Patient Record Form

For

Ciclosporin in the management of Leprosy Reactions
Based at ALERT Hospital

PHYSICIAN TO CHECK CORRECT ALLOCATION OF STUDY NUMBER

Please tick relevant study

Study 1A: new Type 1 Reactions in Leprosy ☐

Study 1B: steroid resistant Type 1 Reactions in Leprosy ☐

Study 2A: new Erythema Nodosum Leprosum ☐

Study 2B: chronic or recurrent Erythema Nodosum Leprosum ☐

ASSESSMENT RECORD

Start Date: (dd/mm/yyyy) __ __ / __ __ / __ __ __ __

	Date due dd/mm/yyyy	Date done dd/mm/yyyy	Extra notes
Base line			
Week 2			
Week 4			
Week 6			
Week 8			
Week 12			
Week 16			
Week 20			
Week 24			
Week 28			
Week 32			
Unscheduled review			
Unscheduled review			
Adverse Events			
Study Termination			

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

PHYSICIAN WORKSHEET AT REGISTRATION **Baseline – Day 0**

Leprosy History

<table>
<tr><td>Study Patient Number:
|__|__|__|__||__|__|__||__|__|__|</td><td colspan="2">Hospital File number: _____
Leprosy Registration number: _____</td></tr>
<tr><td>Assessed by:
Name</td><td colspan="2">Today's Date: _ _/ _ _ / _ _ _ _
dd/mm/yyyy</td></tr>
<tr><td>Patient Initial: |__|__|__|</td><td colspan="2">Home village / town</td></tr>
<tr><td>Sex: M |__| F |__|</td><td colspan="2">Age (Yrs): |__|__|</td></tr>
<tr><td rowspan="2">Date of leprosy diagnosis:
_ _ / _ _/ _ _ _ _</td><td colspan="2">Classification (Ridley- Jopling):</td></tr>
<tr><td>Clinically
1. TT |__|
2. BT |__|
3. BB |__|
4. BL |__|
5. LL |__|</td><td>Histology
1. TT |__|
2. BT |__|
3. BB |__|
4. BL |__|
5. LL |__|</td></tr>
<tr><td>Duration of leprosy (number of months since first sign)
|__|__|__|</td><td colspan="2">Classification of leprosy (WHO):
1. PB |__|
2. MB |__|</td></tr>
<tr><td>Bacterial Index at time of diagnosis:
|__|__|__|__|__|__|
Date: _ _ / _ _/ _ _ _ _</td><td colspan="2">Most recent Bacterial Index:
|__|__|__|__|__|__|
Date: _ _ / _ _/ _ _ _ _</td></tr>
<tr><td>MDT Start Date: _ _ / _ _/ _ _ _ _

MDT Stop Date: _ _ / _ _/ _ _ _ _
(RFT)</td><td colspan="2">Previous Treatment Default?
1. Yes |__|
2. No |__|</td></tr>
</table>

<table>
<tr><td>Is this a presentation of a new Reaction?
1. Yes |__|
2. No |__|
What type of reaction is it: T1R
(circle) ENL</td><td>Date of onset of Leprosy Reaction
_ _ / _ _/ _ _ _ _

Duration of Reaction symptoms on this occasion (in days /weeks):
_____</td></tr>
<tr><td>Previous history of reactions:
1. Yes |__|
2. No |__|
Details (how many?):
_____
_____</td><td>Time since last reaction (in months) if first reaction then record X

_____</td></tr>
</table>

General Medical History

	1. Yes	2.No
Any major medical diagnoses?	☐	☐

If yes, specify:

1. Diabetes |__|
2. Hypertension |__|
3. Tuberculosis |__|
4. Other |__|

_____

Other Medical History

Diagnosis	Date of onset	Date of resolution *
1.	/ /	/ /
2.	/ /	/ /
3.	/ /	/ /

Known allergies: _____

_____

Current medications (other than MDT and including analgesia)

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

PREDNISOLONE HISTORY:

If the patient has taken prednisolone in the past please describe in detail dosage and period:

_____ _____

_____ _____

_____ _____

_____ _____

Baseline symptoms questionnaire.

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

	1. Yes	2.No
Consider TB screening (if long term cough, night sweats, weight loss- refer for CXR and sputum AFBs)	☐	☐

Describe events: _____
_____
_____
_____

Nerve function History

Ask the patient if s/he has experienced any of the following symptoms in the last 6 months:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions in the last 6 months:

When did they notice the first patch?				
When did the skin patches become inflammed?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

EXAMINATION AT REGISTRATION - PHYSICIAN

Baseline Physical Examination – Month 0

Date: (dd/mm/yyyy) __ __ / __ __ / __ __ __ __

I. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

II. Weight: |__|__|__|.|__|kg

III. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

IV. Leprosy Examination

i. Nerves - signs and symptoms of neuritis (new = less than 6 months)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

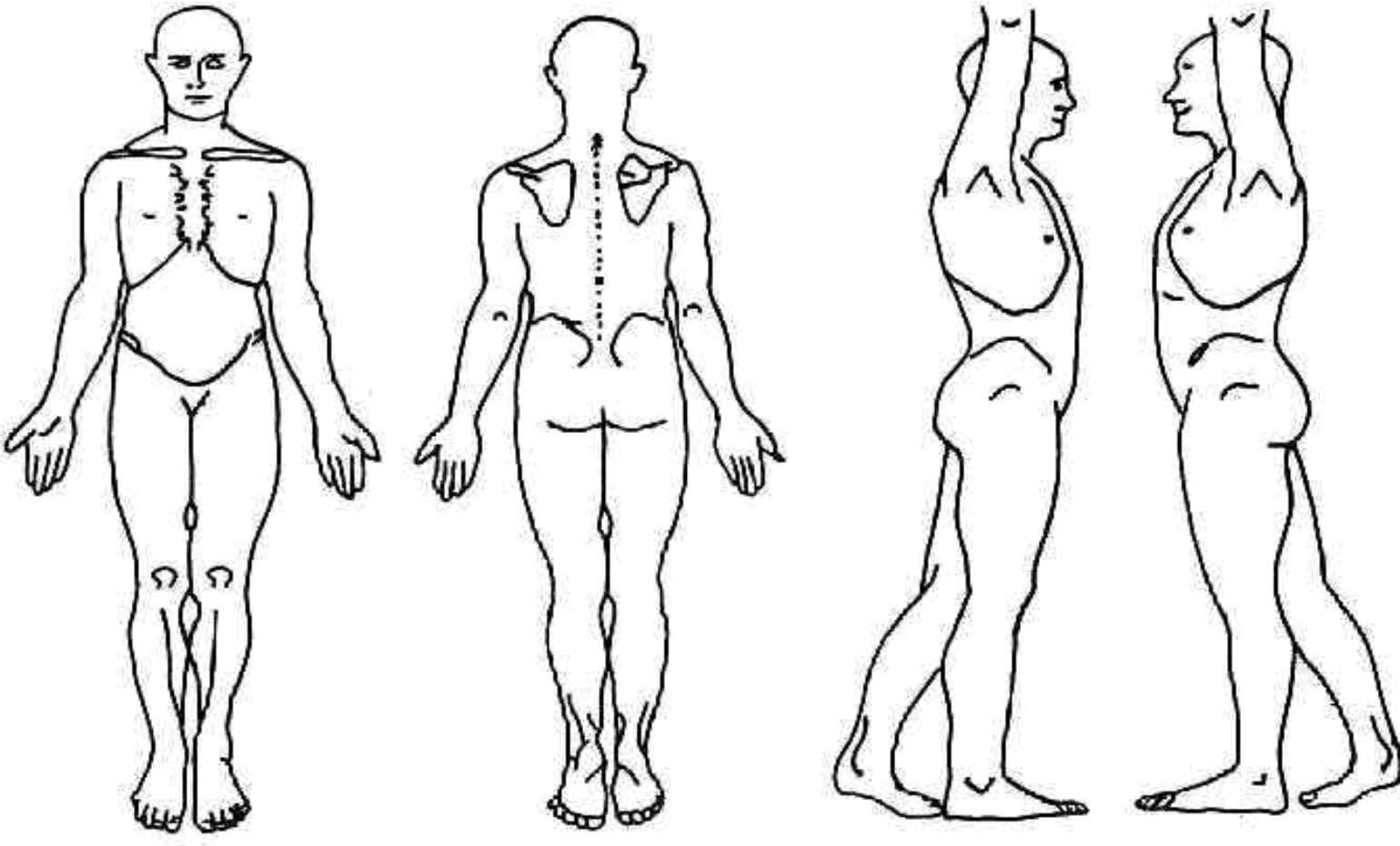
* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

EXAMINATION AT REGISTRATION **Baseline – Day 0**

ii. Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM **Baseline – Day 0**

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation	Withdraws	
Bone tenderness (shin):	None	Tender on palpation	Withdraws	
Oedema (ankle, face, hands):	None	Present	Gross	
Joint swelling:	None	Present	Affects function Which: _____	
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C	level: _____	
Proteinuria (by dipstick):	Negative	Positive	level: _____	
Red eyes:	Yes	No	Ophthalmology diagnosis:_____	

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……

……

……

……

INVESTIGATIONS – Physician to Complete **Baseline – Day 0**

Laboratory tests **(record results)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

Skin Smear and Biopsy

1. Confirm skin smear already done at diagnosis ☐
2. Skin Biopsy taken from a typical skin lesion for Ridley- Jopling classification and histology.

