Study: _ Study number: _	Patient Initials: _
Patient Record Fo	nrm
Tatient Record T	
For	
Ciclosporin in the management of Leg Based at ALERT Hospit	
PHYSICIAN TO CHECK CORRECT ALLOCATI	ON OF STUDY NUMBER
Please tick relevant study	y
Study 1A: new Type 1 Reactions in Leprosy	
Study 1B: steroid resistant Type 1 Reactions in Lepro	
Study 2A: new Erythema Nodosum Leprosum	
Study 2B: chronic or recurrent Erythema Nodosum I	<u>Leprosum</u>

Study: _ _	Study number: _	Patient Initials: _
ASSESSMENT RECORD		
Start Date: (dd/mm/yyyy)	//	

	Date due dd/mm/yyyy	Date done dd/mm/yyyy	Extra notes
Base line		3.3	
Dasc fine			
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			
	1	L	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	_ 2/111
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Study: _ Study number:	Patient Initials: _ _
PHYSICIAN WORKSHEET AT REGISTR.	ATION Baseline – Day 0
Leprosy History	
Study Patient Number:	Hospital File number:
	Leprosy Registration number:
Assessed by:	Today's Date://
Name	dd/mm/yyyy Home village / town
Patient Initial: _	Home vinage / town
Sex: M _ F _	Age (Yrs): _
	Classification (Ridley- Jopling):
Date of leprosy diagnosis:	Clinically Histology
//	1. TT _ 1. TT _
	2. BT
	3. BB _ 3. BB _
	4. BL _
Duration of leprosy (number of months	Classification of leprosy (WHO):
since first sign)	1. PB
	2. MB
<u> </u>	
Bacterial Index at time of diagnosis:	Most recent Bacterial Index:
Date://	Date://
MDT Start Date: //	Previous Treatment Default?
MIDTE CL. ID. 4	1. Yes _
MDT Stop Date:// (RFT)	2. No
(RF1)	
Is this a presentation of a new Reaction?	Date of onset of Leprosy Reaction
1. Yes	//
2. No	
What type of reaction is it: T1R	Duration of Reaction symptoms on this
(circle) ENL	occasion (in days /weeks):
Previous history of reactions:	Time since last reaction (in months) if
1. Yes	first reaction then record X
2. No	
Details (how many?):	

Study: _ Study no	umber: _	_ Patient]	Initials: _	_
General Medical History		1	. Yes	2.No
Any major medical diagnoses? If yes, specify:				
1. 1 2. 1 3. 1	Diabetes Hypertension Tuberculosis Other	 		
Other Medical History			_	
Diagnosis	Date of onse	t Date of	resolution *	
1.	/ /	/	/	
2	/ /	/	/	
3	/ /	/	/	
Current medications (other than MD Drug and reason starting]	g analgesia) Date started dd/mm/yyyy	Ongoing treatment Yes or No	
1.		/ /	1 es or ino	
2		/ /		
3.		/ /		
PREDNISOLONE HISTORY: If the patient has taken prednisolone in period:		e describe in de		nd
Ciclosporin Studies (20.06.11) PRF comp	leted by:	Dat	te:	4/1

Baseline symptoms qu	estionnaire		
-	estionnan e.		
Symptoms related to:			
Moon face			
Acne			
Gum hyperplasia			
Cutaneous (including nails)			
Gastric pain requiring antaci	d		
Gastrointestinal bleeding			
Nocturia, polyuria, polydipsi	ia		
Diabetes mellitus			
Psychosis or other mental he	ealth problems		
Weight loss >5kg			
Weight gain			
Glaucoma			
Cataract			
	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 (hyp	perkalaemia, abnormal LFT)		
Pruritus	,		
		1. Yes	2.No
	reening (if long term cough, night sweaters-refer for CXR and sputum AFBs)	ats, \square	
Describe events:			
Describe events.			

Diminished sensation – eg unable to feel hot or cold, numbness (Y/N) New Weakness (Y/N)	E L B O W	H A N D	SHT K N E E	F O O T	E L B	H A N D	FT K N E	<i>F</i> 0	OTHER	
or cold, numbness (Y/N)	L B O	A N	N E	0	L B O	A N	N E	0	OTTIER	
or cold, numbness (Y/N)			1		W		_	T		
Paraesthesia - eg pins and needles, insects crawling (Y/N)										
Verve Pain eg burning sensation, shooting pain Y/N)										
When did the skin patches become in the skin patch (Y/N) How many new skin patches have detailed the skin patches become in the skin patches becom	nes re	cent								
ecently? Do you feel your skin is worse, the s	ame	or he	etter	?						
	Jaiiio	<u> </u>	<u> </u>	•						
Facial patch? (Y/N)										

	AT REGIST	ΓRA	Baseline	Ph	ysical Ex	 xaminatio /		
I. Vital signature Temp		ulse	,			B.P. (sv	ystolic/ di	astolic)
<u> </u>								<u></u>
<u> </u>	_ . _ examinatio		g					
	1.Normal	2.4	Abnormal	3.N	Vot	If abno	rmal spec	eify
				exa	mined		1	J
Head and neck								
Lymph nodes								
Skin (non leprosy)								
Lungs								
Heart								
Abdomen								
Liver								
Spleen								
Ext Genitalia								
(male)								
IV. Leprosyi. Nerves - s	Examination is signs and sy		oms of ne	uritis	s (new =	less than	6 months))
Name of nerve	Nerve		Nerve		Motor s	ymptoms –		symptoms –
	tenderness	_						s, pain(√if yes
	Grade*		(yes or no)		Old	New	Old	New
R Cervical/GA, Facial							N/A	N/A
IN CCI VICAI/CIA. Facial								
L Cervical/ GA, Facial								
L Cervical/ GA, Facial R Ulnar								
L Cervical/ GA, Facial R Ulnar L Ulnar								
L Cervical/ GA, Facial R Ulnar L Ulnar R Median							27/4	N/A
L Cervical/ GA, Facial R Ulnar L Ulnar R Median L Median							I NI/A	
L Cervical/ GA, Facial R Ulnar L Ulnar R Median L Median R Radial/ R.C.							N/A N/A	
L Cervical/ GA, Facial R Ulnar L Ulnar R Median L Median R Radial/ R.C. L Radial/ R.C.							N/A N/A	N/A N/A
L Cervical/ GA, Facial R Ulnar L Ulnar R Median L Median R Radial/ R.C. L Radial/ R.C. R lat popliteal								
L Cervical/ GA, Facial R Ulnar L Ulnar R Median L Median R Radial/ R.C. L Radial/ R.C. R lat popliteal L lat popliteal R Post Tibial								
L Cervical/ GA, Facial R Ulnar L Ulnar R Median								

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	7/111
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Study	y :		Study number:		Patient Initials:		

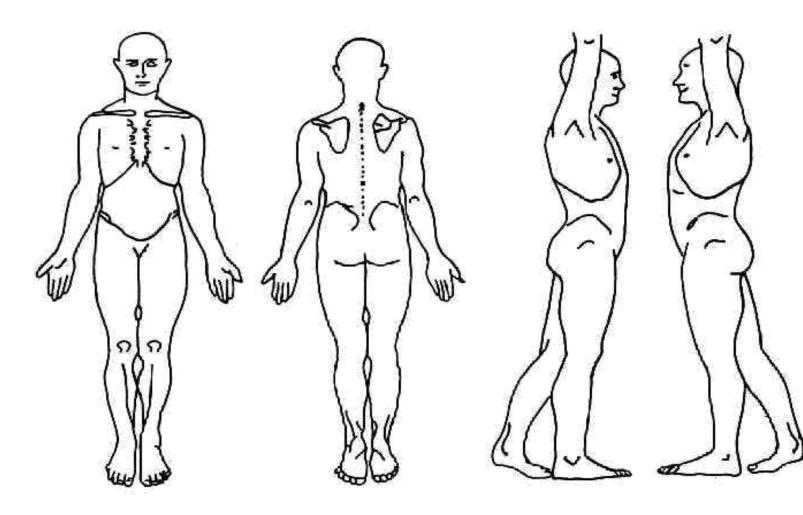
EXAMINATION AT REGISTRATION

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	Visible, but		Oedema affecting function					
	A SCORE								

PRF completed by: _____ Date: _____ 8/111

Study: _ _	Study	number	: _ _	Patier	nt Initia	ls: _
IF PATIENT HAS ENL-P DATA COLLECTING FO		IAN TO	O COMPLE	TE THE		OWING ENI ine – Day 0
Symptoms of ENL						
How many days have you been fee	eling unw	ell for (th	is episode of E	NL):	days	
		(@ <u>@</u>)				(A)
		0	1 2 HURTS HURTS A LITTLE BIT A LITTLE MOR	3 HURTS	4	5
How unwell do you feel now (tick	one face)	? HURT	HURTS HURTS A LITTLE BIT A LITTLE MOR	E EVEN MORE A W	HURTS H /HOLE LOT W	URTS ORST
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscle	es?					
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?						
Any visual distaibance:		<u> </u>				
Examination						
Number of ENL lesions (circle):		0	1-5		6-20	>20
Inflammation in the ENL lesions (circle):	None	10		0 = 0	
	,	Erythen	na and pain – fu	nction not a	affected	
		Erythen	na and pain – fu	nction affect	eted	
		Erythen	na and pain – fu	nction affect	cted plus	ulceration
(If patient has previous records us					,	MDC 42
VMT:)	MRC=4			MRC<3
ST decreased in: Nerve tenderness: None	None	Tandar	One nerve on palpation	i wo ne	rve Withdr	
Nerve tenderness.		1 chaci	on parpation		vv itilai	aws
Bone tenderness (shin):	None		Tender on pal	nation	Withdr	aws
Oedema (ankle, face, hands):	None		Present	oution .	Gross	4115
Joint swelling:	None		Present			function
						:
Lymph nodes:	Normal		Enlarged and t			
Testicles:	Normal		Tender (? Size	;)	101-	
Temperature:	≤37.5°C		>37.5°C Positive		level: _	
Proteinuria (by dipstick):	Negativ Yes	е	No		level:	llmology
Red eyes:	1 68		INU	diao		umology
				anagi		

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	9/111
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dy: _	Study number:	Patient Initials: _
ONFIRM YOU HAV	E SEEN AND ATTACHED VI	MT/ST FORM
	Second Physician comn	nent:
PATIENT HAS:	TYPE 1 REACTION	
	ENL	
Specialist opinion	on the severity of today's React	tion:
	Moderate	
	Mild	
Comment and sugg	gest normal therapy you would	have prescribed:

Laboratory tests	(record results)
	Date taken dd/mm/yyyy	Result
FBC	/	Hb: _ . g/dl WCC: _ _ Plt: ESR
Renal function	/	Creat:
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
Jrinalysis (dipstick)	/	1. Positive 2. Negative Specify:
Pregnancy test (urine)	/	1. Positive 2. Negative Advise re contraception options
Skin Smear and Biopsy		
and histology.	n from a typical sk	in lesion for Ridley- Jopling classification AHRI number Site of biopsy:
EXTRA MEDICATION	PRESCRIBED T	TODAY:
COMPLETE PHAR	RMACY CARD A	AND SEND PATIENT TO PHARMACY
Ciclosporin Studies (20.06.11)	PRF completed by	v: Date: 11

Study: _ Study number: _ Patient Initials: _
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
 Write in date of next planned visit on page 2: Assessment Record Tell Investigator about completed patient review in order to transfer data
to CRF

				We	ek to:	1	<u> </u>	 		
Ask patient about new symptoms since Did you notice any new loss or sensation Did you notice any new dryness of your h Did you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (I New additional medications (other than M Ask the patient if s/he has experienced an	in your lands par hand of and new burning IDT and	han alms or fee edle: / sho d ind	ds or for the state of the stat	feet? ot sol our ha)? g ana	es? ands o	or fee	t?			
assessment: Patient's report of new	w symn	toms	s since	last	asses	sm <i>o</i> n	t]
Tunem s report of <u>ne</u>	<u>v</u> symp			· iasi	1		EFT			
			IGHT	1				1		
	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	F O O T	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	$\begin{vmatrix} H \\ A \\ N \\ D \end{vmatrix}$	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ } {\sf cold,\ numbness\ (Y/N)}$,,					
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 skin lesions since last a Have the inflamed skin patches imp (Y/N/STABLE) How many skin patches have improvisit? Have they developed new skin patches (Y/N)	oroved oved s thes re	ince	e last							
How many new skin patches have depending?										
Do you feel your skin is worse, the Facial patch? (Y/N)	same	or k	etter	?						
Facial patch inflammation. (Circle)	NONE		ERY	ГНЕМ	/IA	AN		EMA	ULCE	RATED
Ciclosporin Studies (20 06 11) PRF complete	d by:				Dat	e·			13/111	

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

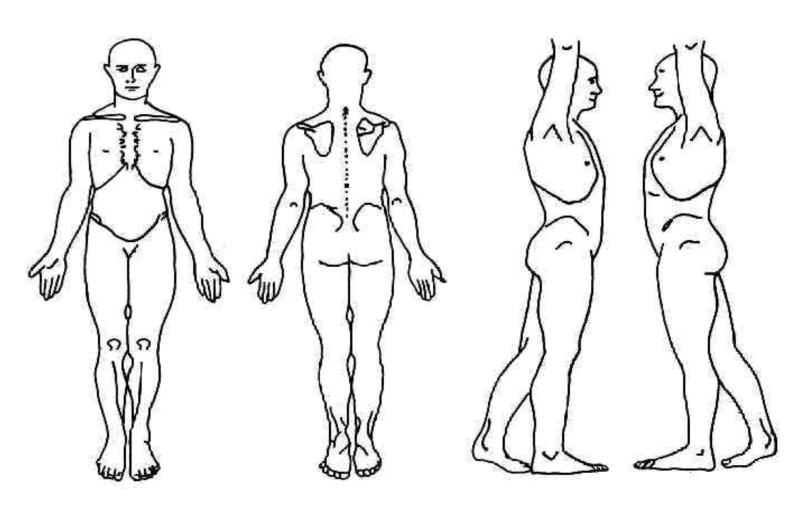
Study: |__|_|_|

Week _		Date:	//
New medications:			
Drug and reason starting	Date st dd/mr	tarted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
Acne			
Gum hyperplasia Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastric pain requiring antacid			
Gastrointestinal bleeding			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia		+	
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract	11/52		
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	e least 1/52 apart		
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		
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 Infections Infected ulcers	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions			

