IeDEA TB-SRN Case Report Forms (CRFs)

Following are the paper case report forms (CRFs) for the IeDEA TB-SRN Study. Some sites alternately use a digital version of the CRFs available in REDCap which include questions identical to the paper CRFs. A full REDCap version is available upon request. For questions regarding the CRFs or to request a REDCap file, please contact laquita.mcdade@vumc.org

IeDEA/TB SRN

[1] INCLUSION			
IeDEA/TB SRN ID			
Type of visit	☐ Baseline		
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|		
Inclusion criteria (*include if all items 1-3 are present*)	**Yes**	**No**	**Specify**
1. Age ≥15 years	☐	☐	
2. Diagnostic criteria – At least one of the diagnostic criteria 2a-2c is met	☐	☐	
2a. Clinically diagnosed pulmonary TB and plan to initiate TB treatment with: - Any signs or symptoms and CXR findings consistent with pulmonary TB, OR - Respiratory signs and symptoms			☐
2b. Microbiologically confirmed pulmonary TB based on sputum or other respiratory samples - Smear positive, OR - Positive rapid molecular TB tests (Xpert MTB/RIF Ultra), OR - Positive TB culture			☐
2c. Positive lipoarabinomannan (LAM) urine test and clinical diagnosis of pulmonary TB as defined above			☐
3. HIV test documented or willingness to be tested: - Documented HIV infection, OR - Any HIV test less than or equal to 90 days earlier, OR - Willingness to be tested for HIV (if no recent test available – *test to be done within 7 days for inclusion*)	☐	☐	
Exclusion criteria (*exclude if ≥1 of items 4-7 present*)	**Yes**	**No**	**Specify**
4. Has received TB treatment for more than 7 days within the prior 30 days, excluding TB preventive therapy	☐	☐	
5. Plans to move to a distant site that would interfere with ability to complete all study visits	☐	☐	
6. Substantial cognitive impairment that may interfere with the ability to give reliable informed consent	☐	☐	
7. Currently imprisoned	☐	☐	
Consent and enrolment			
8. Signed and dated informed consent or witnessed oral consent	☐	☐	
8a. *For minors (under age 18):* Signed and dated informed consent of a primary caregiver (and informed adolescent assent where required)	☐	☐	
9. Date of enrolment *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|		
Additional questions			
10. Type of setting where enrolled	☐ Inpatient setting ☐ Outpatient setting		
11. Currently co-enrolled in other research study?	☐ Yes (fill **Other Research** form) ☐ No		

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA/TB SRN

[2] DEMOGRAPHICS	
IeDEA/TB SRN ID	
Type of visit	☐ Baseline
Visit date *(dd/mm/yyyy)*	|___|___| / |___|___| / |___|___|___|___|
1. Sex at birth	☐ Male ☐ Female ☐ Other ☐ Unknown
2. Date of birth *(dd/mm/yyyy)* *(estimate if unknown)*	|___|___| / |___|___| / |___|___|___|___|
3. Current Marital status (*Check one option that best applies*)	☐ Single ☐ Married ☐ Widowed ☐ Separated ☐ Divorced ☐ Living with partner
4. Highest level of education completed (*Check one option that best applies*)	☐ None ☐ Primary education ☐ Lower secondary or end of basic education ☐ Upper secondary ☐ Post-secondary non-tertiary (e.g., post-secondary certificate or diploma) ☐ University ☐ Post-graduate ☐ Koranic school ☐ Other, only if none of the previous options applies ☐ Do not know / unknown
5. Current Profession (occupation) *(Check all that apply)*	☐ Cook ☐ Craftsman ☐ Employee, private sector ☐ Employee, public sector ☐ Farmer, pastoralist ☐ Homemaker (e.g., housewife, househusband) ☐ Housekeeper

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	☐ Policeman, serviceman/military, customs officer ☐ Storekeeper ☐ Street / market seller ☐ Student ☐ Truck driver, taxi driver ☐ Retired ☐ Unemployed ☐ Other ☐ Do not know / unknown
6. Currently working or living in a health care setting, institutional setting, or other high TB-risk setting	☐ No / not applicable ☐ Yes
7. If yes, specify. (*Check all that apply*)	☐ Hospital or clinic ☐ Nursing home or long-term care facility ☐ Orphanage, shelter, or another residential center ☐ Dormitory (school) ☐ Military ☐ Prison ☐ Refugee camp ☐ Other ☐ Do not know / unknown
8. Number of people residing in the household *(including full-time and part-time residents)*	|___|___|
9. Number of children <5 years residing in the household *(full-time or part-time)*	|___|___|
10. Total household monthly income *(Including all sources of household / family monthly income*; *check one option that best applies*)	☐ < 40 USD or local currency equivalent ☐ ≥ 40 AND < 80 USD ☐ ≥ 80 AND < 200 USD ☐ ≥ 200 AND <400 USD ☐ ≥ 400 USD ☐ Do not know

11. Current dwelling location	☐ City/urban area (specify type below) ☐ Peri-urban area ☐ Rural area
12. City/urban area type	☐ Formal housing ☐ Slum/shantytown/favela
13. Type of dwelling (*Check one option that best applies or applies most of the time*)	☐ Free-standing house ☐ Apartment, condominium, or other residential building ☐ Boarding school or college ☐ Institution ☐ Homeless / street living ☐ Other
14. Distance from residence to clinic *(km)*	|___|___|___|___| km
15. Transportation mode to TB clinic (*Check all that apply*)	☐ Foot ☐ Bicycle ☐ Motorcycle ☐ Personal automobile (car, truck) ☐ Public transportation (bus, train, etc.) ☐ Taxi or rideshare service (including hired car, mini-van, motorbike) ☐ Medical vehicle ☐ Other
16. Typical transportation cost *to and from* TB clinic (both ways, local currency)	_____ (local currency)

Investigator: _____ Signature: _____ Date |__|__|/|__|__|/|__|__|__|__|

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IeDEA/TB SRN

[3] Adolescent and Young Adult Characteristics for All Participants under Age 25	
IeDEA/TB SRN ID	
Visit	☐ Baseline
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
Adolescent and Young Adult questions	
1. Biological mother alive?	☐ Yes ☐ No ☐ Unknown ☐ Refused
2. Biological father alive?	☐ Yes ☐ No ☐ Unknown ☐ Refused
3. Currently in a relationship with someone? *(May be a spouse, a partner, a girlfriend, a boyfriend, …).*	☐ Yes ☐ No ☐ Unknown ☐ Refused
4. Has the participant had any biological children? *(Biological children may or may not be living.)*	☐ Yes ☐ No ☐ Unknown ☐ Refused
5. With whom does the participant live? *(If multiple places on a regular basis, check all that apply.)*	☐ Immediate family members ☐ Extended family members (family members other than biological parents and siblings) ☐ With a peer or partner ☐ With school ☐ In children's home or institution ☐ Living independently (includes those living on the street) ☐ Other: _____ ☐ Unknown ☐ Refused
6. Main caregiver (*Check the option that best applies*.)	☐ Self (SKIP to #9) ☐ Mother ☐ Father ☐ Aunt/Uncle ☐ Grandparent ☐ Sibling ☐ Spouse/partner ☐ Other relative ☐ Guardian, non-relative ☐ Unknown ☐ Refused
7. Do the participant and the main caregiver currently live in the same place?	☐ Yes ☐ No, adolescent at boarding school or college ☐ No, adolescent living on the street ☐ No, other circumstance ☐ Unknown

(Are both spending most nights at the same residence in a given week?)	☐ Refused
8. Role(s), if any, of main caregiver in participant medical care *(Examples might include bringing participant to clinic visits or to the hospital when sick or picking up medications. Choose all that apply.)*	☐ None / not involved in medical care ☐ Bringing the adolescent to clinic visits ☐ Bringing the adolescent to the hospital when sick ☐ Supervising the adolescent taking medications ☐ Picking up prescribed medications for the adolescent ☐ Providing transportation fare for the adolescent to attend clinic ☐ Other: _____ ☐ Unknown ☐ Refused
9. Is participant currently attending school (including college or other higher learning)?	☐ Yes (SKIP to #12) ☐ No ☐ Unknown ☐ Refused
10. Main reason for not attending school (or college or other higher learning)	☐ Sick ☐ Doesn't like school ☐ Has to look after family members ☐ Not enough money ☐ School too far away ☐ Have to work ☐ Have completed school ☐ Other: _____ ☐ Unknown ☐ Refused
11. If attending school (or college or other higher learning), does the participant reside at school? (*e.g., in boarding school, dormitory, or residential housing?*)	☐ Yes ☐ No ☐ Unknown ☐ Refused
12. Main source of income	☐ Self (money earned as employee, self-employment, interest/dividends, loans or bursaries or welfare payments/ grants) ☐ Dependent on someone else's income (parents, caregiver, partner, other relatives) ☐ Unknown ☐ Refused
Disclosure Screening questions: *Only for adolescents and young adults with HIV,* to assess adolescent's awareness of their status.	
13. Why do you come for visits at this clinic (or at another site)?	**DO NOT READ OPTIONS, THIS IS AN OPEN-ENDED QUESTION** ☐ HIV ☐ Other: _____ ☐ Unknown
14. Do you have any health conditions (other than tuberculosis or TB)?	**DO NOT READ OPTIONS, THIS IS AN OPEN-ENDED QUESTION** ☐ HIV ☐ Other: _____ ☐ Unknown

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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15. For what conditions do you take medications (other than for tuberculosis or TB)?	**DO NOT READ OPTIONS, THIS IS AN OPEN-ENDED QUESTION** ☐ HIV ☐ Other: _____ ☐ Unknown
16. Do you have questions about why you need to take medications?	☐ Yes ☐ No ☐ Unknown
17. If yes, what questions do you have? *(Refer to clinical care providers.)*	_____ _____ _____
If the answers to all of questions 13-15 were "Unknown" or "Other," may need to consider the adolescent NOT DISCLOSED. Please refer to procedures for avoiding accidental disclosure of status.	

