Sponsor
UZ Gent
C. Heymanslaan 10
9000 Gent

SPARTACUS

EARLY DISCONTINUATION VISIT
Worksheet

Studienummer:

Datum: __ /__ / ___

LATENT TB SCREENING

Was the TB questionnaire completed? ☐ Yes ☐ No

If Yes,

1. Have you or an immediate family member or other close contact ever been diagnosed or treated for tuberculosis?
   ☐ Yes ☐ No
2. Have you lived in or had prolonged travels to countries in the following regions?

   ☐ No
   ☐ Africa
   ☐ Eastern europe
   ☐ Asia
   ☐ Russia
   ☐ Latin America
   ☐ Caribbean Islands

3. Have you lived or worked in a prison, refugee camp, homeless shelter, immigration center, or nursing home?
   ☐ Yes ☐ No
4. Have you, or an immediate family member, had any of the following problems for the past 3 weeks or longer?

   ☐ No
   ☐ Chronic Cough
   ☐ Production of Sputum
   ☐ Blood-Streaked Sputum
   ☐ Unexpected Weight Loss
   ☐ Fever
   ☐ Fatigue / Tiredness
   ☐ Night Sweats
   ☐ Shortness of Breath

PHYSICAL EXAMINATION

Was the physical examination performed? ☐ No ☐ Yes, ___ / ___ /_____

Any abnormalities? ☐ No ☐ Yes, ……

VITAL SIGNS

Blood pressure : ____ / ____ mmHg
Heart rate : _____ bpm
Weight: _____ kg

BASMI + CHEST EXPANSION

	Left	**right**
Tragus to wall distance	……. cm	……. cm
Lumbar flexion, modified Schöber	……. cm (10 cm)	
Cervical rotation	……. °	……. °
Lateral flexion	……. cm	……. cm
Intermalleolar distance	……. cm	
Chest expansion	……. cm	

PSORIATIC SKIN EVALUATION

Investigator Global Assessment score :

Score	Description
☐ Clear	- No signs of psoriasis (post-inflammatory hyperpigmentation may be present)
☐ Almost clear	- Normal to pink coloration of lesions - No thickening - No to minimal focal scaling
☐ Mild disease	- Pink to light red coloration - Just detectable to mild thickening - Predominantly fine scaling
☐ Moderate disease	- Dull bright red, clearly distinguishable erythema - Clearly distinguishable to moderate thickening - Moderate scaling
☐ Severe disease	- Bright to deep dark red coloration - Severe thickening with hard edges - Severe / coarse scaling covering almost all or all lesions

JOINT COUNT : Tender joints present during the visit? ☐ No ☐ Yes (if yes, indicate in the table below)

Swollen joints present during the visit? ☐ No ☐ Yes (if yes, indicate in the table below)

Were any joints excluded from the examination? ☐ No ☐ Yes (if yes, indicate in the table below)

Worksheet (tender & swollen joint count) : 1 = present, 0 = absent, ND/NA

	Right						Left					
Joint	**Pain/tenderness**			**Swelling**			**Pain/tenderness**			**Swelling**		
Temporomandibular	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Sternoclavicular	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Acromio-clavicular	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Shoulder	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Elbow	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Wrist	0	1	NA	0	1	NA	0	1	NA	0	1	NA
CMC1	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metacarpophalangeal 1	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metacarpophalangeal 2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metacarpophalangeal 3	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metacarpophalangeal 4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metacarpophalangeal 5	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Thumb Interphalangeal	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Prox. Interphalangeal 2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Prox. Interphalangeal 3	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Prox. Interphalangeal 4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Prox. Interphalangeal 5	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Dist. Interphalangeal 2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Dist. Interphalangeal 3	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Dist. Interphalangeal 4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Dist. Interphalangeal 5	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Hip	0	1	NA				0	1	NA			
Knee	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Ankle	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Tarsus	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metatarsophalangeal 1	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metatarsophalangeal 2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metatarsophalangeal 3	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metatarsophalangeal 4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Metatarsophalangeal 5	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Great Toe / Hallux	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Interphalangeal 2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Interphalangeal 3	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Interphalangeal 4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
Interphalangeal 5	0	1	NA	0	1	NA	0	1	NA	0	1	NA
DIP2	0	1	NA	0	1	NA	0	1	NA	0	1	NA
DIP3	0	1	NA	0	1	NA	0	1	NA	0	1	NA