Study: _ _	Stı	udy number:		Patient I	nitials:	_
Week _	_l			Date: _	_//_	
FOLLOW UP EXA	AMINATIO	N -				
I. Weig II. Vital sig	ght: _ ns	_ . kg				
Temp _ .		ulse 		B.P. (sy	stolic/ dia	astolic)
III. General	examination	n				
	1.Normal		3.Not examined	If abno	ormal spec	eify
Head and neck						
Lymph nodes						
· · · ·						
Skin (non leprosy)						
Lungs						
Heart						
Abdomen						
Liver						
Spleen						
Ext Genitalia						
(male)						
	Nerves - sign	ns and symptom	Motor sy	mptoms –	Sensory	symptoms – s, pain(\sqrt{i} if yes)
	Grade*	(yes or no)	Old	New	Old	New
D. Carrieral/C.A. Facial			_		NT/A	DT/A
R Cervical/GA, Facial L Cervical/ GA, Facial					N/A	N/A
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		2= withdrawal/	wincing	3= not al	tenderness lowing pa	llpation
Ciclosporin Studies (20.06.11)	PRF	completed by: _		Dat	e: _	15/11

		7 T T T T T T T T T T T T T T T T T T T	
elosporin Studies (20.06.11)	PRF completed by:	Date:	15/111

Study: _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- oedema of the hands and/	
	- mark skin biopsy site,	
	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 SCOR	RE			

Ciclosporin Studies (20.06.11)

PRF completed by: ______ Date: _____ 16/111

IF PATIENT HAS ENL-P DATA COLLECTING FO		AN TC	O COMPLE	Date:/ TE THE FOI	
Symptoms of ENL					
How many days have you been fe	eling unwe	ll for (thi	is episode of E	NL): days	
		(@®)	(@) (@)		(\$\hat{\phi})
How unwell do you feel now (tick	one face)?	NO HURT	HURTS HURTS A LITTLE BIT A LITTLE MOI	3 4 HURTS HURTS RE EVEN MORE A WHOLE LOT	HURTS WORST
Have you noticed		NO	YES		
Any new lumps on your skin?					
Any new sensory loss?					
Any new weakness in your muscle	es?				
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
	(circle):	None	1 i C		. 1
		T 41		inction not affects	ea
Inflammation in the ENL lesions (Erythem	a and pain – fu	inction affected	
		Erythem	a and pain – fu		
Inflammation in the ENL lesions (Erythem Erythem	a and pain – fu a and pain – fu	nction affected anction affected p	
Inflammation in the ENL lesions ((If patient has previous records us	se comparis	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST	unction affected unction affected p	lus ulceration
	se comparis	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST	unction affected unction affected p	
Inflammation in the ENL lesions ((If patient has previous records us VMT:	se comparis MRC=5 None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4	nnction affected punction affected punction affected punction affected punctions. MRC=3 Two nerve	lus ulceration MRC<3
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None	se comparis MRC=5 None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation	Inction affected unction affected purction affected purction affected purctions affected purction affe	lus ulceration MRC<3 ≥ three nerves
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin):	se comparis MRC=5 None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve	Inction affected unction affected purction affected purction affected purctions affected purction affected purctions affected p	MRC<3 ≥ three nerves ndraws
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands):	se comparis MRC=5 None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation	Inction affected inction affected protesting): MRC=3 Two nerve With Gross Affe	MRC<3 ≥ three nerves ndraws ndraws sects function
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling:	None None None None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation Tender on pal Present Present	resting): MRC=3 Two nerve With pation With Gros Affe Whi	MRC<3 three nerves ndraws
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes:	None None None None None None	Erythem Erythem	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation Tender on pal Present Present	resting): MRC=3 Two nerve With pation With Gros Affe White Witnerse	MRC<3 ≥ three nerves ndraws ndraws sects function
(If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes: Testicles:	Se comparis MRC=5 None None None None Normal	Erythem Erythem Fon to pro	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation Tender on pal Present Present	resting): MRC=3 Two nerve With pation With Gross Affe Whitender	MRC<3
Inflammation in the ENL lesions ((If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes: Testicles: Temperature:	None None None Normal Normal S37.5°C	Erythem Erythem con to pro	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation Tender on pal Present Present Enlarged and Tender (? Size	resting): MRC=3 Two nerve With pation With Gross Affe Whitender	MRC<3
(If patient has previous records us VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes:	Se comparis MRC=5 None None None None Normal	Erythem Erythem con to pro	a and pain – fu a and pain – fu evious VMT/ST MRC=4 One nerve on palpation Tender on pal Present Present Enlarged and Tender (? Size >37.5°C	rection affected processing affected processin	MRC<3 ≥ three nerves ndraws ndraws sects function

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	17/111
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Study: _	Study number: _	Patient Initials: _
Week _		Date://
	E SEEN AND ATTACHED VMVMT or ST compared to last as	
	Second Physician comm	nent:
PATIENT HAS:	TYPE 1 REACTION	
	ENL	
Specialist opinion of	on the severity of today's React	ion:
	Severe Moderate	
	Mild	
NB: IF NERVE F	UNCTION HAS WORSENED	D SINCE LAST REVIEW
Ciclosporin Studies (20.06.11)	PRF completed by:	Date: 18/111

Laboratory tests	(record results Date taken	if done) Result
	dd/mm/yyyy	Rosult
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
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

ype of adverse event	Date of onset	Date of re	solution
omments on managemen	nt of adverse events:		
Did the patient require hos	spital admission?	1.Yes □	2. No □
admitted was a SERIOU	JS ADVERSE EVENT FOR	M filled in?	
		1.Yes □	2. No □
Vas the DSMB notified		1.Yes □	2. No □
Vhat action was taken?			

Study: _ Study number: Patient Initials: _
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 Record6. Tell Investigator about completed patient review in order to transfer data
to CRF

				We	ek te: _	1	<u> </u>			
Ask patient about new symptoms since I Did you notice any new loss or sensation in Did you notice any new dryness of your had Did you notice any new weakness in your Did you notice any new sensation of pins a Did you notice any new pain sensations (b) New additional medications (other than M). Ask the patient if s/he has experienced any	n your ands pa hand o and ne urning DT an	han alms or fed edle g/ sho d ind	ds or for et? s in your ooting cludin	feet? ot sol our ha)? g ana	es? ands c	or fee	t?			
assessment: Patient's report of new	, svmp	toms	s since	e last	asses	smen	et			7
			IGHT				EFT			-
	Г				Г				OTHER	4
	E L B O W	H A N D	K N E E	F O O T	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	F O O T	OTHER	
$\begin{array}{c} Diminished \ sensation - \ eg \ unable \ to \ feel \ hot \ or \\ cold, \ numbness \ (Y/N) \end{array}$,,					_
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 skin lesions since last as					1					
Have the inflamed skin patches imp (Y/N/STABLE)	roved	1 ?								
How many skin patches have improvisit?	ved s	inc	e last							
Have they developed new skin patcl (Y/N)										
How many new skin patches have d recently?										
Do you feel your skin is worse, the	same	or k	oetter	?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONI	E	ERY	THEN	//A	AN		EMA	ULCE	RATE
Ciclosporin Studies (20.06.11) PRF completed	l by:				Dat	e:			22/111	

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

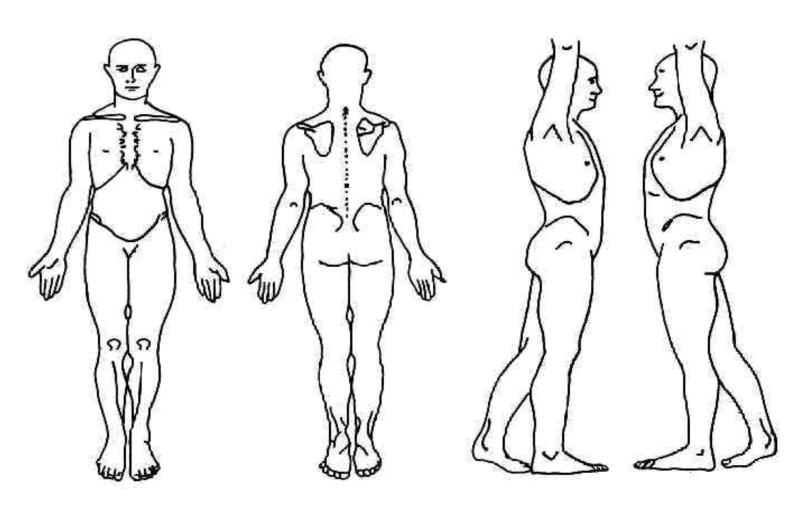
Study: |__|_|

	Date: //
New medications:	
Drug and reason starting	Date started Ongoing
	dd/mm/yyyy treatment
	Yes or No
1.	/ /
	, ,
2	/ /
2	
3.	/ /
J.	/ /
the following symptoms or conditions diagnosmuscular 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	
Waight loss >5kg	
	+
Weight gain	
Weight gain Glaucoma	
Weight gain Glaucoma Cataract	
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections	
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	dings at least 1/52 apart
Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diagraphysis	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting	dings at least 1/52 apart

Study: Patient Initials:								
Week _						Date: _	_//_	
FOLLOW UP EXA	AMINAT	ON	-					
V. Weig VI. Vital sig	ght: _ ns	.	kg					
Temp Pulse B.P. (systolic/ diastolic)						astolic)		
VII. General	examinat	ion						
	1.Norma	1 2.	Abnormal		Not amined	If abno	rmal spec	ify
Head and neck				UA	ammod			
		-						
Lymph nodes						1		
Skin (non leprosy)								
Lungs								
Heart								
Abdomen								
Liver								
Spleen								
Ext Genitalia								
(male)								
VIII. Leprosy ii. Name of nerve	Nerves - s	igns	and sympto		Motor sy	mptoms –	Sensory	symptoms –
	tenderne	SS -	enlargemen	ıt				$\sqrt{\text{pain}(\sqrt{\text{if yes})}}$
	Grade*		(yes or no)		Old	New	Old	New
R Cervical/GA, Facial						+	N/A	N/A
L Cervical/ GA, Facial						†	11/11	11/11
R Ulnar						1		
L Ulnar						1		
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						1		
L Post Tibial								
* Grading for nerve	tendernes		none withdrawa	ıl/ w	incing		enderness lowing pa	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	24/111

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	 type of lesions (patches, p signs of inflammation in l 	esions
	- oedema of the hands and/- mark skin biopsy site,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	
А3	Peripheral oedema due to reaction	None	Minimal	Visible, but not affecting function	Oedema affecting function	
A SCORE						

PRF completed by: _____ Date: _____ 25/111

Study: _ _	Study	numbe	r: _	_ _		Patien	t Initia	ls:
Week _ _ IF PATIENT HAS ENL-P DATA COLLECTING FO		IAN T	0 (COMPL	ETE	Date: THE	/_ FOLL	_/ OWING ENL
Symptoms of ENL								
How many days have you been fee	eling unw	ell for (t	his e	pisode of	fENL):	: d	lays	
)(
How unwell do you feel now (tick	one face)	? O NO HURT	А	1 ; HURTS HU LITTLE BIT A LITTL		3 IURTS I N MORE A WI	4 HURTS HI HOLE LOT WA	5 URTS ORST
Have you noticed		NO)	YES				
Any new lumps on your skin?								
Any new sensory loss?								
Any new weakness in your muscle	es?							
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): Inflammation in the ENL lesions (circle):	Eryther	ma a	1-5 nd pain – nd pain – nd pain –	- functio	on affec	eted	>20 ulceration
(If patient has previous records us	e compar	ison to n	revi	ous VMT	/ST test	tino)·		
VMT:	MRC=5			RC=4		MRC=3		MRC<3
ST decreased in:	None			ne nerve		Two ner		≥ three nerves
Nerve tenderness: None		Tender		palpation			Withdra	
Bone tenderness (shin):	None		Te	ender on p	nalnatic	n	Withdra	aws
Oedema (ankle, face, hands):	None			esent	Juiputic	,11	Gross	uws
Joint swelling:	None			esent				function
voint on time.	1,0110			••••				
Lymph nodes:	Normal		Er	larged ar	nd tende	er		
Testicles:	Normal			ender (? S				
Temperature:	≤37.5°C			7.5°C	,		level: _	
Proteinuria (by dipstick):	Negativ			sitive			level:	
Red eyes:	Yes		No				Ophtha	lmology
-7	- ~		•			diagr	-	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	26/111
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Study: _ _	Study number: _	Patient Initials: _	_l
Week _		Date://	
	SEEN AND ATTACHED VM		
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion or	n the severity of today's React	ion:	
	Severe		
	Moderate		
	Mild		
	est normal therapy you would h		
	GE 21 OF SOP FOR INDICA		
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	27/111

Laboratory tests	(record results Date taken	if done) Result
	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)	/	Positive Negative Advise re contraception options

ype of adverse event	Date of onset	Date of re	solution
omments on managemen	nt of adverse events:		
Did the patient require hos	spital admission?	1.Yes □	2. No □
f admitted was a SERIOU	JS ADVERSE EVENT FOR	LM filled in?	
		1.Yes □	2. No □
Vas the DSMB notified		1.Yes □	2. No □
Vhat action was taken?			