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

[4] TB History and Current TB Diagnosis	
IeDEA/TB SRN ID	
Type of visit	☐ Baseline ☐ Tx F/R/W (for TB recurrence only)
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
For the items below, choose the best single option unless otherwise indicated.	
Previous TB history (*fill only at baseline visit*)	
1. Previous TB preventive therapy (TPT) received	☐ Yes ☐ No ☐ Unknown
2. TPT regimen previously prescribed +++ *(Most recent TPT course, if multiple previous TPT regimens)*	☐ 6 to 9 months daily isoniazid (6H or 9H) ☐ 4 months daily rifampicin (4R) ☐ 3 months weekly rifapentine plus isoniazid (3HP) ☐ 3 months daily isoniazid plus rifampicin (3HR) ☐ 1 month daily rifapentine plus isoniazid (1HP) ☐ Other, please specify: _____ ☐ Unknown
3. TPT completion *(Most recent TPT course)*	☐ Yes ☐ No ☐ Unknown
4. Date of TPT completion/interruption *(dd/mm/yyyy; most recent TPT course)*	|__|__|/|__|__|/|__|__|__|__|
5. Previous TB disease treated	☐ Yes ☐ No (if no go to section "current TB episode")
6. Type of TB during previous TB episode (*Check one*; *most recent TB episode, if multiple previous TB episodes)*	☐ Pulmonary ☐ Extrapulmonary (specify below) ☐ Pulmonary and extrapulmonary (specify below) ☐ Unknown
7. Resistance pattern for previous TB episode *(Most recent TB episode, if multiple previous TB episodes)*	☐ Drug-susceptible (DS-TB) ☐ Drug-resistant (DR-TB) – *if resistance to one or more agents* ☐ Unknown
8. Extrapulmonary location for previous TB episode *(Check all that apply; most recent TB episode, if multiple previous TB episodes)*	☐ Lymph node ☐ Pleural ☐ Bone / joint ☐ Genitourinary ☐ Gastrointestinal ☐ Miliary ☐ Meningeal / CNS

IeDEA TB SRN

	☐ Other, please specify: _____ ☐ Unknown
9. End of previous TB treatment date *(dd/mm/yyyy; if multiple, most recent TB episode)*	|__|__|/|__|__|/|__|__|__|__|
10. TB treatment outcome *(Most recent previous TB episode; WHO/IUATLD outcomes)*	☐ Cured ☐ Treatment completed ☐ Treatment failed ☐ Lost to follow-up ☐ Transferred out ☐ Not evaluated ☐ Unknown
11. Source of TB history (*Check all that apply*)	☐ TB register ☐ Medical record ☐ Participant report
Current TB episode (*baseline + recurrence*)	
12. History of known contact with TB	☐ Yes ☐ No (SKIP to #15) ☐ Unknown
13. Time since most recent contact with TB	☐ < 1 year ☐ ≥ 1 year & <2 years ☐ ≥ 2 years ☐ Unknown
14. Place of contact (*Check one*)	☐ Household ☐ Occupational ☐ School or college ☐ Other institutional setting (not school, work, or housing/residential contact) ☐ Other ☐ Unknown
15. Approximate date of start of symptoms *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
16. Locations of care-seeking for this TB episode *(Exclude current facility; check all that apply)*	☐ Primary health care clinic (primary-level) ☐ Public district/provincial hospital (secondary-level) ☐ Public teaching/referral hospital (tertiary-level) ☐ Private practice ☐ Private hospital ☐ Pharmacy / dispensary ☐ Self-management / self-medication ☐ Traditional healer ☐ Other

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	☐ Unknown
17. Date of first consultation at any facility (clinic or hospital) for the current TB episode *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
18. Number of visits to any health facility (clinic or hospital) during illness course prior to TB diagnosis	|__|__| ☐ Unknown
19. Inpatient hospital admission during current TB illness	☐ Yes ☐ No (SKIP to #21) ☐ Unknown
20. If yes, duration of hospitalization *(days)*	|__|__| days ☐ Ongoing (return to form to complete duration after discharge) ☐ Unknown
21. Date of TB diagnosis *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
22. Patient TB category (WHO/IUATLD)	☐ New case ☐ Relapse ☐ Treatment after failure ☐ Treatment after loss to follow-up ☐ Transfer in ☐ Other ☐ Unknown
23. TB diagnosis (type of TB)	☐ Pulmonary ☐ Pulmonary and extrapulmonary (specify) ☐ Unknown
24. Extrapulmonary location *(Check all that apply)*	☐ Lymph node ☐ Pleural ☐ Bone / joint ☐ Genitourinary ☐ Gastrointestinal ☐ Miliary ☐ Meningeal / CNS ☐ Other, please specify: _____ ☐ Unknown
25. TB-SRN pulmonary TB diagnostic criteria (*Check all that apply*)	☐ Respiratory symptoms ☐ CXR feature suggestive of PTB ☐ Positive MTB tests on respiratory samples
26. Microbiological status (*Fill detailed test results in **TB Lab** form)*	☐ No samples collected ☐ Negative MTB testing only (e.g., smear, Xpert, culture, or LAM; specify results in **TB Lab** form)

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	☐ Any Positive MTB test result(s) (e.g., smear, Xpert, culture, or LAM; specify results in **TB Lab** form) ☐ Pending
27. Resistance pattern at diagnosis (*Fill detailed tests results in **TB Lab** form*)	☐ Drug-susceptible (DS-TB) ☐ Drug-resistant (DR-TB) – *if presumed or known resistance to one or more agents* ☐ Unknown
28. TB treatment initiation	☐ Yes (already initiated) ☐ Planned (within 7 days)
29. Date of TB treatment initiation *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
30. Type of TB treatment initiated *(Enter regimen details in **TB treatment** form)*	☐ 1st line regimen (DS-TB) ☐ 2nd line regimen (DR-TB) ☐ Other, specify: _____

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Investigator: _____ Signature: _____ Date |__|__|/|__|__|/|__|__|__|__|

IeDEA TB SRN

[5] MEDICAL HISTORY FORM	
IeDEA/TB SRN ID	
Visit	☐ Baseline
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
For each of the conditions below, indicate if there is any history of each condition (current or past)	
1. Asthma	☐ Yes ☐ No ☐ Unknown
2. Chronic obstructive pulmonary disease (COPD) or emphysema	☐ Yes ☐ No ☐ Unknown
3. Pulmonary fibrosis or interstitial lung disease	☐ Yes ☐ No ☐ Unknown
4. History of COVID-19	☐ Yes (complete COVID-19 test data in **Other Lab** form) ☐ No (SKIP to #5) ☐ Unknown (SKIP to #5)
4a. Number of COVID-19 diagnosed episodes?	|__|__| episodes
4b. Date of most recent COVID-19 diagnosis *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
5. Other lung disease	☐ Yes ☐ No (SKIP to #6) ☐ Unknown (SKIP to #6)
5a. If yes, specify lung disease	_____
6. Hypertension	☐ Yes ☐ No (SKIP to #7) ☐ Unknown (SKIP to #7)

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6a. Current treatment for hypertension	☐ Yes ☐ No ☐ Unknown
6b. If yes, specify anti-hypertensive medications	☐ ACE inhibitors (e.g., enalapril) ☐ Calcium channel blockers (e.g., amlodipine, nifedipine) ☐ Diuretics (e.g., lasix, aldactone, hydrochlorothazide) ☐ Angiotensin receptor blockers (e.g., losartan) ☐ Beta blockers (e.g., atenolol) ☐ Other
7. Coronary heart disease	☐ Yes ☐ No ☐ Unknown
8. Heart failure	☐ Yes ☐ No ☐ Unknown
9. Pulmonary hypertension	☐ Yes ☐ No ☐ Unknown
10. Diabetes	☐ Yes ☐ No (SKIP to #11) ☐ Unknown (SKIP to #11)
10a. Current anti-diabetes treatment	☐ Yes ☐ No (SKIP to #11) ☐ Unknown (SKIP to #11)
10b. If yes, specify anti-diabetes medications	☐ Metformin ☐ Glibenclamide ☐ Gliclazide ☐ Insulin ☐ Unknown ☐ Other (specify): _____

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10c. If yes, specify route	☐ Oral ☐ Injection ☐ Other ☐ Unknown
11. Kidney disease	☐ Yes ☐ No (SKIP to #12) ☐ Unknown (SKIP to #12)
11a. If yes, currently on dialysis	☐ Yes ☐ No ☐ Unknown
12. Liver disease	☐ Yes ☐ No (SKIP to #13) ☐ Unknown (SKIP to #13)
12a. If yes, type of liver disease. *Check all that apply*	☐ Cirrhosis ☐ Alcohol related liver disease ☐ Non-alcoholic fatty liver disease ☐ Hepatitis B ☐ Hepatitis C ☐ Other (specify): _____
13. Cancer	☐ Yes ☐ No(SKIP to #14) ☐ Unknown (SKIP to #14)
13a. If yes, specify type of cancer	☐ Anal ☐ Breast ☐ Colon ☐ Invasive cervical ☐ Kaposi's Sarcoma ☐ Lung ☐ Non-Hodgkin lymphoma ☐ Prostate

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	☐ Skin: melanoma ☐ Skin: non-melanoma ☐ Unknown ☐ Other _____
14. Immunosuppressor history	☐ Yes ☐ No (SKIP to #15) ☐ Unknown (SKIP to #15)
14a. If yes, specify ongoing immunosuppressor treatment	☐ None ☐ Steroid (e.g., prednisone, hydrocortisone) ☐ Biologic (e.g., infliximab, adalimumab, etanercept) ☐ Chemotherapy ☐ Other: _____ ☐ Unknown
15. Disorder of the brain or spinal cord	☐ Yes ☐ No ☐ Unknown
16. Mental health diagnosis	☐ Yes ☐ No (SKIP to #17) ☐ Unknown (SKIP to #17)
16a. If yes, Specify mental health diagnoses *(Check all that apply)*	☐ Depression ☐ Post-Traumatic Stress Disorder (PTSD) ☐ Anxiety ☐ Substance dependence ☐ Other: _____ ☐ Unknown
16b. Receiving counseling for mental health diagnos(es)	☐ Yes ☐ No ☐ Unknown

IeDEA TB SRN

16c. Receiving medication for mental health diagnos(es)	☐ Yes ☐ No ☐ Unknown
17. Other health condition	☐ Yes ☐ No (SKIP to #18) ☐ Unknown (SKIP to #18)
17a. Specify health condition(s).	_____ _____ _____
18. Notes on medical history *(Optional free text notes)*	_____ _____ _____ _____ _____

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

[6] HIV History	
IeDEA/TB SRN ID	
Type of visit	☐ Baseline
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
HIV testing	
1. Date of most recent HIV test *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| or ☐ Not yet done
2. HIV status	☐ Positive (enter result in **Other Lab** form) ☐ HIV testing planned (results to report in **Other Lab** form; if found to be positive, return to complete HIV care section below) ☐ Negative within 90 days (if negative, SKIP to END)
HIV care (if HIV positive)	
3. Date of HIV diagnosis *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
4. Enrolment into HIV care	☐ Yes ☐ No (SKIP to #6) ☐ Unknown
5. Date of enrolment in HIV care *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
6. Previous hospitalizations for HIV complications	☐ Yes ☐ No (SKIP to #8) ☐ Unknown
7. Date of most recent hospital discharge *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
8. WHO stage (highest, *prior to TB)*	☐ 1 (SKIP to #14) ☐ 2 ☐ 3 ☐ 4 ☐ Not applicable (using CDC staging) ☐ Unknown
9. CDC stage (highest, *prior to TB*)	☐ 1 (SKIP to #14) ☐ 2 ☐ 3 ☐ Not applicable (using WHO staging) ☐ Unknown
10. CDC/WHO stage defining illness #1 *(other than current TB)*	…… ☐ Past/resolved ☐ Ongoing ☐ Unknown

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11. CDC/WHO stage defining illness #2 *(other than current TB)*	…… ☐ Past/resolved ☐ Ongoing ☐ Unknown
12. CDC/WHO stage defining illness #3 *(other than current TB)*	…… ☐ Past/resolved ☐ Ongoing ☐ Unknown
13. CDC/WHO stage defining illness #4 (other than current TB)	…… ☐ Past/resolved ☐ Ongoing ☐ Unknown
14. Currently on cotrimoxazole	☐ Yes ☐ No ☐ Unknown
15. ART initiated	☐ Yes ☐ No (SKIP to END) ☐ Unknown
16. ART initiation date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
17. Currently on ART (fill **ART form**)	☐ Yes ☐ No

Reminder to complete the **Other Lab Resu**lts form (for HIV-related labs) and **ART** form!