AHRI number -_____

Date done (dd/mm/yyyy): _ _ / _ _ /_ _ _ _ Site of biopsy: _____

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____

_____

_____

<u>COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY</u>

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

1. **mark off visit on page 2: Assessment Record**
2. **Write in date of next planned visit on page 2: Assessment Record**
3. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms <u>since last review</u>:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms <u>since the last assessment</u>:

Patient's report of <u>new</u> symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions <u>since last assessment</u>

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

I. Weight: |__|__|__|.|__|**kg**

II. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

III. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

IV. Leprosy Examination

i. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

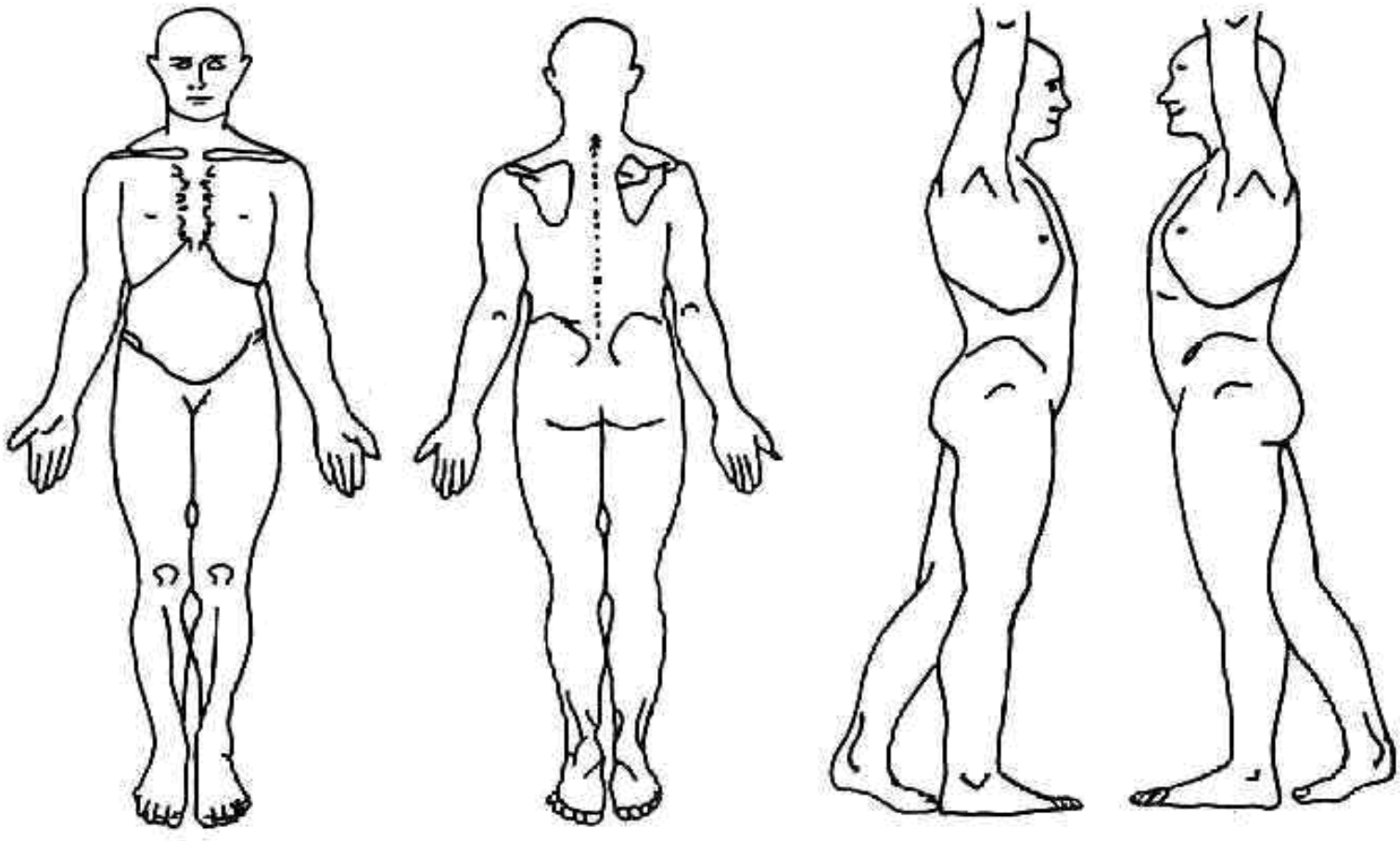
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

4. **mark off visit on page 2: Assessment Record**
5. **Write in date of next planned visit on page 2: Assessment Record**
6. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms <u>since last review</u>:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms <u>since the last assessment</u>:

Patient's report of <u>new</u> symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions <u>since last assessment</u>

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

V. Weight: |__|__|__|.|__|**kg**

VI. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

VII. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

VIII. Leprosy Examination

ii. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

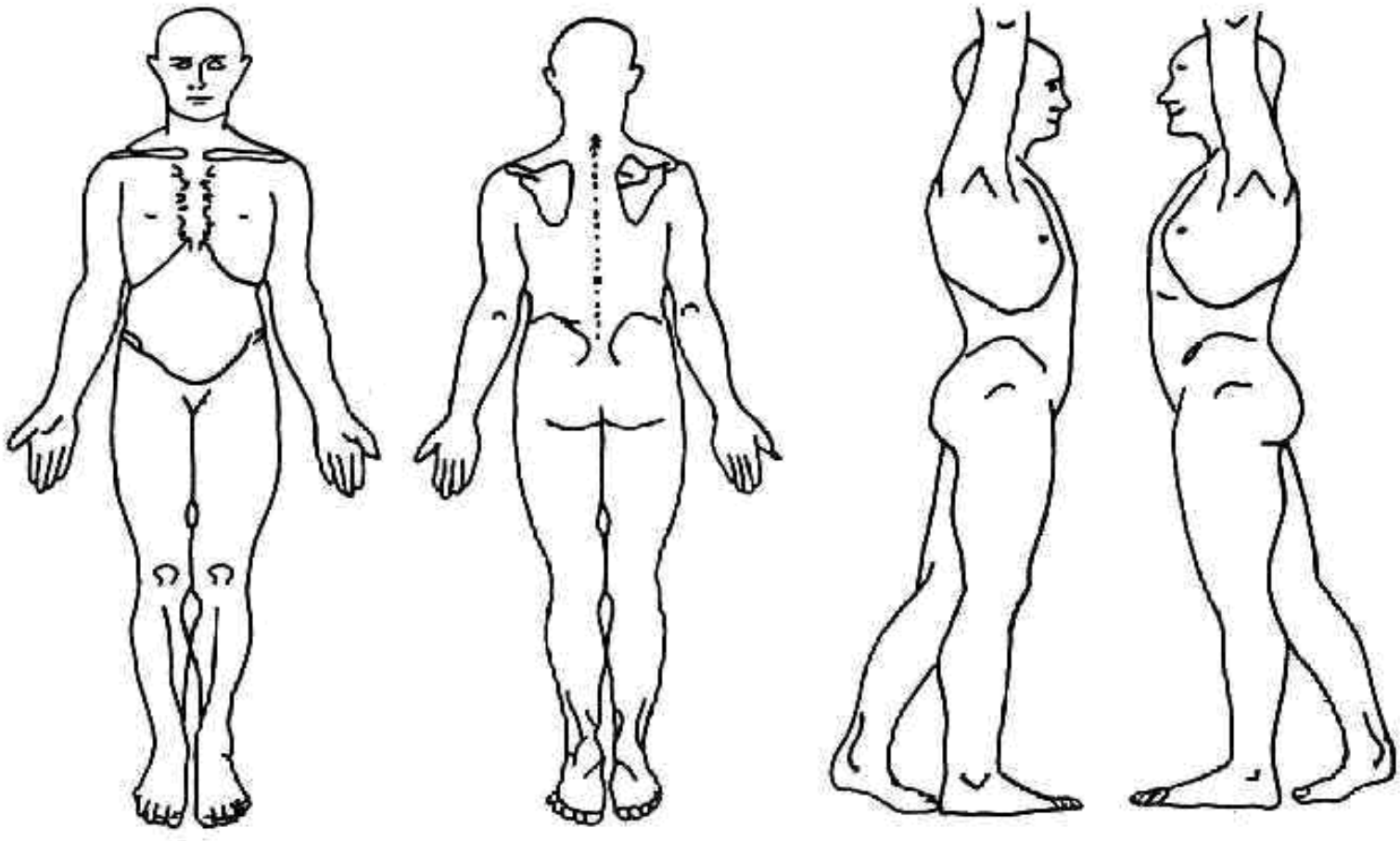
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