Study: _ _	Study number: _	_ Patient Initials: _
PHYSICIAN WORK S	HEET: FOLLOW-	UP
AT EACH REVIEW AND	UNPLANNED VISIT,	COMPLETE:
Insert the relevant week	k number:	Week _
And date:	I	Date://
Physician to complete histo	ry and examination and	d ensure lab results are entered
Physician to complete adve	rse event form if necess	sary
Ensure correct physiothera	py form is attached to	PRF
	page 2: Assessment Re	
		age 2: Assessment Record nt review in order to transfer data

				We	ek to:	1	<u> </u>			
Ask patient about new symptoms since Did you notice any new loss or sensation is Did you notice any new dryness of your had you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (by New additional medications (other than Management)	in your ands pa hand c and nec ourning	han alms or fee edle	ds or so for the solution of t	feet? ot sol our ha)?	es? ands o	or fee			-	
Ask the patient if s/he has experienced any assessment:								e last		1
Patient's report of <u>nev</u>	<u>v</u> symp	toms	s since	e last	asses	smen	t			
		RI	IGHT			LE	EFT			
	E L B O W	H A N D	K N E E	F O O T	E L B O W	H A N D	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ } {\sf cold,\ numbness\ (Y/N)}$	"				,,					
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 skin lesions since last a										
(Y/N/STABLE)										
How many skin patches have improvisit?										
Have they developed new skin patc (Y/N)										
How many new skin patches have drecently?										
Do you feel your skin is worse, the	same	or k	oetter	?						
Facial patch? (Y/N)	NONE	- 1	EDVI		/ A	LED	VTII		шег	
Facial patch inflammation. (Circle)	NONE	-	ERY1	ПЕМ	ИΑ	AN		EMA	ULCEI	KATEL
Ciclosporin Studies (20.06.11) PRF completed	d by:				Dat	e·			31/111	

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

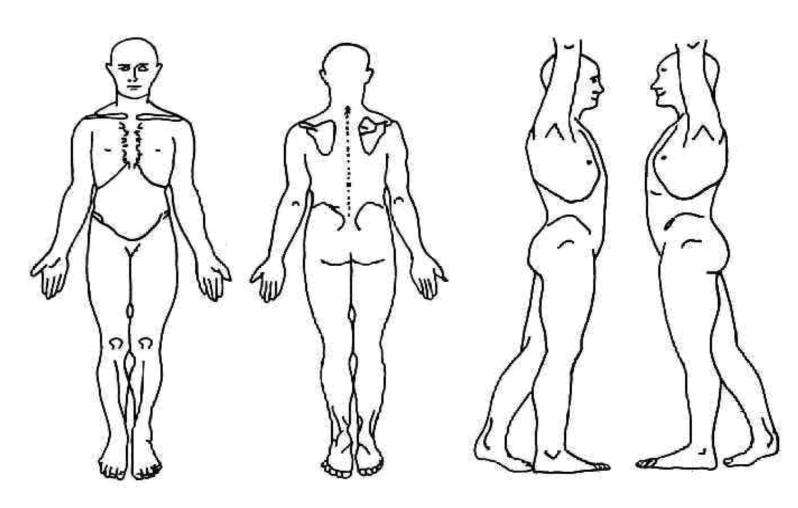
Study: |__|_|_|

	Date: //
New medications:	
Drug and reason starting	Date started Ongoing
	dd/mm/yyyy treatment
	Yes or No
1.	/ /
	, ,
2	/ /
2	
3.	/ /
J.	/ /
the following symptoms or conditions diagnosmuscular 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	
Waight loss >5kg	
	+
Weight gain	
Weight gain Glaucoma	
Weight gain Glaucoma Cataract	
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections	
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	dings at least 1/52 apart
Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diagraphysis	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	dings at least 1/52 apart
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate read Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting	dings at least 1/52 apart

- kg se .Abnormal	3.Not examined	B.P. (s	ystolic/ dis	astolic)
kg se Abnormal and sympto	examined	If abnot	/	
Abnormal and sympto	examined	If abnot	/	
Abnormal and sympto	examined	If abnot	/	
and sympto	examined		ormal spec	eify
and sympto	examined		ormal spec	eify
and sympto				
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
and sympto	oms of new	ritis (since l		
Nerve enlargemen	Motor	r symptoms –	Sensory	symptoms – s, pain(√ if yes)
(yes or no)	Old	New	Old	New
1			NT/A	NT/A
1			N/A	N/A
			1	
			N/A	N/A
			N/A	N/A
1				
1			1	
			1	
	none withdrawa			none l= mild tenderness

Ciclosporin Studies (20.06.11)	PRF completed by:	 Date:	33/111

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	 type of lesions (patches, p signs of inflammation in l 	esions
	- oedema of the hands and/- mark skin biopsy site,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						

Ciclosporin Studies (20.06.11)

PRF completed by: ______ Date: _____ 34/111

Study:	Study n	number	: [Patien	t Initials	: _ _
Week _ _ IF PATIENT HAS ENL-P DATA COLLECTING FO		AN TO	О СОМРІ		/ FOLLO	
Symptoms of ENL						
How many days have you been fee	ling unwe	ell for (th	is episode o	f ENL): d	ays	
		(e)				
How unwell do you feel now (tick	one face)	O NO HURT	1 HURTS HI A LITTLE BIT A LITT	2 3 Urts Hurts H Le More even More A WH	4 5 URTS HURT: HOLE LOT WORS	5 T
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscle	s?					
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): Inflammation in the ENL lesions (circle)		Erythen	na and pain -	5 - function not a - function affec - function affec	ted	>20
(If patient has previous records use	e compari	son to ni	revious VMT	VST testing):		
VMT:	MRC=5		MRC=4	MRC=3		MRC<3
ST decreased in:	None		One nerve			≥ three nerves
Nerve tenderness: None	1,0110	Tender	on palpation		Withdray	
Bone tenderness (shin):	None		Tender on p		Withdray	
Oedema (ankle, face, hands):	None		Present	outpution	Gross	W 5
Joint swelling:	None		Present		Affects f	inction
Joint Swelling.	Tione		Tresent			
Lymph nodes:	Normal		Enlarged ar	nd tender		
Testicles:	Normal		Tender (? S			
Temperature:	≤37.5°C		>37.5°C	-)	level:	
Proteinuria (by dipstick):	Negative		Positive		level:	
Red eyes:	Yes	•	No		Ophthalr	nology
2.00.0,00.	1 00		110	diagn		
				a.wg.i	- ~-~ -	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	35/111
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Study: _	Study number: _	Patient Initials: _	
Week _		Date://	
	SEEN AND ATTACHED VMMT or ST compared to last as:		
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion or	the severity of today's React	ion:	
	Moderate		
	Mild		
NB: IF NERVE FU	NCTION HAS WORSENEI	D SINCE LAST REVIEW	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date: 36/1	111

Laboratory tests	(record results Date taken	if done) Result
	dd/mm/yyyy	Result
FBC	//	Hb: . _ g/dl WCC: _ _ Plt: ESR
Renal function	/	Creat:
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
Jrinalysis (dipstick)	//	1. Positive 2. Negative Specify:
Pregnancy test (urine)	/	1. Positive 2. Negative Advise re contraception options

Type of adverse event	Date of onset	Date of re	solution
omments on managemen	t of adverse events:		
id the patient require hos	pital admission?	1.Yes □	2. No □
admitted was a SERIOU	IS ADVERSE EVENT FORM	M filled in?	
admitted was a service	O LID VERGE E VEIVI I ORG	1.Yes □	2. No □
as the DSMB notified		1.Yes □	2. No □
hat action was taken?			

Study: _ _	Study number: _	<u> </u>	Patient Initials: _
PHYSICIAN WORK S	SHEET: FOLLOV	V-UP	
AT EACH REVIEW AND	UNPLANNED VISI	T, COMP	LETE:
Insert the relevant wee	k number:	Week	1 1 1
			·
And date:		Date:	//
Physician to complete histo	ory and examination	and ensur	e lab results are entered
Physician to complete adve	erse event form if nec	essary	
Ensure correct physiothera	apy form is attached	to PRF	
After each visit: 10. mark off visit or	n page 2: Assessment	Record	
12. Tell Investigator	next planned visit on r about completed pa		Assessment Record ew in order to transfer data
to CRF			

				We	ek	1	<u> </u>	 		
Ask patient about new symptoms since Did you notice any new loss or sensation Did you notice any new dryness of your h Did you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (I New additional medications (other than M Ask the patient if s/he has experienced an	in your lands part hand coand new burning	han alms or fed edle / sho d ind	ids or s or fo et? s in yo ooting cludin	feet? ot sol our ha)? g ana	es? ands c	or fee	t?			
assessment: Patient's report of ne	w symp	toms	s since	e last	asses	smen	t]
			IGHT		1		EFT			
	E			E	F			E	OTHER	
	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	F O O T	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	$egin{array}{c} H \\ A \\ N \\ D \end{array}$	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ } {\sf cold,\ numbness\ (Y/N)}$,,,					
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 skin lesions since last a Have the inflamed skin patches imp (Y/N/STABLE) How many skin patches have improvisit?	oroved oved s	ince	e last							
Have they developed new skin pato (Y/N)										
How many new skin patches have or recently?										
Do you feel your skin is worse, the	same	or k	oetter	?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONE	=	ERY	ГНЕМ	//A	AN		EMA	ULCEI	RATED
Ciclosporin Studies (20.06.11) PRF complete	d bv				Dat	e·			40/111	

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

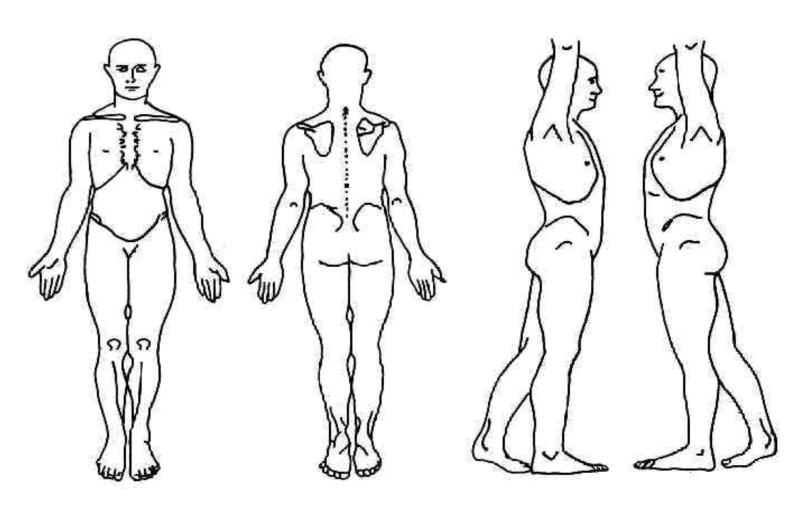
Study: |__|_|_|

I <u></u> I		Date:	_//
New medications:			
Drug and reason starting	Date st dd/mn	arted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
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			
Wainlet lang > 51-2			
Weight gain			
Weight gain Glaucoma			
Weight gain Glaucoma Cataract	11/50		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcers	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting			

Study: _	udy number: [Patient 1	nitials:	_ _	
Week _	I			Date: _	_//_	
FOLLOW UP EXA	MINATIO	N -				
XIII. Weigl XIV. Vital sign	ht: 18	_ . kg				
Temp		ulse _		B.P. (sy	ystolic/ di _ / _	astolic)
XV. General	examinatio	n				
	1.Normal	2.Abnormal	3.Not examined	If abno	ormal spec	eify
Head and neck						
Lymph nodes						
5 1						
Skin (non leprosy)						
Lungs						
Heart						
Abdomen						
Liver						
Spleen						
Ext Genitalia						
(male)						
XVI. Leprosy iv. N		on ns and sympto	oms of neuriti	s (since la	ast review)
Name of nerve	Nerve	Nerve	Motor sy	mptoms –	Sensory	symptoms –
	tenderness	_				s, pain($\sqrt{\text{if yes}}$)
	Grade*	(yes or no)	Old	New	Old	New
R Cervical/GA, Facial				1	N/A	N/A
L Cervical/ GA, Facial				1		
R Ulnar						
L Ulnar						
R Median				1		
L Median				1	37/4	27/4
R Radial/ R.C.				1	N/A	N/A
L Radial/ R.C.				1	N/A	N/A
R lat popliteal L lat popliteal				1		
R Post Tibial				1		
L Post Tibial				1		
* Grading for nerve t		0=none 2= withdrawa	ıl/ wincing		tendernes lowing pa	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	42/111

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	 type of lesions (patches, p signs of inflammation in l 	esions
	- oedema of the hands and/- mark skin biopsy site,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						

Ciclosporin Studies (20.06.11)