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

[7] PREGNANCY / POST-PARTUM HISTORY and UPDATES	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
Baseline Questions (If NOT Baseline, SKIP to #4)	
1. Ever pregnant, currently or in the past (baseline)	☐ Yes ☐ No (SKIP to #6) ☐ Unknown
2. If yes, number of pregnancies (including current pregnancy if pregnant) (baseline)	|__|__|
3. If yes, number of live born infants (baseline)	|__|__|
Pregnancy Status	
4. Currently pregnant	☐ Yes (complete **Pregnancy and Infant Outcomes** form, or update existing form) ☐ No ☐ Unknown
5. Recent pregnancy or delivery (*For pregnancy ending in the **12 months prior to study** enrolment, or any time thereafter.*)	☐ Yes (complete a separate **Pregnancy and Infant Outcomes** form for each pregnancy in this time period, or update existing form) ☐ No ☐ Unknown
6. Able to be pregnant in the future?	☐ Yes ☐ No (e.g., hysterectomy, tubal ligation, menopause) → Do not need to ask pregnancy questions at future visits. ***At future visits, update infant outcomes for recent pregnancies if applicable.*** ☐ Unknown
For each recent or ongoing pregnancy, complete a separate Pregnancy and Infant Outcomes form, which will be updated at subsequent study visits	

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Pregnancy Hx Page 1 of 1

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IeDEA TB SRN

[8] PREGNANCY and INFANT OUTCOMES	
IeDEA/TB SRN ID	

Visit	**Date (dd/mm/yyyy)**	**Visit**	**Date (dd/mm/yyyy)**
☐ Baseline	|__|__| / |__|__| / |__|__|__|__|	☐ End of Tx	|__|__| / |__|__| / |__|__|__|__|
☐ 6-M Post-Tx	|__|__| / |__|__| / |__|__|__|__|	☐ Tx F/R/W	|__|__| / |__|__| / |__|__|__|__|

Recent or Ongoing Pregnancy History and Outcomes

- Time period: begin with any pregnancy ending <12 months before enrollment, and continue recording any pregnancy thereafter during the study.
- If **multiple pregnancies,** complete a **separate form for each pregnancy** and associated infant outcomes for all infants.
- **Revisit and update details**, including for new pregnancies, during subsequent study visits.

1. Pregnancy number *(Complete a separate form for each pregnancy ending <12 months prior to enrollment or any time thereafter.)*	|__|__|
2. Outcome of recent pregnancy	☐ Ongoing ☐ Born alive ☐ Stillborn ☐ Spontaneous abortion (miscarriage) ☐ Induced abortion ☐ Unknown
3. If ongoing, Date of last menstrual period (LMP)	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
4. If ongoing pregnancy, estimated date of delivery (EDD)	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
5. If pregnancy ended, date of delivery or other outcome	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
6. If born alive, term at delivery	☐ Full term (37 to 41 weeks) ☐ Post-term (≥42 weeks) ☐ Pre-term 34 to 36 weeks ☐ Pre-term < 34 weeks ☐ Unknown
7. Did you receive any of these during pregnancy? (Check all that apply.)	☐ TB preventive therapy ☐ TB treatment ☐ ART (HIV treatment, if applicable) ☐ None ☐ Unsure/Unknown
8. Conditions or complications during pregnancy	☐ Anemia, or having lower than the normal number of red blood cells ☐ High blood pressure, swelling, or protein in the urine ☐ Diabetes, or elevated blood sugar ☐ Urinary tract infection(s) ☐ Other infection(s): _____ _____

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	☐ Symptoms of depression (low or sad mood; lost interest in activities; changes in appetite, sleep, and energy; feelings of worthlessness, shame or guilt; thoughts that life is not worth living) ☐ Other medical problem for the mother: _____ ☐ Problem with the baby noted during pregnancy: _____ _____ ☐ Preterm (early) labor ☐ Bleeding ☐ Other: _____ _____ ☐ None ☐ Unsure/Unknown
9. Conditions or complications for the infant after delivery	☐ Pre-term birth (<37 weeks) ☐ Low birth weight (<2500 g) ☐ Low blood sugar ☐ Jaundice ☐ Birth defects ☐ Birth injuries ☐ Breathing problems ☐ Slow growth / failure to thrive ☐ Developmental delay ☐ Neurologic problems ☐ Other medical problems: _____ _____ ☐ Other: _____ ☐ None ☐ Unsure/Unknown
Infant Live Status and TB treatment/TPT	
10. Number of infants born alive for this pregnancy *(Infants from different pregnancies should be recorded on separate form.)*	|__|
11. TB treatment for infant 1	☐ Yes ☐ No ☐ Unknown
12. TB prevention therapy for infant 1	☐ Yes ☐ No ☐ Unknown
13. Infant 1 status at 12 months of life or by 12Mo Post-Tx visits	☐ Alive at ≥12 months of age ☐ Alive, not yet 12 months of age (update at future visit) ☐ Deceased ☐ Unknown
14. Cause of infant 1 death, if known	☐ Diagnosed TB ☐ Pneumonia / lung infection ☐ Other infectious cause: _____ _____ ☐ Other non-infectious cause: _____ _____ ☐ Decline to answer ☐ Unknown
15. TB treatment for infant 2	☐ Yes ☐ No

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	☐ Unknown
16. TB prevention therapy for infant 2	☐ Yes ☐ No ☐ Unknown
17. Infant 2 status at 12 months of life or by 12Mo Post-Tx visits	☐ Alive at ≥12 months of age ☐ Alive, not yet 12 months of age (update at future visit) ☐ Deceased ☐ Unknown
18. Cause of infant 2 death, if known	☐ Diagnosed TB ☐ Pneumonia / lung infection ☐ Other infectious cause: _____ _____ ☐ Other non-infectious cause: _____ _____ ☐ Decline to answer ☐ Unknown
19. TB treatment for infant 3	☐ Yes ☐ No ☐ Unknown
20. TB prevention therapy for infant 3	☐ Yes ☐ No ☐ Unknown
21. Infant 3 status at 12 months of life or by 12Mo Post-Tx visits	☐ Alive at ≥12 months of age ☐ Alive, not yet 12 months of age (update at future visit) ☐ Deceased ☐ Unknown
22. Cause of infant 3 death, if known	☐ Diagnosed TB ☐ Pneumonia / lung infection ☐ Other infectious cause: _____ _____ ☐ Other non-infectious cause: _____ _____ ☐ Decline to answer ☐ Unknown

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Pregnancy and Infant Outcomes Page 3 of 3
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IeDEA TB SRN

[9] VISIT AND CLINICAL EVALUATION	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit Date *(dd/mm/yyyy)*	|__|__| / |__|__| / |__|__|__|__|
Details on type of visit	
1. Visit type	☐ In-person visit ☐ Phone visit ☐ Data abstraction without patient contact ☐ Not performed
2. Reasons for visit not performed	☐ Lost to follow up (from study) ☐ Withdrawn ☐ Transferred out ☐ Death ☐ Missed visit ☐ Other ☐ Unknown
3. If missed visit, provide details	…… …… ……
4. If patient is lost to follow up from study, provide details if known	…… ……
5. Any adverse event to report since last visit or today	☐ Yes ☐ No
Tx F/R/W visit only	
6. Reason for Tx F/R/W study visit	☐ TB Tx failure ☐ TB recurrence assessment (SKIP TO #8) ☐ Withdrawal requested by patient (SKIP TO #9)
7. TB Tx failure	☐ Confirmed (fill a **Treatment Outcomes** form) ☐ Suspected, not confirmed ☐ Alternative diagnosis (specify) ……
8. TB recurrence	☐ Confirmed (fill a **TB History and Current TB Diagnosis** form and a **Treatment Outcomes** form) ☐ Suspected, not confirmed ☐ Alternative diagnosis (specify) ……

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9. Reason for withdrawal *(collected only if patient agrees)*	……
Baseline TB symptoms (*within the past 4 weeks*) – *at Baseline visit only*	
10. Cough	☐ Yes ☐ No ☐ Unknown
10a. If yes, cough duration (weeks)	|__|__|
10b. If yes, presence of blood (haemoptysis)	☐ Yes ☐ No ☐ Unknown
11. Fever	☐ Yes ☐ No ☐ Unknown
11a. If yes, fever duration (weeks)	|__|__|
12. Night sweats	☐ Yes ☐ No ☐ Unknown
13. Weight loss	☐ Yes ☐ No ☐ Unknown
14. Chest pain	☐ Yes ☐ No ☐ Unknown
15. Dyspnea / shortness of breath	☐ Yes ☐ No ☐ Unknown
16. Tiredness or fatigue	☐ Yes ☐ No ☐ Unknown
17. Loss of appetite	☐ Yes ☐ No ☐ Unknown
18. Abdominal pain	☐ Yes ☐ No ☐ Unknown
Symptoms experienced at current visit – *at all visits AFTER the baseline visit*	
19. Cough	☐ Yes ☐ No
19a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
19b. If yes, presence of blood (haemoptysis)	☐ Yes ☐ No ☐ Unknown
20. Fever	☐ Yes

IeDEA TB SRN

	☐ No
20a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
21. Night sweats	☐ Yes ☐ No
21a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
22. Weight loss	☐ Yes ☐ No
22a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
23. Chest pain	☐ Yes ☐ No
23a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
24. Dyspnea/shortness of breath	☐ Yes ☐ No
24a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
25. Tiredness or fatigue	☐ Yes ☐ No
25a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
26. Loss of appetite	☐ Yes ☐ No
26a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
27. Abdominal pain	☐ Yes ☐ No
27a. If yes, change since previous visit	☐ Improved ☐ Worsened or new ☐ No change
Vital signs	
28. Temperature (°Celsius)	|__|__|.|__|
29. Height (m) (for adults at baseline only)	|__|.|__|__| m
30. Weight (kgs)	|__|__|__|.|__| kg
31. Systolic blood pressure (mmHg)	|__|__|__|

IeDEA TB SRN

32. Diastolic blood pressure (mmHg)	|__|__|__|
33. Heart rate (beats/min)	|__|__|__|
34. Respiratory rate (breaths/min)	|__|__|
35. SpO2 (%)	|__|__|
35a. On oxygen when SpO2 measured	☐ Yes ☐ No
Physical signs	
36. Respiratory distress (grunting, nose flaring, chest indrawing, sweating, cyanosis)	☐ Yes ☐ No
37. Crackles on pulmonary auscultation	☐ Yes ☐ No
38. Wheezing on pulmonary auscultation	☐ Yes ☐ No
39. Decreased lung sounds on auscultation	☐ Yes ☐ No
40. Skin rash	☐ Yes (complete **Adverse Event** form) ☐ No
41. Hepatomegaly	☐ Yes (complete **Adverse Event** form) ☐ No
41a. If yes, measurement below the costal margin (cm)	|__|__| cm
42. Cervical or supra-clavicular lymphadenopathy	☐ No ☐ Single ☐ Multiple ☐ Unknown
43. Neurological symptoms	☐ Yes ☐ No ☐ Unknown
43a. If yes, detail symptoms	…… …… …… ……

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Visit & Clinical Evaluation Page 4 of 4
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CRF [10] ASSIST

The **A**lcohol, **S**moking and **S**ubstance **I**nvolvement **S**creening **T**est is a validated assessment of substance use. Due to copyright restrictions, this CRF is not included in this packet.

