PID assignment

PID	_____
Screening number If different from PID	_____

Screening Checklist

Screening checklist

Date of screening

_____

Add relevant criteria for eligibility in the list below

	Yes	No
Screening criteria met	◯	◯
Literacy assesment administered	◯	◯
All necessary samples taken	◯	◯
Screening consent signed	◯	◯

Literacy assessment details

Date of literacy test

_____

	Yes	No
Has the participant completed the literacy assessment?	◯	◯
Does the participant require an impartial witness?	◯	◯

Screening outcome

Proceed with study main consent

Do not proceed with study main consent

Screening failure reason

◯ Does not meet criteria
◯ Samples flagged
◯ Too ill to participate

Enrolment checklist

Enrolment checklist

Date of enrolment

_____

Add relevant criteria for enrolment in the list below

	Yes	No
ICF provided in language of choice	◯	◯
ICF completed	◯	◯
ICF quality control done	◯	◯
ICF signed copy provided to participant	◯	◯
Assessment of understanding done	◯	◯
Concerns raised by participant	◯	◯
Participant visits scheduled	◯	◯

Details of concerns

How were concerns addressed?

Proceed with enrolling participant

Do not proceed with enrolling participant

Reason for not enrolling

_____

Screening consent

Project Name

Project Description

This form must be completed as a survey form to use the e-consent process. Use the survey options dropdown at the top of this form to launch this page as a survey form

Research Project Information

Research project information
In hac habitasse platea dictumst. Proin scelerisque bibendum enim, in tempus urna luctus at. Morbi pretium massa et ante tempor porta. Morbi pretium volutpat leo, et pharetra tortor sagittis sit amet. Nam sagittis ex a mauris sollicitudin scelerisque.

Date of screening consent _____

Start time of screening consent _____

Add relevant screening consent questions below

Q1 Q1
Screening question

◯ Yes ◯ No

Q2 Q2
Screening question

◯ Yes ◯ No

Q3 Q3
Screening question

◯ Yes ◯ No

Participant confirmation

☐ I understand that signing this form electronically is the equivalent of signing a physical document

Participant full name
as on SA ID _____

Thumbprint needed ◯ Yes ◯ No

Participant thumbprint

Participant signature

_____

Witness full name
as on ID

_____

Witness signature

_____

End time of consent

_____

Staff member administering consent

Staff member
Full Name

_____

Staff member signature

_____

Main consent

Project name

Project description

This form must be completed as a survey form to use the e-consent process. Use the survey options dropdown at the top of this form to launch this page as a survey form

Research Project information

Who are we?
Lorem ipsum dolor sit amet, consectetur adipiscing elit. Aliquam accumsan iaculis quam, a placerat justo ultrices ut. Curabitur libero mi, aliquam sit amet maximus ut, suscipit bibendum dui.

Why are we doing this study?
Ut quam leo, consectetur nec sem sed, suscipit tincidunt nisl. Quisque condimentum bibendum semper.

How many people will take part in the study?
Sed ut venenatis lorem, et rutrum nunc. Nam vel accumsan elit, sed eleifend massa. Curabitur molestie erat eget nisl interdum vulputate.

How long will the study last?
Morbi a arcu est. Etiam ac elementum magna. Donec vitae neque id leo condimentum lobortis. In augue ligula, porttitor ut ligula a, egestas pharetra leo

What do we do to decide if you are eligible to be take part?
Vivamus non euismod quam. Duis egestas, lacus at bibendum ornare, nisi risus tempus nulla, a semper dolor tellus eget enim. Phasellus auctor quam eget felis convallis, et porttitor urna euismod. Donec quis justo in augue auctor mollis.

What will happen if you decide to take part in the study?
Fusce ex odio, ullamcorper vehicula pretium sit amet, placerat vitae dolor. Aliquam finibus aliquet leo in commodo. Curabitur iaculis nisi eget ipsum posuere, quis rhoncus nunc malesuada. Phasellus consequat lectus vitae ligula accumsan tristique.

What will we ask for?
Fusce malesuada tortor nec ex consequat consectetur. Donec facilisis nulla sapien, at commodo nisi sagittis non. Fusce sed est aliquet, elementum nibh in, venenatis quam.

What are the risks?
Fusce malesuada tortor nec ex consequat consectetur. Aenean ullamcorper quam et libero venenatis pharetra. Etiam dictum mauris dignissim ipsum hendrerit maximus.

What happens if I get hurt taking part in this study?
Duis risus felis, maximus id urna eu, egestas bibendum orci. Pellentesque sem massa, porttitor a orci sit amet, consectetur imperdiet odio. Vestibulum sed condimentum justo. Vivamus nec eros sit amet sapien semper ullamcorper vel in elit.

Are there any benefits to you for being in the study?
Maecenas blandit magna et sagittis scelerisque. Nunc bibendum libero sit amet pellentesque porta. Donec cursus accumsan erat, nec pretium lacus porta non. In posuere libero in velit tincidunt varius

What other choices do you have?
Donec facilisis nulla sapien, at commodo nisi sagittis non. Fusce sed est aliquet, elementum nibh in, venenatis quam. Ut commodo libero eget metus blandit, in consequat lacus varius. Ut pharetra velit libero, id eleifend quam vehicula quis.

What will happen when the study is over?
Etiam rutrum sodales consequat. Phasellus a risus convallis, finibus velit id, accumsan ligula. Morbi a odio quis mauris iaculis tincidunt non ut diam. Aliquam ultrices sem id felis ultricies porta.

Will your test results be shared with you?
Ut convallis sem et eros interdum, sit amet convallis libero tincidunt. Fusce faucibus erat eget volutpat dictum.

Will the results of the research be shared with you?
Cras ac metus sapien. Integer fermentum sit amet nulla et imperdiet. Duis id finibus ante, lobortis scelerisque ligula. Suspendisse nunc ex, placerat et ultrices scelerisque, mollis eu orci. Nam quis nibh rutrum enim dapibus sollicitudin in sit amet urna. Cras tincidunt a leo sit amet venenatis. Ut vitae turpis metus.

What will we do with your data and samples?
Quisque fermentum sit amet est in rhoncus. Sed laoreet magna quis massa fringilla, non dictum nunc euismod. Vivamus lorem lorem, volutpat eu quam sed, interdum ultricies diam. Integer a feugiat sem.

Will any of your blood, tissue or other samples be stored and used for research in the future?
Vestibulum luctus lectus ac nunc tempor, a vestibulum sem aliquam. In hendrerit ultrices lorem, ut auctor ligula gravida sed. Vivamus eu elit posuere, elementum nibh ac, tempus lorem.

Will you receive any reward (money or food vouchers) for taking part in this study?
Vivamus lorem lorem, volutpat eu quam sed, interdum ultricies diam. Integer a feugiat sem. Aenean ullamcorper quam et libero venenatis pharetra.

Who will see the information which is collected about you during the study?
Ut quam leo, consectetur nec sem sed, suscipit tincidunt nisl. Quisque condimentum bibendum semper. Phasellus auctor quam eget felis convallis, et porttitor urna euismod. Donec quis justo in augue auctor mollis.

How will we protect your information?
Quisque fermentum sit amet est in rhoncus. Sed laoreet magna quis massa fringilla, non dictum nunc euismod. Morbi ut nibh fermentum, luctus est sit amet, tristique mi. Aenean facilisis purus id lobortis euismod.