7. **mark off visit on page 2: Assessment Record**
8. **Write in date of next planned visit on page 2: Assessment Record**
9. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

IX. Weight: |__|__|__|.|__|**kg**

X. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XI. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XII. Leprosy Examination

iii. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

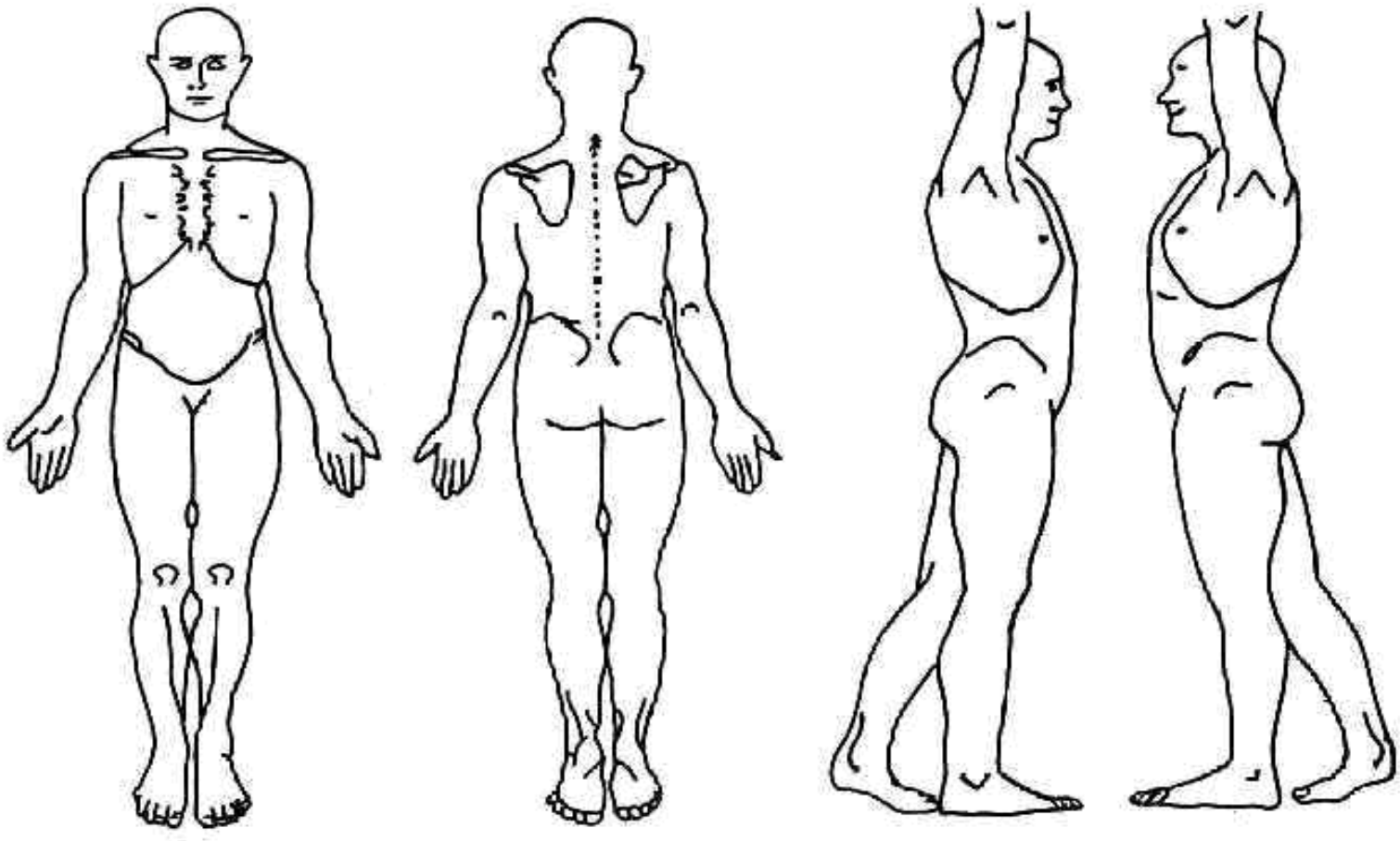
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation	Withdraws	
Bone tenderness (shin):	None	Tender on palpation	Withdraws	
Oedema (ankle, face, hands):	None	Present	Gross	
Joint swelling:	None	Present	Affects function Which: _____	
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C	level: _____	
Proteinuria (by dipstick):	Negative	Positive	level: _____	
Red eyes:	Yes	No	Ophthalmology diagnosis:_____	

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

10. **mark off visit on page 2: Assessment Record**
11. **Write in date of next planned visit on page 2: Assessment Record**
12. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms <u>since last review</u>:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms <u>since the last assessment</u>:

Patient's report of <u>new</u> symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions <u>since last assessment</u>

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XIII. Weight: |__|__|__|.|__|**kg**

XIV. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XV. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XVI. Leprosy Examination

iv. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

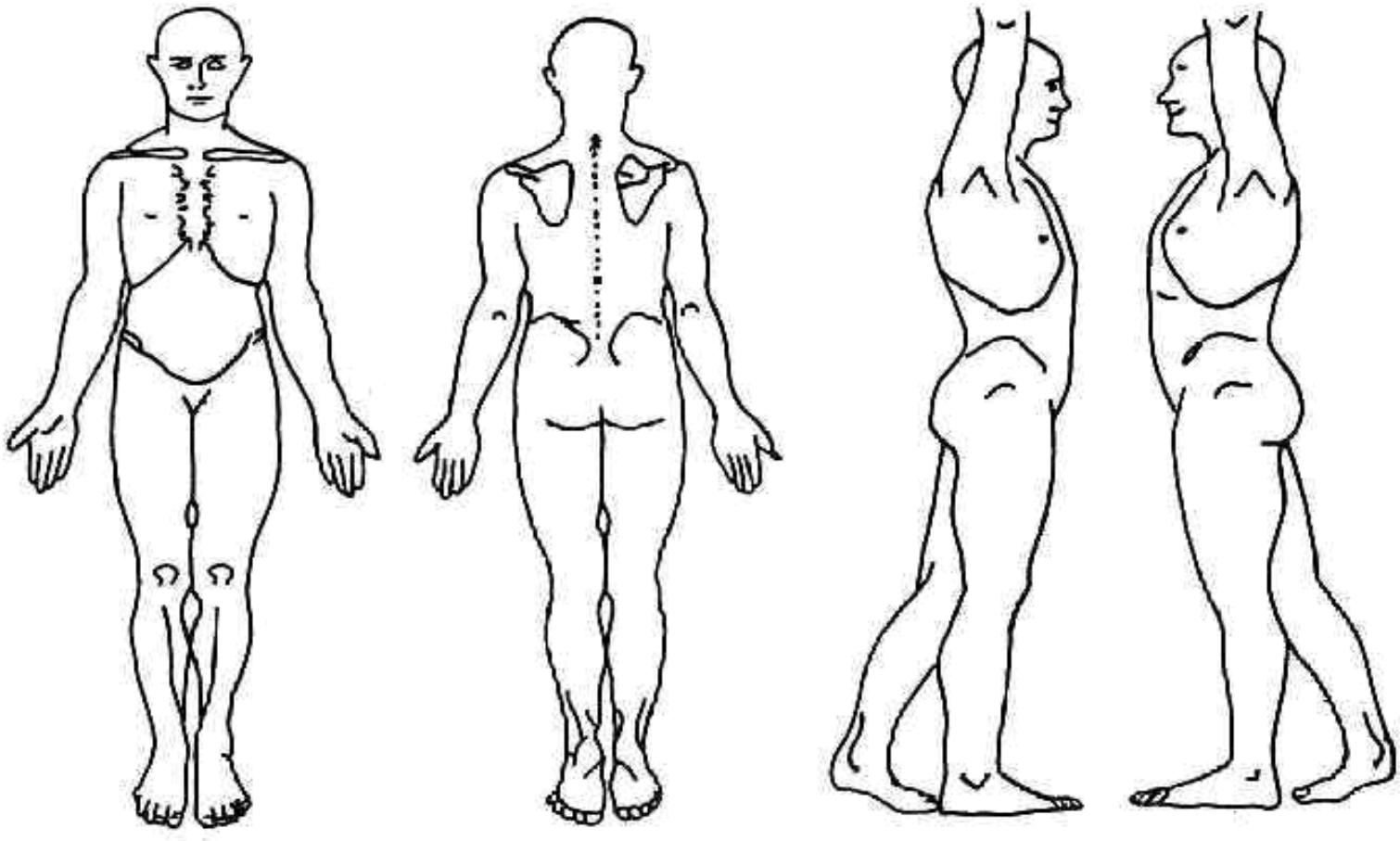
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

