONS -Physician to complete BASELINE - DAY 1 Laboratory tests* HIV:	radio 1 Positive 2 Negative
187	base_bepb	Hep B HBsAg and anti-HBc:	radio 1 Positive 2 Negative
188	base_hepc	Hep C antibody:	radio 1 Positive 2 Negative
189	base_preg_test	Pregnancy test (urine): *Advise contraception options*	radio 1 Positive 2 Negative
190	base_skin_biopsy	Skin biopsy:	radio 1 LL 2 BL 3 Not applicable
191	base_skin_smear	Slit skin smear (mean BI):	text
192	base_xray	Chest Xray:	radio 1 Normal 2 Abnormal 3 Not done
193	base_other_invest	Other investigations:	text
194	base_not_dapsone	CONFIRM THAT PARTICIPANT IS NOT ON DAPSONE Is the patient on Dapsone? If he/she is STOP Dapsone, arrange the proper procedure.	yesno, Required 1 Yes 0 No
195	base_folic_acid	Section Header: *MEDICATION TO BE PRESCRIBE Baseline - Day 1* Folic acid - 5mg od x 52 weeks	yesno 1 Yes

		(6 days a week- not on day of MTX)	0 No
196	base_ivermectin	Ivermectin - 200mcg/kg od x2d (every 6 months)	yesno 1 Yes 0 No
197	base_ranitidine	Histamine 2-blockers (eg. Cimetidine, Famotidine, Nizatidine):	yesno 1 Yes 0 No
198	base_paracetamol	Paracetamol	yesno 1 Yes 0 No
199	base_paracetamol1 Show the field ONLY if: [base_paracetamol] = '1'	If yes, please specify dosage/time	text
200	base_calcium_vitd	Calcium + Vitamin D	yesno 1 Yes 0 No
201	base_ondansertron	Ondansetron or other antiemetic medication:	yesno 1 Yes 0 No
202	base_ondansetron1 Show the field ONLY if: [base_ondansertron] = '1'	If yes, please specify dosage/time	text
203	base_contraception Show the field ONLY if: [gender] = '2'	Contraception: *Does the participant needs to have contraception prescribed?*	radio 1 Yes 2 No 3 Not aplicable
204	base_contracp_specify Show the field ONLY if: [base_contraceptio	If yes, please specify:	text

	n] = '1'		
205	base_tramadol	Tramadol:	yesno 1, Yes 0, No
206	base_tramadol1 Show the field ONLY if: [base_tramadol] = '1'	If yes, please specify dosage/time	text
207	base_extra_med	**EXTRA MEDICATION PRESCRIBED TODAY**:	text
208	base_final_inst	COMPLETE PARTICIPANT CARD AND SEND PATIENT TO PHARMACY. CHECK IF PARTICIPANT RECEIVED MEDICATION CORRECTLY AND UNDERSTANDS THE INSTRUCTIONS. Check SF 36 and DLQI have been completed and if patient aware of next review date.	descriptive
209	baseline_visit_complete	Section Header: *Form Status* Complete?	dropdown 0, Incomplete 1, Unverified 2, Complete
Instrument: Laboratory test (laboratory_test)			
210	lab_date	Date sample was taken:	text (date_dmy)
211	lab_fbc_hb	FBC/ Hb (g/dl):normal values: 11-18	text (number)
212	lab_fbc_wcc	FBC/WCC (x109 cells/l):normal values: 4-11	text (number)
213	lab_fbc_plt	FBC/Platelets (cells/mm3):normal values: 150000- 450000	text (number)
214	lab_fbc_mcv	FBC/MCV (fl): normal range 80-96	text (number)
215	lab_rf_creat	Renal Function/ Creatinine (mg/dl):normal values: 0.5-1.2	text (number)
216	lab_rf_k	Renal Function/ Potassium (mmol/l):normal values: 3.6 - 5.2	text (number)
217	lab_rf_urea	Renal Function/ Urea (mg/dl): normal values: 7-20	text (number)
218	lab_bloodsugar_glucose	Blood sugar/ glucose (mg/dl): normal values:70-130	text (number)
219	lab_lft_alkphos	LFT/ Alkaline phosphatase (u/l):normal values: 30-300	text (number)