What to do if you have questions or change your mind about being in the study.
In hac habitasse platea dictumst. Proin scelerisque bibendum enim, in tempus urna luctus at. Morbi pretium massa et ante tempor porta. Morbi pretium volutpat leo, et pharetra tortor sagittis sit amet. Nam sagittis ex a mauris sollicitudin scelerisque.

Page 1

Date of consent

_____

Start time of consent

_____

Q1 Do you agree for us to collect these body fluid samples and your health information for this study we have described about how genes might affect [specific health phenotype]?

◯ Yes ◯ No

Q2 Do you agree for us to use your genetic samples together with your health information for other studies in the future that want to study the effect of genes on [specific health phenotype]?

◯ Yes ◯ No

Q3 Do you agree for us to use your genetic samples together with your health information for other studies in the future to study the effect of genes on other conditions or biological processes?

◯ Yes ◯ No

Q4 Sometimes researchers combine the genetic information from everyone in the study and provide a summary of genetic data for the whole group. Do you agree for us to use your information when providing combined information about the whole research group (x total individuals in this study)?

◯ Yes ◯ No

Q5 Sometimes what we find from a study like this might lead to new studies being done in the future. Can other researchers contact you in the future to invite you to take part in other research studies?

◯ Yes ◯ No

How would you like to be contacted?

◯ Telephone
◯ Letter
◯ Visit

Q6 In this study we hope to identify genetic factors that mean someone is more likely to [outcome, such as susceptibility to a disease]. If someone has this genetic factor there is [no treatment/we recommend X treatment]. If we find during this study that you have this kind of genetic factor would you like us to tell you this information?

◯ Yes ◯ No

Page 2

Sometimes what we find from our research might include new information about your health. Would you like us to contact you again if we believe we have new information that may directly affect your health...

Q7a - if there is some kind of action or treatment that might be able to help you with the health issue?

◯ Yes ◯ No

Q7b - if there is NO kind of action or treatment that might be able to help you with the health issue?

◯ Yes ◯ No

Participant confirmation

☐ I understand that signing this form electronically is the equivalent of signing a physical document

Participant full name as on ID

_____

Thumbprint required

◯ Yes
◯ No

Participant thumbprint

Participant signature

Witness full name
as on ID

_____

Witness signature

_____

End time of consent

_____

Staff member administering consent

Staff member
Full Name

_____

Staff member signature

_____

Participant information

Participant information	
First Name	_____
Other names	_____
Last name	_____
Date of birth	_____
Age	_____ (Calculated)
Nationality	◯ South African ◯ Other
Specify nationality	_____
RSA ID	_____
Medical record number	_____
Were you born male or female?	◯ Male ◯ Female ◯ Rather not say ◯ Other
Add relevant questions for this section	
Which religion do you observe?	_____
Marital status	◯ Single (never married) ◯ Married ◯ Living together ◯ Divorced ◯ Widowed ◯ Rather not say

What is your highest level of education?	◯ Did not finish school ◯ Primary school ◯ High school without Matric ◯ Matric/Grade 12 ◯ Some college ◯ Diploma ◯ Degree
Are you employed?	◯ Yes ◯ No ◯ Unable to work
What kind of work do you do?	_____
Have you ever worked in a mine?	◯ Yes ◯ No
What is your average income per month?	◯ Less than R1000 per month ◯ R1000 - R5000 per month ◯ R5000 - R10 000 per month ◯ More than R10 000 per month ◯ Rather not say
Do you receive a social grant/s?	◯ Yes ◯ No
Have you ever been in prison?	◯ Yes ◯ No

Household information

Click Yes to capture information about the participant's household, otherwise click No.	◯ Yes ◯ No
Household ID	_____ (For grouping purposes only)
Is your home situated in a rural or urban setting?	◯ Urban ◯ Rural
Type of housing	◯ Formal (brick) ◯ Informal (shack) ◯ Wendy house/ bungalow ◯ Shelter ◯ No housing
Number of people in home	_____
Number of adults	_____
Number of children	_____

Household amenities	☐ Electricity ☐ Electric stove ☐ Paraffin or gas stove ☐ Fireplace ☐ Wood stove ☐ Inside tap ☐ Outside tap ☐ Inside toilet ☐ Outside toilet ☐ Bucket system
What is the average household income per month?	◯ Less than R1000 per month ◯ R1000 - R5000 per month ◯ R5000 - R10000 per month ◯ R10000 - R15 000 per month ◯ More than R15 000 per month ◯ Rather not say

Participant Tracking Information

Tracking information

Street address

Closest landmark

_____

Home phone

_____

Work phone

_____

Cell phone

_____

Alternate contact details

Consent obtained to use alternative contact/s

◯ Yes
◯ No

Alternate contact 1

_____
(Full name)

Alternative contact 1 number

_____

Alternate contact 2

_____
(Full name)

Alternative contact 2 number

_____

Alternate contact 3

_____
(Full name)

Alternative contact 3 number

_____

Alternate contact 4

_____
(Full name)

Alternative contact 4 number

_____

Alternate contact 5

_____
(Full name)

Alternative contact 5 number

_____

Visit Information

Visit information	
Visit completed	◯ Yes ◯ No
Reason why not completed	◯ Time constraint ◯ Outstanding procedures ◯ Missed visit
Reason why visit missed	◯ Unable to schedule an agreed date ◯ Unable to attend due to family responsibility ◯ Participant lost to follow-up ◯ Participant away from home ◯ Participant hospitalized ◯ Participant too ill to attend ◯ Participant not reachable ◯ Participant lacking transportation means ◯ Participant incarcerated ◯ Participant suffering from drug side effects ◯ Participant died ◯ Other
Can also use SOE if its not too lengthy	
Visit type	◯ Baseline ◯ Follow-up ◯ Unscheduled ◯ Pharmacokinetic procedure ◯ Telephonic
Reason for unscheduled visit	_____
Visit date	_____
Visit Time	_____

Randomization

Randomization	
Randomization date	_____
Randomization should be set-up before the project goes into production. Statistician/Data manager should create allocation tables in cases of blinded studies. Placeholders have been set below for the button and arm allocation.	
Randomize	_____ (Button)
Arm allocation	◯ A ◯ B ◯ C ◯ D

TB Symptoms

TB symptoms		
	Yes	No
Cough	◯	◯
Chest pain	◯	◯
Dyspnea	◯	◯
Fever	◯	◯
Headache	◯	◯
Hemoptysis	◯	◯
Loss of appetite	◯	◯
Malaise/ Fatigue	◯	◯
Night Sweats	◯	◯
Photophobia	◯	◯
Sputum production	◯	◯
Unintentional weight loss	◯	◯
Vomiting	◯	◯

TB History

Previous TB history

Did you have TB before?	◯ Yes ◯ No
Number of previous episodes	_____
Site of previous TB episode	☐ Pulmonary TB ☐ Extra pulmonary TB ☐ Pulmonary & extra pulmonary TB ☐ Unsure
Extrapulmonary sites involved	☐ Abdominal ☐ Bone/joint ☐ CNS Tuberculoma/s ☐ Meningitis ☐ Pericardial ☐ Peripheral nodes ☐ Pleural effusion ☐ Spinal ☐ Other
State other extrapulmonary site	_____

