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endTB Data Privacy Policy

endTB (Expand new drug markets for TB) is a partnership between Partners In Health, Médecins Sans Frontières and Interactive Research & Development that aims to find shorter, less toxic and more effective treatments for multidrug resistant TB (MDR-TB) through access to new drugs, one observational study and two clinical trials, and advocacy at national and global levels.

To learn more about the endTB project, please visit the endTB website.

Within endTB, the security and confidentiality of personal data is of the greatest importance. This statement explains how we use personal data and how one can exercise its rights.

In this Data Privacy Policy, we refer to personal data coming from 3 different groups of people:

- **"Participants"** are patients consented and enrolled in one of the endTB studies (the observational study and the two clinical trials) which allowed the establishment of a unique set of data on MDR-TB in terms of volume, geography origin and quality (hereafter "endTB Data"). The data is first used for the endTB analysis. They can also be shared with others for other analysis, either through the endTB Data Sharing Initiative (eDSI – see section 1 below) or also outside of eDSI, always in agreement with the terms of the consents signed by the Participants and after a Data Sharing/Access Agreement is signed. Unless explicitly specified, the provisions linked to Participants' data apply the same way to data outside or within eDSI.

- **"Data Requestors"** are institution(s) or individual researcher(s) who share the common goal of increasing knowledge and disseminating information to improve care for patients with tuberculosis, and wish to access certain endTB Data through the Platform for the purpose of a research.

- "**Committees members**" are members of the eDSI Steering Committee and eDSI Data Access Committee involved in the governance and implementation of eDSI.

- **"Interested Individuals"** are individuals asking to receive information on eDSI by sharing their contact details in a form on the website.

Summary

1. What is eDSI?

The endTB Data Sharing Initiative (eDSI) consists of an online data repository (hereafter the "Platform") that hosts the endTB Data. The purpose of this Platform is to allow access to endTB Data to a range of users who share the common goal of increasing knowledge and disseminating information to improve care for DR-TB patients, contributing to a broader public health benefit.

To learn more about eDSI, please visit the endTB website, data sharing initiative

2. What are your rights over your personal data?

Participants, Data Requestors, Committees members and Interested Individuals have the following rights over their personal data. They may exercise them by following the procedure described in this policy, respectively in sections 3.10 (for Participants), 4.9 (for Data Requestors), 5.9 (for Committees members) and 6.9 (for Interested Individuals).

- Access right: they may request confirmation that their data is processed by the data controllers and obtain information on the processing activities carried out. They may also request a copy of the personal data that is processed.
- Rectification right: they may request the rectification of inaccurate personal data concerning them or the completion of incomplete personal data by the data controllers.
- Deletion right: they may request the erasure of their personal data without undue delay, in particular when these data are no longer necessary for the purposes for which they were collected or when Participants or Data Requestors or Committees members or Interested Individuals object to the processing of their personal data.
  Please note that deletion right will not be applicable when deletion is likely to render impossible or seriously impair the achievement of the objectives of the processing carried out for scientific research purposes.
- Restriction right: they may request the restriction of the processing of their personal data by the data controllers when they contest the processing activities carried out. In such a case, personal data will not be processed anymore with the exception of storage and for the establishment, exercise or defense of legal claims.
- Objection right: they may object, at any time, to the processing of their personal data by the data controllers, on grounds relating to their particular situation.
  Please note that the objection may be refused if the data controllers demonstrate compelling legitimate grounds for the processing and if such objection deletion is likely to render impossible or seriously impair the achievement of the objectives of the processing carried out for scientific research purposes.
- Right to portability: when the processing activities are based on the contract with the Data Requestors, Data Requestors may request a copy of their personal data in a structured, commonly used and machine-readable format.

