WHO GLOBAL aDSM DATABASE FOR THE SURVEILLANCE OF ADVERSE EVENTS IN THE SCOPE OF ACTIVE DRUG SAFETY MONITORING AND MANAGEMENT OF ANTI-TUBERULOSIS DRUGS

DATA TRANSFER AGREEMENT

This Agreement is by and between the < INSERT INSTITUTION NAME (acronym) > and the WHO Global aDSM Database for collection of safety data (AE and/or SAE) in the scope of the surveillance of aDSM of anti-TB drugs by World Health Organization, hereafter individually referred to as "Party" and collectively as the "Parties"

PURPOSE

This Agreement establishes the terms and conditions under which <insert name> will provide data to the WHO Global aDSM Database for the Surveillance of adverse events in the scope of active drug safety monitoring and management of anti-tuberculosis drugs.

The specific purposes of this agreement are to:

- Set out the responsibilities of the Data Owner for the provision of data to the WHO Global aDSM Database.
- Set out how the WHO Global aDSM Database will store, maintain and administer data provided by the Data Owner, and set out the terms and conditions under which the WHO Global aDSM Database is licensed to hold, manipulate and disseminate the Data.
- Ensure the proper protection of the privacy and confidentiality of those individuals that the data relates to.

Any other uses will be subject to prior approval by the Data Owner.

BACKGROUND

(A) WHO issued interim policy on the use of two new drugs, bedaquiline and delamanid in 2013 and 2014 respectively, and active pharmacovigilance is one of the conditions set for the implementation of the new and repurposed drugs.

(B) In 2016 the WHO Global Tuberculosis Programme released a framework for the implementation of active TB drug safety monitoring and management[1] (hereafter abbreviated to "aDSM"), representing a consensus position with stakeholders on how active pharmacovigilance can be applied within the context of national TB programmes and other local providers. aDSM is intended as a component of routine programme management within the scope of article 3(b) of WHA16.36[2] and national authorities are invited to share these data with WHO within the organization's mandate of public health monitoring.

(C) The WHO Global Tuberculosis Programme and the Special Programme for Research and Training in Tropical Disease has developed a Global aDSM Database for the collection and collation of adverse event data from national aDSM database. The data management system was developed to facilitate data sharing and pooling safety data issued from national or local database developed in the context of aDSM. Contributing countries or sites collect their local data according to their local / national procedures.

[1] Active tuberculosis drug-safety monitoring and management (aDSM). Framework for implementation.(WHO/HTM/TB/2015.28). Geneva, World Health Organization; 2015. Available from: http://apps.who.int/iris/bitstream/10665/204465/1/WHO_HTM_TB_2015.28_eng.pdf

[2] Resolution WHA16.36. Clinical and Pharmacological Evaluation of Drugs. In: Thirteenth plenary meeting, 23 May 1963, Committee on Programme and Budget, fifth report. In Geneva: World Health Organization; Available from: http://apps.who.int/iris/bitstream/10665/89155/1/WHA16.36_eng.pdf

(D) The purpose of this database is to promote and facilitate the aggregation of high quality data on the safety of new TB drugs. It is specifically designed to capture information on serious or non-serious adverse events.

(E) The database will allow early detection of any potential signal through pooling of data. The database will enable analysis of the relation between drugs exposure and adverse events, and will provide evidence to inform future treatment guidelines.

(F) The final objective of the database is strengthening evidence base on safety of TB drugs. This surveillance system is to improve the quality of care of TB patients. It is built as part of the WHO mandate to help countries strengthening public health.

(G) The country data collected by the WHO in the Global aDSM Database will not be used for commercial purpose.

THE PARTIES AGREE AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

Data	Means the information on patient demographics, treatment received, and adverse event characteristics as defined in other technical documents.
Data Custodian	means the party hosting the data, here the WHO Global aDSM Database developed by GTB and TDR at the WHO;
Data Owner	means the Owning Party who is transferring data to the WHO Global aDSM Database;
Project Management Committee	means the core team responsible for managing the WHO Global aDSM Database and maintenance of the data management system, collating data centrally, carrying out routine monitoring of the data, preparing bi-annual reports as well as coordinating communications with all members;
Transferring Party	means <INSERT INSTITUTION NAME (acronym) >
WHO Global aDSM Database	means the database developed by WHO/GTB and WHO/TDR containing data on adverse events reported in the context of the aDSM for anti TB drugs.

2. PRINCIPLES

2.1 This data transfer agreement covers the transfer of Data from <INSERT ACRONYM OF TRANSFERRING PARTY> and the use of the Data by the WHO Global aDSM Database only for the purpose of the surveillance of drug safety in the context of the aDSM for anti TB drugs and not as part of a trial, an operational research activity or a commercial endeavour

2.2 This Agreement supersedes any and all previous data transfer agreements with the Data Owner relating to transfer of data that is used to promote and facilitate the aggregation of high quality data on the safety of new TB drugs.

2.3 The terms of this Agreement can be changed only by a written modification of the agreement by the authorised signatories of the Parties (or their designated representatives) to this Agreement or by the parties adopting a new agreement in place of this Agreement.