	Yes	No	Not applicable	Unknown
Were any of these episodes rifampicin resistant TB?	◯	◯	◯	◯
Did you complete TB treatment of last TB episode?	◯	◯	◯	◯

Previous TB episode treatment	☐ Amikacin ☐ Bedaqualine ☐ Capreomycin ☐ Carbapenem (Imi/Mero) ☐ Clofazimine ☐ Cycloserine ☐ Delamanid ☐ Ethambutol ☐ Ethionamide ☐ Gatifloxacin ☐ Isoniasid ☐ Kanamycin ☐ Levofloxacin ☐ Linezolid ☐ Moxifloxacin ☐ Ofloxacin ☐ PAS ☐ Prothionamide ☐ Pyrazinamide ☐ Rifabutin ☐ Rifampicin ☐ Streptomycin ☐ Terizadone ☐ Other (specify) ☐ None
State other therapy taken	_____
When did you complete treatment for last TB episode?	_____
Has the participant ever previously taken preventive therapy?	◯ Yes ◯ No
Duration of preventive treatment	_____
Outcome of episode	◯ Cured/Completed treatment ◯ Defaulted treatment ◯ Treatment failure ◯ Unsure
Details of previous TB episode	

Current TB episode	
Do you currently have TB?	◯ Yes ◯ No
Did you have close contact with anyone that has TB?	◯ Yes ◯ No
If yes, indicate the type of contact:	◯ Household ◯ Family/partner/close friend outside the household ◯ Place of work/study/prayer/recreation ◯ Not applicable
When did the contact occur?	◯ Current ◯ Within the last 6 months ◯ Within the last 6-24 months ◯ Beyond the last 24 months ◯ Not applicable
Date of diagnosis	_____
Site of TB for current episode	☐ Pulmonary TB ☐ Extrapulmonary TB ☐ Pulmonary and extrapulmonary TB ☐ Unsure
Extrapulmonary sites	☐ Abdominal ☐ Bone/joint ☐ CNS Tuberculoma/s ☐ Disseminated ☐ Meningitis ☐ Miliary TB ☐ Pericardial effusion ☐ Peripheral nodes ☐ Pleural effusion ☐ Spinal ☐ Other
Extrapulmonary site, other	_____
Is the participant currently on TB treatment?	◯ Yes ◯ No
Is the participant currently taking preventive therapy?	◯ Yes ◯ No
Has treatment been completed?	◯ Yes ◯ No
If yes, date IPT completed:	_____
Details of most recent TB episode	

HIV History

HIV history

Is HIV status known?	◯ Yes ◯ No
HIV status	◯ HIV Negative ◯ HIV Positive ◯ HIV tested, results unknown ◯ Not tested ◯ Refused to disclose ◯ Refused HIV testing
Are you currently on ART?	◯ Yes ◯ No
ART status	◯ Current ◯ Naive ◯ Interrupted ◯ Refused
ART start date	_____
ART duration	_____
Current ART regimen	☐ 3TC = Lamivudine ☐ ABC = Abacvir ☐ ATV = Atazanavir ☐ ATV/r = Atazanavir + ritonavir ☐ AZT = Zidovidine ☐ d4T = Stavudine ☐ ddI = Didanosine ☐ DRV = Darunavir ☐ DRV/r = Darunavir + ritonavir ☐ DTG = Dolutegravir ☐ EFV = Efivarenz ☐ ETR = Etravirine ☐ FTC = Emtricitibine ☐ LPV/r = Lopinavir + ritonavir (Kaletra/Aluvia) ☐ NVP = Nevirapine ☐ RAL = Raltegravir ☐ TDF = Tenofovir disoproxil fumarate ☐ TDF+3TC+DTG as fixed dose combination (Acriptega) ☐ TDF+FTC as fixed dose combination (Truvada) ☐ TDF+FTC+EFV as fixed dose combination (Trimune/Tribuss/Odimune /Atroiza /Atripla) ☐ Other
Other, specify name	_____
Have you ever defaulted on your HIV treatment?	◯ Yes ◯ No

Previous ART start date	_____
Previous ART end date	_____
WHO staging	◯ I ◯ II ◯ III ◯ IV ◯ Not applicable
Details of HIV disease Lab results or other notes	

Substance Use History

Smoking Habits

Have you ever smoked?	◯ Yes ◯ No
Do you currently smoke?	◯ Yes ◯ No
For how long have you been smoking?	_____
What is the number of cigarettes smoked per day?	_____
Pack years	_____ (Calculated)

Alcohol consumption

Have you ever used alcohol?	◯ Yes ◯ No
Do you currently drink?	◯ Yes ◯ No
Have you ever felt you needed to Cut down on your drinking?	◯ Yes ◯ No
Have people Annoyed you by criticizing your drinking?	◯ Yes ◯ No
Have you ever felt Guilty about drinking?	◯ Yes ◯ No
Have you ever felt you needed a drink first thing in the morning (Eye-opener) to steady your nerves or to get rid of a hangover?	◯ Yes ◯ No
For how long have you been using alcohol?	_____

Drug use

	Ever taken	Currently taking
Anabolic Steroids	☐	☐
Cocaine	☐	☐
Crack	☐	☐
Ecstasy	☐	☐
Heroin	☐	☐
Inhalants	☐	☐
LSD (Acid)	☐	☐
Marijuana	☐	☐
Methamphetamine (Speed, Crank, Crystal Meth)	☐	☐
Mushrooms	☐	☐
OxyContin	☐	☐
Painkillers	☐	☐
PCP (Angel Dust)	☐	☐
'Special K'	☐	☐
Other	☐	☐

Specify other drug from ever taken list

_____

Specify other drug from currently taking list

_____

For how long have you been using drugs?

_____

Other Medical History

Co-morbidities

Does the participant have any pre-existing medical conditions or co-morbidities?
- ◯ Yes
- ◯ No

Myocardial

	Yes	No
Angina	◯	◯
Valve disease	◯	◯
Myocardial infarction	◯	◯
Congestive Heart failure	◯	◯

Vascular

	Yes	No
Cerebrovascular disease	◯	◯
Hypertension	◯	◯
Peripheral vascular disease or claudication	◯	◯

Pulmonary

	Yes	No
Asthma	◯	◯
COPD	◯	◯

Neurological

	Yes	No
Dementia	◯	◯
Hemiplegia	◯	◯
Paraplegia	◯	◯
Neurological illness e.g. Parkinsons	◯	◯
Other disability	◯	◯

Specify other disability _____

Endocrine

	Yes	No
Diabetes Type 1	◯	◯
Diabetes Type 2	◯	◯

Gastrointestinal

	Yes	No
Gastroesophageal reflux disease	◯	◯
Inflammatory bowel disease	◯	◯
Liver disease	◯	◯
Peptic ulcer	◯	◯

Cancer

	Yes	No
Leukemia	◯	◯
Lymphoma	◯	◯
Solid organ cancer	◯	◯

Psychological

	Yes	No
Anxiety or Panic Disorders	◯	◯
Depression	◯	◯
Post-traumatic stress disorder	◯	◯

Muscoskeletal

	Yes	No
Arthritis	◯	◯
Connective Tissue disease	◯	◯
Degenerative Disc disease	◯	◯
Osteoporosis	◯	◯

