

**WHO TB-IPD PLATFORM
DATA ACCESS AGREEMENT**

This Data Access Agreement (DAA) is made on **[INSERT DATE]**

BETWEEN:

(1) **UNIVERSITY COLLEGE LONDON**, a body corporate established by Royal Charter with company number RC000631 and whose principal place of business is Gower Street, London WC1E 6BT (**Data Curator**);

AND

(2) **[INSERT]** whose principal place of business is at **[INSERT]** (**Data Analyst**).

BACKGROUND

- A. The Data Curator has entered into an arrangement with the WHO under which the Data Curator has agreed to act as the data curator of a global anonymised individual patient data platform for tuberculosis treatment (**TB-IPD Platform**) for and on behalf of the WHO. The Data Curator's role includes setting up, hosting, managing and providing access to the TB-IPD Platform for and on behalf of the WHO.
- B. The TB-IPD Platform pools effectively anonymised individual patient data provided to the Data Curator from a range of relevant global resources, including researchers, local and national databases relating to TB and development and public health research and surveillance projects. Where appropriate, some types of data, will not be pooled but held within the platform.
- C. The Data Curator will make the data held in the TB-IPD Platform available for analysis by approved individuals and organisations, including the Data Analyst, for the primary purpose of informing future TB treatment guidelines. The Steering Committee will have responsibility for oversight of the TB-IPD.
- D. This DAA sets out the terms and conditions upon which the Data Curator will make available to the Data Analyst, and the Data Analyst will use, the data held within the TB-IPD Platform.

Signed for and on behalf of the Data Curator

Signature	
Name of Authorised Signatory	
Date	

Signed for and on behalf of the Data Analyst

Signature	
Name of Authorised Signatory	
Date	

IT IS AGREED:

1. DEFINITIONS AND INTERPRETATION

In this DAA (including the Background):

1.1. Definitions

1.1.1. the following words and expressions have the following meanings:

Approved Project	a project to be undertaken by the Data Analyst involving analysis of the Project Data for the Purpose and in respect of which (i) the Data Analyst has submitted a Data Access Request Form to the Data Accs Committee; and (ii) the Data Access Committee has approved in writing the Data Analyst's access to and analysis of the Project Data on the basis set out in this DAA as well as the agreed Data Access Request Form;
Business Day	a day other than a Saturday or Sunday or a bank holiday or public holiday in England and Wales;
Confidential Information	any information or materials (whether in writing, electronic form, oral or otherwise) concerning the affairs of one Party that the other Party obtains or receives as a result of the discussions leading up to or the entering into or the performance of this DAA that is confidential in nature or is marked or identified as confidential at the time of disclosure;
Data	effectively anonymised individual patient data submitted/or to be submitted to the TB-IPD Platform derived from studies of patients with TB;
Data Access Committee	the committee with responsibility for reviewing and accepting or rejecting applications for data access. It will be comprised of a combination of Data Contributors, the WHO and UCL, and other stakeholders as deemed appropriate;
Data Access Request Form	a written request for access to the Data submitted to the Data Access Committee by the Data Analyst which shall include details of the research objectives, analytical methodology, data storage, ethics approval, funding and publication plans;
Data Contributor	an individual or entity who contributes Data to the TB-IPD Platform;
Derived Data	any data derived from use or analysis of the Project Data in the course of the research performed by the Data Analyst (and / or the Named Delegates) and any collections of data, datasets and databases housing the foregoing and any database rights in or relating thereto;
Effectively anonymised	the term 'effectively anonymised' refers to data which: (i) does not relate to an identified or identifiable individual; or (ii) has been rendered anonymous in such a way that individuals are not (or are no longer) identifiable;