3. Participants' data

3.1. Which entities are responsible for your original study data?

The following entities are independently responsible for your study data:

- Observational study: PIH, MSF France, MSF Switzerland, MSF Holland, IRD (individually)
    - **Partners In Health (PIH),** 700 Boylston Street, Suite 300, Boston, MA
    - **Médecins Sans Frontières France (MSF France),** 14-34, avenue Jean Jaurès, 75019 Paris, France
    - **Médecins Sans Frontières Holland (MSF Holland),** Plantage Middenlaan 14, 1018 DD Amsterdam, The Netherlands
    - **Médecins Sans Frontières Switzerland (MSF Switzerland),** 140 Route de Ferney, PO Box 1224, Geneva 1202, Switzerland
    - **Interactive Research and Development (IRD),** 16 Raffles Quay, #16-02, Hong Leong Building, Singapore 047571
- endTB and endTB-Q Clinical trials: the Sponsor
    - **Médecins Sans Frontières France (MSF),** 14-34, avenue Jean Jaurès, 75019 Paris,

To exercise their rights over their personal data, the participants may follow the procedure set out in the section 3.10 of this policy.

For other questions, Médecins sans Frontières France DPO can be contacted by email at the following address: dpo@paris.msf.org

3.2. Which entities are responsible for your data after they are transferred to eDSI?

For eDSI, PIH, MSF France and IRD are acting as joint data controllers for the purposes set out in section 3.5.

MSF is responsible for eDSI data hosting and maintaining the servers that hold the Platform and for preparing/minimizing and sharing the datasets to approved Data Requestors.

PIH is responsible for maintaining the endTB website where information on how the Data Requestors may request access to endTB Data through eDSI are made available, along with information regarding the personal data processing.

IRD is responsible for appointing the eDSI Administrator who will receive the Data Access Request from Data Requestors and communicate with the Data Access Committee, the Steering Committee and with the Data Requestors.

3.3. *Source of data*

If you are a Participant, your personal data has been collected during one of the following endTB studies:

- **The endTB observational study**, which is a multicenter, prospective observational cohort looking at the effectiveness and the safety of MDR-TB treatment regimens containing bedaquiline and/or delamanid in 17 countries where enrollment was carried out from April 2015 until December 2019:

  - PIH sites: Democratic People's Republic of Korea, Ethiopia, Kazakhstan, Lesotho, Peru, Haiti,
  - MSF France sites: Armenia, Georgia, Kenya
  - MSF Holland sites: Belarus, Myanmar
  - MSF Switzerland sites: Kyrgyzstan
  - IRD sites: Bangladesh, Indonesia, Pakistan, South Africa, Vietnam
- **The endTB clinical trial (fluoroquinolone-susceptible MDR-TB)**, which was Sponsored by MSF France and consisted in testing five new, all oral, 9-month regimens compared to the current standard of care in 7 countries where enrollment was carried out from February 2017 until October 2021:
  - PIH sites: Kazakhstan, Lesotho, Peru
  - MSF France sites: Georgia
  - MSF Belgium sites: India, South Africa
  - IRD sites: Pakistan
- **The endTB-Q clinical trial (fluoroquinolone-resistant MDR-TB)**, which was Sponsored by MSF France and consisted in testing a new, all oral regimen compared to the current standard of care in 6 counties where enrollment was carried out between April 2020 and March 2023:
  - PIH sites: Kazakhstan, Lesotho, Peru
  - MSF Belgium site: India
  - IRD sites: Pakistan
  - University of California San Francisco sites: Vietnam

3.4. *Type of data*

PIH, MSF and IRD may process the following type of data about the Participants depending on the exact information collected during the observational Study, endTB and endTB-Q clinical trials:

- Identification and characteristics (for instance: pseudonymous identifier, age group, gender, height, weight, etc.)
- Lifestyle (alcohol consumption – when collected, etc.)
- Professional life (unemployed, etc.)
- Health data, such as:
  - Medical analysis or examination results, sample analysis results
  - Medical personal or family history, illnesses or associated events
  - Treatment, medical prescription, study drugs, non-study drugs, concomitant medication
  - Diagnosis, medical or paramedical observation
  - Data collected from medical devices
  - HCV Genotyping
  - Interval between dates associated with the conduct of the clinical trial
  - Actions taken during the clinical trial
  - Data related to adverse effects
  - Treatment outcome
  - Pregnancy status
  - Mental health assessment

Particular attention is paid on participants' health data. Strong security measures are implemented to ensure their confidentiality and security considering the sensitivity of such information. Health data is

collected and processed by the data controllers in the public interest to improve care for MDR-TB patients.