PRF completed by: ______ Date: _____ 43/111

IF PATIENT HAS ENL-I DATA COLLECTING FO		AN T	O COMPL	Date: ETE THE	FOLLO	/ WING EN
Symptoms of ENL						
How many days have you been fe	eeling unwe	ll for (tl	nis episode of	ENL):	days	
		(@®)				(
		\bigcirc			\bigcirc \bigcirc \bigcirc	
How unwell do you feel now (tick	k one face)?	NO HURT	HURTS HURT A LITTLE BIT A LITTLE I	S HURTS MORE EVEN MORE A V	HURTS HURTS WHOLE LOT WORST	
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscl	es?					
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?						
Tilly visual distarbance:		ı				
Examination						
Number of ENL lesions (circle):		0	1-5		6-20	>20
realmost of ErrE lesions (effect).		None	1 3		0 20	- 20
Inflammation in the ENL lesions				function not	affected	
Inflammation in the ENL lesions		Ervther	na and pain –	tunction not a		
Inflammation in the ENL lesions			na and pain – : na and pain – :			
Inflammation in the ENL lesions		Eryther	na and pain — ina and and pain — ina and and and and and and and and and a	function affe	cted	ceration
	,	Eryther Eryther	na and pain – ina and pain – i	function affection affection	cted	ceration
(If patient has previous records u	se comparis	Eryther Eryther	na and pain — na and pain — na and pain — na and pain — na revious VMT/S	function affection affection from a ffection affection affection affection from the following states affection affec	cted cted plus ul	
(If patient has previous records u VMT:	se comparis MRC=5	Eryther Eryther	na and pain – na and pain – na and pain – na and pain – nevious VMT/S MRC=4	function affection affection from affection affection affection affection from the function affection affe	cted cted plus ul	MRC<3
(If patient has previous records u VMT: ST decreased in:	se comparis MRC=5 None	Erythen Erythen	na and pain – na	function affection affection from a ffection affection affection affection from the following states affection affec	eted cted plus ul	MRC<3 three nerves
(If patient has previous records u VMT: ST decreased in:	se comparis MRC=5 None	Erythen Erythen	na and pain – na and pain – na and pain – na and pain – nevious VMT/S MRC=4	function affection affection from affection affection affection affection from the function affection affe	cted cted plus ul	MRC<3 three nerves
(If patient has previous records uVMT: ST decreased in: Nerve tenderness: None	se comparis MRC=5 None	Erythen Erythen	na and pain – na and pain – na and pain – na and pain – nevious VMT/S MRC=4 One nerve on palpation	function affection affection from the function affection of the function affection of the function affection affecti	cted cted plus ul 3 rve Withdraw	MRC<3 three nerves
(If patient has previous records uVMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin):	se comparis MRC=5 None	Erythen Erythen	na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa	function affection affection from the function affection of the function affection of the function affection affecti	eted plus ul B I rve Withdraw Withdraw	MRC<3 three nerves
(If patient has previous records u VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands):	se comparis MRC=5 None None	Erythen Erythen	na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa	function affection affection from the function affection of the function affection of the function affection affecti	eted plus ul B I rve Withdraw Withdraw Gross	MRC<3 ≥ three nerves
(If patient has previous records u VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands):	se comparis MRC=5 None	Erythen Erythen	na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa	function affection affection from the function affection of the function affection of the function affection affecti	etted etted plus ul B I I I I I I I I I I I I I I I I I I	MRC<3 ≥ three nerves vs vs unction
(If patient has previous records uVMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling:	se comparis MRC=5 None None	Erythen Erythen	na and pain — na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa Present Present	function affection affecti	etted etted plus ul B I I I I I I I I I I I I I I I I I I	MRC<3 ≥ three nerves
(If patient has previous records uVMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling:	se comparis MRC=5 None None None None	Erythen Erythen	na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa	function affection affecti	etted etted plus ul B I I I I I I I I I I I I I I I I I I	MRC<3 ≥ three nerves vs vs unction
(If patient has previous records u VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes: Testicles: Temperature:	se comparis MRC=5 None None None None	Erythen Erythen	na and pain — na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa Present Present Enlarged and	function affection affecti	eted plus ul B I I rve E Withdraw Withdraw Gross Affects fi Which: level:	MRC<3 three nerves s inction
(If patient has previous records uVMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes: Testicles: Temperature: Proteinuria (by dipstick):	se comparis MRC=5 None None None Normal Normal ≤37.5°C Negative	Eryther Eryther con to pr Tender	na and pain — na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa Present Present Enlarged and Tender (? Siz >37.5°C Positive	function affection affecti	eted plus ul B	MRC<3 three nerves s unction
(If patient has previous records u VMT: ST decreased in: Nerve tenderness: None Bone tenderness (shin): Oedema (ankle, face, hands): Joint swelling: Lymph nodes: Testicles:	se comparis MRC=5 None None None None Normal Normal ≤37.5°C	Eryther Eryther con to pr Tender	na and pain — na and pain — na and pain — revious VMT/S MRC=4 One nerve on palpation Tender on pa Present Present Enlarged and Tender (? Siz >37.5°C	function affection affecti	cted cted plus ul serve	MRC<3 three nerves s unction

Study: _ _	Study number: _	Patient Initials: _	
Week _		Date://	
	SEEN AND ATTACHED VM MT or ST compared to last as		
	Second Physician comm	nent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion of	n the severity of today's React	ion:	
	Severe		
	Moderate		
	Mild		
NB: IF NERVE FU	UNCTION HAS WORSENED	D SINCE LAST REVIEW	
PREDNISOLONE.	Carlot Soi I Oli in in in in	ZZZOTIO Z OM BIRMA	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date: 4	45/11

Study: _	Study number: [
Week	NS – physician to	Date://
Laboratory tests	(record results	if done)
	Date taken dd/mm/yyyy	Result
FBC	/	Hb: . _ g/dl WCC: ESR
Renal function	//	Creat: _ mg/dl Urea . _ mg/dl K+: . _ meq/l Na: . meq/l
LFT	//	Glucose mg/dl Alk phos iu/l ASAT iu/l
HIV Rapid test (via VCT)	//	ALAT _ iu/l Bilirubin total mg/dl 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)	/	 Positive Negative Advise re contraception options
EXTRA MEDICATION	PRESCRIBED T	ΓΟDAY:

Type of adverse event	Date of onset	Date of re	solution
Comments on managemen	t of adverse events:		
Did the patient require hos	pital admission?	1.Yes □	2. No □
f admitted was a SERIOU	S ADVERSE EVENT FORM	filled in?	
		1.Yes □	2. No □
Was the DSMB notified		1.Yes □	2. No □
Vhat action was taken?			

Study: _ Patient Initials: _
PHYSICIAN WORK SHEET: FOLLOW-UP
AT EACH REVIEW AND UNPLANNED VISIT, COMPLETE:
Insert the relevant week number: Week
insert the relevant week number.
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
DDF completed by

				We	ek to:	1	<u> </u>			
Ask patient about new symptoms since Did you notice any new loss or sensation is Did you notice any new dryness of your h Did you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (b New additional medications (other than M	in your ands pa hand c and nec ourning	han alms or fe edle	ds or so for the solution of t	feet? ot sol our ha)?	es? ands o	or fee				
Ask the patient if s/he has experienced any assessment:								e last		1
Patient's report of <u>nev</u>	<u>v</u> symp	toms	s since	e last	asses	smen	t			
		RI	IGHT			LE	EFT			
	E L B O W	H A N D	K N E E	F O O T	E L B O W	H A N D	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ } {\sf cold,\ numbness\ (Y/N)}$	"				,,					-
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 skin lesions since last a										
(Y/N/STABLE)										
How many skin patches have improvisit?										
Have they developed new skin patc (Y/N)										
How many new skin patches have or recently?										
Do you feel your skin is worse, the	same	or k	oetter	?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONE		ERY1	ГНЕМ	ЛΑ	AN		EMA	ULCE	RATE
Ciclosporin Studies (20,06.11) PRF completed	d hv				Dat		- 		49/111	

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

Study: |__|_|_|

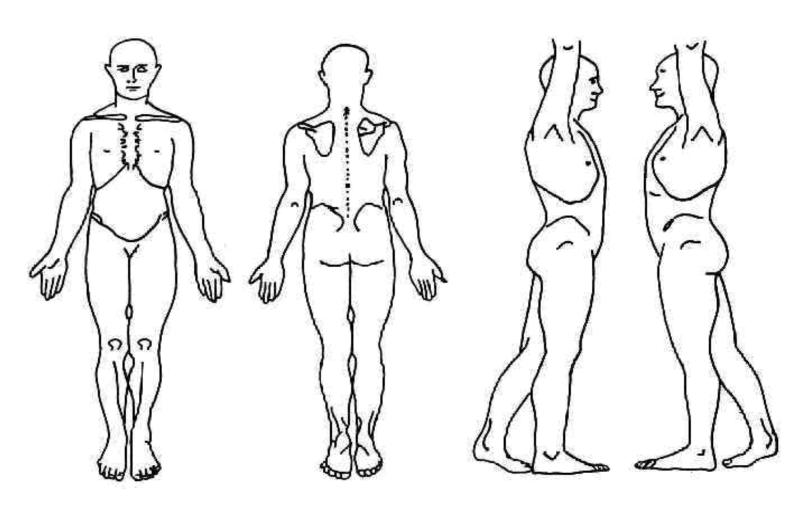
Week _		Date:	_//
New medications:			
Drug and reason starting	Date st dd/mn		Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
Acne			
Gum hyperplasia Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastrointestinal bleeding		1	—
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 1	least 1/52 apart		
Infections			
inicctions			
Infected ulcers			
Infected ulcers Corneal ulcer Tuberculosis			
Infected ulcers Corneal ulcer Tuberculosis Night sweats			
Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions			
Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting			
Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea			
Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea Breathing difficulties			
Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	FT)		

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	50/111
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Study: _ _	St	udy number:		Patient I	nitials:	_ _	
Week _	⅃			Date: _	_//_		
FOLLOW UP EXA	AMINATIO	ON -					
XVII. Weig XVIII. Vital sig	ght: _ ns	_ . kg					
Temp		ulse 		B.P. (sy	ystolic/ dia	astolic)	
XIX. General	examinatio	n					
	1.Normal		3.Not examined	If abno	ormal spec	eify	
Head and neck							
Lymph nodes							
2 1							
Skin (non leprosy)							
Lungs							
Heart							
Abdomen							
Liver							
Spleen							
Ext Genitalia							
(male)							
(mare)							
	Examination Nerves - sig	ns and sympton		s (since la) symptoms –	
Name of herve	tenderness		weakness	$(\sqrt{\text{if ves}})$	numbness, pain($\sqrt{\text{if yes}}$)		
	Grade*	(yes or no)	Old	New	Old	New	
		() 12 3 3)		- 1011	0.00		
R Cervical/GA, Facial					N/A	N/A	
L Cervical/ GA, Facial				1			
R Ulnar				1			
L Ulnar				1			
R Median				1			
L Median					37/4	37/4	
R Radial/ R.C.				1	N/A	N/A	
L Radial/ R.C.				1	N/A	N/A	
R lat popliteal							
L lat popliteal R Post Tibial				1			
L Post Tibial				+			
* Grading for nerve		0=none 2= withdrawal/	wincing		tenderness lowing pa		
Ciclosporin Studies (20.06.11)	PRF	completed by:		Dat	e: _	51/11	

sporin Studies (20.06.11)	PRF completed by:	Date:	51/111

Study: _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- 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	
А3	Peripheral oedema due to reaction	None	Minimal	Visible, but not affecting function	Oedema affecting function	
A SCORE						

Ciclosporin Studies (20.06.11)

PRF completed by: ______ Date: _____ 52/111

Study:	Study n	number	: [Patien	t 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 fee	ling unwe	ell for (th	is episode o	f ENL): d	ays		
		(3)					
How unwell do you feel now (tick	one face)	O NO HURT	1 HURTS HI A LITTLE BIT A LITT	2 3 Urts Hurts H Le More even More A WH	4 5 URTS HURT: HOLE LOT WORS	5 T	
Have you noticed		NO	YES				
Any new lumps on your skin?							
Any new sensory loss?							
Any new weakness in your muscle	s?						
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): Inflammation in the ENL lesions (Erythen	na and pain -	5 - function not a - function affec - function affec	ted	>20	
(If patient has previous records use	e compari	son to ni	revious VMT	VST testing):			
VMT:	MRC=5		MRC=4	MRC=3		MRC<3	
ST decreased in:	None		One nerve			≥ three nerves	
Nerve tenderness: None	1,0110	Tender	on palpation		Withdray		
Bone tenderness (shin):	None		Tender on p		Withdray		
Oedema (ankle, face, hands):	None		Present	outpution	Gross	W 5	
Joint swelling:	None		Present		Affects f	inction	
Joint Swelling.	Tione		Tresent				
Lymph nodes:	Normal		Enlarged ar	nd tender			
Testicles:	Normal		Tender (? S				
Temperature:	≤37.5°C		>37.5°C	-)	level:		
Proteinuria (by dipstick):	Negative		Positive		level:		
Red eyes:	Yes	•	No		Ophthalr	nology	
2.00.0,00.	1 00		110	diagn			
				a.wg.i	- ~-~ -		

Ciclosporin Studies (20.06.11)	PRF completed by: _	Date:	53/111
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Study: _ _	Study number: _	Patient Initials: _	_
Week _		Date://	
	SEEN AND ATTACHED VMMT or ST compared to last as:		
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion on	the severity of today's Reacti	on:	
	Moderate		
	Mild		
NB: IF NERVE FU	NCTION HAS WORSENEI	O SINCE LAST REVIEW	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	54/111

Laboratory tests	(record results Date taken	if done) Result
	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

Type of adverse event	Date of onset	Date of re	solution
omments on managemer	nt of adverse events:		
id the patient require hos	spital admission?	1.Yes □	2. No □
admitted was a SERIOU	JS ADVERSE EVENT FOR	M filled in?	
		1.Yes □	2. No □
as the DSMB notified		1.Yes □	2. No □
hat action was taken?			