Enriched Data	any new or additional data that is collected by the Data Analyst (and / or the Named Delegates) for the purpose of their research and which incorporates the Project Data (or any part thereof) and any collections of data, datasets and databases housing the foregoing and any database rights in or relating thereto;
Intellectual Property Rights	means any and all patents, copyright, registered designs, design rights, trade marks, database rights, regulatory rights in data exclusivity and market exclusivity, know how and any other intellectual property rights anywhere in the world in each case whether registered or unregistered, including any and all applications for such rights and the right to make such applications and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;
Named Delegates	the individuals of the Data Analyst as named in Appendix 1 who are granted access to the Project Data in accordance with this DAA and a final agreed Data Access Request Form;
Parties	the Data Curator and the Data Analyst;
Personal Data	any information relating to an identified or identifiable living individual;
Project Data	Data that the Data Curator provides to the Data Analyst for the purposes of undertaking the Approved Project;
Purpose	(a) to inform, develop, review and/or update: (i) public health and/or clinical guidance in connection with TB treatment which is or may be published by WHO on its website(s) and/or in its printed, electronic or other publications, including the <i>WHO consolidated guidelines on TB treatment</i> ; (ii) WHO's internal research, scientific or public health prioritisation purposes, and/or (iii) any activities or materials relating to any of the foregoing; and/or (b) for research and scientific purposes by (i) educational or research institutions, country programmes and/or non-governmental institutions, and/or (ii) other organisations authorised by the Data Access Committee from time to time;
Research	the research performed by the Data Analyst (and/or its Named Delegates);
Research Results	the results of the Research using the Project Data, including all Intellectual Property Rights, Derived Data and Enriched Data that are generated, or otherwise collected, arising, identified or first reduced to practice, in the course of research (but excluding the Project Data itself);
Steering Committee	the committee with responsibility for oversight and coordination of the TB-IPD Platform;
TB	tuberculosis;
TB-IPD Platform	has the meaning given to it in paragraph A of the Background section of this DAA; and

WHO

World Health Organization;

1.2. Interpretation

- 1.2.1. words importing the singular shall include the plural and vice versa, words importing a gender shall include all genders and words importing persons shall include bodies corporate, unincorporated associations and partnerships;
- 1.2.2. references to Clauses and Schedules are references to clauses and schedules of this DAA;
- 1.2.3. the Schedules form part of this DAA and shall have full force and effect as if expressly set out in the body of this DAA and any reference to this DAA shall include the Schedules;
- 1.2.4. Clause and Schedule headings are included for convenience only and shall not affect the interpretation of this DAA;
- 1.2.5. any reference to persons includes natural persons, firms, partnerships, companies, corporations, associations, organisations, governments, states, governmental or state agencies, foundations and trusts (in each case whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);
- 1.2.6. a reference to a statute or statutory provision is a reference to that statute or statutory provision and to all orders, regulations, instruments or other subordinate legislation made under the relevant statute;
- 1.2.7. any reference to a statute, statutory provision, subordinate legislation, code or guideline (legislation) is a reference to such legislation as amended and in force from time to time and to any legislation which re-enacts or consolidates (with or without modification) any such legislation; and
- 1.2.8. any phrase introduced by the terms including, include, in particular, for example or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

2. PURPOSE AND SCOPE

- 2.1. The purpose of this DAA is to govern the Data Analyst's access to and use of Data in respect of which it is not the Data Contributor.
- 2.2. The Data Analyst shall only be entitled to access the TB-IPD Platform and use Data in respect of which it is not the Data Contributor in relation to Approved Projects.
- 2.3. The Data Analyst shall not use, or allow any other person to use, Data in respect of which it is not the Data Contributor otherwise than as expressly permitted under this DAA.

3. DATA ACCESS REQUEST FORM AND APPROVED PROJECTS

- 3.1. The Data Analyst shall request access to the Data in relation to a project to be undertaken by the Data Analyst by completing in full and submitting to the Data Access Committee a Data Access Request Form.
- 3.2. In submitting a Data Access Request Form, the Data Analyst shall ensure that it requests access only to those parts of the Data to which it needs access in order to carry out the project to which the Data Request Form relates.
- 3.3. The Data Access Committee decides, at its sole discretion, whether or not to make Data available to the Data Analyst pursuant to a Data Access Request Form. The Data Access Committee will inform the Data Analyst of its decision in writing and, as part of any approval, will provide the Data Analyst the final agreed version of their completed Data Access Request Form.
- 3.4. In respect of each Approved Project:
 - (a) the Data Curator shall make available to the Data Analyst, via remote access to the TB-IPD Platform the Project Data requested in the final agreed Data Access Request Form;

- (b) the Data Analyst shall use the Project Data solely for the purposes of the undertaking the Approved Project, subject to and in accordance with the terms of this DAA; and
- (c) the Data Analyst shall not use the Project Data for any other purpose, including in relation to other projects undertaken, or to be undertaken, by the Data Analyst.