220	lab_lft_ast	LFT/ AST (SGOT) u/l:normal values: 5-35	text (number)
221	lab_lft_alt	LFT/ ALT (SGPT) u/l:normal values: 5-35	text (number)
222	lab_lft_bil	LFT/ Bilirubin (mg/dl):normal values: 0.1-1.2	text (number)
223	lab_lft_alb	LFT/ Albumin (g/dl): normal values: 3.5-5.5	text (number)
224	lab_hepb_serology	Hepatitis B serology (HBsAg AND anti-HBc):	radio 1 Positive 2 Negative
225	count_tests_out_of_range	Count of routine tests out of range If any routine test is out of range, please review and refer to the monitoring investigations table below and fill adverse event form. Abnormality Action Follow up Total WBC count < 3.0 x109cells/l Withhold MTX If repeat labs are < 3.0 x109 cells/l then withdraw participant Neutrophils < 1.0 x109 cells/l (if available) Withhold MTX Platelets < 100 x109 cells/l Withhold MTX If repeat platelets are < 100,000/mm3 then withdraw participant MCV > 105 fl (if available) Consider withholding dose of MTX; check serum B12, folate and thyroid function tests AST and ALT increased by less than two times the ULN Continue MTX. Repeat LFTs in 2-4 weeks If LFTs are less than twice ULN continue MTX and monitor again in 4 weeks AST and ALT greater than 2 but less than or equal to 3 times the ULN Withhold MTX; Repeat LFTs in 4 weeks Consider other risk factors (including alcohol consumption) If LFTs are less than twice ULN resume MTX and monitor again in 4 weeks AST and ALT greater 3 times the normal Withdrawal from study Monitor until normal or cause identified New or increasing dyspnoea or cough Withhold MTX; repeat chest X-ray Treat according to investigations Severe sore throat, abnormal bruising Withhold MTX; check FBC immediately Treat according to investigations Creatinine > 2 × ULN Withhold MTX. Repeat in 4 weeks If repeat creatinine > 2x ULN withdraw participant *Calculated field*	calc Calculation: if([lab_fbc_hb]< 11,1, if([lab_fbc_hb]>18,1,0))+ if([lab_fbc_wcc]< 4,1, if([lab_fbc_wcc]>14,1,0))+ if([lab_fbc_plt]< 150000,1, if([lab_fbc_plt]>450000,1,0))+ if([lab_rf_creat]< 0.5,1, if([lab_rf_creat]>1.2,1,0))+ if([lab_rf_k]< 3.6,1, if([lab_rf_k]>5.2,1,0))+ if([lab_rf_urea]< 7,1, if([lab_rf_urea]>20,1,0))+ if([lab_bloodsugar_glucose]< 70,1, if([lab_bloodsugar_glucose]>130,1,0))+ if([lab_lft_alkphos]< 30,1, if([lab_lft_alkphos]>300,1,0))+ if([lab_lft_ast]< 5,1, if([lab_lft_ast]>35,1,0))+ if([lab_lft_alt]< 5,1, if([lab_lft_alt]>35,1,0))+ if([lab_lft_bil]< 0.1,1, if([lab_lft_bil]>1.2,1,0))+ if([lab_lft_alb]< 3.5,1, if([lab_lft_alb]>5.5,1,0))
226	lab_pregtest Show the field ONLY if:	Pregnancy test (urine): if positive, report as adverse event and withdraw the participant of the study.	radio 0 Negative 1 Positive

	[gender] = '2'		2 Not applicable
227	lab_other_invest	Other investigations:	text
228	lab_ae	Do you want to report a adverse event? If yes, complete an adverse event form!	yesno 1 Yes 0 No
229	laboratory_test_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Follow up Visit (follow_up_visit)			
230	follup_date	Section Header: *Physician to complete history and examination and ensure lab results are entered Physician to complete adverse event form if necessary Ensure correct physiotherapy form and QoL questionnaires are attached to PRF After each visit: 1. Mark off visit on page 1 2. Write in date of next planned visit on page 1 3. Tell Investigator about completed patient review in order to transfer data to CRF* Date:	text (date_dmy)
231	follup_researcher	Assessment done by:	text
232	follup_sympt	Compared to the last review, does the participant feel:	radio 1 Better 2 Somewhat better 3 Same 4 Somewhat worse 5 Worse
233	follup_bloodtest	Were last set of bloods satisfactory as per trial protocol ?	yesno 1 Yes 0 No
234	follup_taken_med	Has the participant taken all study medication?	yesno 1 Yes 0 No
235	follup_newhist	Any relevant new history?	text
236	follup_new_med	Any new additional medications including steroids, dapsone-free MDT and analgesia	text

		since last visit? (Please specify: drug, dose, reason to starting, start date and if the it is a ongoing treatment)	
237	follup_fev	Section Header: *Does the patient complain of any of the following (new since last visit?)* Fevers	radio (Matrix) 0 NO 1 YES
238	follup_cut_infec	Cutaneous (including nails) fungal infections	radio (Matrix) 0 NO 1 YES
239	follup_infect	Infections	radio (Matrix) 0 NO 1 YES
240	follup_infec_ulcer	Infected ulcers	radio (Matrix) 0 NO 1 YES
241	folloup_recenttb	Recent tuberculosis diagnosis	radio (Matrix) 0 NO 1 YES
242	follup_sweats	Night sweats	radio (Matrix) 0 NO 1 YES
243	follup_nausea	Nausea	radio (Matrix) 0 NO 1 YES
244	follup_jaundice	Jaundice	radio (Matrix) 0 NO 1 YES
245	follup_dyspepsia	Dyspepsia	radio (Matrix) 0 NO 1 YES
246	follup_gast_pain	Gastric pain requiring antacid	radio (Matrix) 0 NO 1 YES