13. **mark off visit on page 2: Assessment Record**
14. **Write in date of next planned visit on page 2: Assessment Record**
15. **Tell Investigator about completed patient review in order to transfer data to CRF**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms <u>since last review</u>:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms <u>since the last assessment</u>:

Patient's report of <u>new</u> symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions <u>since last assessment</u>

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XVII. Weight: |__|__|__|.|__|**kg**

XVIII. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XIX. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XX. Leprosy Examination

v. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

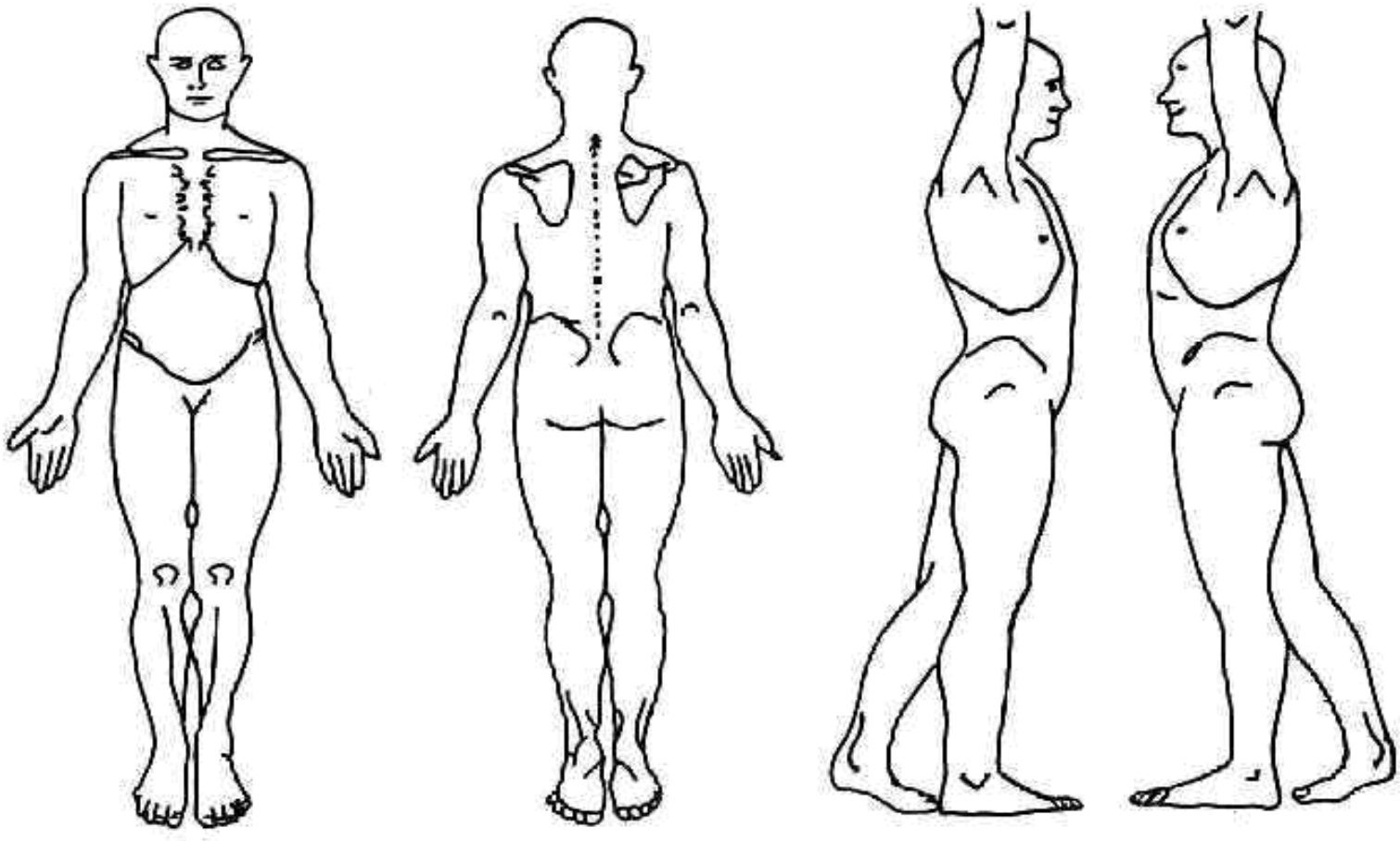
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

16. **mark off visit on page 2: Assessment Record**
17. **Write in date of next planned visit on page 2: Assessment Record**
18. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XXI. Weight: |__|__|__|.|__|**kg**

XXII. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XXIII. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XXIV. Leprosy Examination

vi. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

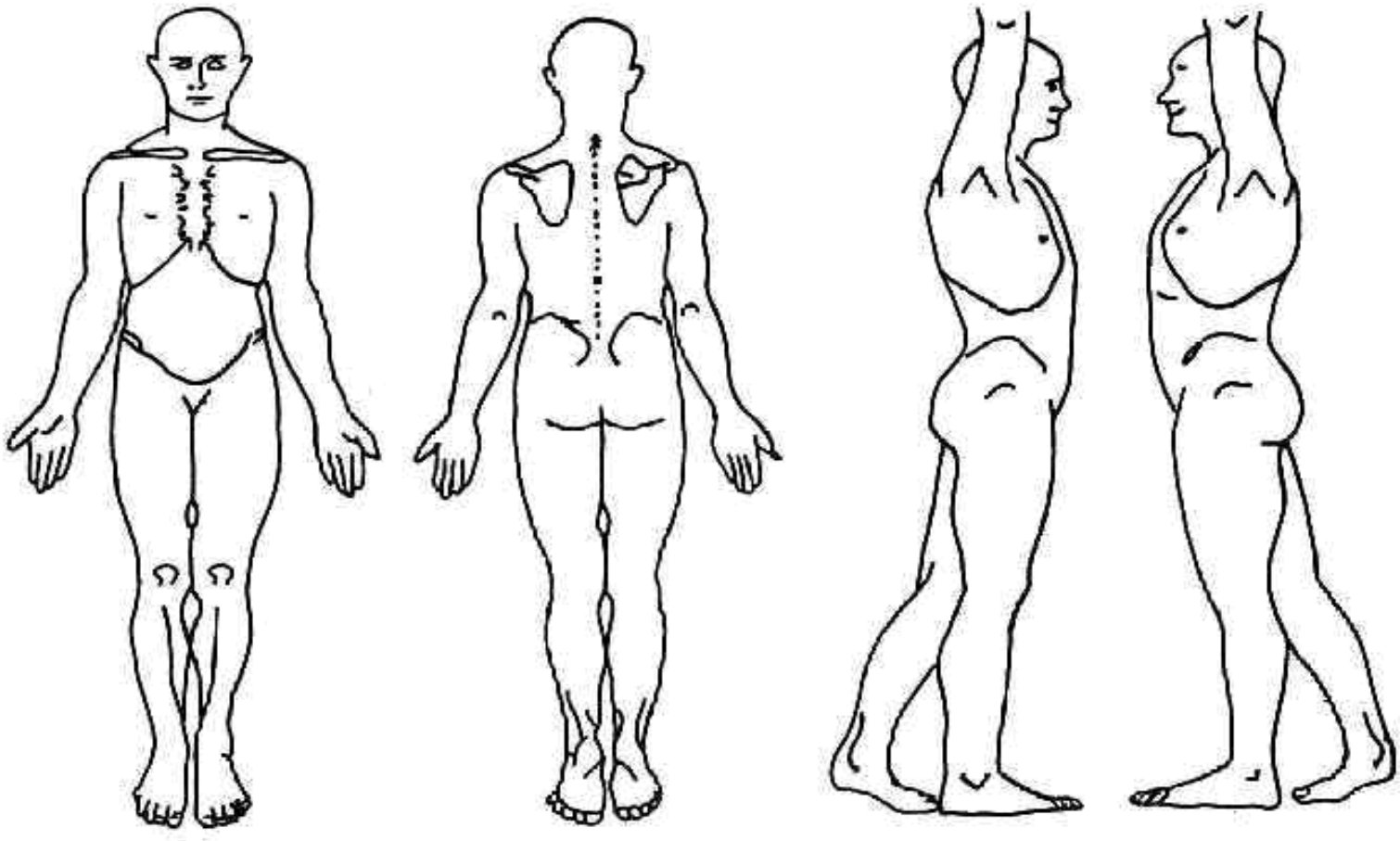
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