Miscellaneous

	Yes	No
Hearing Impairment	◯	◯
Visual Impairment	◯	◯
Other	◯	◯

If other, specify additional co-morbidity _____

Observations

Observations	
Date of observation	_____
Weight	_____ (kg)
Height	_____ (cm)
BMI	_____ (Calculated)
Temperature	_____ (degrees celsius)
Blood pressure: Systolic	_____ (mmHg)
Blood pressure: Diastolic	_____ (mmHg)
BP position	◯ Sitting ◯ Standing ◯ Lying down
Heart rate	_____ (Beats per minute)
Respiratory rate	_____ (Breaths per minute)
Pulse oximeter	_____ (%)
Glucometer	_____ (mmol/l)

Initial clinical assessment

General Exam

	Normal	Abnormal	Not done
Head, eyes, ears, nose, and throat	◯	◯	◯
Cardiovascular	◯	◯	◯
Endocrine	◯	◯	◯
Gastrointestinal	◯	◯	◯
Lymphatic	◯	◯	◯
Neurological	◯	◯	◯
Psychiatric	◯	◯	◯
Respiratory	◯	◯	◯
Skin	◯	◯	◯
Urogenital	◯	◯	◯

Performance status
(ECOG grading used)

◯ 0 - Fully active, able to carry on all pre-disease performance without restriction
◯ 1 - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, i.e., light housework, office work
◯ 2 - Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
◯ 3 - Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
◯ 4 - Completely disabled. Cannot carry out any self-care. Totally confined to bed or chair

Comments on general exam

Pregnancy screen

Sexually active?
◯ Yes
◯ No

Protection during intercourse
◯ Yes
◯ No

Birth control
◯ Yes
◯ No

Type of birth control
_____

Last menstruation
_____

Suspected pregnancy?
◯ Yes
◯ No

Abdominal assessment

Abdominal assessment

	Yes	No
Abdominal distension	◯	◯
Dupuytren's contracture	◯	◯
Gynaecomastia	◯	◯
Hepatic flap	◯	◯
Masses	◯	◯
Pulsation	◯	◯
Stoma	◯	◯
Virchow's node	◯	◯

Bowel sounds

◯ Normal
◯ Abnormal
◯ Absent

Percussion

◯ Normal
◯ Abnormal

Bruits

	Present L	Present R	Absent L	Absent R
Aortic bruit	☐	☐	☐	☐
Renal bruit	☐	☐	☐	☐

Light palpation

	Tenderness	Rebound tenderness	Guarding	Masses	Normal
Right hypochondriac region	☐	☐	☐	☐	☐
Epigastric region	☐	☐	☐	☐	☐
Left hypochondriac region	☐	☐	☐	☐	☐
Right Lumbar region	☐	☐	☐	☐	☐
Umbilical region	☐	☐	☐	☐	☐
Left Lumbar region	☐	☐	☐	☐	☐
Right Iliac region	☐	☐	☐	☐	☐
Hypogastric region	☐	☐	☐	☐	☐
Left Iliac region	☐	☐	☐	☐	☐

Deep palpation		
	Normal	Abnormal
Aorta	◯	◯
Bladder	◯	◯
Gallbladder	◯	◯
Kidneys	◯	◯
Liver	◯	◯
Spleen	◯	◯

Comments on abdominal assessment

Cardiac assessment

Cardiac assessment

	Yes	No
Chest wall deformities	◯	◯
Oedema	◯	◯
Visible pulsations	◯	◯

Other signs

	Normal	Abnormal
Capillary refill time	◯	◯
Hepatojugular reflux	◯	◯
Jugular venous pressure	◯	◯

Pulses

	Normal L	Normal R	Abnormal L	Abnormal R
Anterior Tibial	☐	☐	☐	☐
Brachial	☐	☐	☐	☐
Carotid	☐	☐	☐	☐
Dorsalis Pedis	☐	☐	☐	☐
Femoral	☐	☐	☐	☐
Popliteal	☐	☐	☐	☐
Radial	☐	☐	☐	☐

Palpation

	Yes	No
Apex beat	◯	◯
Heaves	◯	◯
Thrills	◯	◯

Valves

	Normal	Abnormal
Aortic	◯	◯
Mitral	◯	◯
Pulmonary	◯	◯
Tricuspid	◯	◯

Heart sounds

	Yes	No
Are there any extra sounds?	◯	◯
Are the heart sounds normal in character?	◯	◯
Are there any murmurs?	◯	◯
Can you hear any rub?	◯	◯

Comments on cardiac assessment

Respiratory assessment

Respiratory assessment

	Yes	No
Cough	◯	◯
Cachexia	◯	◯
Fine tremor	◯	◯
Flapping tremor	◯	◯
Intercostal retractions	◯	◯
Nasal flare	◯	◯
Pulsus paradoxus	◯	◯
Stridor	◯	◯
Supplemental oxygen	◯	◯
Wheeze	◯	◯

Trachea deviation

◯ Right
◯ Left

Percussion

☐ Resonant throughout
☐ Dullness
☐ Stony dullness
☐ Hyper-resonant

Auscultation

☐ Decreased air-entry
☐ Bronchial breathing
☐ Fine crackles
☐ Coarse crackles
☐ Wheezing

Comments on respiratory examination

Neuro assessment

Neurological assessment

Decreased level of consciousness	◯ Yes ◯ No
Motor Score	◯ Obeys commands (+6) ◯ Localizes pain (+5) ◯ Withdrawal from pain (+4) ◯ Flexion to pain (+3) ◯ Extension to pain (+2) ◯ No motor response (+1) ◯ Not testable (NT)
Verbal score	◯ Oriented (+5) ◯ Confused (+4) ◯ Inappropriate words (+3) ◯ Incomprehensible sounds (+2) ◯ No verbal response (+1) ◯ Not testable (NT)
Eye-opening score	◯ Spontaneously (+4) ◯ To verbal command (+3) ◯ To pain (+2) ◯ No eye opening (+1) ◯ Not testable (NT)
Total GCS Score out of 15	_____ (Calculated)
Does the score need to be adapted? Score out of 10	◯ Yes ◯ No
GCS adapted score Score out of 10	_____
GCS outcome	◯ Severe: GCS 8 or less ◯ Moderate: GCS 9-12 ◯ Mild: GCS 13-15

Paralysis

	Yes	No	Unable to test
Cerebellar signs	◯	◯	◯
Nuchal rigidity	◯	◯	◯
Monoplegia	◯	◯	◯
Hemiplegia	◯	◯	◯
Paraplegia	◯	◯	◯

Cranial nerves

	Normal	Abnormal	Not tested	Unable to test
I Olfactory nerve	○	○	○	○
II Optic nerve	○	○	○	○
III Oculomotor nerve	○	○	○	○
IV Trochlear nerve	○	○	○	○
V Trigeminal nerve	○	○	○	○
VI Abducens nerve	○	○	○	○
VII Facial nerve	○	○	○	○
VIII Vestibulocochlear nerve	○	○	○	○
IX Glossopharyngeal nerve	○	○	○	○
X Vagus nerve	○	○	○	○
XI Accessory nerve	○	○	○	○
XII Hypoglossal nerve	○	○	○	○

Motor system

	Normal	Abnormal	Not tested	Unable to test
Right arm	○	○	○	○
Left arm	○	○	○	○
Right leg	○	○	○	○
Left leg	○	○	○	○