3.5. *Purposes of the processing of your data*

Participants' personal data has been collected and processed for the following purposes:

- Collection and analyses of data in the frame of the observational study and the clinical trials;
- Further data sharing after dataset deidentification and minimization, including sharing through the eDSI platform, to develop and promote research on treatment and diagnosis of drug-resistant TB.

In the Platform, Participants' personal data are pseudonymized (all direct identifiers have been carefully removed) and securely hosted to be shared with researchers for further research projects to help understanding MDR-TB better and improve patients' care with more suitable treatment. Participants' personal data are only shared with researchers priorly approved by the Data Access Committee.

Legal basis: These processing activities are based on the legitimate interests of the data controllers to promote research on treatment and diagnosis on DR-TB and improve care for MDR/RR-TB patients.

3.6. Who are the recipients of your data?

Participants' personal data is processed by authorized staff of the data controllers MSF, PIH and IRD to conduct the endTB studies and analyze data.

In eDSI, before MSF can prepare and share the datasets to approved Data Requestors, the following data processors are also contributing:

- Harvard Medical School and Epicentre are in charge of deidentifying the datasets from the observational study and the clinical trials respectively, and of uploading them into the Platform;
- Microsoft Azure as the hosting provider for the Platform;
- MSF Shared IT Services for maintenance activities on the Platform infrastructure.

As part of eDSI, pseudonymized Participants' personal data will be shared with Data Requestors whose research project has been approved by the Data Access Committee to conduct further research and analysis on treatment and diagnosis on DR-TB.

Outside of eDSI, pseudonymized Participants' personal data will be shared with other institutions, such as the World Health Organization or universities, including for the purpose of WHO guidelines revisions.

In any case, data are highly deidentified before data transfer/ sharing, with no direct identifiers being shared. Datasets are also minimized to what is necessary for the approved research project.

3.7. Where is your data stored and in which countries is it transferred?

As part of eDSI, Participants' personal data are stored in servers located in the European Union. Participants' personal data may be transferred outside European Union when shared with Data Requestors whose research project has been approved by the Data Access Committee. In such case, the approved Data Requestor and data controllers will enter into the European Commission's Standard contractual clauses for international transfers. Moreover, particular attention will be paid on the security measures applied by the recipient and appropriate safeguards will be implemented to ensure a secure data transfer.

Outside of eDSI, Participants' personal data from the original studies/ trials are stored in France for MSF data from the observational study and for the clinical trials; in the US for PIH and IRD data from the observational study; The consolidated dataset for the observational study is stored by HMS in the US.

3.8. How long is your data kept?

Participants' personal data will not be kept for longer than is necessary to achieve the purposes set out in section 3.5.

Participants' personal data will be stored outside of the Platform for the retention period set out in the respective research protocol (observational study or clinical trials). Data retention periods are determined according to the applicable legal obligations. Participants' personal data is securely retained and stored during their retention period, and they might be archived if data controllers are legally required to keep them for a longer period.

For eDSI, it may depend on the data controllers' operational needs to manage the Platform. In any case, Participants' personal data may be stored in the Platform for up to ten years before being deleted. Once deleted from the Platform, Participants' data will be kept up to 180 days in backups before being automatically destroyed.

3.9. How is your data secured?

Appropriate technical and organizational measures are implemented to protect Participants' personal data from loss, alteration or unauthorized disclosure.

For eDSI in particular, the following measures are implemented for the Platform:

- Pseudonymisation of Participants' data;
- Platform network segmentation;
- Filtering measures for network traffic;
- Encryption measures for data flows;
- Strict access management policy;
- Strong authentication procedure;
- Physical access control to the servers;
- History logs;
- Regular backups;
- Data Requestors' security assessment;
- Personal data and security training for staff involved in the data processing and/or management of the Platform.