Study: _ _	Study number: _		Patient Initials: _
PHYSICIAN WORK S	SHEET: FOLLOV	V-UP	
AT EACH REVIEW AND	UNPLANNED VISI	T, COMP	LETE:
Insert the relevant wee	k number:	Week	<u> _ _</u>
And date:		Date:	//
Physician to complete histo	ory and examination	and ensur	e lab results are entered
Physician to complete adve	erse event form if nec	essary	
Ensure correct physiothera	apy form is attached	to PRF	
	page 2: Assessment		
	next planned visit or about completed pa		Assessment Record ew in order to transfer data

				We	ek te: _	1				
Ask patient about new symptoms since I Did you notice any new loss or sensation in Did you notice any new dryness of your had Did you notice any new weakness in your Did you notice any new sensation of pins a Did you notice any new pain sensations (but New additional medications (other than Mines). Ask the patient if s/he has experienced any	n your unds pa hand o und ne urning DT an	han alms or fee edles s/ sho d inc	ds or for the state of the stat	feet? ot sol our ha)? g ana	es? ands c	or fee	t?			
assessment: Patient's report of new	, symp	toms	s since	last	asses	smen	ıt			7
7 3			IGHT				EFT			-
	T.	,		F	F			F	OTHER	-
	E L B O W	H A N D	K N E E	F O O T	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ cold,\ numbness\ (Y/N)}$,,				,,					_
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 skin lesions since last as										
(Y/N/STABLE)	OVEC	• •								
How many skin patches have improvisit?										
Have they developed new skin patch (Y/N)										
How many new skin patches have derecently?										
Do you feel your skin is worse, the	same	or k	etter	?						
Facial patch? (Y/N)	ייבסוג		EDV		1 A		VTII		111 05	
Facial patch inflammation. (Circle)	NONI		ERY1	HEN	/IA	AN		EMA	ULCEI	KATEL
Ciclosporin Studies (20.06.11) PRF completed	by:				Dat	e:			58/111	

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

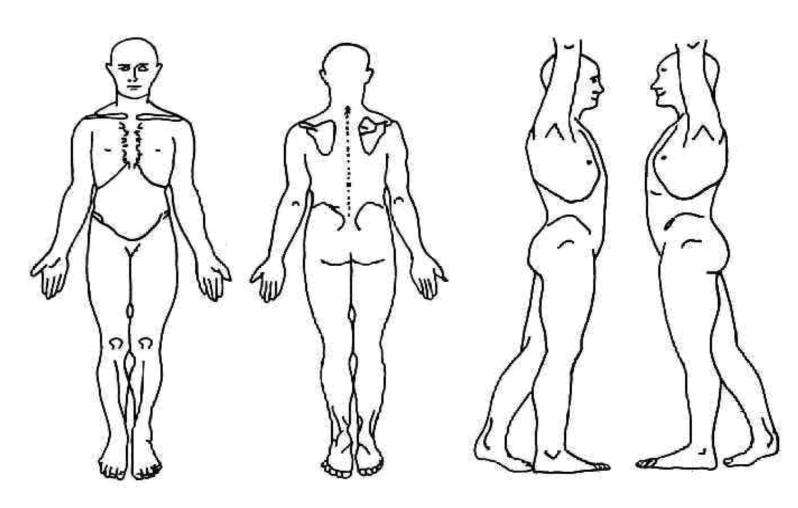
Study: |__|_|

I <u></u> I		Date:	_//
New medications:			
Drug and reason starting	Date st dd/mn	arted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
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			
Wainlet lang > 51-2			
Weight gain			
Weight gain Glaucoma			
Weight gain Glaucoma Cataract	11/50		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcers	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting			

Study: _ _		Study number: _				Patient Initials: _			
Week _	_l					Date: _	_//_		
FOLLOW UP EXA	AMINATI	ON	-						
XXI. Weig XXII. Vital sign	ht: ns	.	kg						
Temp .		Pulse			B.P. (systolic/ diastolic)				
XXIII. General	examinat	ion							
	1.Normal	2.	Abnormal		Not amined	If abno	ormal spec	rify	
Head and neck				UA	ummou				
Lymph nodes		-							
Skin (non leprosy)									
Lungs									
Heart									
Abdomen									
Liver									
Spleen									
Ext Genitalia									
(male)									
XXIV. Leprosy vi. <u>N</u>			and sympto	oms	of neuritis	s (since la	nst review)	
Name of nerve	Nerve		Nerve Motor syn		mptoms –	Sensory	symptoms –		
	tenderne	ss -	enlargemen	ıt				s, pain($\sqrt{\text{if yes}}$)	
	Grade*		(yes or no)		Old	New	Old	New	
R Cervical/GA, Facial							N/A	N/A	
L Cervical/GA, Facial					1		11/71	1 1/ /1	
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		none withdrawa	ıl/ w	rincing		tenderness lowing pa		

Ciclosporin Studies (20.06.11)	PRF completed by: _	 Date:	60/111

Study: _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- oedema of the hands and/	
	- mark skin biopsy site,	
	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						

PRF completed by: ______ Date: _____ 61/111

Study: _	Study n	umber: _	_ _ _	Patien	t Initials	s: _
Week _ _ IF PATIENT HAS ENL-P DATA COLLECTING FO		AN TO	COMPL	Date: LETE THE	/ FOLLO	_/_ DWING ENI
Symptoms of ENL						
How many days have you been fe	eling unwel	l for (this	episode of	ENL): d	ays	
		(e) (
How unwell do you feel now (tick	one face)?	NO HURT	HURTS HUI A LITTLE BIT A LITTU	Z 3 RTS HURTS HI E MORE EVEN MORE A WH	4 5 URTS HUR IOLE LOT WOR	rs st
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscle	es?					
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): Inflammation in the ENL lesions ((circle):	Erythema a	and pain –	function not a function affection affection affection	ted	>20
(If patient has previous records us	a aomnanis	on to muon	ious VMT	(ST testing):		
VMT:	MRC=5		10 <i>us v 1</i> 417/ IRC=4	MRC=3		MRC<3
ST decreased in:	None		ne nerve	Two ner	ve	≥ three nerves
Nerve tenderness: None		Tender on		1 WO HOI	Withdra	
			_			
Bone tenderness (shin):	None		ender on p	alpation	Withdra	WS
Oedema (ankle, face, hands):	None		resent		Gross	
Joint swelling:	None	P	resent		Affects the Which:	function
Lymph nodes:	Normal	Е	nlarged an	d tender		
Testicles:	Normal		ender (? S			
Temperature:	≤37.5°C		37.5°C	,	level:	
Proteinuria (by dipstick):	Negative		ositive		level:	
Red eyes:	Yes	N			Ophthali	mology
		- 1		diagn	osis:	
				Č		

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Describe any changes in V	SEEN AND ATTACHED VM On ST compared to last as	sessment:
	Second Physician comm	nent:
PATIENT HAS:	TYPE 1 REACTION	
	ENL	
Specialist opinion o	n the severity of today's React	ion:
	Severe	
	Moderate	
	Mild	
NB: IF NERVE FU	UNCTION HAS WORSENE	D SINCE LAST REVIEW
PREDNISOLONE. Ciclosporin Studies (20.06.11)	PRF completed by:	Date: 63/11

Study: _ _	Study number: [Patient Initials:
Week _		Date://
FORM: INVESTIGATIO	NS – physician to	o fill in
Laboratory tests	(record results	if done)
	Date taken dd/mm/yyyy	Result
FBC	/	Hb: . _ g/dl WCC: _ ESR
Renal function	/	Creat: mg/dl Urea mg/dl K+: meq/l Na: meq/l
LFT	/	Glucose mg/dl Alk phos iu/l ASAT iu/l ALAT iu/l Bilirubin total mg/dl
HIV Rapid test (via VCT)	/	1. Positive
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 T	ΓΟDAY:

Type of adverse event	Date of onset	Date of re	solution
omments on managemen	t of adverse events:		
id the patient require hos	pital admission?	1.Yes □	2. No □
admitted was a SERIOU	S ADVERSE EVENT FORM	A filled in?	
		1.Yes □	2. No □
Vas the DSMB notified		1.Yes □	2. No □
hat action was taken?			

Study: _	Study number:		Patient Initials: _	
PHYSICIAN WORK	X SHEET: FOLLO	W-UP		
AT EACH REVIEW AN	ND UNPLANNED VIS	SIT, COM	PLETE:	
Insert the relevant w	eek number:	Week	<u> _</u>	
And date:		Date:	//	
		2		
Physician to complete hi	story and examination	and ensu	re lab results are entered	
Physician to complete ad	lverse event form if no	ecessary		
Ensure correct physiothe	erapy form is attached	l to PRF		
After each visit: 19. mark off visit	on page 2: Assessmen	t Record		
21. Tell Investiga	of next planned visit of tor about completed p		Assessment Record iew in order to transfer da	nta
to CRF				
Ciclosporin Studies (20.06.11)	PRF completed by:		Date:	66/111

				We	ek	1	<u></u> /			
Ask patient about new symptoms since Did you notice any new loss or sensation in Did you notice any new dryness of your had Did you notice any new weakness in your Did you notice any new sensation of pins a Did you notice any new pain sensations (b New additional medications (other than M Ask the patient if s/he has experienced any	n your ands pa hand cand ne urning DT an	han alms or fe edle g/ sho d in	ids or s or fo et? s in yo ooting cludin	feet? ot sol our ha g)? ig ana	es? ands c	or fee	t?			
assessment: Patient's report of new	v svmp	toms	s since	e last	asses	smen	et			1
	- · · · · · · ·		IGHT				EFT			_
	-				-				OTHER	-
	E L B O W	H A N D	K N E E	F O O T	E L B O W	H A N D	K N E E	F O O T	OTHER	
$\begin{array}{c} Diminished \ sensation - \ eg \ unable \ to \ feel \ hot \ or \\ cold, \ numbness \ (\mathbf{Y/N}) \end{array}$,,									
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 skin lesions since last a										
Have the inflamed skin patches imp (Y/N/STABLE)	rovec	1?								
How many skin patches have improvisit?	ved s	inc	e last	•						
Have they developed new skin patch (Y/N)										
How many new skin patches have d recently?										
Do you feel your skin is worse, the	same	or k	<u>oettei</u>	r?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONI	E	ERY	ГНЕМ	ЛΑ	AN		EMA	ULCEI	RATED
Ciclosporin Studies (20.06.11) PRF completed	l by:				_ Dat	e:			67/111	

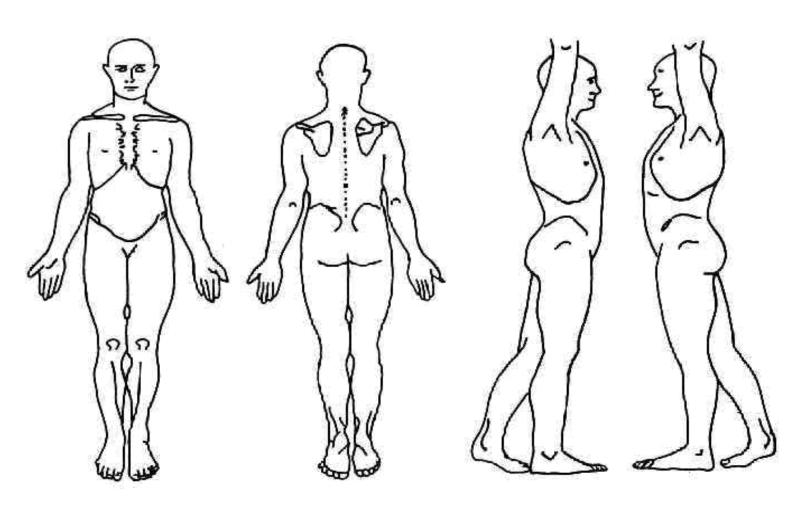
Study number: |__|_| Patient Initials: |__|_|

Study: |__|_|

Week _		Date:	.//
New medications:			
Drug and reason starting	Date st dd/mr	tarted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
Moon face Acne			
Gum hyperplasia Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia		+	
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract			
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		
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 Infections	least 1/52 apart		
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 Infections Infected ulcers	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions			

Study: _ _		Study number: Patient Initials:					_	
Week _	_l					Date: _	_//_	
FOLLOW UP EXA	AMINAT	ION	-					
XXV. Weight: _ . kg XXVI. Vital signs								
Temp		Puls	se	1	ı	B.P. (sy	/stolic/ di	astolic)
_ .							/	
XXVII. Gene	eral exam	inati	on					
	1.Norma	al 2.	Abnormal	3.1	Not	If abno	rmal spec	eify
				ex	amined			
Head and neck								
Lymph nodes								
Skin (non leprosy)								
Lungs								
Heart								
Abdomen								
Liver								
Spleen								
Ext Genitalia								
(male)								
(IIIaic)								
VVVIII I omm	ogy Evor	nim a t	ion					
XXVIII. Lepr	osy Exai	шпац	1011					
vii. <u>1</u>	Nerves -	signs	and sympto	oms	of neuritis	s (since la	ıst review)
Name of nerve	Nerve		Nerve		Motor svi	nptoms –	Sensory	symptoms –
	tendern	ess -		ıt	weakness	$(\sqrt{1})$ if yes)	numbness	s, pain($\sqrt{\text{if yes}}$)
	Grade*		(yes or no)		Old	New	Old	New
R Cervical/GA, Facial							N/A	N/A
L Cervical/ GA, Facial							IN/A	IN/A
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								
E 1 05t 110141						1		
* Grading for nerve	tendernes		none withdrawa	ıl/ w	rincing		tenderness lowing pa	
					_		2.1	

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- 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						

Ciclosporin Studies (20.06.11)