19. **mark off visit on page 2: Assessment Record**
20. **Write in date of next planned visit on page 2: Assessment Record**
21. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XXV. Weight: |__|__|__|.|__|**kg**

XXVI. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XXVII. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XXVIII. Leprosy Examination

vii. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

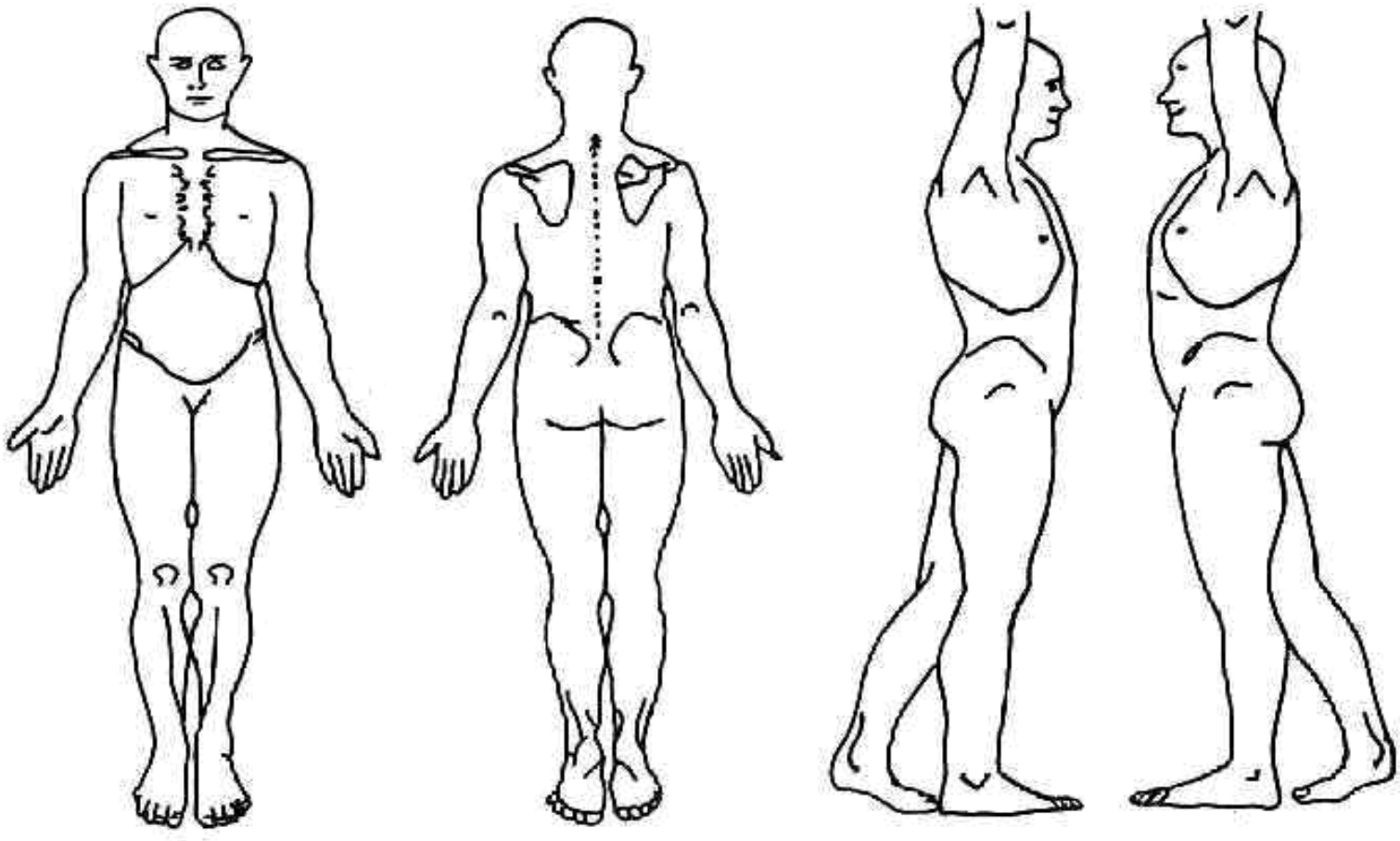
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation	Withdraws	
Bone tenderness (shin):	None	Tender on palpation	Withdraws	
Oedema (ankle, face, hands):	None	Present	Gross	
Joint swelling:	None	Present	Affects function Which: _____	
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C	level: _____	
Proteinuria (by dipstick):	Negative	Positive	level: _____	
Red eyes:	Yes	No	Ophthalmology diagnosis:_____	

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

22. **mark off visit on page 2: Assessment Record**
23. **Write in date of next planned visit on page 2: Assessment Record**
24. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XXIX. Weight: |__|__|__|.|__|**kg**

XXX. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XXXI. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XXXII. Leprosy Examination

viii. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

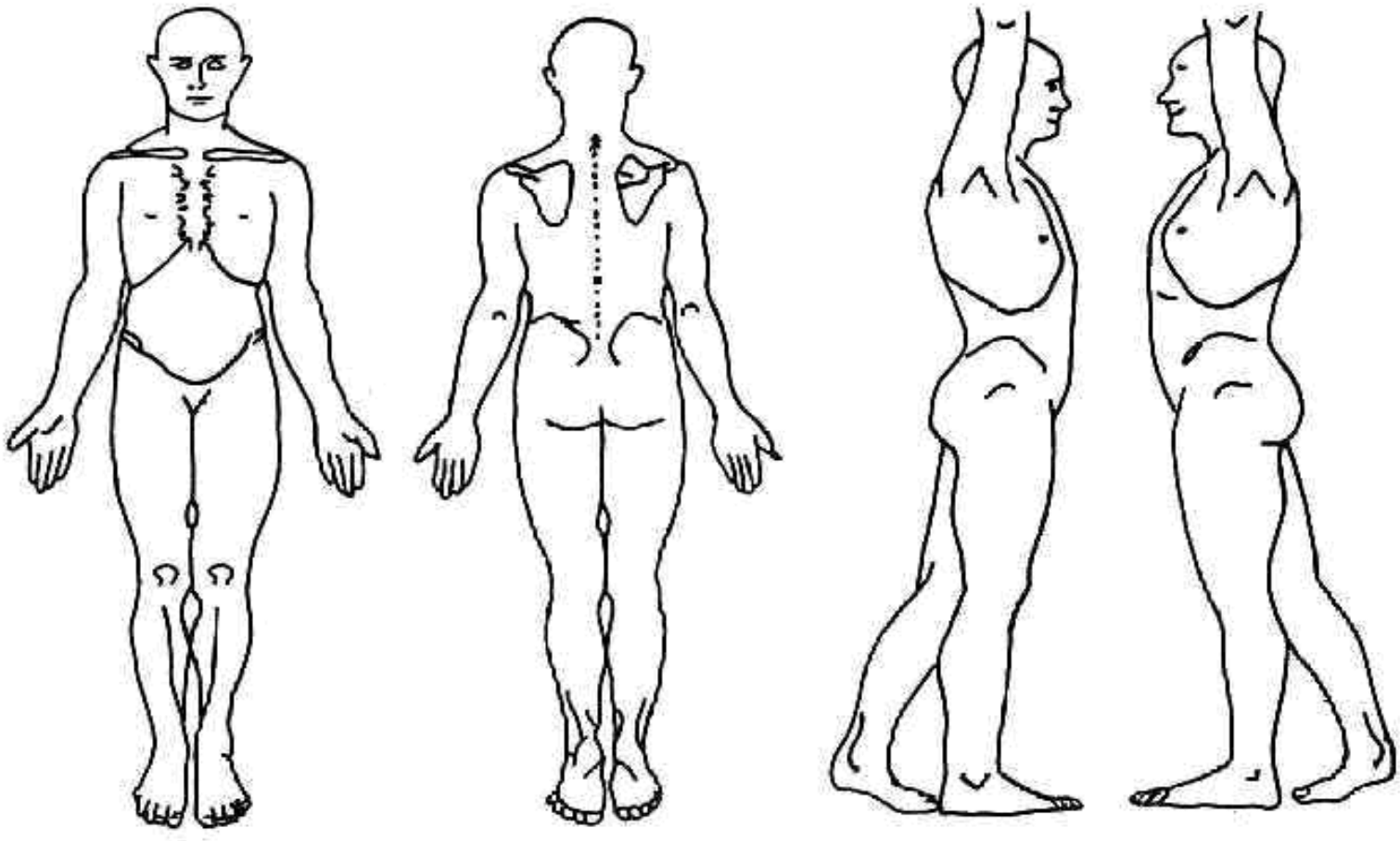
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