247	follup_gast_bleed	Gastrointestinal bleeding/ Melena	radio (Matrix) 0 NO 1 YES
248	follup_vomit	Vomiting	radio (Matrix) 0 NO 1 YES
249	follup_diarrhoea	Diarrhoea	radio (Matrix) 0 NO 1 YES
250	follup_ulcermouth	Ulcers in the mouth	radio (Matrix) 0 NO 1 YES
251	follup_moonface	Moon face	radio (Matrix) 0 NO 1 YES
252	follup_anorexia	Anorexia	radio (Matrix) 0 NO 1 YES
253	follup_weightlost	Weight lost >5kg in 3 months	radio (Matrix) 0 NO 1 YES
254	follup_weightgain	Weight gain	radio (Matrix) 0 NO 1 YES
255	follup_nocturia	Nocturia, polyuria, polydipsia	radio (Matrix) 0 NO 1 YES
256	follup_ht	Hypertension BP> 160/90 on 2 separate readings at least 1week apart	radio (Matrix) 0 NO 1 YES
257	follup_otherrashs	Other rashes	radio (Matrix) 0 NO 1 YES

258	follup_hairloss	Hair loss	radio (Matrix) 0 NO 1 YES
259	follup_pruritus	Pruritus	radio (Matrix) 0 NO 1 YES
260	follup_acne	Acne	radio (Matrix) 0 NO 1 YES
261	follup_peripheraloedema	Peripheral oedema	radio (Matrix) 0 NO 1 YES
262	follup_shortbreath	Shortness of breath	radio (Matrix) 0 NO 1 YES
263	follup_chronic_cough	Chronic cough	radio (Matrix) 0 NO 1 YES
264	follup_chestpain	Chest pain	radio (Matrix) 0 NO 1 YES
265	follup_easybruising	Easy bruising/Haematoma	radio (Matrix) 0 NO 1 YES
266	follup_dizzness	Dizziness	radio (Matrix) 0 NO 1 YES
267	follup_headache	Headaches	radio (Matrix) 0 NO 1 YES
268	follup_convulsion	Convulsions	radio (Matrix) 0 NO 1 YES

269	follup_psychosis	Psychosis or other mental health problems	radio (Matrix) 0 NO 1 YES
270	follup_recentfractures	Recent fractures	radio (Matrix) 0 NO 1 YES
271	follup_menorrhagia	Menorrhagia	radio (Matrix) 0 NO 1 YES
272	follup_amenorrhea	Amenorrhea	radio (Matrix) 0 NO 1 YES
273	follup_glaucoma	Corner Glaucoma	radio (Matrix) 0 NO 1 YES
274	follup_cornealulcer	Corneal ulcer	radio (Matrix) 0 NO 1 YES
275	follup_cataract	Cataract	radio (Matrix) 0 NO 1 YES
276	follup_quest_other_symp	Any other symptoms:	text
277	follup_ae1	Do you want to report an adverse event? IF YES FILL IN ADVERSE EVENT FORM	yesno 1 Yes 0 No
278	follup_temp	Section Header: *Vital signs* Temperature oC:	text (number)
279	follup_pulse	Pulse (b/min):	text (number)
280	follup_bp	Blood Pressure (systolic/diastolic):	text
281	follup_weight	Weight:	text (number), Required
282	follup_mouth	Section Header: *Examination* Mouth:	radio 1 Normal 2 Abnormal

			3 Not examined
283	follup_mouth1 Show the field ONLY if: [follup_mouth] = '2'	If abnormal specify:	text
284	follup_lungs	Lungs:	radio 1 Normal 2 Abnormal 3 Not examined
285	follup_lungs1 Show the field ONLY if: [follup_lungs] = '2'	If abnormal, specify:	text
286	follup_heart	Heart:	radio 1 Normal 2 Abnormal 3 Not examined
287	follup_heart1 Show the field ONLY if: [follup_heart] = '2'	If abnormal, specify:	text
288	follup_abdomen	Abdomen:	radio 1 Normal 2 Abnormal 3 Not examined
289	follup_abdomen1 Show the field ONLY if: [follup_abdomen] = '2'	If abnormal, specify	text
290	follup_orchitis Show the field ONLY if: [gender] = '1'	Does the patient has orchitis?	yesno 1 Yes 0 No
291	follup_redeyes	Does the patient have painful or red eyes?	yesno 1 Yes