IeDEA TB SRN

[11] ADDITIONAL SMOKING HISTORY	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ End of Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
1. Do you currently smoke tobacco? (This and the following questions also include *vaping* as a form of smoking.)	☐ Yes → SKIP to #4 ☐ No → SKIP to #2
2. If no, have you ever smoked tobacco in the past?	☐ Yes → SKIP to #3 ☐ No / Never-smoker → END of Form
3. If you stopped smoking, how long ago did you last smoke tobacco?	|__|__| Days |__|__| Months |__|__| Years ☐ Unknown
4. For approximately how many years have you (did you) smoke?	|__|__| Years ☐ Unknown
5. If you smoke(d) cigarettes, how many cigarettes do you (did you) smoke during a typical day?	☐ <1 ☐ 1-4 ☐ 5-10 ☐ 11-20 ☐ 21-30 ☐ 31-40 ☐ More than 40 ☐ Have taken other forms of tobacco, but not cigarettes ☐ Unknown

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Additional Smoking Hx Page 1 of 1
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CRF [12] SGRQ

The **S**aint **G**eorge **R**espiratory **Q**uestionnaire is a validated measure of the perceived impact of respiratory symptoms on the patient's daily quality of life. Due to copyright restrictions, this CRF is not included in this packet.

CRF [13] PHQ-9

The **P**atient **H**ealth **Q**uestionnaire **– 9** is a validated measure which accesses presence and severity of depression symptoms as well as presence and degree of suicide risk. Due to copyright restrictions, this CRF is not included in this packet.

IeDEA/TB SRN

[14] SPIROMETRY	
IeDEA/TB SRN ID	
Visit	☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
1. Is the patient able to perform/complete spirometry?	☐ Yes ☐ No ☐ Not done/not applicable
2. If no, why not?	☐ Too Sick ☐ Delirious/Demented/Confused ☐ Has contraindication such as recent MI, surgery, PE, hemoptysis ☐ Attempted, but unable to get good quality test ☐ Other, please specify _____
Pre bronchodilator measured values	
3. FVC *(Liters)*	|__|.|__|__|__|
4. FEV1 *(Liters)*	|__|.|__|__|__|
5. FEF 25-75 *(Liters)*	|__|.|__|__|__|
6. Peak Flow (PEF) *(Liters/second)*	|__|__|__|
7. Spirometry grade/quality	☐ A ☐ B ☐ C ☐ D ☐ F
Post bronchodilator measured values	
8. FVC value *(Liters)*	|__|.|__|__|__|
9. FEV1 value *(Liters)*	|__|.|__|__|__|
10. FEF 25-75 value *(Liters)*	|__|.|__|__|__|
11. Peak Flow (PEF) *(Liters/second)*	|__|__|__|
12. Spirometry grade/quality	☐ A ☐ B ☐ C ☐ D ☐ F
Final Interpretation	
13. Interpretation done by	☐ Spirometry technician ☐ Pneumologist ☐ Spirometer itself ☐ Other

ID Number _____ Spirometry Page 1 of 2
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	☐ Unknown
14. Obstructive pattern detected	☐ Yes (FEV1/FVC < LLN) if yes fill below ☐ No ☐ Unknown
15. FEV1 (severity) % of predicted value	☐ 80%-100% ☐ 50-80% ☐ 30-50% ☐ <30%
16. Bronchodilator Response	☐ No change (FVC <12% & 200ml or FEV1 <12% & 200ml over baseline) ☐ Improved (FVC 12% AND 200ml or FEV1 12% AND 200ml over baseline) ☐ Normalized (FEV1/FVC ratio after bronchodilator normalized) ☐ Unknown
17. Restrictive pattern detected	☐ Yes (FVC<LLN) ☐ No ☐ Unknown

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Spirometry Page 2 of 2
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IeDEA TB SRN

[15] FUNCTIONAL ASSESSMENT 1 MINUTE SIT TO STAND TEST	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
1. Patient able to complete the sit-to-stand test	☐ Yes ☐ No ☐ Not done / not applicable
2. Reasons why unable	☐ Too Sick ☐ Delirious / Demented / Confused ☐ Has lower extremity injury that prevents standing ☐ Other
At Rest	
3. SpO2 *(%)*	|__|__|
4. Heart rate *(beats per minute)*	|__|__|__|
5. Modified Borg Dyspnea Scale *"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0, where your breathing is causing you no difficulty at all, and progresses through to number 10, where your breathing difficulty is maximal.* ***How much difficulty is your breathing causing you right now?"***	☐ 0 Nothing at all ☐ 0.5 Very, very slight (just noticeable) ☐ 1 Very slight ☐ 2 Slight ☐ 3 Moderate ☐ 4 Somewhat severe ☐ 5 Severe ☐ 6 ☐ 7 Very severe ☐ 8 ☐ 9 Very, very severe (almost maximal) ☐ 10 Maximal
Post sit-to-stand test	
6. SpO2 *(%)*	|__|__|
7. Heart rate *(beats per minute)*	|__|__|__|
8. Modified Borg Dyspnea Scale *"This is a scale that asks you to rate the difficulty of your breathing. It starts at number 0, where your breathing is causing you no difficulty at all, and progresses through to number 10, where your breathing difficulty is maximal.* ***How much difficulty is your breathing causing you right now?"***	☐ 0 Nothing at all ☐ 0.5 Very, very slight (just noticeable) ☐ 1 Very slight ☐ 2 Slight ☐ 3 Moderate ☐ 4 Somewhat severe ☐ 5 Severe ☐ 6 ☐ 7 Very severe ☐ 8 ☐ 9 Very, very severe (almost maximal) ☐ 10 Maximal
9. Number of sit-to-stands completed in 1 min	|__|__|

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ Stand Test Page 1 of 1
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IeDEA TB SRN

[16] TB MICROBIOLOGY	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ TX F/R/W
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
Instructions: *Enter all available test results which may have been performed or which may have resulted since the last study visit. If this is the baseline visit, enter all available results to date for this TB illness course.*	
Smear microscopy	
1. Number of smears done *(If none, enter '0')*	☐ 0 (SKIP TO #5) ☐ 1 ☐ 2 ☐ 3 or more ☐ Unknown
2. Smear 1 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
2a. Smear 1 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
2b. Smear 1 result	☐ Negative ☐ Scanty ☐ 1+ ☐ 2+ (++) ☐ 3+ (+++) ☐ 4+ (++++) ☐ Unknown
3. Smear 2 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
3a. Smear 2 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
3b. Smear 2 result	☐ Negative ☐ Scanty ☐ 1+ ☐ 2+ (++) ☐ 3+ (+++) ☐ 4+ (++++) ☐ Unknown
4. Smear 3 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
4a. Smear 3 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
4b. Smear 3 result	☐ Negative ☐ Scanty ☐ 1+ ☐ 2+ (++)

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	☐ 3+ (+++) ☐ 4+ (++++) ☐ Unknown
Xpert MTB/RIF or Ultra	
5. Number of Xpert tests done *(If none, enter '0')*	☐ 0 (SKIP TO #10) ☐ 1 ☐ 2 ☐ 3 or more ☐ Unknown
6. Xpert TB type of test	☐ Xpert MTB/RIF ☐ Xpert MTB/RIF Ultra ☐ Other ☐ Unknown
7. Xpert TB test 1 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
7a. Xpert TB test 1 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
7b. Xpert TB test 1 MTB result	☐ Detected (MTB+) ☐ Not detected (MTB-) ☐ Indeterminate/error ☐ Unknown
7c. Xpert TB test 1 result category	☐ Trace ☐ Very low ☐ Low ☐ Medium ☐ High
7d. Xpert TB test 1 RIF resistance	☐ Detected ☐ Not detected ☐ Indeterminate ☐ Unknown
8. Xpert TB test 2 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
8a. Xpert TB test 2 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
8b. Xpert TB test 2 MTB result	☐ Detected (MTB+) ☐ Not detected (MTB-) ☐ Indeterminate/error ☐ Unknown
8c. Xpert TB test 2 result category	☐ Trace ☐ Very low ☐ Low ☐ Medium ☐ High
8d. Xpert TB test 2 RIF resistance	☐ Detected ☐ Not detected ☐ Indeterminate ☐ Unknown
9. Xpert TB test 3 date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|

IeDEA TB SRN

9a. Xpert TB test 3 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
9b. Xpert TB test 3 MTB result	☐ Detected (MTB+) ☐ Not detected (MTB-) ☐ Indeterminate/error ☐ Unknown
9c. Xpert TB test 3 result category	☐ Trace ☐ Very low ☐ Low ☐ Medium ☐ High
9d. Xpert TB test 3 RIF resistance	☐ Detected ☐ Not detected ☐ Indeterminate ☐ Unknown
TB Culture	
10. Number of cultures done *(If none, enter '0')*	☐ 0 (SKIP TO #15) ☐ 1 ☐ 2 ☐ 3 or more ☐ Unknown
11. Type of TB culture	☐ Lowenstein Jensen (LJ) ☐ MGIT ☐ LJ and MGIT ☐ Unknown
12. TB Culture 1 start date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
12a. TB Culture 1 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
12b. TB Culture 1 result date (positivity or sterile)	|__|__|/|__|__|/|__|__|__|__|
12c. TB Culture 1 result	☐ Pending (mark form as **Incomplete** and update result if/when available) ☐ Positive MTB ☐ Positive NTM ☐ Contaminated ☐ Negative (sterile) ☐ Unknown
13. TB Culture 2 start date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
13a. TB Culture 2 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown
13b. TB Culture 2 result date (positivity or sterile)	|__|__|/|__|__|/|__|__|__|__|
13c. TB Culture 2 result	☐ Pending (mark form as **Incomplete** and update result if/when available) ☐ Positive MTB ☐ Positive NTM