25. **mark off visit on page 2: Assessment Record**
26. **Write in date of next planned visit on page 2: Assessment Record**
27. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XXXIII. Weight: |__|__|__|.|__|**kg**

XXXIV. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XXXV. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XXXVI. Leprosy Examination

ix. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

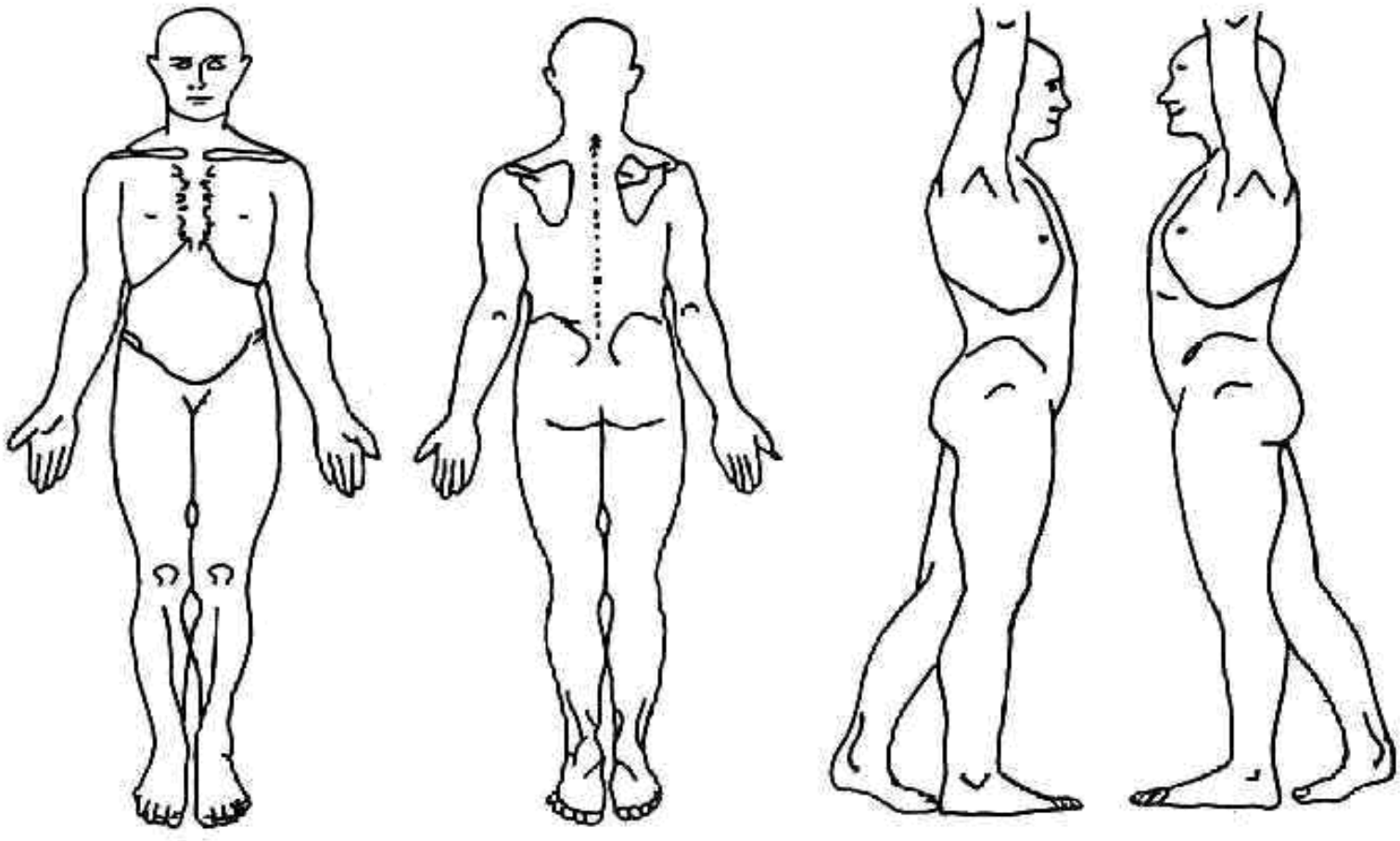
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation	Withdraws	
Bone tenderness (shin):	None	Tender on palpation	Withdraws	
Oedema (ankle, face, hands):	None	Present	Gross	
Joint swelling:	None	Present	Affects function Which: _____	
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C	level: _____	
Proteinuria (by dipstick):	Negative	Positive	level: _____	
Red eyes:	Yes	No	Ophthalmology diagnosis:_____	

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

28. **mark off visit on page 2: Assessment Record**
29. **Write in date of next planned visit on page 2: Assessment Record**
30. **Tell Investigator about completed patient review in order to transfer data to CRF**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms <u>since last review</u>:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms <u>since the last assessment</u>:

Patient's report of <u>new</u> symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions <u>since last assessment</u>

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XXXVII. Weight: |__|__|__|.|__|**kg**

XXXVIII. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XXXIX. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XL. Leprosy Examination

x. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

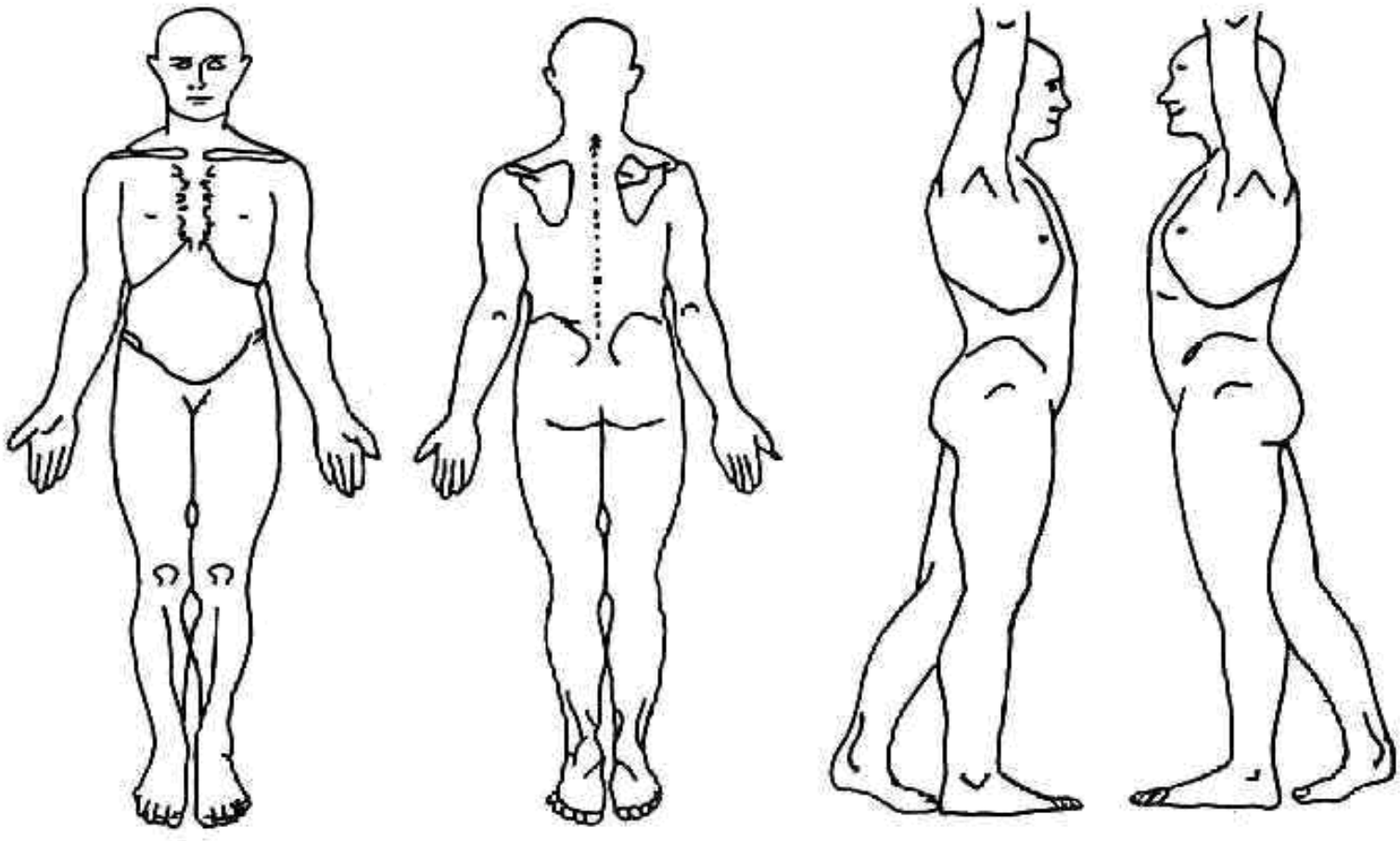
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation		Withdraws
Bone tenderness (shin):	None	Tender on palpation		Withdraws
Oedema (ankle, face, hands):	None	Present		Gross
Joint swelling:	None	Present		Affects function Which: _____
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C		level: _____
Proteinuria (by dipstick):	Negative	Positive		level: _____
Red eyes:	Yes	No		Ophthalmology diagnosis:_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

PHYSICIAN WORK SHEET: FOLLOW-UP

AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:

Insert the relevant week number: **Week** |__|__|

And date: **Date:** _ _ / _ _ / _ _ _ _

Physician to complete history and examination and ensure lab results are entered

Physician to complete adverse event form if necessary

Ensure correct physiotherapy form is attached to PRF

After each visit:

31. **mark off visit on page 2: Assessment Record**
32. **Write in date of next planned visit on page 2: Assessment Record**
33. **Tell Investigator about completed patient review in order to transfer data to CRF**

Week |__|__|
Date: _ _ / _ _ / _ _ _ _

Ask patient about new symptoms since last review:
Did you notice any new loss or sensation in your hands or feet?
Did you notice any new dryness of your hands palms or foot soles?
Did you notice any new weakness in your hand or feet?
Did you notice any new sensation of pins and needles in your hands or feet?
Did you notice any new pain sensations (burning/ shooting)?
New additional medications (other than MDT and including analgaesia)

Ask the patient if s/he has experienced any of the following symptoms since the last assessment:

Patient's report of new symptoms since last assessment									
	RIGHT				*LEFT*				
	ELBOW	*HAND*	*KNEE*	*FOOT*	*ELBOW*	*HAND*	*KNEE*	*FOOT*	*OTHER*
Diminished sensation – **eg unable to feel hot or cold, numbness (Y/N)**									
New Weakness **(Y/N)**									
Paraesthesia - **eg pins and needles, insects crawling (Y/N)**									
Nerve Pain **eg burning sensation, shooting pain (Y/N)**									

*Patient's report of s*kin lesions since last assessment

Have the inflamed skin patches improved? (Y/N/STABLE)				
How many skin patches have improved since last visit?				
Have they developed new skin patches recently? (Y/N)				
How many new skin patches have developed recently?				
Do you feel your skin is worse, the same or better?				
Facial patch? (Y/N)				
Facial patch inflammation. (Circle)	**NONE**	**ERYTHEMA**	**ERYTHEMA AND RAISED**	**ULCERATED**

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

New medications:

Drug and reason starting	Date started dd/mm/yyyy	Ongoing treatment Yes or No
1.	/ /	
2.	/ /	
3.	/ /	

Symptoms questionnaire. ***Has the patient had any problems with the reaction treatment or any of the following symptoms or conditions diagnosed since starting the reaction treatment?***

Symptoms related to:	
Moon face	□
Acne	□
Gum hyperplasia	□
Cutaneous (including nails) fungal infections	□
Gastric pain requiring antacid	□
Gastrointestinal bleeding	□
Nocturia, polyuria, polydipsia	□
Diabetes mellitus	□
Psychosis or other mental health problems	□
Weight loss >5kg	□
Weight gain	□
Glaucoma	□
Cataract	□
Hypertension BP > 160/90 on 2 separate readings at least 1/52 apart	□
Infections	□
Infected ulcers	□
Corneal ulcer	□
Tuberculosis	□
Night sweats	□
Convulsions	□
Vomiting	□
Diarrhoea	□
Breathing difficulties	□
Abnormal blood results (hyperkalaemia, abnormal LFT)	□
Pruritus	□

Any other relevant new history:

_____

_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FOLLOW UP EXAMINATION -

XLI. Weight: |__|__|__|.|__|**kg**

XLII. Vital signs

Temp	Pulse	B.P. (systolic/ diastolic)
|__|__|. |__|	|__|__|__|	|__|__|__| / |__|__|__|

XLIII. General examination

	1.Normal	2.Abnormal	3.Not examined	If abnormal specify
Head and neck				
Lymph nodes				
Skin (non leprosy)				
Lungs				
Heart				
Abdomen				
Liver				
Spleen				
Ext Genitalia (male)				

XLIV. Leprosy Examination

xi. Nerves - signs and symptoms of neuritis (since last review)

Name of nerve	Nerve tenderness - Grade*	Nerve enlargement (yes or no)	Motor symptoms – weakness (√ if yes)		Sensory symptoms – numbness, pain(√ if yes)	
			Old	New	Old	New
R Cervical/GA, Facial					N/A	N/A
L Cervical/ GA, Facial						
R Ulnar						
L Ulnar						
R Median						
L Median						
R Radial/ R.C.					N/A	N/A
L Radial/ R.C.					N/A	N/A
R lat popliteal						
L lat popliteal						
R Post Tibial						
L Post Tibial						

* Grading for nerve tenderness: 0=none 1= mild tenderness
2= withdrawal/ wincing 3= not allowing palpation