PRF completed by: ______ Date: _____ 70/111

Study: _ _	Study	numb	er: _	_		Patien	t Initial	s: _
Week _ _ IF PATIENT HAS ENL-P DATA COLLECTING FO		IAN T	го (COMPI	LET	Date: E THE	/_ FOLL	_/ OWING ENL
Symptoms of ENL								
How many days have you been fee	ling unw	ell for ((this e	episode of	f ENI	L): d	lays	
			9		<u>)</u>			
How unwell do you feel now (tick	one face)	NO	RT A	HURTS HU LITTLE BIT A LITTL	JRTS LE MORE	HURTS IN EVEN MORE A WI		RTS RST
Have you noticed		N	О	YES				
Any new lumps on your skin?					-			
Any new sensory loss?								
Any new weakness in your muscle	s?							
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): Inflammation in the ENL lesions (circle):	0 None Ervthe	ema a	1-: and pain –		etion not a	6-20	>20
				ınd pain –				
								ulceration
		-		_			_	
(If patient has previous records us	e compar	ison to	previ	ious VMT	/ST te	esting):		
VMT:	MRC=5			RC=4		MRC=3		MRC<3
ST decreased in:	None			ne nerve		Two ner		\geq three nerves
Nerve tenderness: None		Tende	er on	palpation			Withdra	aws
Dana tandamasa (shin)	Mana		т.		1 4	.:	W7:41, J.,.	
Bone tenderness (shin): Oedema (ankle, face, hands):	None None			ender on p esent	parpar	uon	Withdra Gross	iws
Joint swelling:	None			esent				function
Joint swening.	None		11	CSCIII				Tunction
Lymph nodes:	Normal		Fı	nlarged ar	nd ten	der	W IIICII.	
Testicles:	Normal			ender (? S		idei		
Temperature:	≤37.5°C			37.5°C	,		level: _	
Proteinuria (by dipstick):	Negativ			ositive			level:	
Red eyes:	Yes	-	N				Ophtha	lmology
,			- '			diagr	-	
						J		

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	71/111
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Study: _ _	Study number: _	Patient Initials: _	_
Week _		Date://	
	SEEN AND ATTACHED VM		
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion of	n the severity of today's React	ion:	
	Severe		
	Moderate		
	Mild		
NB: IF NERVE FU	UNCTION HAS WORSENED	D SINCE LAST REVIEW	
PLEASE LOOK AT PAC PREDNISOLONE.	GE 21 OF SOP FOR INDICA	ATIONS FOR EXTRA	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	72/111

Laboratory tests	(record results Date taken	if done) Result
	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
FT	/	Alk phos _ _ iu/l ASAT _ _ iu/l ALAT _ _ iu/l Bilirubin total mg/dl
IIV Rapid test (via VCT)	/	1. Positive _ 2. Negative
lood sugar (glucometer)	/	
tool for ova, cysts and arasites	/	1. Positive 2. Negative
Jrinalysis (dipstick)	//	1. Positive 2. Negative Specify:
regnancy test (urine)	//	1. Positive 2. Negative Advise re contraception options

Type of adverse event			
omments on managemen	t of adverse events:		
id the patient require hos	pital admission?	1.Yes □	2. No □
admitted was a SERIOU	S ADVERSE EVENT FORM	M filled in?	
		1.Yes □	2. No □
Vas the DSMB notified		1.Yes □	2. No □
/hat action was taken?			

Study: _	Study number: _		Patient Initials: _
PHYSICIAN WORK S	SHEET: FOLLOV	V-UP	
AT EACH REVIEW AND	IINPLANNED VISI	T. COM	PLETE:
AT EXCIT REVIEW AND	ON EMNED VISI	1, com	LEDIE.
Insert the relevant wee	k number:	Week	
And date:		Date:	//
Physician to complete histo	ory and examination :	and ensu	re lab results are entered
Physician to complete adve	erse event form if nec	essary	
Ensure correct physiothera	apy form is attached t	to PRF	
23. Write in date of	n page 2: Assessment next planned visit on r about completed pa	page 2:	Assessment Record iew in order to transfer data

				We	ek	1	<u></u> /			
Ask patient about new symptoms since I Did you notice any new loss or sensation in Did you notice any new dryness of your had Did you notice any new weakness in your Did you notice any new sensation of pins a Did you notice any new pain sensations (b New additional medications (other than M Ask the patient if s/he has experienced any	n your ands pa hand o and ne urning DT an	han alms or fe edle s/ sho d in	ds or for et? s in your ooting cludin	feet? ot sol our ha)? g ana	es? ands c	or fee	t?			
assessment: Patient's report of new										1
T attent 5 report of new	<u>-</u> <i>symp</i>			· iasi			EFT			-
		,	IGHT	1						
	E L B O W	H A N D	K N E E	F O O T	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	F O O T	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 skin lesions since last as	ssessn	<u>nent</u>								
Have the inflamed skin patches imp (Y/N/STABLE)										
How many skin patches have improvisit?										
Have they developed new skin patcl (Y/N)	hes re	ecer	ntly?							
How many new skin patches have d recently?	evelo	pec	i							
Do you feel your skin is worse, the s	same	or k	oetter	?						
Facial patch? (Y/N)		_	<u> </u>			LED	\ 			DATES
Facial patch inflammation. (Circle)	NONI	=	ERY1	HEN	/IA	AN		EMA	ULCE	RATED
Ciclosporin Studies (20.06.11) PRF completed	l by:				Dat	e:			76/111	

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

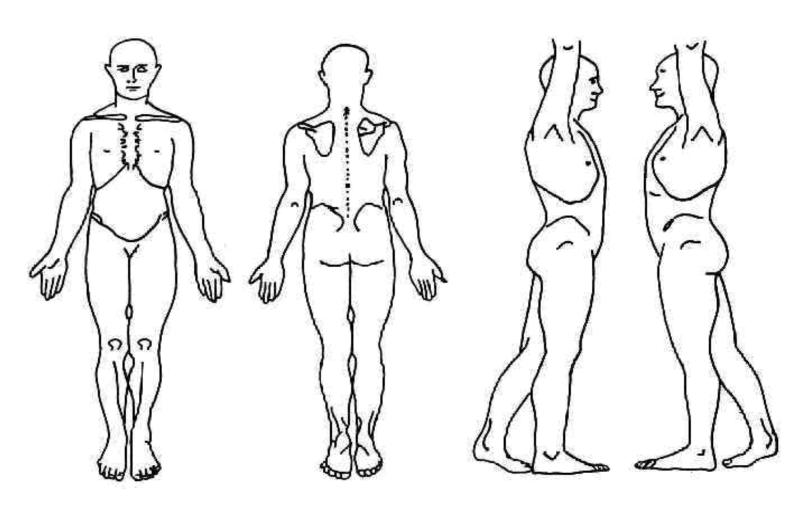
Study: |__|_|

Week _		Date:	_//
New medications:			
Drug and reason starting	Date st dd/mn	arted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face			
Acne			
Gum hyperplasia			
Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastrointestinal bleeding			
Nocturia, polyuria, polydipsia			
Diabetes mellitus			
Diabetes mellitus Psychosis or other mental health problems			
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg			
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain			
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma			
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract	at locat 1/52 corret		
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		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer Tuberculosis	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	at least 1/52 apart		
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea Breathing difficulties			
Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea			

Study: _ _	S	tudy number:		Patient I	nitials:	_ _	
Week _	_			Date: _	_//_		
FOLLOW UP EXA	AMINATI(ON -					
XXIX. Weig XXX. Vital sign	·	. kg					
Temp . .	I	Pulse		B.P. (sy	B.P. (systolic/ diastolic)		
XXXI. General	examinatio	on					
	1.Normal	2.Abnormal	3.Not examined		ormal spec	eify	
Head and neck			CAUTITIO				
Lymph nodes							
Skin (non leprosy)							
Lungs							
Heart							
Abdomen							
Liver							
Spleen							
Ext Genitalia							
(male)							
-	osy Exami <u>Nerves</u> - sig	nation gns and sympt	oms of neur	ritis (since la	st review)	
Name of nerve	Nerve	Nerve	Motor	symptoms –	Sensory	symptoms –	
	tendernes	s - enlargeme	nt weakn	ess ($\sqrt{\text{if yes}}$)	numbnes	s, pain($\sqrt{\text{if yes}}$)	
	Grade*	(yes or no)) Old	New	Old	New	
R Cervical/GA, Facial					N/A	N/A	
L Cervical/GA, Facial					11/71	11/71	
R Ulnar							
L Ulnar							
R Median		<u> </u>					
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 2= withdraw	al/ wincing		tendernes lowing pa		

Ciclosporin Studies (20.06.11)	PRF completed by:	Da	ite:	78/111

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- 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						

PRF completed by: ______ Date: _____ 79/111

Study:	Study	numbei	r: _	_ _		Patien	t Initia	ls: _
Week _ _ IF PATIENT HAS ENL–P DATA COLLECTING FO		IAN T	0 (COMPI	LETH	Date: E THE	/_ FOLL	_/ OWING ENL
Symptoms of ENL								
How many days have you been fee	eling unw	ell for (tl	his e	pisode o	f ENL): d	lays	
		(@))((E)	<u></u>	(a)		
		O NO HURT	/ \	HURTS HI	2 JRTS	3 HURTS I	4 IURTS HU	5 RRTS
How unwell do you feel now (tick	one face)	? HURT	A	LITTUE BIT A LITT	LE MORE E	EVEN MORE A WI	HOLE LOT W	DRST
Have you noticed		NO)	YES				
Any new lumps on your skin?								
Any new sensory loss?								
Any new weakness in your muscle	es?							
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): Inflammation in the ENL lesions (circle):	Eryther	na a	nd pain -	- funct - funct	tion not a tion affection affec	ted	>20 ulceration
				171.67	VCT.			
(If patient has previous records us					/SI tes			MDC~2
VMT: ST decreased in:	MRC=5 None			RC=4 ne nerve		MRC=3 Two ner		MRC<3 ≥ three nerves
Nerve tenderness: None	None	Tender		ne herve palpation		I WO HEI	Withdra	
refre tenderness.		1 chaci	011 }	aipation			vv itilare	. ws
Bone tenderness (shin):	None		Te	nder on p	nalnati	ion	Withdra	aws
Oedema (ankle, face, hands):	None			esent			Gross	
Joint swelling:	None			esent			Affects	function
Č							Which:	
Lymph nodes:	Normal		En	larged ar	nd tend	der		
Testicles:	Normal			nder (? S				
Temperature:	≤37.5°C			7.5°C	,		level: _	
Proteinuria (by dipstick):	Negativ		Po	sitive			level:	
Red eyes:	Yes		No				Ophtha	lmology
-						diagn	-	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	_ 80/11
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Study: _ _	Study number: _	Patient Initials: _
Week		Date://
	E SEEN AND ATTACHED VMVMT or ST compared to last as:	
	Second Physician comm	<u>ent:</u>
PATIENT HAS:	TYPE 1 REACTION	
	ENL	
Specialist opinion of	on the severity of today's React	ion:
	Severe	
	Moderate	
	Mild	
NB: IF NERVE F	UNCTION HAS WORSENED	D SINCE LAST REVIEW
Ciclosporin Studies (20.06.11)	PRF completed by:	Date: 81/111

Laboratory tests	(record results Date taken	if done) Result
	dd/mm/yyyy	result
BC	//	Hb: . _ g/dl WCC: _ _ Plt: ESR
Lenal function	/	Creat: _ mg/dl Urea _ mg/dl K+: _ meq/l Na: _ _ meq/l Glucose mg/dl
FT	/	Alk phos iu/l ASAT iu/l ALAT iu/l Bilirubin total mg/dl
IIV Rapid test (via VCT)	/	1. Positive 2. Negative
lood sugar (glucometer)	//	
tool for ova, cysts and arasites	/	1. Positive 2. Negative
Jrinalysis (dipstick)	//	1. Positive 2. Negative Specify:
regnancy test (urine)	/	1. Positive 2. Negative Advise re contraception options

	Date of onset	Date of res	solution
mments on manageme	ent of adverse events:		
id the patient require ho	ospital admission?	1.Yes □	2. No □
admitted was a SERIO	US ADVERSE EVENT FC	ORM filled in? 1.Yes □	2. No □
as the DSMB notified		1.Yes □	2. No □
That action was taken?			