			0 No
292	follup_nerves	Section Header: *Leprosy Examination* Nerves - signs and symptoms of neuritis (NEW = SINCE LAST REVIEW) Is there an abnormality?	yesno 1 Yes 0 No
293	follup_nerves1 Show the field ONLY if: [follup_nerves] = '1'	If yes, which one and where?	checkbox 1 follup_nerves1___1 New sensory loss 2 follup_nerves1___2 New motor loss
294	follup_vmt_st	CONFIRM YOU HAVE SEEN VMT/ST FORM	yesno 1 Yes 0 No
295	follow_up_photo	If you like to upload a file or a picture, please do it here:	descriptive
296	follup_eess	ENLIST ENL Severity Scale total score:	text (number)
297	follup_dapsone	Section Header: *Medication to be prescribed* CONFIRM THAT PARTICIPANT IS NOT ON DAPSONE. *Please write yes on the box to confirm that they participant is not taking dapsone.*	text
298	follup_studymed	Has the participant taken all study medication?	yesno 1 Yes 0 No
299	follup_folic_acid	Folic acid (5mg od x 52 weeks, 6 days a week, not on day of MTX):	yesno 1 Yes 0 No
300	follup_ranitidine	Histamine 2-blockers (eg. Cimetidine, Famotidine, Nizatidine):	yesno 1 Yes 0 No
301	follup_paracetamol	Paracetamol (max 4g/day):	yesno 1 Yes 0 No
302	follup_paracetamol1 Show the field ONL	If yes, dosage/time:	text

	Y if: [follup_paracetamol] = '1'		
303	follup_calcium_vitd	Calcium + vitamin D:	yesno 1 Yes 0 No
304	follup_ondansertron	Ondansetron or other antiemetic medication:	yesno 1 Yes 0 No
305	follup_ondasertron1 Show the field ONL Y if: [follup_ondansertron] = '1'	If yes, dosage/time:	text
306	follup_contraception Show the field ONL Y if: [gender] = '2'	Contraception: *Does participant needs contraception to be prescribed?*	radio 1 Yes 2 No 3 Not aplicable
307	follup_tramadol	Tramadol or other opioid medication:	yesno 1 Yes 0 No
308	follup_tramadol1 Show the field ONL Y if: [follup_tramadol] = '1'	If yes, dosage/time:	text
309	follup_ivermectine	*Prescribe Ivermectine every 6 months after enrolment.*EXTRA MEDICATION PRESCRIBED TODAY*: Please write down in the text box if that was prescribe according protocol.	text
310	follup_additional_pred	Do you wish to prescribe additional prednisolone?	yesno 1 Yes 0 No
311	follup_add_pred_reason	If prescribing additional prednisolone please indicate reason: *COMPLETE PARTICIPANT CARD AND SEND PATIENT TO*	radio 1 A flare or deterioration in ENL (ENL symptoms and/or signs

	Show the field ONLY if: [follup_additional_pred] = '1'	*PHARMACY*	resulting in a increased EESS score to 9 or more; an increase in EESS score of 5 or more; orchitis not responding to conservative management; iritis not responding to topical steroids/mydriatics) 2 | New or a deterioration in NFI (motor impairment - a two grade change in MRC grade; sensory impairment - loss of ability to feel 2 g on the hands or 10 g on the feet at three points) 3 | Leprosy Type 1 reaction
312	follow_up_visit_complete	Section Header: *Form Status* Complete?	dropdown 0 | Incomplete 1 | Unverified 2 | Complete
Instrument: Adverse Events (adverse_events)			
313	ad_date	Section Header: *Adverse Events At each review and unplanned visit, the follow form must be completed if there is an adverse event to be recorded.* Date	text (date_dmy)
314	ad_unplanned_visit	Is this an unplanned visit?	yesno 1 | Yes 0 | No
315	ae_type	Please describe the type adverse event? If the participant has a positive pregnancy test you should write it down and refer to pre-natal care and manage accordingly.	text
316	ae_date_onset	Date of onset:	text (date_dmy)
317	ae_serious	Is this a serious adverse event?	yesno 1 | Yes 0 | No
318	ae_management	How you managed the adverse event?	radio 1 | Stop medication 2 | Decrease medication 3 | Give medication for symptoms

			4 Take participant out of the study 5 Hospitalisation
319	ae_manage_comments	Comments on management of adverse event:	text
320	ae_another_ae	Do you want to report another adverse event?	yesno 1 Yes 0 No
321	ae_type2 Show the field ONLY if: [ae_another_ae] = '1'	Type of adverse event:	text
322	ae_date_onset2 Show the field ONLY if: [ae_another_ae] = '1'	Date of onset:	text (date_dmy)
323	ae_serious2 Show the field ONLY if: [ae_another_ae] = '1'	Is this a serious adverse event?	yesno 1 Yes 0 No
324	ae_management2 Show the field ONLY if: [ae_another_ae] = '1'	How you managed the adverse event:	radio 1 Stop medication 2 Decrease medication 3 Give medication for symptoms 4 Take participant out of the study 5 Hospitalisation
325	ae_manage_comments2 Show the field ONLY if: [ae_another_ae] = '1'	Commets on management of adverse event:	text
326	ae_another_ae3 Show the field ONLY if:	Do you want to report another adverse event?	yesno 1 Yes 0 No