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	☐ Contaminated ☐ Negative (sterile) ☐ Unknown			
14. TB Culture 3 start date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|			
14a. TB Culture 3 type of sample	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown			
14b. TB Culture 3 result date (positivity or sterile)	|__|__|/|__|__|/|__|__|__|__|			
14c. TB Culture 3 result	☐ Pending (mark form as **Incomplete** and update result if/when available) ☐ Positive MTB ☐ Positive NTM ☐ Contaminated ☐ Negative (sterile) ☐ Unknown			
Drug susceptibility testing				
15. 1st line TB drug-susceptibility testing done	☐ Yes (fill below) ☐ No (SKIP TO #20) ☐ Unknown			
16. Type(s) of 1st line TB-drug susceptibility testing *(Check all that apply)*	☐ Culture-based DST ☐ Genotypic DST (MTBDRplus / LPA-1) ☐ Xpert Ultra ☐ Other: _____ ☐ Unknown			
17. Date of sample, 1st line DST	|__|__|/|__|__|/|__|__|__|__|			
17a. Type of sample, 1st line DST	☐ Expectorated sputum ☐ Other: _____ ☐ Unknown			
17b. For each first-line drug, indicate results of DST.	Isoniazid (INH)	☐ S	☐ R	☐ Unk
	Rifampin (RIF)	☐ S	☐ R	☐ Unk
	Pyrazinamide (PZA)	☐ S	☐ R	☐ Unk
	Ethambutol (EMB)	☐ S	☐ R	☐ Unk
	Streptomycin (SM)	☐ S	☐ R	☐ Unk
18. 2nd line TB drug-susceptibility testing done	☐ Yes (if yes fill below) ☐ No ☐ Unknown			
18a. Type(s) of 2nd line TB-drug susceptibility testing *(Check all that apply)*	☐ Culture-based DST ☐ Genotypic DST (MTBDRsl / LPA-2) ☐ Xpert MTB-XDR ☐ Other: _____ ☐ Unknown			
18b. For each second-line drug, indicate results of DST.	Bedaquiline	☐ S	☐ R	☐ Unk
	Moxifloxacin	☐ S	☐ R	☐ Unk
	Levofloxacin	☐ S	☐ R	☐ Unk
	Ciprofloxacin	☐ S	☐ R	☐ Unk
	Linezolid	☐ S	☐ R	☐ Unk
	Clofazimine	☐ S	☐ R	☐ Unk
	Cycloserine	☐ S	☐ R	☐ Unk

Enane LA, *et al. BMJ Open* 2024; 14:e079138. doi: 10.1136/bmjopen-2023-079138

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	Amikacin	☐ S	☐ R	☐ Unk
	Carbapenems	☐ S	☐ R	☐ Unk
	Delaminid	☐ S	☐ R	☐ Unk
	Ethionamide	☐ S	☐ R	☐ Unk
	Prothionamide	☐ S	☐ R	☐ Unk
	Kanamycin	☐ S	☐ R	☐ Unk
	P-aminosalicylic acid	☐ S	☐ R	☐ Unk
	Capreomycin	☐ S	☐ R	☐ Unk
	Azithromycin	☐ S	☐ R	☐ Unk
	Clarithromycin	☐ S	☐ R	☐ Unk
	Amoxicillin-clavulanate	☐ S	☐ R	☐ Unk
	Other (specify)_____	☐ S	☐ R	☐ Unk
	Other (specify)_____	☐ S	☐ R	☐ Unk
Urine LAM test				
20. Urine LAM test done	☐ Yes ☐ No ☐ Unknown			
20a. Type of urine LAM test done	☐ Alere LAM ☐ Fujifilm LAM ☐ Unknown			
20b. Date urine LAM test done *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|			
20c. Results of urine LAM test	☐ Positive ☐ Negative ☐ Unknown			

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____

IeDEA TB SRN

[17] OTHER LABORATORY RESULTS	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
Instructions: *Enter results for any new lab results since last study visit. If multiple tests were done for a given item, use the most recent. Exception: If a positive HIV diagnostic test, positive COVID diagnostic test, or unsuppressed HIV viral load, enter the first positive/abnormal result.*	
HIV related tests	
1. HIV test done	☐ Yes ☐ No ☐ Unknown
2. HIV test date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
3. HIV test result	☐ Positive ☐ Negative ☐ Unknown
4. CD4 T-cell count	☐ └┴┴┴┴┘ /mm^3 ☐ └┴┴┘ . └┴┴┘ % ☐ Not done ☐ Not applicable Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
5. HIV viral load	☐ └┴┴┴┴┴┴┴┴┴┴┘ cp/ml ☐ Undetectable ☐ Not done ☐ Not applicable Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
COVID-19 tests	
6. COVID test	☐ Done ☐ Not done
If a COVID test was done, specify details below. If there was a positive test, record the results for the positive test. (If multiple positive tests, record the details for the first positive test.)	
7. COVID test date	Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|

ID Number _____ Other Labs Page 1 of 3
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8. COVID-19 test type	☐ Molecular test / PCR ☐ Antigen test (e.g., rapid test) ☐ Unknown
9. COVID-19 test result	☐ Positive ☐ Negative ☐ Indeterminate
Complete blood count (CBC)	
10. CBC	☐ Done ☐ Not done ☐ Not applicable
11. CBC Date	Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
11a. Hemoglobin	└┴┴┘. └┴┘ ❑ g/dl ❑ g/L
11b. White blood cells	└┴┴┴┴┴┴┘. └┴┘ ❑ /mm^3 ❑ x10^3/µL ❑ giga (10^9)/L
11c. Monocytes (absolute)	└┴┴┴┴┴┴┘. └┴┘ ❑ /mm^3 ❑ x10^3/µL ❑ giga (10^9)/L
11d. Neutrophils (absolute)	└┴┴┴┴┴┴┘. └┴┘ ❑ /mm^3 ❑ x10^3/µL ❑ giga (10^9)/L
11e. Eosinophils (absolute)	└┴┴┴┴┴┴┘. └┴┘ ❑ /mm^3 ❑ x10^3/µL ❑ giga (10^9)/L
11f. Lymphocytes (absolute)	└┴┴┴┴┴┴┘. └┴┘ ❑ /mm^3 ❑ x10^3/µL ❑ giga (10^9)/L
11g. Platelets	└┴┴┴┴┴┴┘. └┴┘ ❑ x10^3/mm^3 ❑ /µL
Biochemistry	
12. Hemoglobin A1c (HbA1c)	└┴┘. └┴┘ % ☐ Not done Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
13. Random blood glucose	└┴┴┘. └┴┘ ❑ mmol/L ❑ mg/L ❑ g/L ☐ Not done Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
14. C-reactive protein (CRP)	└┴┴┘ mg/L ☐ Not done Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
15. Procalcitonin	└┴┴┘. └┴┘ µg/L ☐ Not done Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|
Biochemistry: Metabolic Panel	
16. Metabolic Panel	☐ Done ☐ Not done ☐ Not applicable
17. Metabolic Panel Date	Date (dd/mm/yyyy): |__|__|/|__|__|/|__|__|__|__|

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17a. ALT (SGPT)	└┴┴┴┴┴┘ ❑ mg/L ❑ mg/dL ❑ UI/L
17b. AST (SGOT)	└┴┴┴┴┴┘ ❑ mg/L ❑ mg/dL ❑ UI/L
17c. Creatinine	└┴┴┴┴┘ . └┴┘ ❑ µmol/L ❑ mg/L ❑ mg/dL
17d. Alkaline phosphatase	└┴┴┴┴┘ UI/L
17e.Total bilirubin	└┴┘ mg/L
17f. Conjugated bilirubin	└┴┘ mg/L
17g. Sodium	└┴┴┴┘ mmol/L
17h. Potassium	└┴┘ . └┴┘ mmol/L

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

[18] CHEST X-RAY RESULTS	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
1. Was an x-ray performed (at any time since last visit)?	☐ Yes ☐ No (End of form)
2. Date of chest x-ray	|__|__|/|__|__|/|__|__|__|__|
3. Interpreter	☐ Clinician ☐ Research assistant ☐ Radiologist ☐ Other
4. Quality of chest X-ray	Patient identification: ☐ Appropriate ☐ Not acceptable Rotation: ☐ Absence or minimal ☐ Not acceptable Penetration: ☐ Good (vertebra visible behind heart) ☐ Not acceptable Inspiration: ☐ Good (8th or 9th posterior rib visible) ☐ Not acceptable Defective lung fields: ☐ No ☐ Yes
4a. Result:	☐ Normal (in both lungs) ☐ Abnormal
5. Cavitation	☐ Yes (present) ☐ No (absent) ☐ Not possible to determine based on test
5a. If yes,	☐ Unilateral ☐ Bilateral
6. Miliary Lesions	☐ Yes ☐ No ☐ Not possible to determine based on test
7. Alveolar opacity(ies) (infiltrate)	☐ Yes ☐ No ☐ Not possible to determine based on test
7a. If yes,	☐ Unilateral ☐ Bilateral
8. Interstitial opacities	☐ Yes ☐ No ☐ Not possible to determine based on test
8a. If yes,	☐ Unilateral ☐ Bilateral
9. Pleural effusion	☐ Yes ☐ No

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	☐ Not possible to determine based on test
10. Calcification	☐ Yes ☐ No ☐ Not possible to determine based on test
11. Mediastinal lymphadenopathy/adenopathy	☐ Yes ☐ No ☐ Not possible to determine based on test
12. Enlarged Cardiac Silhouette (>50% of thoracic diameter)	☐ Yes ☐ No ☐ Not possible to determine based on test
13. Nodules or Masses	☐ Yes ☐ No ☐ Not possible to determine based on test
13a. If yes,	☐ Single ☐ Multiple
13b. If yes, size of largest lesion	☐ < 1 cm ☐ 1-5 cm ☐ >5 cm
14. Percentage of lung fields affected by any kind of lesion (alveolar or interstitial opacities)	|__|__|__| %
15. Are any of these other findings seen based on chest x-ray?	☐ Bronchiectasis ☐ Emphysema ☐ Lung fibrosis ☐ Signs of pulmonary hypertension ☐ Signs of right heart failure ☐ Other
16. Evolution since last CXR *(If applicable)*	☐ Worsened ☐ Unchanged ☐ Improved ☐ Complete resolution of lesions
Image Files	
17. Number of x-ray films	|__|__|
18. Original x-ray format	☐ Digital (DICOM) ☐ Film ☐ Unknown
19. X-ray digitization date	|__|__|/|__|__|/|__|__|__|__|
20. Image upload status	☐ Complete ☐ Incomplete/partial