2.4 The <INSERT ACRONYM OF TRANSFERRING PARTY> retains all ownership rights to the data. The WHO Global aDSM Database will not claim any rights of ownership in any data submitted but, in order to allow the WHO Global aDSM Database Management Committee to operate, it requires your permission to use the data for the purposes set out in this agreement.

3. RESPONSIBILITIES

3.1 <INSERT ACRONYM OF TRANSFERRING PARTY> agrees to provide the Data specified in Schedule 1 to the WHO Global aDSM Database and it has the authority to submit the Data to be used in accordance with these terms of submission.

3.2 <INSERT ACRONYM OF TRANSFERRING PARTY> represents and warrants that it has obtained all consents that are necessary and appropriate to enable the sharing of the data with WHO for the purposes described herein and confirms that all submitted data:

3.2.1 have been obtained in accordance with any laws and ethical approvals applicable in its country of origin;

3.2.2 will be provided in a fully anonymized form by using the highest anonymization standards and techniques to avoid possible re-identification of the anonymized data, and as required by regulations that govern in the location where the data are held by the Data Owner;

3.2.3 where applicable, have been reviewed by the competent Institutional Review Board approvals and that Informed Consent document language have been completed to allow sharing of anonymized data for other analysis by a third party.

3.3 The Data Custodian will be responsible for complying with all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorised use and disclosure of the Owner's Data provided under this Agreement.

3.4 The Data Custodian will provide appropriate administrative, technical, and physical safeguards to ensure the confidentiality and security of the Owner's Data and to prevent unauthorized use or access to it.

3.5 Except as authorised in writing, the Data Custodian shall not disclose, release, reveal, show, sell, or otherwise grant access to the Data covered by this Agreement to any person outside the scope of the WHO Global aDSM Database.

3.6 The Data Custodian shall not, under any circumstances, attempt to establish the identity of or make contact with any subjects included in the Data.

3.7 The Data Custodian will ensure that its employees, agents and sub-contractors involved in the performance of this Agreement are aware of and comply with their obligations to protect the Data from misuse, loss or any unauthorised access, use, modification or disclosure and that these obligations will continue after their employment ceases.

4. CONDITIONS OF ACCESS AND USE

4.1 <INSERT ACRONYM OF TRANSFERRING PARTY> agrees that the Data provided can be included in the WHO Global aDSM Database and will be accessible only to them, and the Project Management Committee.

4.2 <INSERT ACRONYM OF TRANSFERRING PARTY> will have access to their own Data entered into the WHO Global aDSM Database and any reporting tools that may be in the future integrated in the data management system.

4.3 The Data shall not be used for any purpose other than to address the aim of the WHO Global aDSM Database and subject to the restrictions set out herein. Special permission could be asked for other uses with no obligation for the contributors to grant access.

4.4 The Data shall be used in compliance with all applicable statutes, regulations and ethical requirements.

4.5 <INSERT ACRONYM OF TRANSFERRING PARTY> will continue to own your data. The Data Custodian will not claim any rights of ownership in any data submitted but, in order to operate, it requires your permission to use the data for the purposes set out in this Agreement.

4.6 The parties mutually agree that any derivative data or file(s) that is created from the original data may be retained in the WHO Global aDSM Database.

4.7 The shared data may be further processed by the WHO Global aDSM Database Management Team and used in combination with other data to carry out analyses and create reports.

4.8 The WHO Global aDSM Database Management Committee will use data in its database to produce on regular basis several types of reports described below:

4.8.1 specialised analyses of pooled data in relation to a particular drug or patient group to identify emerging safety signals;

4.8.2 carry out analysis based on specific request by any WHO department in association with policy review.

5. PUBLICATION OF DATA

5.1 Submission of data to the WHO Global aDSM Database does not affect the right of contributing sites to share or publish those data, which <INSERT ACRONYM OF TRANSFERRING PARTY> may do entirely at their own discretion and without consent from or reference to the WHO Global aDSM Database.

5.2 The WHO may publish the results of the analysis of the data from the WHO Global aDSM Database.

5.3 Authorship for publications or presentations based on meta-analysis of data from the WHO Global aDSM Database will reflect the genuine contributions of investigators, in accordance with the criteria for authorship as outlined by the International Committee of Medical Journal Editors.

5.4 Any publication or presentation based on meta-analysis of data from the WHO Global aDSM Database where the authors are not the Data Owners, should include an acknowledgement using the text below: [We thank < Insert names of the contributing projects > for providing data for the present analysis]

6. TERM AND TERMINATION

6.1 This Agreement commences from the last date of its signature and will continue into force for so long as the Data Custodian continues to hold the Data.

6.2 The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, the Data Owner will notify the Data Custodian to destroy or return such data at Data Custodian expense.

6.3 Except as explicitly provided in this Agreement, no Party shall, in any statement or material of a promotional nature, refer to the relationship of the Parties under this Memorandum of Understanding and/or any subsequent letters of agreement, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of that other Party.

6.4 Nothing in or relating to this Agreement shall be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

6.5 Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

On behalf of both parties the undersigned individuals hereby attest that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Signed for and on behalf of)

World Health Organization)

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Signature

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Name

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Title

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Date

Signed for and on behalf of	)
Transferring Organisation	)
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	Signature
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	Name
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	Title
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	Date