DIP4	0	1	NA	0	1	NA	0	1	NA	0	1	NA
DIP5	0	1	NA	0	1	NA	0	1	NA	0	1	NA

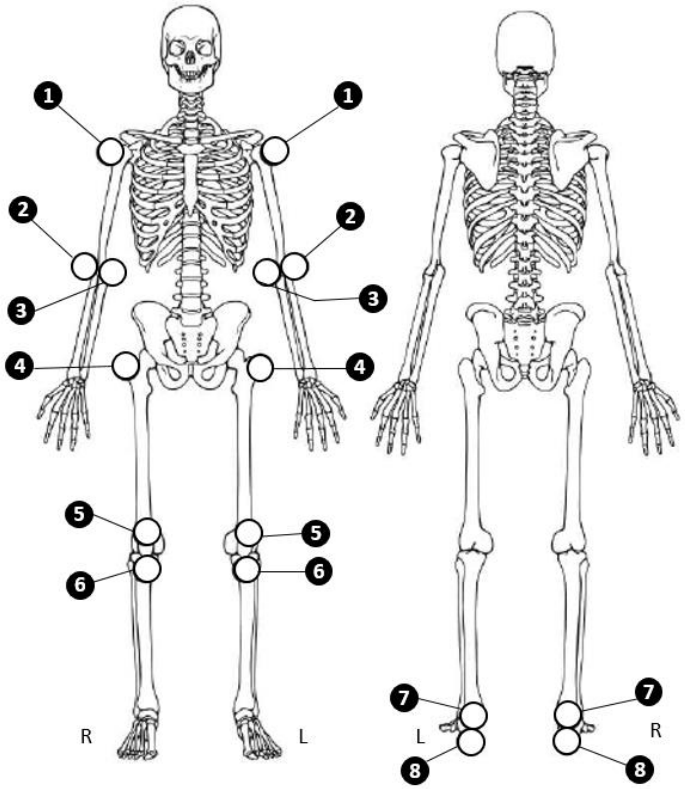
DACTYLITIS Was dactylitis present? ☐ No ☐ Yes (if yes, indicate in the table below)

Were any joints excluded from the examination? ☐ No ☐ Yes (if yes, indicate in the table below)

(Code: 0 = Absent, 1 = Present)

Joint	Right	Left
Finger 1 (thumb)	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Finger 2	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Finger 3	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Finger 4	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Finger 5	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Toe 1 (big toe)	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Toe 2	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Toe 3	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Toe 4	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA
Toe 5	☐ 0 ☐ 1 ☐ NA	☐ 0 ☐ 1 ☐ NA

ENTHESITIS : Enthesitis present during the visit? ☐ No ☐ Yes (if yes, indicate on the figure below)

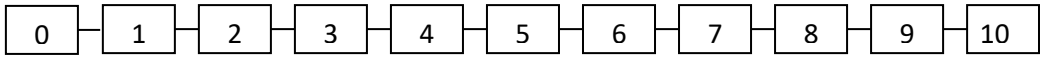


❶	Supraspinatus insertion
❷	Lateral epicondyle humerus
❸	Medial epicondyle humerus
❹	Greater trochanter
❺	Quadriceps insertion into superior border of patella
❻	Patellar tendon insertion inferior pole of patella OR tibial tubercle*
❼	Achilles tendon
❽	Insertion plantar fascia

* For scoring purposes, the inferior patella and tibial tuberosity are considered 1 site because of their anatomical proximity.

Total MASES score: ___ / 16

PHYSICIAN GLOBAL ASSESSMENT OF DISEASE ACTIVITY



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SAFETY LAB TEST

☐ No ☐ Yes, ___ / ___ /_____

Were all results within the reference ranges? ☐ Yes ☐ No

ESR – CRP

Blood test	Test performed	date	value	Unit
ESR	☐ Yes ☐ No	___ / ___ / _____		
CRP	☐ Yes ☐ No	___ / ___ / _____		

ONLY IN CASE OF SUSTAINED CLINICAL REMISSION → RESEARCH SAMPLES PHASE B – W0

4 x 8ml blood-CPT collected: ☐ *Yes* ☐ *No*

2 x 5ml Serum tubes collected: ☐ *Yes* ☐ *No (only at UZ Gent & UZ Leuven)*

TRAL CONTINUATION EVALUATION

SUSTAINED CLINICAL REMISSION : ☐ Yes ☐ No

TREATMENT ALLOCATION FOR NEXT TREATMENT PERIOD

Treatment until NEXT visit:

- ☐ Phase B (drug free)
- ☐ Reimbursement group
- ☐ Discontinuation
- ☐ Early termination / Lost for FU

Check and complete the medication diary

Planned date for NEXT visit : ___ / ___ / _____

AE :

changes: □ No □ Yes (if yes, register the AE in RedCap)

CONC. MEDICATIONS:

changes : □ No □ Yes (If yes, update the concomitant medication in RedCap)

USUS:

changes : □ No □ Yes (If yes, update in RedCap)

Smoking : ☐ Never
☐ History but cessation of more than 3 years
☐ History but cessation of less or equal than 3 years
☐ Current smoker → number of pack years: ____
(1 pack = 20 cigarettes; 10 cigarettes during 20 years = 10 pack years)

Alcohol: ☐ Never
☐ History but cessation
☐ Current and < 3 units/day
☐ Current and ≥ 3 units/day