Regional Prospective Observational Research for Tuberculosis (RePORT)

RePORT International

Data Elements Bank Overview and Application Guide

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The Regional Prospective Observational Research for Tuberculosis (RePORT) International Data Elements Bank is a global set of requirements for database design. Forms, modules, variables, and codelists are based on the RePORT India model. Each RePORT consortium is expected to collect and store data according to this global requirement to facilitate future data sharing.

The Data Elements Bank was created in MS Excel format with tabs to identify the details of questions, forms, modules, and codelists. Within the Questions tab, is a column named "CORE." This "CORE" column will determine if a RePORT Question is required, required (comparable question/group), or optional. To explain this in more detail, the instructions for each of these three terms are provided below:

<u>Required</u>: Identifies questions to be developed in your database exactly as specified in the Data Elements Bank with no deviation, including codelist and attributes. These are global elements, meaning that all questions and responses will be the same across all countries.

Required (Comparable Question/Group): Identifies questions to be developed in your database as specified in the "required" definition above (i.e., using the specified question name). However, since these questions were developed specifically for India, a question flagged as "Required (comparable question/group)" may be modified in the question label or codelist from what is specified in the Data Elements Bank, as long as the question addresses the same topic. Questions flagged as "Required (comparable question/group)" allow users to ask participants questions in a slightly different manner or to use a response codelist specific to a country.

<u>Optional</u>: Identifies questions to be developed in your database only if the question applies to the country, or is a question of interest. If included in the country-specific database development specification, the question will follow the Required (comparable question/group) rule (i.e., the question short name will remain the same as in the Data Elements Bank, but the label and/or codelist may be different).

A set of annotated case report forms (CRFs) was developed to accompany the Data Elements Bank. These annotated CRFs are to be used as a visual tool to indicate the variable naming convention for each question in the Data Element Bank. Database developers can see how each question from the Data Element Bank will be grouped on the form and whether the question is Required ('R'), Required Comparable Question/Group (RC), or Optional (O).

Along with the Questions tab, the Data Elements Bank includes separate tabs for Forms, Modules, and Codelists, a Help tab, and a tab for Rules and Conventions. The Forms and Modules tabs are critical for maintaining the groupings of questions listed in the Questions tab. To share and analyze data across RePORT countries, these groupings <u>must</u> be maintained. Changing the name of a form to be different

from the Data Elements Bank will be allowed, but modifying the naming convention for modules or the codelists **IS NOT ALLOWED**, as this will be used to form the question groups for data analysis.

<u>Note</u>: If a codelist specified in the Data Elements Bank does not exactly match the case report form format (i.e., capitalized letters, hyphens, commas, etc.), use the codelist language from the Data Elements Bank, as this will be the database design standard.