Coordination

	Normal	Abnormal	Not tested	Unable to test
Finger to nose ~ right hand	○	○	○	○
Finger to nose ~ left hand	○	○	○	○
Heel to shin ~ right leg	○	○	○	○
Heel to shin ~ left leg	○	○	○	○

Sensation

	Normal	Abnormal	Not tested	Unable to test
Light touch	○	○	○	○
Pain	○	○	○	○
Proprioception	○	○	○	○
Stereognosis	○	○	○	○
Temperature	○	○	○	○
Two point discrimination	○	○	○	○
Vibration	○	○	○	○

Reflexes

	Normal	Absent	Hypoactive	Hyperactive, no clonus	Hyperactive, clonus	Not tested	Unable to test
Left biceps	○	○	○	○	○	○	○
Left triceps	○	○	○	○	○	○	○
Left knee	○	○	○	○	○	○	○
Left ankle	○	○	○	○	○	○	○
Right biceps	○	○	○	○	○	○	○
Right triceps	○	○	○	○	○	○	○
Right knee	○	○	○	○	○	○	○
Right ankle	○	○	○	○	○	○	○

Plantar response

	Flexor	Extensor	Indeterminate	Not tested	Unable to test
Right foot	○	○	○	○	○
Left foot	○	○	○	○	○

Comments on neurologial exam

Skin assessment

Skin assessment

Skin type

- ◯ Pale white skin
- ◯ White skin
- ◯ Light brown skin
- ◯ Moderate brown skin
- ◯ Dark brown skin
- ◯ Black skin

Skin appearance

- ☐ Normal
- ☐ Acanthosis nigricans
- ☐ Bruising
- ☐ Track marks
- ☐ Tabacco staining
- ☐ Xanthomata
- ☐ Xanthelasma
- ☐ Jaundice
- ☐ Peripheral cyanosis
- ☐ Petechiae
- ☐ Spider naevi

Distribution

- ☐ Acral - affecting distal areas, hands and feet
- ☐ Extensor - extensor surfaces, elbows, knees
- ☐ Flexural - flexural surfaces, axillae, genital areas, cubital fossa
- ☐ Follicular - arising from hair follicles
- ☐ Dermatomal - corresponding with nerve root distribution
- ☐ Seborrhoeic - associated with areas where there are sebaceous glands, face and scalp

Skin lesions

Configuration of the lesion

- ☐ Discrete lesions - individual lesions, clearly separated from one another
- ☐ Confluent lesions - lesions that appear to be merging together
- ☐ Linear lesions - e.g. scratching related lesions
- ☐ Discoid (coin-shaped) - discoid eczema/discoid lupus
- ☐ Target lesions - concentric rings of varying colour - resembles a bullseye - erythema multiforme
- ☐ Annular - ring-like lesions

Primary Morphology

- ☐ Macule - flat lesion less than 1 cm, without elevation or depression
- ☐ Patch - flat lesion greater than 1 cm, without elevation or depression
- ☐ Plaque - flat, elevated lesion, usually greater than 1 cm
- ☐ Papule - elevated, solid lesion less than 1 cm
- ☐ Nodule - elevated, solid lesion greater than 1 cm
- ☐ Vesicle - elevated, fluid-filled lesion, usually less than 1 cm
- ☐ Pustule - elevated, pus-filled lesion, usually less than 1 cm
- ☐ Bulla - elevated, fluid-filled lesion, usually greater than 1 cm
- ☐ Abscess - localized accumulation of pus
- ☐ Wheal - oedematous papule or plaque caused by dermal oedema
- ☐ Boil / furuncle - staphylococcal infection around or within a hair follicle
- ☐ Carbuncle - staphylococcal infection of adjacent hair follicles

Secondary Morphology

- ☐ Serum (Dry crust)
- ☐ Fissure
- ☐ Lichenification
- ☐ Erosion
- ☐ Ulceration
- ☐ Scaling
- ☐ Excoriation
- ☐ Scar
- ☐ Striae

Demarcation

- ◯ Well-demarcated
- ◯ Not well-demarcated

Colour

- ☐ White
- ☐ Red
- ☐ Purple
- ☐ Brown
- ☐ Yellow
- ☐ Black
- ☐ Blue

Comments on lesions

Nails and hands

Nail pathology

- ☐ Nail pitting
- ☐ Onycholysis
- ☐ Koilonychia
- ☐ Nail clubbing
- ☐ Leukonychia
- ☐ Splinter haemorrhages
- ☐ Palmar erythema

Hair and scalp

Natural hair colour	◯ Red ◯ Blonde ◯ Chestnut or dark blonde ◯ Dark brown ◯ Black
Loss of hair	☐ Alopecia areata ☐ Alopecia totalis
Excess hair	☐ Hirsutism ☐ Hypertrichosis
Scalp	☐ Psoriasis plaques ☐ Dandruff

Oral assessment

	Normal	Abnormal
Lips	◯	◯
Tongue	◯	◯
Soft palate	◯	◯
Hard palate	◯	◯
Uvula	◯	◯
Tonsils and pillars	◯	◯
Buccal mucosa	◯	◯

	Yes	No
Glossitis	◯	◯
Oral candidiasis	◯	◯
Mouth ulcers	◯	◯

Comments on skin assessment

Visual assessment

Visual assessment

Eye colour

- ◯ Light blue, grey, green
- ◯ Blue, grey or green
- ◯ Dark blue or green, light brown
- ◯ Dark brown
- ◯ Brownish black

	Yes	No
Conjunctival pallor	◯	◯
Arcus cornealis	◯	◯

LogMAR scoring done?

- ◯ Yes
- ◯ No

If No, state reason:

_____

LEFT EYE

LogMAR value of lowest line completed

_____

Optotypes correctly identified

_____

LogMAR score

_____
(Calculated)

RIGHT EYE

LogMAR value of lowest line completed

_____

Optotypes correctly identified

_____

LogMAR score

_____
(Calculated)

Ishihara colour vision test

Ishihara colour vision testing done?	◯ Yes ◯ No
If No, state reason	_____
Ishihara outcome	◯ Normal ◯ Abnormal

TB Iris assessment

TB IRIS assessment

Clinical details

Antecedent requirements

☐ Diagnosis of tuberculosis: the tuberculosis diagnosis was made before starting ART and this should fulfil WHO criteria for diagnosis, of smear-positive pulmonary tuberculosis, smear-negative pulmonary tuberculosis, or extrapulmonary tuberculosis
☐ Initial response to tuberculosis treatment: the patient's condition should have stabilised or improved on appropriate tuberculosis treatment before ART initiation-eg, cessation of night sweats, fevers, cough, weight loss. (Note: this does not apply to patients starting ART within 2 weeks of starting tuberculosis treatment since insufficient time may have elapsed for a clinical response to be reported)

TB IRIS symptoms

☐ Recurrent fever
☐ Enlarged lymph nodes
☐ Worsening dyspnea

Days from ART start to TB IRIS symptom manifest

_____

Does this patient have possible paradoxical TB-IRIS?

◯ Yes
◯ No

Clinical criteria

MAJOR CRITERIA

☐ New or enlarging lymph nodes, cold abscesses or other focal tissue involvement.
☐ New or worsening radiological features of tuberculosis.
☐ New or worsening CNS tuberculosis.
☐ New or worsening serositis.