	[ae_another_ae] = '1'		
327	ae_date_onset3 Show the field ONLY if: [ae_another_ae] = '1' and [ae_another_ae3] = '1'	Date of onset:	text (date_dmy)
328	ae_serious3 Show the field ONLY if: [ae_another_ae] = '1' and [ae_another_ae3] = '1'	Is this a serious adverse event?	yesno 1 Yes 0 No
329	ae_management3 Show the field ONLY if: [ae_another_ae] = '1' and [ae_another_ae3] = '1'	How you managed the adverse event:	radio 1 Stop medication 2 Decrease medication 3 Give medication for symptoms 4 Take participant out of the study 5 Hospitalisation
330	ae_manage_comments3 Show the field ONLY if: [ae_another_ae] = '1' and [ae_another_ae3] = '1'	Comments on management of adverse event:	text
331	ae_hospital_admission	Did the patient require hospital admission?	yesno 1 Yes 0 No
332	ae_dsmb_notification	Was the study manager notified?	yesno 1 Yes 0 No
333	ae_dsmb_action	What action was taken?	text
334	sae_onset_date Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' o	Serious Adverse Event Form SAE onset date:	text (date_dmy), Required

	r [ae_serious3] = '1'		
335	sae_stop_date Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	SAE stop date:	text
336	unexp_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Was this an unexpected adverse event?	yesno 1, Yes 0, No
337	description_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Brief description of the nature of the SAE	text
338	category_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Category of the SAE:	checkbox 1, category_sae___1, Death 2, category_sae___2, Life threatening 3, category_sae___3, Hospitalization 4, category_sae___4, Disability/ incapacity 5, category_sae___5, Cangenital anomaly/ birth defect 6, category_sae___6, Required intervention to prevent permanent impairment 7, category_sae___7, Other (specify)
339	date_death Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Date of death:	text (date_dmy)

	or [category_sae(1)] = '1'		
340	other_spec Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1' or [category_sae(7)] = '1'	If other, specify:	text
341	relat_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Relationship of event to intervention:	radio 1 Unrelated (clearly not related to the intervention) 2 Possible (may be related to intervention) 3 Definitive (clearly related to intervention)
342	sae_int Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Was the study intervention discontinued due to event?	yesno 1 Yes 0 No
343	manage_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	What medications were used to treat the SAE?	text
344	sae_treat Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	What other steps were taken to treat the SAE?	radio 1 Withdrawal of the study 2 Hospitalisation 3 Code had to be broken
345	relav_data_sae Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	List any relevant tests, laboratory data, and history, including pre-existing medical conditions:	text
346	date_notif	Notify the study manager immediately!	text (datetime_seconds_dmy),

	Show the field ONLY if: [ae_serious] = '1' or [ae_serious2] = '1' or [ae_serious3] = '1'	Date and time of notification:	Required
347	adverse_events_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: Follow up termination or completion (follow_up_termination_or_completion)			
348	term_date	Completion or termination date:	text (date_dmy)
349	term_med	Did the participant complete the full course of medication?	yesno 1 Yes 0 No
350	term_add_pred	Did the participant receive additional Prednisolone?	yesno 1 Yes 0 No
351	term_add_pred1 Show the field ONLY if: [term_add_pred] = '1'	If so, how many weeks (in total) did the participant receive Prednisolone?	text
352	term_48w	Section Header: *Did the participant report for all examinations after treatment?* Week 48	radio (Matrix) 1 YES 2 NO
353	term_52w	Week 52	radio (Matrix) 1 YES 2 NO
354	term_56w	Week 56	radio (Matrix) 1 YES 2 NO
355	term_60w	Week 60	radio (Matrix) 1 YES 2 NO
356	term_reason	If the patient did not complete the medication or follow-up, select the reason:	radio [ ]

			1 Subject did not return for clinic visit 2 Protocol violation (specify) 3 Subject refused study procedure(s) 4 Voluntary withdrawal 5 Illness (specify) 6 Death (specify date) 7 Severe side effects 8 Pregnancy 9 Other reason (specify)
357	term_other Show the field ONLY if: [term_reason] = '9'	If other, specify:	text
358	term_reason1	Enter details of reason(s) for not completing follow-up	text
359	term_add_com	Additional Comments:	text
360	term_report	I have reviewed the contents of this case report form and found it to be complete and accurate.	file (signature)
361	follow_up_termination_or_completion_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: DLQI (dlqi)			
362	dateassessed_v2	Date assessed	text (date_dmy), Required
363	dlqi01	Section Header: *DLQI - Dermatological Life Quality Index* DLQI01.Over the last week, how itchy, sore, painful or stinging has your skin been?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all
364	dlqi02	DLQI02. Over the last week, how embarrased or self conscious have you been because of your skin?	radio, Required 3 Very much 2 A lot

			1 A little 0 Not at all
365	dlqi03	DLQI03. Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
366	dlqi04	DLQI04. Over the last week, how much has your skin influenced the clothes you wear?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
367	dlqi05	DLQI05. Over the last week, how much has your skin affecetd any social or leisure activities?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
368	dlqi06	DLQI06. Over the last week, how much has your skin made it difficult for you to do any sport?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
369	dlqi07	DLQI07. Over the last week, has your skin prevented you from working or studying?	radio, Required 3 Yes, unable to work or study 2 Able to work or study but skin problem has been "a lot". 1 Able to work or study but skin problem has been "a little" problem. 0 Skin not prevented working or studying
370	dlqi08	DLQI08. Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?	radio, Required 3 Very much 2 A lot 1 A little