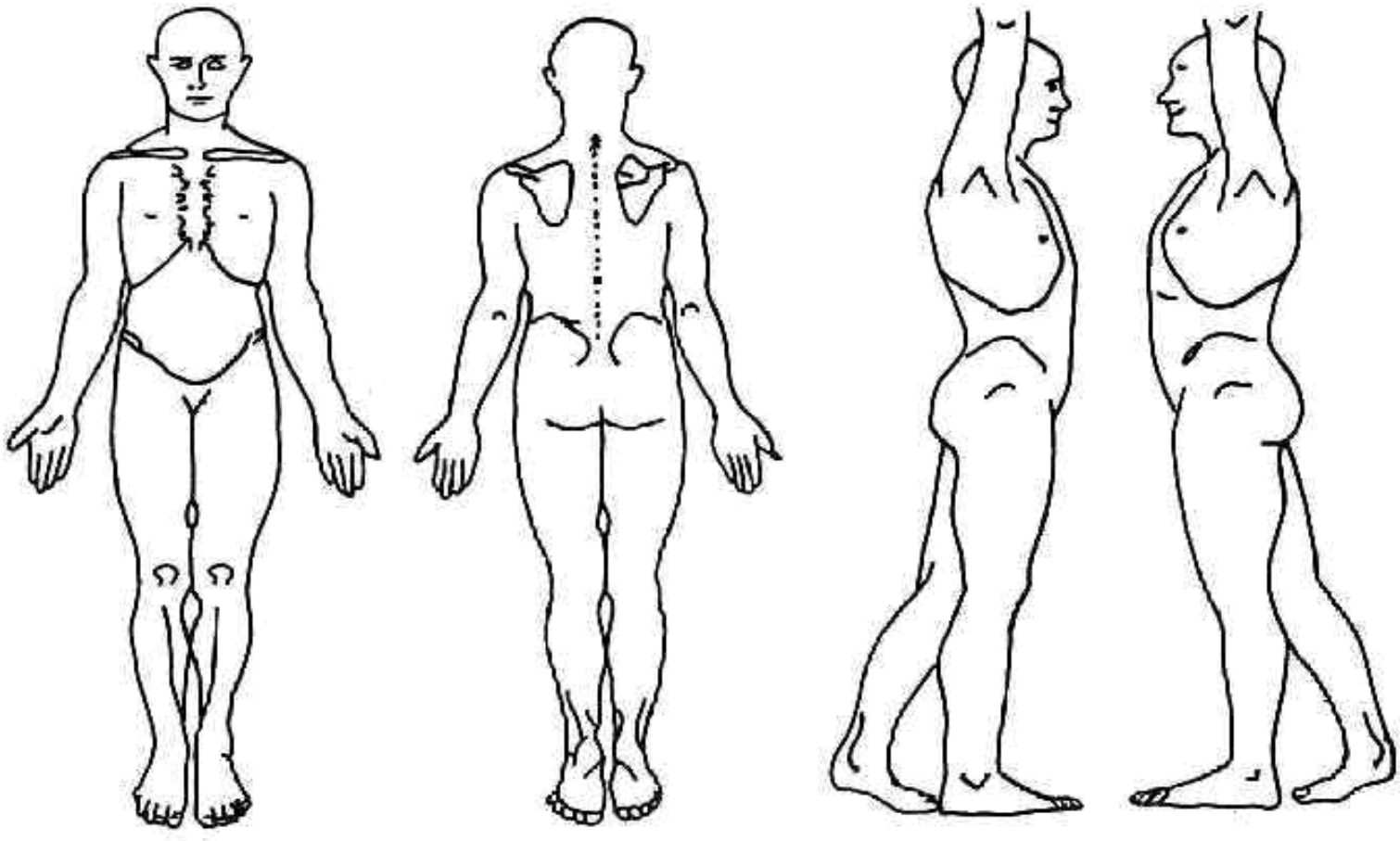
Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Ctn EXAMINATION

Skin - location of lesions (body chart)
- type of lesions (patches, plaques, papules, nodules)
- signs of inflammation in lesions
- oedema of the hands and/or feet
- mark skin biopsy site, Date: _ _ /_ _/_ _ _ _

Body Chart



	Criteria	0	1	2	3	Score
A1	Degree of inflammation of skin lesions	**None**	**Erythema**	**Erythema and raised**	**Ulceration**	
A2	Number of raised and/or inflamed lesions	**0**	**1-5**	**6-10**	**>10**	
A3	Peripheral oedema due to reaction	**None**	**Minimal**	**Visible, but not affecting function**	**Oedema affecting function**	
A SCORE						

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| Date: _ _ / _ _ / _ _ _ _

IF PATIENT HAS ENL–PHYSICIAN TO COMPLETE THE FOLLOWING ENL DATA COLLECTING FORM

Symptoms of ENL

How many days have you been feeling unwell for (this episode of ENL): ____ days

How unwell do you feel now (tick one face)?

Have you noticed….	NO	YES
Any new lumps on your skin?		
Any new sensory loss?		
Any new weakness in your muscles?		
Any new tingling?		
Any new pain in your joints?		
Any new pain in your bones?		
Any new pain in your testicles?		
Painful eyes?		
Any visual disturbance?		

Examination

Number of ENL lesions (circle): 0 1-5 6-20 >20

Inflammation in the ENL lesions (circle):
None
Erythema and pain – function not affected
Erythema and pain – function affected
Erythema and pain – function affected plus ulceration

(If patient has previous records use comparison to previous VMT/ST testing):

VMT:	MRC=5	MRC=4	MRC=3	MRC<3
ST decreased in:	None	One nerve	Two nerve	≥ three nerves
Nerve tenderness:	None	Tender on palpation	Withdraws	
Bone tenderness (shin):	None	Tender on palpation	Withdraws	
Oedema (ankle, face, hands):	None	Present	Gross	
Joint swelling:	None	Present	Affects function Which: _____	
Lymph nodes:	Normal	Enlarged and tender		
Testicles:	Normal	Tender (? Size)		
Temperature:	≤37.5°C	>37.5°C	level: _____	
Proteinuria (by dipstick):	Negative	Positive	level: _____	
Red eyes:	Yes	No	Ophthalmology diagnosis:_____	

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

CONFIRM YOU HAVE SEEN AND ATTACHED VMT/ST FORM □

Describe any changes in VMT or ST compared to last assessment:

_____
_____
_____

Second Physician comment:

PATIENT HAS :

TYPE 1 REACTION ☐

ENL ☐

Specialist opinion on the severity of today's Reaction:

Severe ☐

Moderate ☐

Mild ☐

Comment and suggest normal therapy you would have prescribed:

……
……
……
……

NB: IF NERVE FUNCTION HAS WORSENED SINCE LAST REVIEW PLEASE LOOK AT PAGE 21 OF SOP FOR INDICATIONS FOR EXTRA PREDNISOLONE.

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

FORM: INVESTIGATIONS – physician to fill in

Laboratory tests **(record results if done)**

	Date taken dd/mm/yyyy	Result
FBC	--/--/----	Hb: |__|__|.|__| g/dl WCC: |__|__|__|__| Plt: |__|__|__| ESR |__|__|__|
Renal function	--/--/----	Creat: |__|__|.|__|__| mg/dl Urea |__|__|.|__| mg/dl K+: |__|__|.|__| meq/l Na: |__|__|.|__| meq/l Glucose |__|__|__| mg/dl
LFT	--/--/----	Alk phos |__|__|__| iu/l ASAT |__|__|__| iu/l ALAT |__|__|__| iu/l Bilirubin total |__|__|__| mg/dl
HIV Rapid test (via VCT)	--/--/----	1. Positive |__| 2. Negative |__|
Blood sugar (glucometer)	--/--/----	|__|__|
Stool for ova, cysts and parasites	--/--/----	1. Positive |__| 2. Negative |__|
Urinalysis (dipstick)	--/--/----	1. Positive |__| 2. Negative |__| Specify: _____
Pregnancy test (urine)	--/--/----	1. Positive |__| 2. Negative |__| Advise re contraception options

***EXTRA MEDICATION PRESCRIBED TODAY*:**

_____
_____
_____

Study: |__|__|__|__| Study number: |__|__|__| Patient Initials: |__|__|__|

Week |__|__| **Date:** _ _ / _ _ / _ _ _ _

Record any adverse events here:

Type of adverse event	**Date of onset**	**Date of resolution**

Comments on management of adverse events:

_____
_____
_____
_____

Did the patient require hospital admission? 1.Yes ☐ 2. No ☐

If admitted was a SERIOUS ADVERSE EVENT FORM filled in?

1.Yes ☐ 2. No ☐

Was the DSMB notified 1.Yes ☐ 2. No ☐

What action was taken?

_____
_____
_____
_____

WHEN FINISHED:

COMPLETE PHARMACY CARD AND SEND PATIENT TO PHARMACY

FORM 9: STUDY TERMINATION

Patient Hospital No: _____ Study number: _____

Termination date: ___/___/___

Form completed by:_____

This form must be completed for each patient upon leaving the study

1. Did the patient complete the full course of medication? ☐ No ☐ Yes

2. Did the patient receive additional Prednisolone? ☐ No ☐ Yes

If so, how many weeks (in total) did the patient receive Prednisolone? _____

3. Did the patient report for all examinations after treatment?

Week 24	☐ No	☐ Yes
Week 28	☐ No	☐ Yes
Week 32	☐ No	☐ Yes

4. If the patient did not complete the medication or the follow-up, select the reason:

☐ Subject did not return for clinic visit
☐ Protocol violation (specify) _____
☐ Subject refused study procedure(s): _____
☐ Voluntary withdrawal
☐ Illness (specify): _____
☐ Death: ___/___/___ (date)
☐ Other reason (specify): _____

Comments: _____
_____
_____

I have reviewed the contents of this case report form and found it to be complete and accurate.

Investigator's signature: _____ Date: _ _/_ _ / _ _ _ _