MINOR CRITERIA

☐ New or worsening constitutional symptoms such as fever, night sweats or weight loss.
☐ New or worsening respiratory symptoms such as cough, dyspnoea or stridor.
☐ New or worsening abdominal pain accompanied by peritonitis, hepatomegaly, splenomegaly or abdominal adenopathy.

Does participant have possible neurological TB-IRIS?

◯ Yes
◯ No

New or recurrent neurological symptoms/signs	☐ Headache ☐ Focal neurological deficit ☐ Nuchal rigidity ☐ Confusion ☐ Seizures ☐ Cerebellar signs ☐ Cognitive impairment ☐ Psychiatric manifestations
Adapted major neurologic criteria as per Pepper et al.	☐ New or worsening tuberculous meningitis. ☐ New or worsening intracerebral space-occupying lesion. ☐ New or worsening radiculomyelopathy.

Tests required

Tests required

Pregnancy

_____

Sample marked for testing of

- ◯ TST
- ◯ IGRA
- ◯ Smear
- ◯ Culture
- ◯ GeneXpert
- ◯ DST
- ◯ Haematology
- ◯ HIV
- ◯ Metabolic panel
- ◯ DNA
- ◯ Metabolomics
- ◯ Proteomics

Haematology

- ☐ Full blood cell panel
- ☐ CRP
- ☐ ESR

HIV

- ☐ CD4
- ☐ Viral Load

Metabolic panel

- ☐ Glucose
- ☐ HbA1c
- ☐ Creatinine
- ☐ Calcium
- ☐ Sodium
- ☐ Potassium
- ☐ Urea
- ☐ Albumin (ALB)
- ☐ Alanine Aminotransferease (ALT)
- ☐ Alkaline Phosphatase (ALP)
- ☐ Aspartate Aminotransferase (AST)
- ☐ Gamma-Glutamyl Transferase (GGT)
- ☐ Total bilirubin
- ☐ Total protein
- ☐ eGFR

Test results

Results of TB tests required

Date of smear result	_____
Smear result	◯ Negative ◯ Scanty positive ◯ 1+ smear positive ◯ 2+ smear positive ◯ 3+ smear positive ◯ Not done
Date of culture result	_____
Culture result	◯ MTB Detected ◯ MTB Not Detected ◯ Invalid ◯ Contaminated ◯ No result ◯ Not done
Date of geneXpert result	_____
GeneXpert result	◯ MTB detected ◯ MTB not detected ◯ Indeterminate ◯ Not applicable
RIF resistance	◯ Interminate ◯ Susceptible ◯ Resistant ◯ Not done ◯ Not applicable

Haematology

Date of haematology result	_____
White blood cell count 10^9/L	_____
Red blood cell count 12^12/L	_____
Hemoglobin g/L	_____
Haematocrit %	_____

MCV 10^15/L	_____
MCH fmol/cell	_____
MCHC fmol/cell	_____
Red Cell Distribution Width	_____
White cell differential 10^9/L	_____
Platelet count 10^9/L	_____
Neutrophils 10^9/L	_____
Lymphocytes 10^9/L	_____
Monocytes 10^9/L	_____
Eosinophils 10^9/L	_____
Basophils 10^9/L	_____
% neutrophils	_____
% lymphocytes	_____
% monocytes	_____
% eosinophils	_____
% basophils	_____
CRP mg/L	_____
ESR mm	_____

HIV bloods	
CD4 cells/mm3	_____
VL copies/mL	_____

Metabolic panel	
Glucose mg/dl	_____
HbA1c %	_____
Creatinine mg/dl	_____
Calcium mg/dl	_____
Sodium mmol/L	_____
Potassium mmol/L	_____
Urea mg/dl	_____
Albumin (ALB) g/L	_____
Alanine Aminotransferase (ALT) IU/L	_____
Alkaline Phosphatase (ALP) IU/L	_____
Aspartate Aminotransferase (AST) IU/L	_____
Gamma-Glutamyl Transferase (GGT) IU/L	_____
Total bilirubin mol/L	_____
Total protein g/L	_____
eGFR mL/min/m2	_____

Other tests	
Pregnancy test result	◯ Negative ◯ Positive ◯ Indeterminate
TST result	_____
IGRA result	_____

TB DST results

DST results	
Date of DST results	_____
Result type	◯ Phenotypic ◯ Genotypic

1st line LPA	
MTB complex	◯ Not done ◯ Detected ◯ NOT detected ◯ Indeterminate
INH susceptibility	◯ Not done ◯ Susceptible ◯ Resistant ◯ Indeterminate
RIF susceptibility	◯ Not done ◯ Susceptible ◯ Resistant ◯ Indeterminate
Mutations	◯ KatG ◯ InhA ◯ KatG & InhA

2nd line DST	
FQ susceptibility	◯ Not done ◯ Susceptible ◯ Resistant ◯ Indeterminate
SLI susceptibility	◯ Not done ◯ Susceptible ◯ Resistant ◯ Indeterminate
MTB complex	◯ Not done ◯ Detected ◯ NOT detected ◯ Indeterminate

Drug sensitivity outcome			
	Resistant	Sensitive	Not done
Amikacin	☐	☐	☐
Bedaquiline	☐	☐	☐
Capreomycin	☐	☐	☐
Clofazimine	☐	☐	☐
Cycloserine	☐	☐	☐
Delaminid	☐	☐	☐
Ethambutol	☐	☐	☐
Ethionamide	☐	☐	☐
Imipenem	☐	☐	☐
INH	☐	☐	☐
Kanamycin	☐	☐	☐
Levofloxacin	☐	☐	☐
Linezolid	☐	☐	☐
Moxifloxacin	☐	☐	☐
Ofloxacin	☐	☐	☐
PAS	☐	☐	☐
Prothionamide	☐	☐	☐
Pyrazinamide	☐	☐	☐
Rifabutin	☐	☐	☐
Rifampicin	☐	☐	☐
Streptomycin	☐	☐	☐
Terizidone	☐	☐	☐
Thiacatezone	☐	☐	☐

Protocol Deviation

Protocol deviation	
Protocol deviation number	_____
Date deviation occurred	_____
Date deviation discovered	_____
Site investigator aware of deviation	◯ Yes ◯ No
Reason for deviation	◯ Dispensing/ dosing error ◯ Accidental unblinding ◯ Enrollment of ineligible patient ◯ Other
Deviation, other reason	_____
Action taken	

PK details

STUDY DRUG ADMINISTRATION DETAILS

Date of last meal	_____
Time of last meal	_____
Fasting status	◯ Fasted (min 8 hours) ◯ Low fat diet ◯ Not fasted, no low fat diet
Specify contents of last meal	
Time of last medication dose	_____
Additional concomitant medication during PK event	◯ Yes ◯ No (Update medication log)
Did the participant vomit after meds were given?	◯ Yes ◯ No
If Yes, at what time?	_____
Details of vomiting episode	

PK VISIT COMPLETION

Was the PK visit successful?	◯ Yes ◯ No
If No, give a reason	◯ Withdrawn ◯ Protocol deviation ◯ Other
Other, specify	_____
If the PK visit was NOT successful, was it rescheduled?	◯ Yes ◯ No

If Yes, new PK date _____

Adherence

Adherence

Type of treatment

- ◯ TB
- ◯ HIV

Who administers the treatment?