			0 Not at all or not relevant
371	dlqi09	DLQI09. Over the last week, how much has your skin caused any sexual difficulties?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
372	dlqi10	DLQI10. Over the last week, how much of a problem has the treatment of your skin been, for example, by makng your home messy, or by taking up time?	radio, Required 3 Very much 2 A lot 1 A little 0 Not at all or not relevant
373	dlqiscore	DLQI Score	calc Calculation: ([dlqi01]+[dlqi02]+[dlqi03]+[dlqi04]+[dlqi05]+[dlqi06]+[dlqi07]+[dlqi08]+[dlqi09]+[dlqi10])
374	dlqi_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: SF-36 (sf36)			
375	dateassessed	Date assessed	text (date_dmy), Required
376	sf01	Section Header: *SF36 - Health status* 1. In general would you say your health is ...	radio, Required 1 Excellent 2 Very good 3 Good 4 Fair 5 Poor
377	sf02	2. Compared to one year ago is your health ..	radio, Required 1 Much better now than one year ago 2 Somewhat better now than one year ago 3 About the same 4 Somewhat worse now than one year ago

			5 Much worse now than one year ago
378	sf03	Section Header: *SF36 - Health status and limitation to daily activities* 3a. Does your health now limit vigorous activities such as running, lifting heavy objects, participating in strenuous sports limit your typical daily activities?	radio, Required, Identifier 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
379	sf04	3b. Does your health now limit moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf limit your typical daily activities?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
380	sf05	3c. Does your health now limit lifting or carrying groceries?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
381	sf06	3d. Does your health now limit climbing several sets of stairs?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
382	sf07	3e. Does your health now limit climbing one flight of stairs?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
383	sf08	3f. Does your health now limit bending, kneeling or stooping?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
384	sf09	3g. Does your health limit you in walking more than one mile?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
385	sf10	3h. Does your health limit you in walking several blocks?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all

386	sf11	3i. Does your health limit you in walking one block?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
387	sf12	3j. Does your health limit you in bathing or dressing yourself?	radio, Required 1 Yes - limited a lot 2 Yes - limited a little 3 No - not limited at all
388	sf13	Section Header: *SF36 - Problems with daily activities in last 4 weeks* 4a. During the last 4 weeks have you cut down the time you spent on work or other activities?	dropdown, Required 1 Yes 2 No
389	sf14	4b. During the last 4 weeks have you accomplished less than you would like?	dropdown, Required 1 Yes 2 No
390	sf15	4c. During the last 4 weeks were you limited in the kind of work or other activities you could do?	dropdown, Required 1 Yes 2 No
391	sf16	4d. During the last 4 weeks have you had difficulty in performing the work or other activities you normally do - did it take extra effort?	dropdown, Required, Identifier 1 Yes 2 No
392	sf17	Section Header: *SF36 - Problems with daily activities in last 4 weeks that were the result of emotional problems* 5a. During the past 4 weeks have you had PROBLEMS with your work or daily activities as a result of any emotional problem?	dropdown, Required 1 Yes 2 No
393	sf18	5b. During the past 4 weeks have you ACCOMPLISHED LESS with your work or daily activities as a result of any emotional problem?	dropdown, Required 1 Yes 2 No
394	sf19	5c. During the past 4 weeks have you not worked as CAREFULLY as usual as a result of any emotional problem?	dropdown, Required 1 Yes 2 No
395	sf20	Section Header: *SF36 - During last 4 weeks to what extent have health or emotional problems interfered*	dropdown, Required

		with normal social activities with family or friends? 6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?	1 Not at all 2 Slighlty 3 Moderately 4 Quite a bit 5 Extremely
396	sf21	Section Header: *SF36 - Experience and impact of pain* 7. How much bodily pain have you had in the past 4 weeks?	dropdown, Required 1 None 2 Very mild 3 Mild 4 Moderate 5 Severe 6 Very severe
397	sf22	8. During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework?	dropdown, Required 1 Not at all 2 Slighlty 3 Moderately 4 Quite a bit 5 Extremely
398	sf23	Section Header: *SF36 - Psychological status in last 4 weeks* 9a. How much of the time during the past 4 weeks did you feel full of pep?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
399	sf24	9b. How much of the time during the past 4 weeks have you been a very nervous person?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
400	sf25	9c. How much of the time during the past 4 weeks have you felt so down in the dumps	dropdown, Required 1 All of the time

		that nothing could cheer you up?	2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
401	sf26	9d. How much of the time during the past 4 weeks have you felt cam and peaceful?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
402	sf27	9e. How much of the time during the past 4 weeks did you have a lot of energy?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
403	sf28	9f. How much of the time during the past 4 weeks have you felt downhearted and blue?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
404	sf29	9g. How much of the time during the past 4 weeks did you feel worn out?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