Study: _ _	Study number:	P	atient Initials: _
PHYSICIAN WORK	SHEET: FOLLOW	-UP	
AT EACH REVIEW AND) UNPLANNED VISIT	, COMPL	ÆTE:
Insert the relevant wee	ek number:	Week	<u> _</u>
And date:		Data	1 1
And date.		Date	_//
Physician to complete hist	ory and examination a	nd ensure	lab results are entered
Physician to complete adv	erse event form if nece	ssary	
Ensure correct physiother	apy form is attached to	PRF	
	n page 2: Assessment F f next planned visit on		ssessment Record
			v in order to transfer data
	DDF 1 4 11		D /

				We	ek to:	1	<u> </u>	 		
Ask patient about new symptoms since Did you notice any new loss or sensation Did you notice any new dryness of your h Did you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (I New additional medications (other than M Ask the patient if s/he has experienced and	in your lands part hand of and new burning IDT and	han alms or fee edle: / sho d ind	ds or for the state of the stat	feet? ot sol our ha)? g ana	es? ands c	or fee	t?			
assessment: Patient's report of ne	w symp	toms	s since	last	asses	smen	t]
Tunent breport of ne	<u> </u>		IGHT				EFT			
									OTHER	
	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	H A N D	K N E E	$\begin{bmatrix} F \\ O \\ O \\ T \end{bmatrix}$	$\begin{bmatrix} E \\ L \\ B \\ O \\ W \end{bmatrix}$	$\begin{vmatrix} H \\ A \\ N \\ D \end{vmatrix}$	K N E E	$\begin{bmatrix} F \\ O \\ O \\ T \end{bmatrix}$	OTHER	
$Diminished\ sensation - {\it eg\ unable\ to\ feel\ hot\ or\ cold,\ numbness\ (Y/N)}$,,					
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 skin lesions since last a Have the inflamed skin patches imp (Y/N/STABLE) How many skin patches have improvisit?	oroved oved s	ince	e last							
Have they developed new skin pato (Y/N)										
How many new skin patches have or recently?										
Do you feel your skin is worse, the	same	or k	etter	?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONE	=	ERY	ГНЕМ	ИΑ	AN		EMA	ULCEF	RATED
Ciclosporin Studies (20.06.11) PRF complete	d by:				Dat	e·			85/111	

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

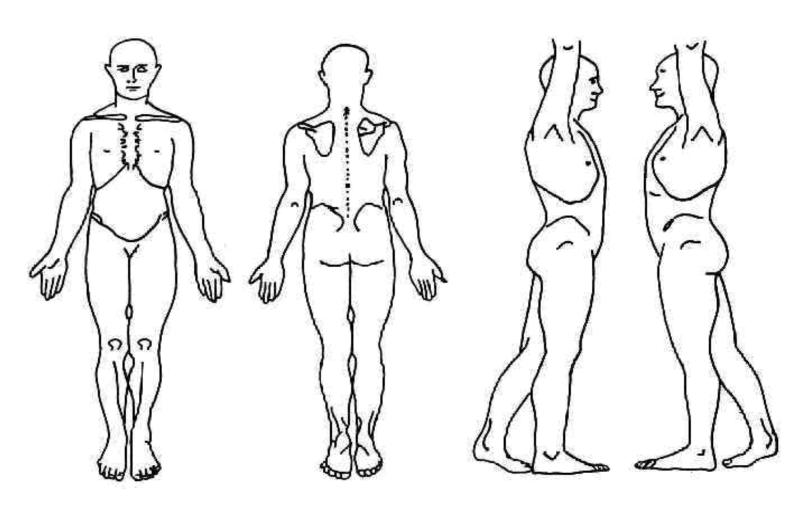
Study: |__|_|_|

Week _		Date:	//
New medications:			
Drug and reason starting	Date st dd/mr	tarted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
Acne			
Gum hyperplasia Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastric pain requiring antacid			
Gastrointestinal bleeding			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia		+	
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma			
Gastrointestinal bleeding Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract	11/52		
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	e least 1/52 apart		
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		
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 Infections Infected ulcers	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	e least 1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions			

Study: _	S	Stud	y number: [_	_ _	Patient I	nitials:	_	
Week _	_l					Date: _	_//_		
FOLLOW UP EXAMINATION -									
XXXIII. Weight: _ . _ kg XXXIV. Vital signs									
Temp		Puls	se _			B.P. (sy	stolic/ dia	astolic)	
XXXV. Gene	ral exami	nati	on						
	1.Normal	2.	Abnormal		Not amined	If abno	rmal spec	eify	
Head and neck		+							
Lymph nodes									
* *		+							
Skin (non leprosy)		1							
Lungs									
Heart									
Abdomen									
Liver									
Spleen									
Ext Genitalia									
(male)									
	<u>Verves</u> - si		and sympto	oms		· 			
Name of nerve	Nerve		Nerve	,	Motor sy	mptoms –		symptoms –	
	tenderne: Grade*	ss -	enlargemen (yes or no)	τ	weakness Old	New	Old	$\frac{1}{1}$ new	
	Grade		(yes of no)		Olu	New	Olu	New	
R Cervical/GA, Facial							N/A	N/A	
L Cervical/ GA, Facial									
R Ulnar									
L Ulnar									
R Median									
L Median							N/A	NI/A	
R Radial/ R.C. L Radial/ R.C.							N/A N/A	N/A N/A	
R lat popliteal					1		1 N /A	IN/A	
L lat popliteal									
R Post Tibial									
L Post Tibial									
* Grading for nerve	tenderness		none withdrawa	ıl/ w	vincing		enderness lowing pa		

Ciclosporin Studies (20.06.11)	PRF completed by:	Da	ate:	87/111

Study: _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- oedema of the hands and/	
	- mark skin biopsy site,	
	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						

PRF completed by: _____ Date: _____ 88/111

Week _ IF PATIENT HAS ENL-H DATA COLLECTING FO		AN TO	COMPLE	Date: TE THE	FOLLO	V WING EN
)KIVI					
Symptoms of ENL						
How many days have you been fe	eling unwel	l for (this	episode of E	NL): d	ays	
			$(\mathfrak{G})(\mathfrak{G})$	$)(\mathfrak{\underline{\mathfrak{P}}})(\mathfrak{z})$	(* <u>*</u>)
How unwell do you feel now (ticl	c one face)?	O NO HURT	1 2 HURTS HURTS A LITTLE BIT A LITTLE MOR	3 HURTS HI RE EVEN MORE A WH	4 5 URTS HURTS OLE LOT WORST	
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscl	es?					
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						
Ni and an aCENII dasiana (cinala).			1.5		(20	> 20
Number of ENL lesions (circle):	(cirolo):	None	1-5		6-20	>20
Inflammation in the ENL lesions			and pain – fu	ination not a	ffootod	
			and pain – fu			
			and pain – fu			eration
	-	31) 111-111	and pain 10		ova pras are	
(If patient has previous records u.	se comparis	on to pre	vious VMT/ST	[testing):		
VMT:	MRC=5	N	MRC=4	MRC=3	N	IRC<3
ST decreased in:	None		One nerve	Two ner		three nerves
Nerve tenderness: None		Γender or	palpation		Withdraws	S
Bone tenderness (shin):	None	7	Tender on pal	nation	Withdraws	,
Oedema (ankle, face, hands):	None		resent	pation	Gross	•
Joint swelling:	None		Present		Affects fur	nction
John Swehing.	rvonc	1	resent			
Lymph nodes:	Normal	F	Enlarged and	tender		
Testicles:	Normal		Γender (? Size			
Temperature:	≤37.5°C		>37.5°C	/	level:	
Proteinuria (by dipstick):	Negative		Positive		level:	
	Yes	1	No		Ophthalmo	
Red eyes:	1 03				1	6)

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	89/111
· · · · · · · · · · · · · · ·	r		

Study: _	Study number: _	Patient Initials: _	_
Week _ _		Date://	_
	SEEN AND ATTACHED VI		
	Second Physician comm	nent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion or	n the severity of today's React	ion:	
	Severe		
	Moderate		
	Mild		
	st normal therapy you would		
PLEASE LOOK AT PAC PREDNISOLONE.	GE 21 OF SOP FOR INDIC.	ATIONS FOR EXTRA	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	90/111

Laboratory tests	(record results Date taken	if done) Result
	dd/mm/yyyy	Result
FBC	//	Hb: . _ g/dl WCC: _ _ Plt: ESR
Renal function	/	Creat:
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
Jrinalysis (dipstick)	//	1. Positive 2. Negative Specify:
Pregnancy test (urine)	/	Positive Negative Advise re contraception options

ype of adverse event	Date of onset	Date of re	solution
omments on managemen	t of adverse events:		
old the patient require hos	pital admission?	1.Yes □	2. No □
admitted was a SERIOU	S ADVERSE EVENT FORM	A filled in?	
		1.Yes □	2. No □
as the DSMB notified		1.Yes □	2. No □
hat action was taken?			

Study: _ _	Study number: _	_ F	Patient Initials: _
PHYSICIAN WORK S	SHEET: FOLLOV	V-UP	
AT EACH REVIEW AND	UNPLANNED VISI	T, COMP	LETE:
Insert the relevant wee	k number:	Week	<u> _ _ </u>
And date:		Date: _	//
Physician to complete histo	ory and examination	and ensur	e lab results are entered
Physician to complete adve	erse event form if nec	essary	
Ensure correct physiothera	apy form is attached	to PRF	
	n page 2: Assessment		
	next planned visit or about completed pa		ssessment Record w in order to transfer data

				We	ek	1	<u> </u>			
Ask patient about new symptoms since Did you notice any new loss or sensation is Did you notice any new dryness of your had you notice any new weakness in your Did you notice any new sensation of pins Did you notice any new pain sensations (by New additional medications (other than Management)	n your ands pa hand c and nec ourning	han alms or fee edle: / sho	ds or for for et? s in your poting	feet? ot sol our ha)?	es? ands o	or fee				
Ask the patient if s/he has experienced any assessment:								e last		1
Patient's report of <u>nev</u>	<u>v</u> symp	toms	since	e last	asses				T	
		RI	<i>GHT</i>			LE	EFT			
	E L B O W	H A N D	K N E E	F O O T	E L B O W	H A N D	K N E E	F O O T	OTHER	
$Diminished\ sensation - {\sf eg\ unable\ to\ feel\ hot\ or\ } {\sf cold,\ numbness\ (Y/N)}$,,,				<i>"</i>					-
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 skin lesions since last a					1					
(Y/N/STABLE)										
How many skin patches have improvisit?										
Have they developed new skin patc (Y/N)										
How many new skin patches have drecently?										
Do you feel your skin is worse, the	same	or k	etter	?						
Facial patch? (Y/N) Facial patch inflammation. (Circle)	NONE	=	ERY	THEN	ΙA	AN		EMA	ULCEF	RATE
Ciclosporin Studies (20,06.11) PRF completed	i by:				Dat		<u></u>	<u>-</u>	94/111	

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

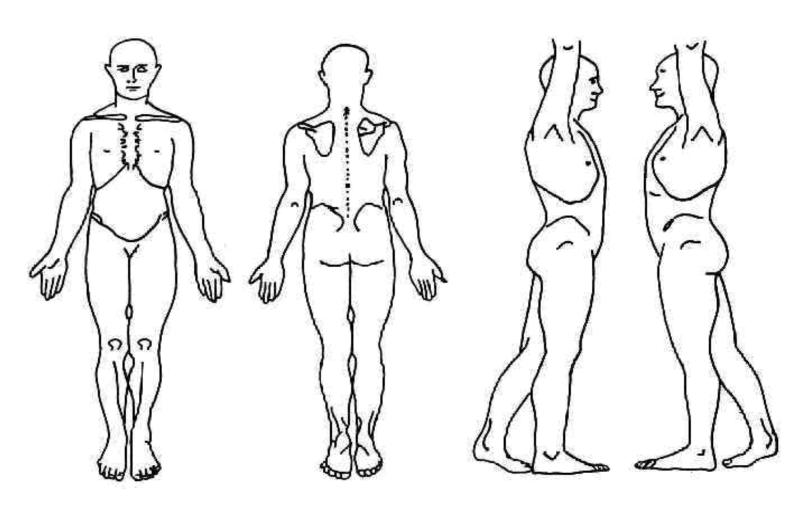
Study: |__|_|_|

I <u></u> I		Date:	_//
New medications:			
Drug and reason starting	Date st dd/mn	arted n/yyyy	Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
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			
Wainlet lang > 51-2			
Weight gain			
Weight gain Glaucoma			
Weight gain Glaucoma Cataract	11/50		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight loss >5kg Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcers	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	least 1/52 apart		
Weight gain Glaucoma Cataract Hypertension BP > 160/90 on 2 separate readings at Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting			

Study: _ _		Stud	y number: [_	_ _	Patient 1	nitials:	_
Week _	_					Date: _	_//_	
FOLLOW UP EXA	MINAT	ION	-					
XXXVII. XXXVIII. Vital	_	t :	_ . I	κg				
Temp		Puls	se			B.P. (sy	ystolic/ dia	astolic)
XXXIX. Gene	ral exam	inati	on					
	1.Norma	1 2.	.Abnormal		Not	If abno	rmal spec	eify
				ex	amined			
Head and neck								
Lymph nodes								
Skin (non leprosy)								
Lungs								
Heart								
Abdomen								
Liver								
Spleen								
Ext Genitalia								
(male)								
(maic)								
	<u> Jerves</u> - s		and sympto	oms		`	•	,
Name of nerve	Nerve	200	Nerve	.4	Motor sy	mptoms –	Sensory	symptoms – s, pain($\sqrt{if yes}$)
	tendern Grade*	ess -	enlargemen (yes or no)	Il	Old	New	Old	New
	Grade		(yes of no)		Olu	TACW	Olu	TYCW
R Cervical/GA, Facial							N/A	N/A
L Cervical/ GA, Facial								
R Ulnar								
L Ulnar			1					
R Median			1					
L Median							NI/A	NT/A
R Radial/ R.C.			1				N/A N/A	N/A N/A
L Radial/ R.C. R lat popliteal			+		-		IN/A	IN/A
L lat popliteal								
R Post Tibial			1					
L Post Tibial								
* Grading for nerve	tendernes		none withdrawa	ıl/ w	rincing		tenderness lowing pa	

Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	96/111

Study: _ _	Study number: _	Patient Initials: _
Week		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	olaques, papules, nodules)
	- signs of inflammation in l	1 1 1 1
	- 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 SCOR	RE			

PRF completed by: _____ Date: _____ 97/111

Week _ _ IF PATIENT HAS ENL-I		AN TO	COMPLE	Date: TE THE	FOLLOW	J VING EN
DATA COLLECTING FO	JKM					
Symptoms of ENL						
How many days have you been fe	eling unwel	l for (this	episode of E	NL): da	ays	
		(@)	() ()			
		9	$\frac{1}{2}$	3	4 5	
How unwell do you feel now (ticl	c one face)?	NO HURT	HURTS HURTS A LITTLE BIT A LITTLE MOR	HURTS HI RE EVEN MORE A WH	JRTS HURTS OLE LOT WORST	
Have you noticed		NO	YES			
Any new lumps on your skin?						
Any new sensory loss?						
Any new weakness in your muscl	es?					
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):	()	1-5		6-20	>20
Inflammation in the ENL lesions		Vone	1.5		0 20	20
		Erythema	and pain – fu	inction not a	ffected	
			and pain – fu			
	I	Erythema	and pain - fu	inction affect	ted plus ulce	ration
		4	· 1/1/4/T/C/T	T \		
(If patient has previous records u			vious v M 1/S1 MRC=4	MRC=3	М	RC<3
VMT: ST decreased in:	None	_	onc—4 One nerve	Two ner		hree nerves
Nerve tenderness: None			palpation	1 WO HCI	Withdraws	ince herves
Titorie terraeriness.	•	ender of	purpution		William Wis	
Bone tenderness (shin):	None	7	Tender on pal	pation	Withdraws	
Oedema (ankle, face, hands):	None		Present	•	Gross	
Joint swelling:	None	F	Present		Affects fund	
Lymph nodes:	Normal	Г	Enlarged and t	tender	Which:	
Testicles:	Normal		Tender (? Size			
Temperature:	≤37.5°C		37.5°C	/	level:	
Proteinuria (by dipstick):	Negative		Positive		level:	-
	Yes		No		Ophthalmol	
Red eyes:	1 65	1	10		Opinimi	· · · · · · · · · · · · · · · · · · ·