3.10. How can Participants exercise their rights?

Participants' may exercise the rights described in section 2 (access, rectification, deletion, restriction, objection) by email by contacting endTB.ClinicalTrial@paris.msf.org.

Participants' shall ensure that they include the following information in their request:

- The right(s) they want to exercise
- Their patient ID, if they still have it
- The study and country in which they got enrolled.

4. Requestors' data

4.1 Which entities are responsible for your data?

The following entities are joint data controller, jointly responsible for your data: PIH, MSF France, IRD.

4.2 Source of data

If you are a Data Requestor, your personal data has been collected directly from you when you sent your Data Access Request to the eDSI Administrator.

4.3 Type of data

PIH, MSF and IRD process the following data about Data Requestors:

- Identification data (e.g. title, first name, surname, ORCID ID, co-Data Requestors)
- Contact details (e.g. email address, phone number)
- Professional information (e.g. CV, Institution name, position, department)
- Information relating to the proposed research.

4.4 *Purposes of the processing of your data*

Data Requestors' personal data is collected and processed by the data controllers to:

- Communicate with the Data Requestors on their Data Access Request;
- Publish the application status on the endTB website;

Legal basis: This processing activities are based on the legitimate interests of the data controllers to securely share endTB Data to promote research on treatment and diagnosis on DR-TB.

Data Requestors' personal data is also collected and processed by the data controllers to:

- Manage and review the Data Access Request submitted to the Data Access Committee;
- Establish the Data Access Agreement when the Data Access Request is approved;
- Ensure the security of the endTB Data as agreed in the Data Access Agreement;
- Monitor compliance with contractual commitments taken in the Data Access Agreement.

Legal basis: This processing activities are based on the performance of the contract established with the approved Data Requestors or for pre-contractual measures taken at Requestors' request.

4.5 Who are the recipients of your data?

Data Requestors' personal data is processed by authorized staff of the data controllers MSF, PIH and IRD and by the following data processors and recipients:

- the eDSI Administrator to manage the Data Access Request, communicate with the Data Requestors and prepare the Data Access Agreement;
- the Data Access Committee to review the request and approve or not the data sharing;
- Zapier to manage Data Access Request;
- Microsoft 365 to manage Data Access Request;
- the data controllers to approve and monitor the implementation of the Data Access Agreement.

Note that the details of all applications pending review or approved will be made publicly available on the endTB website. The information to be publicly disclosed is mentioned within the Data Access Request template.

4.6 Where is your data stored and in which countries is it transferred?

Data Requestors' personal data will be transferred with an appropriate framework outside European Union to manage Data Access Requests, in particular it will be transferred in the United States. Such appropriate frameworks include European Commission's adequacy decisions or Standard contractual clauses for international transfers. When data transfers outside the European Union are not based on these frameworks, they will only occur when a derogation for specific situations as per article 49 of the General Data Protection Regulation is applicable. Indeed, as a derogation, Requestors' personal data will be transferred outside the European Union if it is necessary for pre-contractual measures of for the performance of the Data Access Agreement with the Requestors.

4.7 How long is your data kept?

- Data Requestors' personal data will be retained for the time required to process the request and for ten years after the date of the decision by the Data Access Committee (either approval or rejection).;

4.8 How is your data secured?

Appropriate technical and organizational measures are implemented to protect Requestors' personal data from loss, alteration or unauthorized disclosure.

4.9 How can Requestors exercise their rights?

Data Requestors may exercise the rights described in section 2 (access, rectification, deletion, restriction, objection) by email by contacting edsi.administrator@ird.global

Data Requestors shall ensure that they include the following information in their request:

- The right(s) they want to exercise
- Their name and surname.

5. Committee members' data

5.1. Which entities are responsible for your data?

The following entities are joint data controller, jointly responsible for your data: PIH, MSF France, IRD.