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

[19] TB Treatment (REDCap Flowchart Form)			
IeDEA/TB SRN ID			
Visit	**Date (dd/mm/yyyy)**	**Visit**	**Date (dd/mm/yyyy)**
☐ Baseline	|__|__| / |__|__| / |__|__|__|__|	☐ End of Tx	|__|__| / |__|__| / |__|__|__|__|
☐ Month 1	|__|__| / |__|__| / |__|__|__|__|	☐ Tx F/R/W	|__|__| / |__|__| / |__|__|__|__|
☐ Month 2	|__|__| / |__|__| / |__|__|__|__|		

TB Drug 1	
1. TB Drug 1 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
1a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
1b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
1c. Other drugs - Dose (mg)	|__|__|__|__|
1d. How many times a day is this medication prescribed?	|__|__|__|
1e. How many days a week is this medication prescribed?	|__|__|__|
1f. Start Date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
1g. Stop Date	

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(dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__| ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
1h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 2	
2. TB Drug 2 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
2a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
2b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
2c. Other drugs - Dose (mg)	|__|__|__|__|
2d. How many times a day is this medication prescribed?	|__|__|__|

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2e. How many days a week is this medication prescribed?	|__|__|__|
2f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
2g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
2h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 3	
3. TB Drug 3 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
3a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
3b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets

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	☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
3c.Other drugs - Dose (mg)	|__|__|__|__|
3d. How many times a day is this medication prescribed?	|__|__|__|
3e. How many days a week is this medication prescribed?	|__|__|__|
3f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
3g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
3h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 4	

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4. TB Drug 4 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
4a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
4b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
4c. Other drugs - Dose (mg)	|__|__|__|__|
4d. How many times a day is this medication prescribed?	|__|__|__|
4e. How many days a week is this medication prescribed?	|__|__|__|
4f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
4g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
4h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity

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	☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 5	
5. TB Drug 5 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
5a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
5b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
5c. Other drugs - Dose (mg)	|__|__|__|__|
5d. How many times a day is this medication prescribed?	|__|__|__|
5e. How many days a week is this medication prescribed?	|__|__|__|
5f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
5g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown

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5h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 6	
6. TB Drug 6 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
6a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
6b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
6c. Other drugs – Dose (mg)	|__|__|__|__|
6d. How many times a day is this medication prescribed?	|__|__|__|
6e. How many days a week is this medication prescribed?	|__|__|__|
6f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)

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6g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
6h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 7	
7. TB Drug 7 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
7a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
7b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet

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7c. Other drugs - Dose (mg)	|__|__|__|__|
7d. How many times a day is this medication prescribed?	|__|__|__|
7e. How many days a week is this medication prescribed?	|__|__|__|
7f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
7g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
7h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 8	
8. TB Drug 8 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
8a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
8b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets

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	☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
8c. Other drugs - Dose (mg)	|__|__|__|__|
8d. How many times a day is this medication prescribed?	|__|__|__|
8e. How many days a week is this medication prescribed?	|__|__|__|
8f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
8g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
8h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 9	

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9. TB Drug 9 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
9a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
9b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
9c. Other drugs - Dose (mg)	|__|__|__|__|
9d. How many times a day is this medication prescribed?	|__|__|__|
9e. How many days a week is this medication prescribed?	|__|__|__|
9f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
9g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
9h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment)

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	☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 10	
10. TB Drug 10 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
10a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
10b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
10c. Other drugs - Dose (mg)	|__|__|__|__|
10d. How many times a day is this medication prescribed?	|__|__|__|
10e. How many days a week is this medication prescribed?	|__|__|__|
10f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
10g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)

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	☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
10h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 11	
11. TB Drug 11 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
11a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
11b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
11c. Other drugs - Dose (mg)	|__|__|__|__|
11d. How many times a day is this medication prescribed?	|__|__|__|
11e. How many days a week is this medication prescribed?	|__|__|__|

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11f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
11g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
11h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 12	
12. Drug 12 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
12a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
12b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules

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	☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
12c. Other drugs - Dose (mg)	|__|__|__|__|
12d. How many times a day is this medication prescribed?	|__|__|__|
12e. How many days a week is this medication prescribed?	|__|__|__|
12f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
12g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
12h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 13	
13. TB Drug 13 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____

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13a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
13b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
13c. Other drugs – Dose (mg)	|__|__|__|__|
13d. How many times a day is this medication prescribed?	|__|__|__|
13e. How many days a week is this medication prescribed?	|__|__|__|
13f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
13g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
13h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 14	

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14. TB Drug 14 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
14a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
14b. f RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
14c. Other drugs – Dose (mg)	|__|__|__|__|
14d. How many times a day is this medication prescribed?	|__|__|__|
14e. How many days a week is this medication prescribed?	|__|__|__|
14f. 1Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
14g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
14h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity

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	☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 15	
15. TB Drug 15 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
15a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
15b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
15c. Other drugs – Dose (mg)	|__|__|__|__|
15d. How many times a day is this medication prescribed?	|__|__|__|
15e. How many days a week is this medication prescribed?	|__|__|__|
15f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
15g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)

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	☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
15h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 16	
16. TB Drug 16 (select one)	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
16a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
16b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
16c. Other drugs - Dose (mg)	|__|__|__|__|
16d. How many times a day is this medication prescribed?	|__|__|__|

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16e. How many days a week is this medication prescribed?	|__|__|__|
16f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
16g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
16h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 17	
17. TB Drug 17 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
17a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
17b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet

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	☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
17c. Other drugs - Dose (mg)	|__|__|__|__|
17d. How many times a day is this medication prescribed?	|__|__|__|
17e. How many days a week is this medication prescribed?	|__|__|__|
17f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
17g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
17h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 18	
18. TB Drug 18 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
18a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets

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	☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
18b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
18c. Other drugs - Dose (mg)	|__|__|__|__|
18d. How many times a day is this medication prescribed?	|__|__|__|
18e. How many days a week is this medication prescribed?	|__|__|__|
18f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
18g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
18h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 19	
19. TB Drug 19 (select one)	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine

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	☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
19a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
19b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
19c. Other drugs - Dose (mg)	|__|__|__|__|
19d. How many times a day is this medication prescribed?	|__|__|__|
19e. How many days a week is this medication prescribed?	|__|__|__|
19f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
19g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
19h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up ☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
TB Drug 20	

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20. TB Drug 20 *(Select one)*	☐ RHZE ☐ RH ☐ Rifampicin ☐ Pyrazinamide ☐ Isoniazid ☐ Ethambutol ☐ Streptomycin ☐ Rifabutin ☐ Amikacin ☐ Kanamycin ☐ Capreomycin ☐ Ofloxacin ☐ Levofloxacin ☐ Moxifloxacin ☐ Terizidone ☐ Cycloserine ☐ Ethionamide ☐ Protionamide ☐ Para-aminosalicylic acid (PAS) ☐ Clofazimine ☐ Linezolid ☐ Imipenem ☐ Bedaquiline ☐ Other: _____
20a. If RHZE, combination:	☐ RHZE 150/75/400/275 - 2 tablets ☐ RHZE 150/75/400/275 - 3 tablets ☐ RHZE 150/75/400/275 - 4 tablets ☐ RHZE 150/75/400/275 - 5 tablets
20b. If RH, combination:	☐ RH 150/75 - 2 tablets ☐ RH 150/75 - 3 tablets ☐ RH 150/75 - 4 tablets ☐ RH 150/75 - 5 tablets ☐ RH 300/200 - 1 tablet or capsule ☐ RH 300/200 - 2 tablets or capsules ☐ RH 300/200 - 1 tablet or capsule + RH 150/100 - 1 tablet ☐ RH 300/200 - 2 tablets or capsules + RH 150/100 - 1 tablet
20c. Other drugs - Dose (mg)	|__|__|__|__|
20d. How many times a day is this medication prescribed?	|__|__|__|
20e. How many days a week is this medication prescribed?	|__|__|__|
20f. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
20g. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Treatment Ongoing *(Return to update the status at next visit. Update stop date and reason once medication is stopped.)* ☐ Unknown
20h. Reason for change, interruption or completion	☐ Completed intensive phase ☐ Completed continuation phase ☐ TB treatment failure ☐ Drug resistance ☐ Pregnancy ☐ Side effects or toxicity ☐ Incompatibility with ART (antiretroviral treatment) ☐ Drug interaction ☐ Participant stopped taking the meds ☐ Lost to follow up

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	☐ Dose adjustment (e.g. for weight change) ☐ Death ☐ Other _____ ☐ Unknown
Treatment End Summary	
21. Has this participant finished the prescribed TB treatment?	☐ Yes (complete the **TB Treatment Outcomes** form) ☐ No ☐ Not applicable ☐ Still on treatment
24. Notes (optional)	

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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[20] TB TREATMENT ADHERENCE	
IeDEA/TB SRN ID	
Visit	☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ Tx F/R/W
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
Adherence questions	
1. Any dose of TB drugs missed in the last 4 days	☐ Yes ☐ No ☐ Unknown
1a. If yes, number of TB drugs doses missed in the last 4 days	|__|__| doses
2. Any dose of TB drugs missed in the last 30 days?	☐ Yes ☐ No ☐ Unknown
Pill count for TB drugs	
3. Date of last TB treatment refill *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
4. Expected number of tablets for TB treatment taken daily (since last refill)	|__|__| ☐ Unknown
5. Number of tablets at last refill (tablets given + tablets patient already had)	|__|__|__| ☐ Unknown
6. Number of tablets brought back	|__|__|__| ☐ Unknown
7. Description of any adherence challenges for TB drugs *(Check all that apply)*	☐ Forgetting dose(s) ☐ Difficulty tolerating medication(s) / side effects ☐ Unable to take medication(s) while feeling ill or unwell ☐ Unable to take medication(s) due to not having food ☐ Did not have privacy / unable to take medication(s) while around others ☐ Not willing to take medication(s) ☐ Did not have medication(s) with me at the time for dose ☐ Did not have a sufficient supply of medication(s) ☐ Medication(s) have not been available from pharmacy (e.g., stock-out) ☐ Other (specify) _____ ☐ Unknown ☐ Decline to answer

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ TB Treatment Adherence Page 1 of 1

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[21] Directly Observed Therapy (DOT) for TB	
IeDEA/TB SRN ID	
Visit	☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ Tx F/R/W
Visit date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
1. Is this participant under <u>any form</u> of Directly Observed Therapy (DOT)?	☐ Yes (complete form below) ☐ No ☐ Unknown
Intensive Phase	
2. Which types of DOTs, according to the study protocol definitions, are currently being or will be done for this participant during the intensive phase? *(Check all that apply)*	☐ In person - with healthcare worker ☐ In person - with community health worker ☐ In person - with family member or another trusted person ☐ Virtual - through smartphone via text message, photo or video ☐ Telephone - by telephone calls
3. Start Date of DOT	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
4. Intensive phase ongoing or completed?	☐ Ongoing → SKIP to #8 ☐ Completed (fill below)
5. End Date of DOT (if applicable)	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
6. **Intensive phase: how many doses did the patient take by…**	
a. In-Person DOT with a healthcare worker?	|__|__|__| doses
b. In-Person DOT with a community health worker?	|__|__|__| doses
c. In-Person DOT with a family member or other trusted person?	|__|__|__| doses
d. Virtual DOT?	|__|__|__| doses
e. Telephone DOT?	|__|__|__| doses
f. without being observed? *(e.g., doses administered without DOT, for example weekends, holidays and or treatment days before recruitment in the study)*	|__|__|__| doses

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7. How many doses has the participant missed in the intensive phase?	|__|__|__| doses
8. Has the participant interrupted the intensive phase of TB treatment for any reason, and for any duration?	☐ Yes (report on **TB Treatment** form) ☐ No
Continuation Phase	
9. Continuation phase ongoing or completed?	☐ Not yet started → END form ☐ Ongoing (fill below) ☐ Completed (fill below)
10. Which types of DOTs, according to the study protocol definitions, are currently being or will be done for this participant during the continuation phase? *(Check all that apply)*	☐ In person - with healthcare worker ☐ In person - with community health worker ☐ In person - with family member or another trusted person ☐ Virtual - through smartphone via text message, photo or video ☐ Telephone - by daily telephone calls
11. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
12. Continuation phase	☐ Ongoing → SKIP to #16 ☐ Completed (fill below)
13. End Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
14. **Continuation phase: how many doses did the patient take by…**	
a. In-Person DOT with a healthcare worker?	|__|__|__| doses
b. In-Person DOT with a community health worker?	|__|__|__| doses
c. In-Person DOT with a family member or other trusted person?	|__|__|__| doses
d. Virtual DOT?	|__|__|__| doses
e. Telephone DOT?	|__|__|__| doses
f. without being observed? *(e.g., doses administered without DOT, for example weekends, holidays and or treatment days before recruitment in the study)*	|__|__|__| doses
15. How many doses has the participant missed in the continuation phase?	|__|__|__| doses
16. Has the participant interrupted the continuation phase of TB treatment by any reason?	☐ Yes (report on **TB Treatment** form) ☐ No

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ DOT Page 2 of 2

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IeDEA TB SRN

[22] Antiretroviral Therapy (ART) for HIV (REDCap Flowchart Form)

IeDEA/TB SRN ID	

Visit	Date (dd/mm/yyyy)	Visit	Date (dd/mm/yyyy)
☐ Baseline	|__|__| / |__|__| / |__|__|__|__|	☐ 6-M Post-Tx	|__|__| / |__|__| / |__|__|__|__|
☐ Month 1	|__|__| / |__|__| / |__|__|__|__|	☐ 12-M Post-Tx	|__|__| / |__|__| / |__|__|__|__|
☐ Month 2	|__|__| / |__|__| / |__|__|__|__|	☐ Tx F/R/W	|__|__| / |__|__| / |__|__|__|__|
☐ End of Tx	|__|__| / |__|__| / |__|__|__|__|		

HIV Drug 1	
1. Antiretroviral (ARV) 1 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
1a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
1b. How many times a day is this medication prescribed?	|__|__|__|
1c. How many days a week is this medication prescribed?	|__|__|__|
1d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
1e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed)* ☐ Unknown
1f. Reason for change or interruption	☐ Drug resistance

IeDEA TB SRN

	☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Other _____ ☐ Unknown
HIV Drug 2	
2. ARV 2 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
2a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
2b. How many times a day is this medication prescribed?	|__|__|__|
2c. How many days a week is this medication prescribed?	|__|__|__|
2d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
2e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed)* ☐ Unknown
2f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death

IeDEA TB SRN

	☐ Participant removed from study ☐ Other _____ ☐ Unknown
HIV Drug 3	
3. ARV 3 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
3a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
3b. How many times a day is this medication prescribed?	|__|__|__|
3c. How many days a week is this medication prescribed?	|__|__|__|
3d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
3e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed)* ☐ Unknown
3f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Participant removed from study ☐ Other _____ ☐ Unknown

IeDEA TB SRN

HIV Drug 4	
4. ARV 4 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
4a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
4b. How many times a day is this medication prescribed?	|__|__|__|
4c. How many days a week is this medication prescribed?	|__|__|__|
4d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
4e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed)* ☐ Unknown
4f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Participant removed from study ☐ Other _____ ☐ Unknown

IeDEA TB SRN

HIV Drug 5	
5. ARV 5 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
5a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
5b. How many times a day is this medication prescribed?	|__|__|__|
5c. How many days a week is this medication prescribed?	|__|__|__|
5d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
5e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed)* ☐ Unknown
5f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Participant removed from study ☐ Other _____ ☐ Unknown

IeDEA TB SRN

HIV Drug 6	
6. ARV 6 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
6a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
6b. How many times a day is this medication prescribed?	|__|__|__|
6c. How many days a week is this medication prescribed?	|__|__|__|
6d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
6e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed*) ☐ Unknown
6f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Participant removed from study ☐ Other _____ ☐ Unknown

IeDEA TB SRN

HIV Drug 7	
7. ARV 7 *(Select one)*	☐ abacavir (ABC) ☐ atazanavir (ATV) ☐ darunavir (DRV) ☐ didanosine (ddI) ☐ dolutegravir (DTG) ☐ efavirenz (EFV) ☐ enfuvirtide (ENF) ☐ emtricitabine (FTC) ☐ etravirine (ETR) ☐ lamivudine (3TC) ☐ lopinavir/ritonavir (LPV/r) ☐ maraviroc (MVC) ☐ nevirapine (NVP) ☐ raltegravir (RAL) ☐ ritonavir (RTV) ☐ stavudine (d4T) ☐ tenofovir alafenamide (TAF) ☐ tenofovir disoproxil fumarate (TDF) ☐ tipranavir (TPV) ☐ zidovudine (AZT/ZDV) ☐ Other: _____
7a. Drug is part of a fixed-dose combination	☐ Yes ☐ No
7b. How many times a day is this medication prescribed?	|__|__|__|
7c. How many days a week is this medication prescribed?	|__|__|__|
7d. Start Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Unknown
7e. Stop Date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy) ☐ Ongoing *(Return to update stop date if changed*) ☐ Unknown
7f. Reason for change or interruption	☐ Drug resistance ☐ Drug interaction ☐ Pregnancy ☐ Side effects or toxicity ☐ Compatibility with TB drugs ☐ Participant stopped taking meds ☐ Lost to follow up ☐ Death ☐ Participant removed from study ☐ Other _____ ☐ Unknown

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA TB SRN

Note – in the case of adolescents younger than age 18: assess adolescent disclosure status before proceeding. Follow procedures for avoiding accidental disclosure to adolescents.

[23] ANTIRETROVIRAL TREATMENT ADHERENCE	
IeDEA/TB SRN ID	
Visit	☐ Baseline ☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ 6-M Post-Tx ☐ 12-M Post-Tx ☐ Tx F/R/W
Visit date (dd/mm/yyyy)	|__|__|/|__|__|/|__|__|__|__|
Adherence questions	
1. Any dose of ART missed in the last 4 days	☐ Yes ☐ No ☐ Unknown
2. If yes, number of ART doses missed in the last 4 days	|__|__|
3. Any dose of ART missed in the last 30 days?	☐ Yes ☐ No ☐ Unknown
Pill count for ART drugs	
4. Date of last ART refill *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__| ☐ Unknown
5. Expected number of tablets taken daily for ART since last refill	|__|__| ☐ Unknown
6. Number of tablets at last refill (tablets given + tablets patient already had)	|__|__|__| ☐ Unknown
7. Number of tablets brought back	|__|__|__| ☐ Unknown
8. Description of any adherence challenges for ART regimen *(Check all that apply)*	☐ Forgetting dose(s) ☐ Difficulty tolerating medication(s) / side effects ☐ Unable to take medication(s) while feeling ill or unwell ☐ Unable to take medication(s) due to not having food ☐ Did not have privacy / unable to take medication(s) while around others ☐ Not willing to take medication(s) ☐ Did not have medication(s) with me at the time for dose ☐ Did not have a sufficient supply of medication(s) ☐ Medication(s) have not been available from pharmacy (e.g., stock-out) ☐ Other (specify) _____ ☐ Unknown ☐ Decline to answer

Investigator: _____ Signature: _____ Date: |__|__| / |__|__| / |__|__|__|__|

ID Number: _____ ART Adherence Page 1 of 1
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IeDEA TB SRN

[24] OTHER RESEARCH	
IeDEA/TB SRN ID	
Type of visit	☐ Baseline
Visit date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
Complete only for participants enrolled in other research:	
1. Name or short description of the other study	…… …… ……
2. Does the other research include a medical intervention?	☐ Yes ☐ No ☐ Unknown
2a. If yes, specify medical interventions in each research study for which the individual is co-enrolled.	…… …… …… ……
3. Does the other research include a care support intervention?	☐ Yes ☐ No ☐ Unknown
3a. If yes, specify care support interventions in each research study for which the individual is co-enrolled.	…… …… …… …… ……
4. Any other support or service provided by the other research?	☐ Yes ☐ No ☐ Unknown
4a. If yes, specify other support or service provided in each research study for which the individual is co-enrolled.	…… …… …… …… ……

Investigator: _____ Signature: _____ Date |__|__|/|__|__|/|__|__|__|__|

ID Number _____ Other Research Page 1 of 1
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IeDEA TB SRN

[25] Adverse Event Form Complete one form for each adverse event (AE)	
IeDEA/TB SRN ID	
Visit	☐ Month 1 ☐ Month 2 ☐ End of Tx ☐ Tx F/R/W
1. Has an Adverse Event been noted for this participant?	☐ Yes (if yes, fill below) ☐ No ☐ Unknown
2. Form completion date	|__|__|/|__|__|/|__|__|__|__| (dd/mm/yyyy)
3. Event brief description (signs, symptoms, syndrome)	
4. Start date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
5. Resolved	☐ Yes ☐ No, ongoing ☐ No, deceased or lost-to-follow up before resolution
5a. If yes, end date / resolution *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
6. Type of AE *(check all that apply)*	☐ Dermatologic system (e.g., rash) ☐ Hepatic system (e.g., Drug Induced Liver Injury) ☐ Nervous system ☐ Other: _____
7. Summary of this AE	
8. Severity grading (DAIDS)	☐ 1 (mild) ☐ 2 (moderate) ☐ 3 (severe) ☐ 4 (life-threatening)
9. Adverse drug reaction related to TB Tx	☐ Related / Defined ☐ Unlikely / Doubtful ☐ Likely ☐ Not related ☐ Possible ☐ Not applicable
10. Adverse drug reaction related to ARVs (if positive for HIV)	☐ Related / Defined ☐ Unlikely / Doubtful ☐ Likely ☐ Not related ☐ Possible ☐ Not applicable
11. Final diagnosis	
Notes (optional)	

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____

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IeDEA TB SRN

[26] TB IRIS	
IeDEA/TB SRN ID	
Visit	☐ Month 1 ☐ Month 2
Form completion date *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
IRIS/paradoxical reaction	
1. Suspicion of IRIS/paradoxical reaction *(New/worsened lymphadenopathy, or respiratory, abdominal, or neurological TB symptoms)*	☐ Yes (if yes, fill IRIS section below) ☐ No (END of form)
2. Date of IRIS suspicion *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
3. Fever (as of date of IRIS suspicion)	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No
4. Peripheral lymphadenopathies (as of date of IRIS suspicion)	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No (SKIP to #5)
4a. If yes, clinical aspect *(Check one)*	☐ Swollen ☐ Inflammatory ☐ Suppurative ☐ Necrotic
4b. If yes, location *(Check all that apply)*	☐ Cervical ☐ Axillary ☐ Inguinal ☐ Other
5. Abdominal pain *(as of date of IRIS suspicion)*	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No
6. Central nervous system disorders *(as of date of IRIS suspicion)*	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No (SKIP to #7)
6a. If yes, type of symptoms	☐ Coma ☐ Meningitis ☐ Hemiplegia

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	☐ Hemiparesis ☐ Other: ……..
7. Respiratory symptoms (e.g., cough, dyspnea, stridor) *(as of date of IRIS suspicion)*	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No
8. Chest X-ray abnormalities *(If chest x-ray done, fill **CXR Form**)*	☐ Yes new (since previous visit) ☐ Yes worsened (from previous visit) ☐ Yes unchanged (from previous visit) ☐ No ☐ CXR not performed
9. Abdominal Ultrasound abnormalities	☐ Yes ☐ No ☐ Ultrasound not performed (SKIP to #10)
9a. Date of abdominal ultrasound *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
9b. If yes to abnormalities, abdominal ultrasound findings *(Check all that apply)*	☐ Abdominal adenopathy ☐ Pleural effusion ☐ Peritoneal effusion ☐ Other ……
10. CT scan abnormalities	☐ Yes ☐ No ☐ CT scan not performed (SKIP to #11)
10a. Type of CT scan *(Check all that apply)*	☐ Abdominal ☐ Cerebral ☐ Thoracic
10b. Date of CT scan *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|
10c. If yes to abnormalities, CT abnormalities *(Check all that apply)*	☐ Abdominal adenopathy ☐ Mediastinal adenopathy ☐ Pulmonary infiltrates ☐ Pleural effusion ☐ Peritoneal effusion ☐ Brain mass ☐ Other ……
11. Treatment for IRIS initiated	☐ NSAID ☐ Steroids ☐ None
12. Date of initiation of treatment for IRIS *(dd/mm/yyyy)*	|__|__|/|__|__|/|__|__|__|__|

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number: _____ TB IRIS Page 2 of 2

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IeDEA TB SRN

[27] TREATMENT OUTCOMES	
IeDEA/TB SRN ID	
Visit	☐ End of Tx ☐ Tx F/R/W
TB treatment outcome	
1. Duration of intensive phase *(Report dates and Tx received in TB Tx form)*	☐ 2 months (standard intensive phase for DS-TB) ☐ Other duration, specify: |__|__|.|__| months
2. Duration of maintenance phase *(Report dates and Tx received in TB Tx form)*	☐ 4 months (standard maintenance phase for DS-TB) ☐ Other duration, specify: |__|__|.|__| months
3. Suspicion of treatment failure	☐ Yes → Complete **Tx F/R/W Visit** (and associated forms) ☐ No (SKIP TO #7)
4. Date of clinical suspicion *(dd/mm/yyyy; as documented in TB clinic record)*	|__|__|/|__|__|/|__|__|__|__|
5. Additional microbiological testing requested by clinician	☐ Yes (report results in **TB Microbiology** form) ☐ No
6. Additional chest X-ray requested	☐ Yes (report results in **Chest X-ray** form) ☐ No
TB Tx Outcome at Study Site	
7. TB treatment outcomes *(based on WHO/IUATLD definitions)*	☐ Cured ☐ Treatment completed ☐ Treatment failed ☐ Died (any cause) ☐ Lost to follow-up ☐ Transferred out from study site → *Complete **Outcome from transfer site**, below* ☐ Not known
8. Date of TB treatment outcome *from study site*	|__|__|/|__|__|/|__|__|__|__| *(dd/mm/yyyy)*
TB Tx Outcome obtained from transfer site	***ONLY to be completed for participants who transferred out from the study site – outcome based on follow-up with transfer site***
9. Name of site where transferred out	……..
10. Outcome of treatment after transfer-out *(reported by outside facility; based on WHO/IUATLD definitions)*	☐ Never in care at other site / did not complete transfer ☐ Unable to obtain outcome from other site ☐ Cured ☐ Treatment completed ☐ Treatment failed ☐ Died (any cause) ☐ Lost to follow-up ☐ Transferred out to additional site ☐ Not known (unknown to other site)
11. Date of outcome after transfer	|__|__|/|__|__|/|__|__|__|__| *(dd/mm/yyyy)*

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

ID Number _____ TX Outcome Page 1 of 1 v1.0 26Jul2022

IeDEA TB SRN

[28] DEATH	
IeDEA/TB SRN ID	
1. Date of death *(dd/mm/yyyy)*	|__|__| / |__|__| / |__|__|__|__|
2. Place of death	☐ Home ☐ Hospital ☐ Other, specify …… ☐ Unknown
3. Sudden death	☐ Yes ☐ No ☐ Unknown
4. Death unexpected	☐ Yes ☐ No ☐ Unknown
5. Brief narrative description of the sequence of events leading to death (please include means of diagnosis of illnesses):	…… …… …… …… …… …… ……
Cause of death (Summary of the causal relation between the conditions leading to death)	
6. Condition that directly caused death (immediate cause):	……
6a. Due to or as a consequence of	……
6b. Due to or as a consequence of	……
7. Condition that initiated the train of morbid events (the underlying condition)	……
8. Death considered to be related to TB as a contributing factor to the death	☐ Related/Defined ☐ Likely ☐ Possible ☐ Unlikely/Doubtful ☐ Not related ☐ Not applicable
9. Death considered to be related to a medical treatment	☐ Related/Defined ☐ Likely ☐ Possible ☐ Unlikely/Doubtful ☐ Not related ☐ Not applicable

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9a. If yes, suspicion of relation to	☐ Antiretroviral treatment ☐ Antituberculosis treatment ☐ Other medical treatment, specify……
9b. Brief narrative of the suspected association including the name of the medication	…… …… ……
10. Information on circumstance of death collected from *(Check all that apply)*	☐ Family member ☐ Clinician ☐ Hospital medical record ☐ Outpatient medical record ☐ Death register ☐ Autopsy report ☐ Other, specify …… ☐ Unknown
11. Date death reported to/known to study *(dd/mm/yyyy)*	|__|__| / |__|__| / |__|__|__|__|
12. Notes (optional)	…… …… …… …… …… ……

Investigator: _____ Signature: _____ Date |__|__| / |__|__| / |__|__|__|__|

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IeDEA/TB SRN Form Event Grid

	Treatment Phase				Follow-up Phase			
Form / **Visit**	**SCREENING**	**BASELINE**	**MONTH 1** (Weeks 3-7)	**MONTH 2** (Weeks 8-12)	**End of TX** (-4 to +6 wks)	**6-M POST-TX** (-4 to +6 wks)	**12-M POST-TX** (-4 to +6 wks)	**TX F/R/W**
Informed consent form[a]	X							
Assent form *(if applicable)*	X							
1. Inclusion *(eligibility assessment)*		X						
2. Demographics		X						
3. Adolescent and young adult characteristics[b] *(if applicable)*		X						
4. TB history and current diagnosis		X						X
5. Medical history		X						
6. HIV history[c]		X						
7. Pregnancy and post-partum history[d] *(female participants only)*		X			X	X	X	X
8. Pregnancy and Infant outcomes *(multiple copies, flowsheet, if applicable)*		X			X	X	X	X
9. Visit and clinical evaluation		X	X	X	X	X	X	X
10. ASSIST		X			X		X	X
11. Additional smoking history		X			X		X	X
12. SGRQ		X			X	X	X	X
13. PHQ-9		X			X		X	X
14. Spirometry				X	X	X		
15. 1-minute sit-to-stand test[e]		X		X	X	X	X	
16. TB microbiology[f]		X	X	X	X			X
17. Other labs[f,g,h,i]		X	X	X	X	X	X	X
18. Chest x-ray results[j] *(baseline and End of TX for study. Other forms are data collection only.)*		X	X	X	X	X	X	X
19. TB treatment *(flowsheet)*		X	X	X	X			X
20. TB treatment adherence			X	X	X			X
21. TB directly observed therapy			X	X	X			X
22. Antiretroviral treatment[c] *(flowsheet)*		X	X	X	X	X	X	X
23. ART adherence[c]		X	X	X	X	X	X	X
24. Other research		X						
25. Adverse event form *(repeatable)*			X	X	X			X
26. TB IRIS			X	X				
27. Treatment outcome					X			X
28. Death form[k] *(if applicable, once)*								

Screening and Baseline visits may be combined. Month 1 visit is optional. Tx F/R/W: Treatment Failure, Relapse, or Withdrawal.

[a] Adolescent minors who turn 18 years of age during the study will be re-consented on the first visit after turning age 18.
[b] For all adolescent and young adult participants ages 15-24 on enrollment.
[c] For participants with documented HIV infection.
[d] For all female participants.
[e] Performed if site is participating in the PTLD study aim.
[f] HIV viral load (if applicable), CBC, transaminases, TB testing and microbiology data to be collected if available from routine data and not as part of the study.
[g] HIV testing of participants not known to be positive collected from routine data and not as part of the study.
[h] CD4 count will only be performed on participants who are HIV-positive and who have not had a CD4 count performed in the preceding 3 months.
[l] HbA1C and random blood glucose collected if not available from routine data as part of the study.
[j] Digitized/digitizable CXR at baseline, unless done within 4 weeks prior to the Baseline Visit as part of standard of care. If a CXR is not available at the End of Treatment, it will be obtained as part of the study. CXRs from Month 2 and TX F/R/W Visits will be collected if obtained as part of standard of care. Pregnant women are not required to have a CXR.
[k] To be completed for any participants who die after study enrollment, from any cause.