405	sf30	9h. How much of the time during the past 4 weeks have you been a happy person?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
406	sf31	9i. How much of the time during the past 4 weeks did you feel tired?	dropdown, Required 1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time
407	sf32	10. How much of the time in the past 4 weeks has your physical health or emotional problems interfered with your social activities?	dropdown, Required 1 All of the time 2 Most of the time 3 Some of the time 4 A little of the time 5 None of the time
408	sf33	Section Header: *SF36 - Assessment of own health status* 11a. Do you seem to get sick a little easier than other people?	dropdown, Required 1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitlely false
409	sf34	11b. I am as healthy as anyone I know	dropdown, Required 1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitlely false
410	sf35	11c. I expect my health to get worse	dropdown, Required 1 Definitely true

			2, Mostly true 3, Don't know 4, Mostly false 5, Definitlely false
411	sf36	11d. My health is excellent	dropdown, Required 1, Definitely true 2, Mostly true 3, Don't know 4, Mostly false 5, Definitlely false
412	rsf01	sf01 processsed	calc, Required Calculation: (5-[sf01])*25
413	rsf02	sf02 processsed	calc, Required Calculation: (5-[sf02])*25
414	rsf20	sf20 processsed	calc, Required Calculation: (5-[sf20])*25
415	rsf22	sf22 processsed	calc, Required Calculation: (5-[sf22])*25
416	rsf34	sf34 processsed	calc, Required Calculation: (5-[sf34])*25
417	rsf36	sf36 processsed	calc, Required Calculation: (5-[sf36])*25
418	rsf03	sf03 processsed	calc, Required Calculation: ([sf03]-1)*50
419	rsf04	sf04 processsed	calc, Required Calculation: ([sf04]-1)*50
420	rsf05	sf05 processsed	calc, Required Calculation: ([sf05]-1)*50
421	rsf06	sf06 processsed	calc, Required Calculation: ([sf06]-1)*50
422	rsf07	sf07 processsed	calc, Required Calculation: ([sf07]-1)*50
423	rsf08	sf08 processsed	calc, Required Calculation: ([sf08]-1)*50
424	rsf09	sf09 processsed	calc, Required Calculation: ([sf09]-1)*50
425	rsf10	sf10 processsed	calc, Required Calculation: ([sf10]-1)*50

426	rsf11	sf11 processsed	calc, Required Calculation: ([sf11]-1)*50
427	rsf12	sf12 processsed	calc, Required Calculation: ([sf12]-1)*50
428	rsf13	sf13 processsed	calc, Required Calculation: ([sf13]-1)*100
429	rsf14	sf14 processsed	calc, Required Calculation: ([sf14]-1)*100
430	rsf15	sf15 processsed	calc, Required Calculation: ([sf15]-1)*100
431	rsf16	sf16 processsed	calc, Required Calculation: ([sf16]-1)*100
432	rsf17	sf17 processsed	calc, Required Calculation: ([sf17]-1)*100
433	rsf18	sf18 processsed	calc, Required Calculation: ([sf18]-1)*100
434	rsf19	sf19 processsed	calc, Required Calculation: ([sf19]-1)*100
435	rsf21	sf21 processsed	calc, Required Calculation: (6-[sf21])*20
436	rsf23	sf23 processsed	calc, Required Calculation: (6-[sf23])*20
437	rsf26	sf26 processsed	calc, Required Calculation: (6-[sf26])*20
438	rsf27	sf27 processsed	calc, Required Calculation: (6-[sf27])*20
439	rsf30	sf30 processsed	calc, Required Calculation: (6-[sf30])*20
440	rsf24	sf24 processsed	calc, Required Calculation: ([sf24]-1)*20
441	rsf25	sf25 processsed	calc, Required Calculation: ([sf25]-1)*20
442	rsf28	sf28 processsed	calc, Required Calculation: ([sf28]-1)*20
443	rsf29	sf29 processsed	calc, Required Calculation: ([sf29]-1)*20
444	rsf31	sf31 processsed	calc, Required Calculation: ([sf31]-1)*20
445	rsf32	sf32 processsed	calc, Required Calculation: ([sf32]-1)*25