- ◯ Self
- ◯ Other family
- ◯ Caregiver
- ◯ Multiple caregivers
- ◯ Other

If other, specify:

_____

	Yes	No
Do they know how to take the medication?	◯	◯
Do they have a treatment or pill count card?	◯	◯
Any missed doses on the card?	◯	◯

How many missed doses?

_____

Significant lapse identified

	Yes	No
Restart treatment	◯	◯
Treatment extension	◯	◯
Modify treatment	◯	◯

Study outcome

Study outcome	
Study outcome	◯ Study complete ◯ Participant ineligible after enrolment ◯ Participant withdrew from study ◯ Participant lost to follow up ◯ Participant deceased
TB classification	◯ Definite ◯ Probable ◯ Possible
TB outcome	◯ Cured ◯ Treatment completed ◯ Treatment failed ◯ Died
Reason for treatment failure ◯ Positive TB culture status at 6 months after treatment initiation or thereafter ◯ Relapse within 12 months after treatment completion ◯ Culture reversion after conversion to negative ◯ Evidence of additional acquired 2nd-line drug resistance ◯ Adverse drug reactions	
Date of death	_____
Cause of death	_____
Place of death	_____
Narrative of demise	
Date of last contact	_____
Withdrawal date	_____
Narrative of withdrawal	

Final status

◯ Alive and relapse-free
◯ Alive, but relapsed
◯ Deceased
◯ Unable to confirm

Data sources

☐ Participant self-report
☐ Report from relatives/friends
☐ Laboratory results database
☐ TB register
☐ Deaths register
☐ Other medical records
☐ Other

Comments on final status

Contact log

Contact Log	
Specify visit	_____
Contact attempt	◯ First ◯ Second ◯ Third ◯ Final
Type of contact	◯ Telephone ◯ Home visit
Contact outcome	◯ Successful ◯ Unsuccessful
Date of attempt	_____
Date of contact	_____
Comments	

Chest X-ray log

Chest X-ray information	
CXR ID number	_____
Date of CXR	_____
CXR view	◯ PA ◯ Lateral ◯ PA & lateral ◯ NA
Reader	◯ Reader 1 ◯ Reader 2 ◯ Reader 3 ◯ Consensus ◯ Not applicable
Date of reading	_____
Film quality	◯ Optimal ◯ Suboptimal ◯ Unreadable
Film exposure	◯ Under-exposed ◯ Over-exposed
Film rotation	◯ Towards the right ◯ Towards the left
Inspiratory attempt	◯ Poor inspiratory attempt ◯ Hyper-inflated
CXR outcome	◯ Normal ◯ Abnormal

Abnormalities

	Yes	No
Apical cap	◯	◯
Cardiomegaly	◯	◯
Cavities	◯	◯
Calcification	◯	◯
Consolidation	◯	◯
Hilar lymphadenopathy	◯	◯
Mediastinal lymphadenopathy	◯	◯
Nodules	◯	◯
Miliary infiltrate	◯	◯
Pleural effusion	◯	◯
Tracheal deviation	◯	◯
Tramlines	◯	◯
Tree in bud	◯	◯

Tracheal deviation

◯ Right
◯ Left

Which side/s does the abnormality present?

	Unilateral	Bilateral
Apical cap	◯	◯
Cavities	◯	◯
Calcification	◯	◯
Consolidation	◯	◯
Hilar lymphadenopathy	◯	◯
Mediastinal lymphadenotpathy	◯	◯
Miliary infiltrate	◯	◯
Nodules	◯	◯
Pleural effusion	◯	◯
Tramlines	◯	◯
Tree in bud	◯	◯

Number of cavities

_____

Largest cavity site

_____

Largest cavity size

_____

Number of calcifications

_____

Site of calcification

_____

Size of calcification/s	_____
Site of plerural effusion	_____
Size of pleural effusion	_____
Comments on CXR	

CT scan log

CT scan	
Date of imaging	_____
Imaging complete	◯ Yes ◯ No
Image acquisition type	◯ 2D ◯ 3D
Image quality	◯ Optimal ◯ Suboptimal ◯ Unreadable
Comments on scan	

ECG log

ECG	
12-lead ECG performed	◯ Yes ◯ No
ECG test date	_____
ECG test time	_____
ECG reading to be uploaded to study repository?	◯ Yes ◯ No
Upload ECG to study repository	

ECG Findings	
ECG heart rate	◯ Normal = 60 - 100 bpm ◯ Tachycardia > 100 bpm ◯ Bradycardia < 60 bpm
ECG rhythm	◯ Regular ◯ Irregular
ECG cardiac axis	◯ Normal ◯ Right axis deviation ◯ Left axis deviation
ECG P-waves present	◯ Yes ◯ No
P-R interval	_____ (ms)
QRS complex width	_____ (ms)
QRS complex height	_____ (mm)
QRS complex morphology	◯ Delta wave ◯ Q-waves ◯ R & S waves ◯ J point segment
ST segment	◯ ST elevation ◯ ST depression

ECG T-waves	◯ Tall ◯ Inverted ◯ Biphasic ◯ Flattened
ECG outcome	◯ Normal ◯ Abnormal
Comments on ECG	

Ultrasound log

Ultrasound

Was ultrasound completed
◯ Yes
◯ No

Date of ultrasound
_____

Site of ultrasound
_____

Findings

	Yes	No
Ascites	◯	◯
Adenopathy	◯	◯
Cholecystitis	◯	◯
Gallstone disease	◯	◯
Liver abnormality	◯	◯
Liver infiltrate	◯	◯
Pericardial effusion	◯	◯
Psoas abscess	◯	◯
Renal tract calculi	◯	◯
Splenic abnormality	◯	◯
Splenic microabscesses	◯	◯

Comments on ultrasound

Medication log

Medication log	
Medication category	◯ ConMed ◯ TB ◯ HIV ◯ PK
HIV med name	◯ Abacavir ABC ◯ Atazanavir ATV ◯ Atazanavir / Ritonavir ◯ Darunavir DRV ◯ Darunavir / Ritonavir ◯ Didanosine DDL ◯ Dolutegravir DTG ◯ Efavirenz EFV ◯ Emtricitabine FTC ◯ Enfuvirtide T-20 ◯ Etravirine ETR ◯ Lamivudine 3TC ◯ Lopinavir LPV ◯ Lopinavir LPV / Ritonavir ◯ Maraviroc MVC ◯ Nevirapine NVP ◯ Raltegravir RAL ◯ Rilpivirine RPV ◯ Stavudine d4T ◯ Tenofovir Disoproxil Fumarate TDF ◯ Tenofovir Alafenamide TAF ◯ Zidovudine ZDV