5.2. Source of data

If you are a Committee member, your personal data has been collected directly from you when you sent your registration documentation to the eDSI Administrator or eDSI Project Management Team.

5.3. Type of data

PIH, MSF and IRD process the following data about Committees members:

- Identification data (e.g. title, first name, surname, photo)
- Contact details (e.g. email address, phone number)
- Professional information (e.g. Institution name, position, department)
- Information relating to your potential conflicts of interests.

5.4. Purposes of the processing of your data

Committee members' personal data is collected and processed by the data controllers to:

- Manage eDSI Committees;
- Communicate with the Committee members;
- Publish the Committees membership on the endTB website;

Legal basis: This processing activities are based on the legitimate interests of the data controllers to properly and transparently assess the Data Access Requests in order to share endTB Data to promote research on treatment and diagnosis on DR-TB.

5.5. Who are the recipients of your data?

Committee members' personal data is processed by authorized staff of the data controllers MSF, PIH and IRD and by the following data processors and recipients:

- the eDSI Administrator to manage the eDSI Committees;
- Microsoft 365 to manage the eDSI Committees.

Note that the Committees membership will be made publicly available on the endTB website including identification data and professional information.

5.6. Where is your data stored and in which countries is it transferred?

Committee members' personal data will be transferred with an appropriate framework outside European Union to manage Data Access Requests, in particular it will be transferred in the United States. Such appropriate frameworks include European Commission's adequacy decisions or Standard contractual clauses for international transfers. When data transfers outside the European Union are not based on these frameworks, they will only occur when a derogation for specific situations as per article 49 of the General Data Protection Regulation is applicable. Indeed, as a derogation, Committees members' personal data will be transferred outside the European Union when such transfer is occasional, limited and necessary for the legitimate interest of PIH, IRD and MSF to ensure that Data Access Requests are properly and transparently assessed in order to share endTB Data to promote research on treatment and diagnosis on DR-TB.

5.7. How long is your data kept?

Committee members personal data will be retained the duration of ten years from the end of the membership.

5.8. How is your data secured?

Appropriate technical and organizational measures are implemented to protect Committees members' personal data from loss, alteration or unauthorized disclosure.

5.9. How can Requestors exercise their rights?

Committee members may exercise the rights described in section 2 (access, rectification, deletion, restriction, objection) by email by contacting edsi.administrator@ird.global.

Committee members shall ensure that they include the following information in their request:

- The right(s) they want to exercise
- The Committee they are a member of
- Their name and surname.

6. Interested Individuals' data

2.1. Which entity is responsible for your data?

The following entity is independently responsible for your data: PIH.

2.2. Source of data

If you are an Interested Individual, your personal data has been collected directly from you when you send your request for information through the endTB website form.

2.3. Type of data

PIH processes the following data about Data Requestors:

- Identification data (e.g. title, first name, surname)
- Contact details (e.g. email address)
- Professional information (e.g. Institution name, position)

2.4. Purposes of the processing of your data

Data Requestors' personal data is collected and processed by the data controller to:

- Identify and communicate back with people potentially interested to become Data Requestors.

2.5. Who are the recipients of your data?

PIH will share your data with the eDSI Administrator, other data collected from the endTB website may be shared with website services providers in accordance with the endTB website privacy Policy, the endTB cookie policy and the endTB website Terms of Use.

2.6. Where is your data stored and in which countries is it transferred?

Your data will be stored in the United States and transferred to MSF in the European Union (EU) or to IRD located outside of the EU.

2.7. How long is your data kept?

Your data will be kept for maximum 7 years following the submission of your request for additional information about eDSI data.

2.8. How is your data secured?

Appropriate technical and organizational measures are implemented to protect the Requestor's personal data from loss, alteration or unauthorized disclosure.

2.9. How can Interested Individuals exercise their rights?

Interested Individuals may exercise the rights described in section 2 (access, rectification, deletion, restriction, objection) by email by contacting edsi.administrator@ird.global.

Interested Individuals shall ensure that they include the following information in their request:

- The right(s) they want to exercise
- Their name and surname.