Study: _ _	Study number: _	Patient Initials: _	_l
Week _		Date://	
	SEEN AND ATTACHED VM		
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion or	n the severity of today's React	ion:	
	Severe		
	Moderate		
	Mild		
NB: IF NERVE FU	NCTION HAS WORSENED	D SINCE LAST REVIEW	
PLEASE LOOK AT PAC PREDNISOLONE.	GE 21 OF SOP FOR INDICA	ATIONS FOR EXTRA	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	99/11

Laboratory tests	(record results Date taken	if done) Result
	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
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)	//	Positive Negative Advise re contraception options

ype of adverse event	Date of onset	Date of re	solution
<u> </u>			
omments on managemen	t of adverse events:		
	to of universe events.		
oid the patient require hos	pital admission?	1.Yes □	2. No □
		. C11	
r admitted was a SERIOU	IS ADVERSE EVENT FORM	1.Yes □	2. No □
			2 No 🗆
Vas the DSMB notified		1.Yes □	2. N0 ⊔
		1.Yes □	2. NO 🗀
		1.Yes □	2.110 □
Vas the DSMB notified Vhat action was taken?		1.Yes □	2.100 🗆
		1.Yes □	2. NO 🗆
		1.Yes □	2. NO 🗆

Study: _ _	Study number: _	_	Patient Initials: _
PHYSICIAN WORK S	SHEET: FOLLOV	V-UP	
AT EACH REVIEW AND	UNPLANNED VISI	T, COM	PLETE:
Insert the relevant wee	k number:	Week	<u> </u>
And date:		Date:	//
Physician to complete histo	ory and examination	and ensu	re lab results are entered
Physician to complete adve	erse event form if nec	essary	
Ensure correct physiothers	apy form is attached	to PRF	
	n page 2: Assessment		
	next planned visit or r about completed pa		Assessment Record iew in order to transfer data

				We	ek	1	<u></u> /			
Ask patient about new symptoms since I Did you notice any new loss or sensation i Did you notice any new dryness of your had Did you notice any new weakness in your Did you notice any new sensation of pins a Did you notice any new pain sensations (b New additional medications (other than M Ask the patient if s/he has experienced any	n your ands pa hand o and ne urning DT an	han alms or fe edle s/ sho d in	ds or for et? s in your ooting cludin	feet? ot sol our ha)? g ana	es? ands c	or fee	t?		_	
assessment:								<u> Tust</u>		7
Patient's report of <u>new</u>	<u>z</u> symp	ioms	Since	e iasi	asses				T	
		R_{I}	IGHT			LE	EFT			
	E L B O W	H A N D	K N E E	F O O T	E L B O W	H A N D	K N E E	F O O T	OTHER	
Diminished sensation — eg unable to feel hot or cold, numbness (Y/N) New Weakness (Y/N)	"				<i>'''</i>					
Paraesthesia - eg pins and needles, insects crawling (Y/N) Nerve Pain eg burning sensation, shooting pain (Y/N)										- - -
Patient's report of skin lesions since last as Have the inflamed skin patches imp (Y/N/STABLE)	rovec	I ?								
How many skin patches have impro visit?										
Have they developed new skin patch (Y/N)	hes re	ecer	ntly?							
How many new skin patches have d recently?	evelo	pec	i							
Do you feel your skin is worse, the	same	or k	oetter	?						
Facial patch? (Y/N)										
Facial patch inflammation. (Circle)	NONI		ERY1	THEN	/IA	AN		EMA	ULCE	RATED
Ciclosporin Studies (20.06.11) PRF completed	l by:				_ Dat	e: _			103/111	

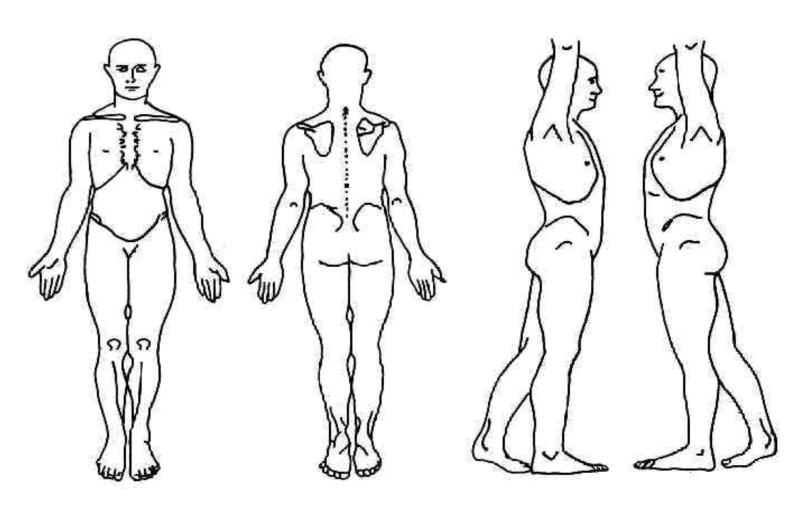
Study number: |__| Patient Initials: |__|_|

Study: |__|_|

		Date:	_//
New medications:	<u> </u>		
Drug and reason starting	Date st dd/mn		Ongoing treatment Yes or No
1.	/	/	
2	/	/	
3.	/	/	
Symptoms related to: Moon face Acne			
Gum hyperplasia			
Cutaneous (including nails) fungal infections			
Gastric pain requiring antacid			
Gastrointestinal bleeding			
Nocturia, polyuria, polydipsia Diabetes mellitus			
Nocturia, polyuria, polydipsia Diabetes mellitus			
Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg			
Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain			
Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma			
Nocturia, polyuria, polydipsia Diabetes mellitus Psychosis or other mental health problems Weight loss >5kg Weight gain Glaucoma Cataract			
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		
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 Infections	1/52 apart		
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 Infections Infected ulcers	1/52 apart		
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 Infected ulcers Corneal ulcer	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vamiting	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions Vomiting Diarrhoea	1/52 apart		
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 Infections Infected ulcers Corneal ulcer Tuberculosis Night sweats Convulsions	1/52 apart		

Study: _		Stud	y number:	_	_	Patient I	nitials:	_ _
Week _	J					Date: _	_//_	
FOLLOW UP EXA	AMINAT	ION	-					
XLI. Weig XLII. Vital sig	ght: _ ns	_ .	kg					
Temp		Puls	se _			B.P. (sy	ystolic/ di	astolic)
XLIII. General	examina	tion						
	1.Norma	1 2.	Abnormal		Not amined	If abno	ormal spec	eify
Head and neck		+				1		
Lymph nodes		_				1		
Skin (non leprosy)		\perp						
Lungs								
Heart								
Abdomen								
Liver								
Spleen								
Ext Genitalia								
(male)								
XLIV. Leprosy xi. 1			and sympto	oms	of neuritis	s (since la	ast review)
NI C	l NI		l M		3.6.4		I a	
Name of nerve	Nerve	000	Nerve	.4	Motor syl	mptoms –	Sensory	symptoms – s, pain($\sqrt{if yes}$)
	tendern Grade*		enlargemen (yes or no)	IL	Old	New	Old	New
	Grade		(yes of no)		Olu	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.						ļ	N/A	N/A
L Radial/ R.C.						1	N/A	N/A
R lat popliteal						1		
L lat popliteal						1		
R Post Tibial						1		
L Post Tibial								
* Grading for nerve	tendernes		none withdrawa	ıl/ w	incing		tenderness lowing pa	

Study: _ _	Study number: _	Patient Initials: _
Week _		Date://
Ctn EXAMINATION		
Skin - location of lesion	ons (body chart)	
	- type of lesions (patches, p	laques, papules, nodules)
	- signs of inflammation in l	esions
	- 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	
А3	Peripheral oedema due to reaction	None	Minimal	Visible, but not affecting function	Oedema affecting function	
		A SCOR	RE			

PRF completed by: _____ Date: _____ 106/111

Study: _		Study n	umber	: _	_	Patient	Initial	S: _
Week _ _ IF PATIENT HAS DATA COLLECT			AN TO	O COMI	PLETI	Date: _ E THE F		
Symptoms of ENL								
How many days have yo	ou been feel	ing unwel	l for (th	is episode	of ENL	.): da	ys	
			(@®	(00)	((()	(a)		(3
						\bigcirc	<i>ک</i> کر	ツ
How unwell do you feel	now (tick o	one face)?	NO HURT	HURTS A LITTLE BIT A	HURTS LITTLE MORE	HURTS HUR EVEN MORE A WHOL	TS HUR ELOT WOR	rs ST
Have you noticed			NO	YES				
Any new lumps on your	skin?							
Any new sensory loss?								
Any new weakness in yo	our muscles	<u> </u>						
Any new tingling?								
Any new pain in your jo								
Any new pain in your bo								
Any new pain in your te	sticles?				_			
Painful eyes?					_			
Any visual disturbance?								
Examination Number of ENL lesions	(circle):	()		1-5	é	5-20	>20
Inflammation in the ENI		ircle):]	None Erythen Erythen	na and pair na and pair	n — funct n — funct	tion not aff tion affects tion affects	fected ed	
(If patient has previous to VMT:	records use	comparis	on to pr	evious VM MRC=4	AT/ST te	esting): MRC=3		MRC<3
ST decreased in:		None		One nerv	e	Two nerv	e	≥ three nerves
Nerve tenderness:	None		Tender (on palpatio			Withdra	
Bone tenderness (shin): Oedema (ankle, face, ha Joint swelling:	nds):	None None None		Tender or Present Present	n palpat	(Withdra Gross Affects:	ws
C						•	Which:	
Lymph nodes:		Normal		Enlarged		der		
Testicles:		Normal		Tender (?	? Size)			
Temperature:		≤37.5°C		>37.5°C]	evel:	
Proteinuria (by dipstick)	:	Negative		Positive		I	evel:	
Red eyes:		Yes		No			Ophthali	mology
						uiagii0	٠١٥	

Study: _	Study number: _	Patient Initials: _	_
Week _		Date://	
Describe any changes in V	SEEN AND ATTACHED VMMT or ST compared to last ass	sessment:	
	Second Physician comm	ent:	
PATIENT HAS:	TYPE 1 REACTION		
	ENL		
Specialist opinion on	the severity of today's Reacti		
	Severe Moderate	П	
	Mild		
NB: IF NERVE FU	NCTION HAS WORSENEI	D SINCE LAST REVIEW	
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	108/111

Laboratory tests	(record results Date taken	if done) Result
	dd/mm/yyyy	Result
FBC	/	Hb: _ . g/dl WCC: _ _ Plt: ESR
Renal function	/	Creat:
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)	//	Positive Negative Advise re contraception options

/eek _		Date: /	/
ecord any adverse event	s here:		
Type of adverse event	Date of onset	Date of re	solution
type of adverse event	Date of offset	Date of re	solution
_			
Comments on managemen	nt of advance avanta:		
Comments on managemen	in of adverse events.		
Did the patient require ho	spital admission?	1.Yes □	2. No □
If admitted was a SERIOU	US ADVERSE EVENT FORM	filled in? 1.Yes □	2. No □
Was the DSMB notified		1.Yes □	2. No □
What action was taken?			
WHEN FINISHEI	D:		
COMPLETE PHA	ARMACY CARD AND SEND	PATIENT TO) PHARMAC
Ciclosporin Studies (20.06.11)	PRF completed by:	Date: _	

D :				
Patient Hospital No: Study numb	ber:			
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		Ye
2. Did the patient receive additional Prednisolone?		No		Ye
If so, how many weeks (in total) did the patient rece	ive Prednis	solone'	?	
3. Did the patient report for all examinations after treatment	?			
Week 24		No		Ye
Week 28		No		Ye
Week 32		No		Yes
4. If the patient did not complete the medication or the follo	w-un sele	ot the 1	easo:	n·
	w-up, sere	ct the i	caso	11.
1 Subject did not femin for chinic visit				
☐ Subject did not return for clinic visit ☐ Protocol violation (specify)				
□ Protocol violation (specify)				
□ Protocol violation (specify)□ Subject refused study procedure(s):				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal 				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): 				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): □ Death:// (date) 				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): □ Death:// (date) □ Other reason (specify): 				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): □ Death:// (date) □ Other reason (specify): 				
☐ Protocol violation (specify) ☐ Subject refused study procedure(s): ☐ Voluntary withdrawal ☐ Illness (specify): ☐ Death:// (date) ☐ Other reason (specify): ☐ Comments:				
 □ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): □ Death:// (date) □ Other reason (specify): 				
☐ Protocol violation (specify)				
□ Protocol violation (specify) □ Subject refused study procedure(s): □ Voluntary withdrawal □ Illness (specify): □ Death:// (date) □ Other reason (specify): □ Comments: □ Indeed the contents of this case report form and for accurate.		e comp	olete a	

Study: _ _	Study number: _	Patient Initials: _	_l
Ciclosporin Studies (20.06.11)	PRF completed by:	Date:	112/111