446	rsf33	sf33 processsed	calc, Required Calculation: ([sf33]-1)*25
447	rsf35	sf35 processsed	calc, Required Calculation: ([sf35]-1)*25
448	physfunc	Physical Functionng (PF)	calc Calculation: ([rsf03]+[rsf04]+[rsf05]+[rsf06]+[rsf07]+[rsf08]+[rsf09]+[rsf10]+[rsf11]+[rsf12])/10
449	rolelimithealth	Limited by physical health (RP)	calc Calculation: ([rsf13]+[rsf14]+[rsf15]+[rsf16])/4
450	rolelimitemotion	Limited by emotional problems (RE)	calc Calculation: ([rsf17]+[rsf18]+[rsf19])/3
451	energyfatigue	Vitality (VT)	calc Calculation: ([rsf23]+[rsf27]+[rsf29]+[rsf31])/4
452	emotionalwellbeing	Emotional well-being (MH)	calc Calculation: ([rsf24]+[rsf25]+[rsf26]+[rsf28]+[rsf30])/5
453	socialfunctioning	Social functioning (SF)	calc Calculation: ([rsf20]+[rsf32])/2
454	pain	Bodily pain (BP)	calc Calculation: ([rsf21]+[rsf22])/2
455	generalhealth	General Health (GH)	calc Calculation: ([rsf01]+[rsf33]+[rsf34]+[rsf35]+[rsf36])/5
456	sf36_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
Instrument: EESS (eess)			
457	dateassessed1	Date assessed	text (date_dmy), Required
458	vas_pain_scale	Section Header: *ENLIST ENL Severity Scale* VAS Pain scale	slider (number, Min: 0, Max: 100) Slider labels: No pain, , Greatest pain Custom alignment: RH
459	eess1	EESS-01Pain score (calculated)	calc Calculation: if([vas_pain_scale]=0, 0, if([vas_pain_scale]< 40,1, if([vas_pain_scale]< 70,2,3)))

460	fever	Current temperature *Enter temperature, degrees centigrade)*	text
461	fever7	Any fever more than 37.5C in last week? *Enter temperature, degrees centigrade)*	radio, Required 0, No 1, Yes
462	eess2	EESS-02 Temperature Score	calc Calculation: if([fever]<=37.5 and [fever7]=0, 0, if([fever]<=37.5 and [fever7]=1, 1, if([fever]>37.5 and [fever]<=38.5, 2,3)))
463	lesioncount	Number of lesions	radio, Required 0, No lesions 1, 1-10 lesions 2, 11-20 lesions 3, 21 or more lesions
464	eess3	EESS-03 Lesion severity	calc, Required Calculation: if([lesioncount]=0,0, if([lesioncount]=1,1, if([lesioncount]=2,2,3)))
465	inflammationseverity	Inflammation severity	radio, Required 0, None tender 1, Redness 2, Painful 3, Complex
466	eess4	EESS-04 Inflammation severity	calc, Required Calculation: if([inflammationseverity]=0,0, if([inflammationseverity]=1,1, if([inflammationseverity]=2,2,3)))
467	lesionextent	Lesion extent	radio, Required 0, None 1, 1-2 regions 2, 3-4 regions 3, 5-7 regions
468	eess5	EESS-05 Lesion extent	calc, Required Calculation: if([lesionextent]=0,0, if([lesionextent]=1,1, if([lesionextent]=2,2,3)))
469	oedemaseverity	Oedema severity	radio, Required

			0 None of face, hands or feet 1 Present at one site 2 Present at two sites 3 Present at three sites
470	eess6	EESS-06 Oedema severity	calc, Required Calculation: if([oedemaseverity]=0,0, if([oedemaseverity]=1,1, if([oedemaseverity]=2,2,3)))
471	bonepainseverity	Bone pain severity	radio, Required 0 None 1 Yes - does not limit activity 2 Yes - sleep or activity disturbed 3 Yes - incapacitating
472	eess7	EESS-07 Bone Pain severity	calc, Required Calculation: if([bonepainseverity]=0,0, if([bonepainseverity]=1,1, if([bonepainseverity]=2,2,3)))
473	jointpainseverity	Joint pain severity	radio, Required 0 None 1 Yes - but does not limit activity 2 Yes - sleep or activity disturbed 3 Yes - incapacitating
474	eess8	EESS-08 Joint pain severity	calc, Required Calculation: if([jointpainseverity]=0,0, if([jointpainseverity]=1,1, if([jointpainseverity]=2,2,3)))
475	lymphadenopathyseverity	Lymphadenopathy severity	radio, Required 0 None 1 Yes - enlarged 2 Yes - pain or tenderness on one group 3 Yes - pain or tenderness in two or more groups
476	eess9	EESS-09 Lymphadenopathy severity	calc, Required Calculation: if([lymphadenopathyseverity]=0,0, if([lymphadenopathyseverity]=1,1, if([lymphadenopathyseverity]=2,2,3)))

477	nervetendernessseverity	Nerve tenderness severity	radio, Required 0 Not tender 1 Absent if attention distracted 2 Present even if attention distracted 3 Patient withdraws limb on examination
478	eess10	EESS-10 Nerve tenderness	calc, Required Calculation: if([nervetendernessseverity]=0,0, if([nervetendernessseverity]=1,1, if([nervetendernessseverity]=2,2,3)))
479	eesstotal	EESS SeverityScore	calc, Required Calculation: [eess1]+[eess2]+ [eess3]+[eess4]+[eess5]+[eess6]+ [eess7]+[eess8]+[eess9]+[eess10]
480	eess_complete	Section Header: *Form Status* Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete