User accounts
Medidata Rave and DMC Portal
Invitation to a study

- Site staff are invited to a study
  - Access *only* to the studies in which the site participates
  - Email notification is sent with each study invitation
For existing accounts

- Staff is invited to Medidata Rave with their actual email address
  - Example: viezile@witshealth.co.za
  - Your @fstrf.org address is not used
- This allows staff to link any existing account to this account
  - One login
  - Account maintenance the same
  - No need to repeat eLearnings
  - Access all of your studies from one login
Required eLearnings appear under tasks

Must be completed for study access
Subject enrollment System

- Sites will continue to use the Subject Enrollment System for all enrollments
  - This process is not changing
- Enrollments will appear in Medidata Rave after a short period
  - At that time, visits and data collection screens will be available to sites for data entry
DMC Portal programs:

*Migration Studies*

- Many DMC portal programs will continue to work, with the exception of:
  - Unanswered Query Report
  - Delinquency Viewer
  - Unresolved Error Report
  - Resolve
- Programs such as these found on the DMC portal will likely still be used:
  - Diagnosis Report
  - Medications Report
  - Participant Data Reports
  - Site Enrollment Report
  - Visit Forecaster
  - Accrual Report
  - TJOIN
Laboratory Data Management System (LDMS)

- Use of the LDMS will continue
ECRF Completion Guide

- To be posted on the DMC portal
- Contains question options and additional instructions
- This replaces traditional CRFs

**Site Support (Skip)**
- 2015 Holiday Schedule (pdf)
- Training Pages
- Computer Account Report
- Computing Manual
- Computing Requirements
- DMC Contacts
- Email Address Book Download
- Email Address Lookup
- Medidata Rave Resources
- Newsletters
- People List
DG W0109: Audiology Assessment

<table>
<thead>
<tr>
<th>Date of Visit/Contact</th>
<th>1. Was audiology testing done at this visit?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Was otoscopy performed?</td>
</tr>
<tr>
<td></td>
<td>a. Indicate results of otoscopy on right ear</td>
</tr>
<tr>
<td></td>
<td>b. Indicate results of otoscopy on left ear</td>
</tr>
<tr>
<td></td>
<td>3. Was tympanometry testing done at this visit?</td>
</tr>
<tr>
<td></td>
<td>a. Indicate results of tympanometry on right ear</td>
</tr>
<tr>
<td></td>
<td>b. Indicate results of tympanometry on left ear</td>
</tr>
<tr>
<td></td>
<td>4. Was otoacoustic emission (OAE) testing done at this visit?</td>
</tr>
<tr>
<td></td>
<td>a. Indicate results of OAE on right ear</td>
</tr>
<tr>
<td></td>
<td>b. Indicate results of OAE on left ear</td>
</tr>
<tr>
<td></td>
<td>5. Was threshold hearing testing done at this visit?</td>
</tr>
<tr>
<td></td>
<td>a. Indicate type of threshold hearing testing</td>
</tr>
<tr>
<td></td>
<td>b. Indicate results of threshold hearing testing on right ear</td>
</tr>
<tr>
<td></td>
<td>If Abnormal, indicate involved frequencies [76]</td>
</tr>
<tr>
<td></td>
<td>c. Indicate results of threshold hearing testing on left ear</td>
</tr>
<tr>
<td></td>
<td>If Abnormal, indicate involved frequencies [76]</td>
</tr>
<tr>
<td></td>
<td>6. What is the overall assessment of hearing?</td>
</tr>
<tr>
<td></td>
<td>a. Overall assessment on right ear</td>
</tr>
<tr>
<td></td>
<td>b. Overall assessment on left ear</td>
</tr>
<tr>
<td></td>
<td>7. Is there any other pertinent information regarding audiology test results?</td>
</tr>
<tr>
<td></td>
<td>a. Comment(s) [140]</td>
</tr>
</tbody>
</table>

- These questions will roll out upon a “Yes” response to Question 1
DGW0112: IMPAACT P1108 Electrocardiogram Results

For documenting performance of ECGs and site interpretation
Log lines can be added as needed to accommodate complete medication history.

**Instructions:**
- List each TB medication on a separate line.
- Only record historical TB medications taken prior to study entry on this form.
- If complete date is not known, estimate date according to "Conventions for Reporting Dates". Refer to the Forms Manual on the DMC Portal (https://www.fstfrf.org) for estimating date conventions.

1. Has the study participant taken any TB medication(s) prior to study entry?

2. Is there any further information regarding TB medication history?
   a. Comment(s)
### Test Results:
- Result in mmol/L
- Quantifier (=, <, >)
- Lower Limit
- Upper Limit

### Classification:
- Low
- Normal
- High
- Indeterminate
LBW0162: Historical TB Microbiology

- Used to document TB microbiology results from specimens collected prior to entering the study
  - Submitted only at entry
  - Can be completed for either child or adult source case

- TB microbiology results for study specimens reported on LBW0163: IMPAACT P1108 TB Microbiology – Study Specimens
  - Part A: Specimen Information
  - Part B: Results of tests done directly on specimen
  - Part C: Culture results, or results of test done on culture only if the culture was positive
### SPECIMEN INFORMATION

1. Is this form for the child or for the adult source case?
   - [ ] Child
   - [ ] Adult source case

2. Was a specimen collected for TB microbiology?
   - [ ] Yes
   - [ ] No

   a. What type of specimen was collected?
   - [ ]

   b. If Other, specify:
   - [ ]

3. Is the date of specimen collection known?
   - [ ] Yes
   - [ ] No

   a. Enter the date:
   - [ ]

4. Is the time of specimen collection known?
   - [ ] Yes
   - [ ] No

   a. Enter the time:
   - [ ]

5. Specimen laboratory accession or reference number (this is the number that the laboratory uses to identify the specimen. Each specimen would have a unique laboratory number):
   - [ ]

6. Is the date of specimen receipt in the laboratory known?
   - [ ] Yes
   - [ ] No

   a. Enter the date:
   - [ ]

7. Is the time of specimen receipt known?
   - [ ] Yes
   - [ ] No

   a. Enter the time:
   - [ ]

8. Was the specimen volume documented?
   - [ ] Yes
   - [ ] No

   a. Enter the volume [mL]:
   - [ ]

**Specimen collection status, date, time, laboratory reference number, laboratory receipt date & time, specimen volume**
Your answers to Part B may roll out additional forms on which you provide follow-up information.
### PART C: Culture results or tests done only if the culture is positive

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. Was a liquid (MGIT) culture done on this specimen?</td>
<td></td>
</tr>
<tr>
<td>14. Was a solid culture done on this specimen?</td>
<td></td>
</tr>
<tr>
<td>15. Was a HAIN Genotype MTBDRplus assay done on the positive culture?</td>
<td></td>
</tr>
<tr>
<td>16. Was a HAIN Genotype MTBDRsI assay done on the positive culture?</td>
<td></td>
</tr>
<tr>
<td>17. Was phenotypic drug susceptibility testing (DST) done on the positive culture?</td>
<td></td>
</tr>
<tr>
<td>18. Indicate the date of final report (all tests results are completed and reported as final by the laboratory).</td>
<td></td>
</tr>
<tr>
<td>19. If this specimen is culture positive, has the isolate (TB culture) been found and sent to the network laboratory?</td>
<td>a. Indicate reason not sent: If Other, specify</td>
</tr>
<tr>
<td>20. Are there any comments?</td>
<td>a. Comment(s):</td>
</tr>
</tbody>
</table>

- As with Part B, your positive responses will trigger the roll out of additional results forms to be completed.
- Susceptibility results: Susceptible, Resistant, Indeterminate
- “Other, specify” box not visible unless 19 and/or 20 are answered affirmatively
P1108 Pharmacokinetics:
PKW0403 – Sparse PK
PKW0404 – Intensive PK

Medications Recorded:
• Bedaquiline
• Background TB Regimen
• Antiretroviral Medications
• Other Medications

Three Time Points Recorded:
• Current dose taken AFTER PK collection
• Last dose prior to PK blood draw
• 2nd last dose prior to PK blood draw

For BDQ: Last dose prior to draw: Was full dose ingested? If not, why not? What is the estimated amount of ingestion? Did any vomiting or reflux occur within 6 hours of ingesting that dose? If so, how much? Were drugs visible?

If the drug formulation is crushed or dispersed, indicate volume of water in which it was dissolved.
### QLW0294: IMPAACT P1108 Baseline TB Assessment

- **Submitted at entry**
<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the source case coughing?</td>
</tr>
<tr>
<td>Is the source case the participant's primary caregiver?</td>
</tr>
<tr>
<td>Does the source case sleep in the same bed as the participant?</td>
</tr>
<tr>
<td>Does the source case sleep in the same room as the participant?</td>
</tr>
<tr>
<td>Does the source case have reported pulmonary TB?</td>
</tr>
<tr>
<td>Does the source case have smear positive sputum?</td>
</tr>
<tr>
<td>Does the source case live in the same household as the participant?</td>
</tr>
<tr>
<td>Does the source case see the participant every day?</td>
</tr>
<tr>
<td>Is there more than one adult TB case in the household?</td>
</tr>
</tbody>
</table>
Please indicate if the participant had any of the following CLINICAL CRITERIA at the time of the participant’s TB diagnosis:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cough:</td>
<td></td>
</tr>
<tr>
<td>1. Is the cough persistent (&gt; 2 weeks non-rminating)?</td>
<td></td>
</tr>
<tr>
<td>b. Weight loss or failure to thrive:</td>
<td></td>
</tr>
<tr>
<td>1. Greater than 5% weight loss compared to highest weight in the last 3 months:</td>
<td></td>
</tr>
<tr>
<td>2. Clear deviation from previous growth trajectory:</td>
<td></td>
</tr>
<tr>
<td>3. Documented crossing of centiles:</td>
<td></td>
</tr>
<tr>
<td>4. Weight for Age Z-score or Height for Age Z-score ≤ 2 AND not responding to nutritional rehabilitation:</td>
<td></td>
</tr>
<tr>
<td>5. Other (weight loss not meeting above criteria), specify:</td>
<td></td>
</tr>
<tr>
<td>Specify [70]:</td>
<td></td>
</tr>
<tr>
<td>c. Persistent unexplained fever (Persistent [greater than 1 week] and unexplained, reported by caregiver or objectively recorded [greater than 38°C] at least once):</td>
<td></td>
</tr>
<tr>
<td>d. Persistent unexplained lethargy or reduced playfulness reported by caregiver/parent:</td>
<td></td>
</tr>
<tr>
<td>e. Infant less than 60 days of age [70]:</td>
<td></td>
</tr>
<tr>
<td>1. Neonatal pneumonia:</td>
<td></td>
</tr>
<tr>
<td>2. Unexplained hepatosplenomegaly:</td>
<td></td>
</tr>
<tr>
<td>3. Sepsis-like illness:</td>
<td></td>
</tr>
<tr>
<td>f. Depressed level of consciousness, new onset seizures or focal neurological signs suggestive of TB meningitis:</td>
<td></td>
</tr>
<tr>
<td>g. Lymph node swelling greater than 2x2 cm for greater than 2 weeks, not responding to antibiotics:</td>
<td></td>
</tr>
<tr>
<td>h. Classic gibbus suggestive of spinal TB:</td>
<td></td>
</tr>
<tr>
<td>i. Any other symptoms suggestive of TB:</td>
<td></td>
</tr>
</tbody>
</table>
Please indicate if the participant had any of the following LABORATORY/RADIOLOGIC CRITERIA in the opinion of the treating physician at the time of the participant’s TB diagnosis:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Chest radiograph suggestive of TB</td>
</tr>
<tr>
<td>b.</td>
<td>AFBs or caseating granulomas on microscopy (not confirmed by culture or Xpert to be TB)</td>
</tr>
<tr>
<td>c.</td>
<td>CSF suggestive of TB (white cell count 5-1000 cells or protein greater than 1 g/dL or glucose less than 2.2 mmol/L)</td>
</tr>
<tr>
<td>d.</td>
<td>CT brain suggestive of CNS TB</td>
</tr>
<tr>
<td>e.</td>
<td>Pleural aspirate or ascitic tap suggestive of TB</td>
</tr>
<tr>
<td>f.</td>
<td>Other, specify</td>
</tr>
</tbody>
</table>

Specify
<table>
<thead>
<tr>
<th>Question</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of diagnosis of DR-TB (dd/mmm/yyyy):</td>
<td>(dd/mmm/yyyy)</td>
</tr>
<tr>
<td>Start date of current DR-TB treatment (dd/mmm/yyyy):</td>
<td>(dd/mmm/yyyy)</td>
</tr>
<tr>
<td>Is the participant currently admitted to the hospital for TB treatment?</td>
<td>(dd/mmm/yyyy)</td>
</tr>
<tr>
<td>Date of hospital admission (dd/mmm/yyyy):</td>
<td>(dd/mmm/yyyy)</td>
</tr>
<tr>
<td>Participant’s weight at start of TB treatment (kg):</td>
<td>(kg)</td>
</tr>
</tbody>
</table>
Documentation of tests of TB infection:

- **Mantoux**
  1. Date applied (dd/mmm/yyyy):
  2. Date read (dd/mmm/yyyy):
  3. Indicate result of test:
    - a. Indicate size of induration [nn.n]:
- **IGRA**
  1. Indicate result of test:
  2. Date IGRA performed (dd/mmm/yyyy):
- **Other**
  1. Specify test and result:
**Subject**: New Subject  
**Page**: QLW0294: IMPAACT P1108 Baseline TB Assessment Baseline TB Classification

1. What is the participant’s baseline TB classification?  
   - Confirmed TB = Positive culture for M. tuberculosis with at least 1 CLINICAL criterion OR 1 LAB/RADIOLOGIC criterion.  
   - Probable TB = at least 1 CLINICAL criterion AND 1 LAB/RADIOLOGIC criterion.  
   - Possible TB = at least 1 CLINICAL criterion OR 1 LAB/RADIOLOGIC criterion but NOT both, AND decision to treat.

2. On what basis was the DR-TB treatment started for this episode?  
   - If Other, specify [70]:

3. Indicate TB disease type:  
   - Please specify all EPTB that are present:  
     - a. Miliary TB  
     - b. TB Meningitis:  
       - 1. Indicate TBM stage:  
         - c. Abdominal:  
         - d. Peripheral lymph node:  
         - e. Pleural effusion:  
         - f. Urogenital TB:  
         - g. Skin TB:  
         - h. Pericardial TB:  
         - i. Bone/Joint/Spine TB:  
     - j. Other, specify:  
       - Specify [70]:
SVW0290: IMPAACT P1108 Study Event Tracking

Date of Visit/Contact

Step Number

1. Is there a pregnancy to report at this visit or since the last visit?
   a. Is it the participant or the participant’s partner who is pregnant?
   b. Is it the participant a female of reproductive potential?
      1. Is the pregnancy test CRF required at this visit according to the Schedule of Evaluations?

2. Is there a birth to report at this visit?

3. Is it developmentally appropriate to ask about this participant’s sexual activity and contraceptive use?

4. Are there any Lactate-Pyruvate Ratio Results to report at this visit?

5. Are there any TB Microbiology for Study Specimens results to report at this visit or since the last visit?

<table>
<thead>
<tr>
<th>#</th>
<th>Test Type</th>
<th>Result to report at this visit?</th>
<th>Visit week specimen collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AFB smear</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>GeneXpert MTB/RIF</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>HAIN Genotype MTBDRplus</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Liquid culture</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Solid culture</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>HAIN Genotype MTBDRplus on a positive culture</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>HAIN Genotype MTBDRsl on a positive culture</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Phenotypic drug susceptibility on a positive culture</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
</tbody>
</table>

6. Have any chest x-ray images been submitted to the FSTRF file exchange utility at this visit or since the last visit?
   a. For which visit week were these images submitted?

Used to trigger forms for conditional events that aren’t expected to be applicable at each visit.
**TBW0095: IMPAACT P1108 Chest X-Ray Evaluation**

<table>
<thead>
<tr>
<th>Step Number</th>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Was a chest x-ray (CXR) performed at this visit?</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>a. Reason not performed [70];</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Please indicate which x-rays were taken:</td>
<td>Yes/No</td>
</tr>
<tr>
<td></td>
<td>a. Antero-posterior (AP) CXR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a1. Date of x-ray.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a2. Was the x-ray uploaded to the FSTRF File Exchange Utility?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a3. What was the quality of the x-ray?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Lateral CXR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b1. Date of x-ray.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b2. Was the x-ray uploaded to the FSTRF File Exchange Utility?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b3. What was the quality of the x-ray?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Postero-anterior (PA) CXR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c1. Date of x-ray.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c2. Was the x-ray uploaded to the FSTRF File Exchange Utility?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c3. What was the quality of the x-ray?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. CXR result:</td>
<td>Normal/Abnormal</td>
</tr>
</tbody>
</table>

**X-Ray views:**
- Antero-posterior (AP)
- Lateral
- Postero-anterior (PA)
2. Please indicate which x-rays were taken:
   a. Antero-posterior (AP) CXR
      a1. Date of x-ray:
      a2. Was the x-ray uploaded to the FSTRF File Exchange Utility?
      a3. What was the quality of the x-ray?

Utilities
- A5288 ARV Cohort Selection
- DataView
- Deconsent Utility
- Eligibility Correction Request
- External Review Program
- File Exchange Utility
- Mother/Infant PID Mapping
- Participant Calendar
- Participant Transfer Request
- Real-time Clinical Review
Utility will be available on the IMPAACT tab of the FSTRF portal and updated with P1108-specific options.
X-Ray Findings: Alveolar (Consolidation), Ghon focus, Expansile, Bronchopneumonic, Cavity, Volume Loss, Calcification (Lung), Fibrosis, Hyperinflation (Lobar/Segmental), Hyperinflation (Generalized)
**TBW0095: IMPAACT P1108 Chest X-Ray Evaluation**

**Nodes, Airways, Pleura, Heart**

### Nodes

1. Are perihilar nodes present?
   
   a. Lung area involved:

2. Are paratracheal nodes present?
   
   a. Lung area involved:

3. Is calcification (nodes) present?
   
   a. Lung area involved:

### Pleura

1. Is effusion present?
   
   a. Lung area involved:

   b. Is it loculated?:

2. Is thickening present?
   
   a. Lung area involved:

   b. Is it loculated?

3. Is the pneumothorax affected?
   
   a. Lung area involved:

### Airways

1. Is bronchial compression present?
   
   a. Lung area involved:

2. Is tracheal compression present?
   
   a. Lung area involved:

### Heart

1. Is enlargement present?
   
   a. Is pericardial effusion suspected?
Conclusion: CXR typical of TB or CXR not typical of TB
### TYPICAL OF TB

#### Radiological Pattern

**Non-Severe Disease**

- a. Uncomplicated LN disease
  - a1. Hilar or mediastinal lymph nodes
  - a2. Lymph nodes with unilateral airway narrowing
  - a3. Lymph nodes with single lobe bronchopneumonia
  - a4. Lymph nodes with segmental opacification (less than 1 lobe)

- b. Isolated Ghon focus
- c. Simple pleural effusion

#### Severe Disease

- d. Complicated LN disease
  - d1. Airway compression with unilateral hyperinflation
  - d2. Airway compression with lobar collapse
  - d3. Bilateral airway compression
  - d4. Lymph nodes with ≥ 1 lobe opacification

- e. Ghon focus with cavitation
- f. Miliary TB

- g. Complicated pleural effusion: alveolar disease with effusion, pneumothorax, loculated pyopneumothorax (air-fluid level)

- h. Adult-type cavitatory disease

- i. TB Bronchopneumonic (consolidation with cavities or presence of lymph nodes)

- j. Suspected pericardial effusion (cardiac enlargement)
**NOT TYPICAL OF TB**

**Radiological Pattern**
- Non-Severe Disease
  - a. Perihilar infiltrates
  - b. Isolated bronchopneumonia (no enlarged lymph nodes and no cavities)
  - c. Isolated segmental opacification (no enlarged lymph nodes)
  - d. Calcification
  - e. Generalized hyperinflation
  - f. Interstitial pneumonia
  - g. Other
    - Specify

**Severe Disease**
- h. Lobar pneumonia
- i. Lymphocytic interstitial pneumonitis (LIP)
- j. Bronchiectasis
- k. Other
  - Specify
• Bedaquiline and Background Regimen medications to be reported on this form.
Overall support for the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network was provided by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) under Award Numbers UM1AI068632 (IMPAACT LOC), UM1AI068616 (IMPAACT SDMC) and UM1AI106716 (IMPAACT LC), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.