TB med name

- ◯ Amikacin AMK
- ◯ Amoxicillin/Clavulanate AMC
- ◯ Bedaquiline BDQ
- ◯ Capreomycin CAP
- ◯ Clofazimine CFZ
- ◯ Clarithromycin CLR
- ◯ Cycloserine CS
- ◯ Delamanid DLM
- ◯ Ethambutol EMB
- ◯ Ethionamide ETO
- ◯ Gatifloxacin GFX
- ◯ Imipenem/Cilastatin IMI
- ◯ Isoniazid INH
- ◯ Kanamycin KM
- ◯ Levofloxacin LFX
- ◯ Linezolid LZD
- ◯ Meropenem MPM
- ◯ Moxifloxacin MFX
- ◯ Olfloxacin OFX
- ◯ Other TB drugs
- ◯ P-aminosalicylic acid PAS
- ◯ Protionamide PTO
- ◯ Pyrazinamide PZA
- ◯ Rifabutin RBT
- ◯ Rifampicin RIF
- ◯ Rifapentine RPT
- ◯ Streptomycin STR
- ◯ Terizidone TRD
- ◯ Thioacetazone THZ

Medication name

_____

(Generic name)

Dose

_____

Dosage unit

- ◯ g
- ◯ gram
- ◯ mg
- ◯ milligram
- ◯ mcg
- ◯ microgram
- ◯ U
- ◯ unit
- ◯ TU
- ◯ thousand units
- ◯ MU
- ◯ million units
- ◯ mmol
- ◯ millimole
- ◯ ml
- ◯ milliliter

Frequency	◯ q.d. once a day ◯ b.i.d. twice a day ◯ t.i.d. three times a day ◯ q.i.d. four times a day ◯ q.h.s. before bed ◯ q.4h every four hours ◯ q.6h every six hours ◯ q.o.d. every other day ◯ prn. as needed ◯ q.t.t. drop ◯ a.c. before meals ◯ p.c. after meals
Route of administration	◯ Imp ◯ Implant ◯ Inhal ◯ Inhalation ◯ Instill ◯ Instillation ◯ IM ◯ Intramuscular ◯ IV ◯ Intravenous ◯ N ◯ Nasal ◯ O ◯ Oral ◯ P ◯ Parenteral ◯ R ◯ Rectal ◯ SL ◯ Sublingual/buccal/oromucosal ◯ TD ◯ Transdermal ◯ V ◯ Vaginal
Reason for starting treatment	◯ Initiation of treatment ◯ Change in treatment
Start date	_____
Start date is an estimate	☐ Estimate
Reason for stopping treatment	◯ Condition resolved ◯ Change in treatment ◯ Patient defaulted ◯ Adverse reaction ◯ Increase in weight
Stop date	_____
Stop date is an estimate	☐ Estimate

Event log

Event	
Event No	_____
Event reported as	◯ AE ◯ SAE ◯ Change in treatment
Type of report	◯ Initial ◯ Follow-up ◯ Final
Narrative of event	
Evet start date	_____
Was the event expected?	◯ Yes ◯ No
What was the severity of the event? In accordance with DAIDS grading system	◯ Grade 1 - Mild ◯ Grade 2 - Moderate ◯ Grade 3 - Severe ◯ Grade 4 - Life-threatening ◯ Grade 5 - Fatal
Relationship to study	◯ Unrelated ◯ Unlikely related ◯ Possibly related ◯ Probably related ◯ Definitely related
If related, specify how	◯ Study participation ◯ Study procedure ◯ Drug administered during a study-specific procedure ◯ Other
If other, specify	_____
Action taken	☐ Cessation of drug administered during study procedure ☐ Cessation of the study procedure ☐ Dose modification ☐ Hospitalization ☐ Medical intervention ☐ Withdrawn from study ☐ None

Reason for treatment change	◯ Adverse drug reaction ◯ Adherence problem ◯ Change dose/frequency ◯ Guideline recommendation ◯ Failure to culture convert ◯ Relapse ◯ Evidence of resistance ◯ End of treatment ◯ Other (specify) (Update medication log with new meds)
Other reason for treatment change	_____
Has this event been reported as an SAE?	◯ Yes ◯ No
Event end date	_____
Event outcome	☐ Death ☐ Ongoing/continuing treatment ☐ Not Recovered/Resolved at end of the study ☐ Recovered with minor sequelae ☐ Recovered with major sequelae ☐ Recovered/Resolved ☐ Unknown

Encounters log

Encounter start information

Encounter start date	_____
Encounter visit type	_____
District	_____
Subdistrict	_____
Facility ID	_____
Facility Name	_____
Reason for encounter	_____
Did the admission result in a prolonged stay?	◯ Yes ◯ No

Encounter end information

Encounter end date	_____
Discharge method	_____
Discharge destination	_____

PK sampling log

PK sampling	
PK visit type	◯ Sparse PK ◯ Intensive PK
Additional data collection fields can be added if required e.g. barcoding for each sample.	
Sample type	◯ Blood ◯ Cerebrospinal fluid ◯ Pericardial fluid
Specific PK time points can be added as a drop down	
PK time point	_____
CSF taken	◯ CSF cryovial 1 ◯ CSF cryovial 2
Scheduled time	_____
Actual time	_____
Time centrifuged	_____
Time placed on dry ice or in the -80? freezer?	_____

Dispensing log

IP dispensing	
Date of prescription	_____
Prescription period	_____ (Number of days)
Treatment collected	◯ Yes ◯ No
Dispensing date	_____
Dispensing time	_____
Associated visit number	_____
Drug name	_____
Drug code	_____ (ATC ontology)
Dispensing control number	_____ (Kit/ Lot number)
Drug formulation	_____
Quantity dispensed	_____
Expiry date	_____
Dispensing done by Full name	_____

Lymphadenopathy log

Lymphadenopathy	
Site	◯ cervical ◯ supra-clavicular ◯ occipital ◯ parotid ◯ submental ◯ sub-mandibular ◯ axillary ◯ supra-condylar ◯ inguinal
Side	☐ Left ☐ Right
Size left maximal diamater	_____
Size right maximal diamter	_____
Consistency	◯ Firm/Hard ◯ Fluctuant ◯ Matted
Sinus	◯ Yes ◯ No

Sample collection log

Sample collection	
Associated visit	_____
Sampling successful	◯ Yes ◯ No
Reason not collected	◯ Unable to produce sputum ◯ Other
Collection via	◯ Routine care ◯ Study team
Sample ID	_____ (or barcode)
Sample type	◯ Ascites ◯ Blood ◯ Cerebrospinal fluid ◯ Fine needle aspirate ◯ Gastric aspirate ◯ Naso pharyngeal aspirate ◯ Pericardial fluid ◯ Saliva ◯ Sputum ◯ Stool ◯ Tracheal/Broncho-alveolar lavage ◯ Urine ◯ Other
Other sample type	_____
Sputum produced	◯ Spontaneously ◯ Induced
Sputum type	◯ Overnight ◯ Early morning ◯ Spot
Sputum quality	◯ Watery ◯ Mucoid ◯ Purulent
Date of collection	_____
Time of collection	_____
Sample destination	_____

Sample processing log

Sample processing

Date processed

_____

Time processed

_____

Storage allocation number

_____

Sample quality

Sample quality

◯ Good
◯ Fair
◯ Poor

Volume collected

◯ Sufficient
◯ Insufficient

Aliquot information

Able to aliquot

◯ Yes
◯ No

Number of sample aliquots

_____

Aliquot IDs

Aliquot storage allocation

_____

Shipment

Samples to be shipped

◯ Yes
◯ No

Shipment destination

_____

Shipment date

_____

Shipment number

_____

Confirmation of shipment receipt	◯ Confirmed ◯ Unconfirmed
Shipment receipt date	_____