4. RESPONSIBILITIES OF THE DATA ANALYST

4.1. In respect of each Approved Project, the Data Analyst shall:

- (a) carry out the Approved Project only on the basis set out in the final agreed Data Access Request Form;
- (b) ensure that:
 - (i) the Approved Project is carried out only by the Data Analyst or the Named Delegate(s);
 - (ii) Project Data are only used by the Data Analyst and the Named Delegates for purposes of the Approved Project and are not used for any other purpose or provided to any other person; and
 - (iii) each Named Delegate has been informed of the Data Analyst's obligations under this DAA (including its obligations of confidentiality in respect of the Project Data and the permitted scope of the Approved Project), and has undertaken to comply with such obligations; and
 - (iv) it and the Named Delegates take all appropriate measures to protect the security and confidentiality of the Project Data.

4.2. In respect of each Approved Project, the Data Analyst shall ensure that the Project Data:

- (a) is not used for any commercial purpose or otherwise in the promotion of a commercial enterprise and/or its products or services;
- (b) is only accessed by Named Delegates on a need-to-know basis; and
- (c) is not sold or otherwise transferred to or discussed with any third party.

4.3. In respect of each Approved Project, the Data Analyst shall ensure that the:

- (a) Approved Project is conducted in accordance with all applicable laws and regulations; and
- (b) All Project Data shall be stored only on a computer system to which access is password protected for an account that can only be accessed by the Data Analyst and Named Delegates, and for which only Data Analyst and Named Delegates knows the password.
- (c) The medium on which the Project Data is supplied to Data Analyst shall be stored by the Data Analyst in a secure location that is accessible only to Data Analyst and Named Delegates.
- (d) Current anti-virus, anti-malware and encryption software shall be installed on all systems and hardware being used to store or access Project Data. For the avoidance of doubt, any portable hardware device being used in conjunction with the Project Data must be encrypted.
- (e) The Data Analyst and Named Delegates shall not transfer the Project Data nor allow it to be transferred.
- (f) Data Analyst and Named Delegates shall not transfer, or allow to be transferred, Project Data over the internet.

- (g) Data Analyst and Named Delegates shall not store, or allow to be stored, Project Data in a folder that is shared or otherwise made accessible to anyone, other than Data Analyst and Named Delegates.

5. OBLIGATIONS OF DATA CURATOR

- 5.1. In respect of each Approved Project, the Data Curator shall:
 - (a) facilitate secure, remote access to the Project Data by the Data Analyst and in a manner which does not require the Data Analyst and Named Delegates to be physically present at any premises of the Data Curator;
 - (b) be entitled to suspend the Data Analyst's access to the Project Data at any time at its discretion; and
 - (c) terminate the Data Analyst's access to the Project Data with immediate effect where the Data Analyst is in breach of its obligations under this DAA.
- 5.2. The Data Analyst acknowledges and agrees that access to and use of Project Data is for Approved Projects only and such access and use is made available by the Data Curator free of charge on an "as is" and "as available" basis. The Data Curator makes no representations, and gives no warranties or undertakings, in respect of the Data or its availability. All warranties, conditions, terms, undertakings and obligations implied by statute, common law, custom, trade usage, course of dealing or otherwise are hereby excluded to the fullest extent permitted by law.

6. INTELLECTUAL PROPERTY RIGHTS

- 6.1. The Data Analyst acknowledges that all Intellectual Property Rights subsisting in the Data shall be owned by and remain with the Data Contributor at all times and the Data Analyst shall not acquire any rights or interest in such Intellectual Property Rights except as expressly set out in this DAA.
- 6.2. The Parties acknowledge and agree that the Intellectual Property Rights in the Research Results shall be owned by the Data Analyst. The Data Analyst grants to the Data Curator a perpetual, irrevocable, fully-paid up, worldwide, non-exclusive and royalty-free licence, with a right to sublicense, to all Intellectual Property Rights in the Research Results for all purposes as may be required by the Data Curator.

7. PUBLICATIONS

- 7.1. The Data Curator may publish on its website materials received from the Data Analyst including:
 - (a) copies of any written reports received from the Data Analyst describing their use of the Project Data and/or any benefits derived therefrom; and
 - (b) any Research Results,and in such circumstances the Data Curator shall give the Data Analyst due attribution.
- 7.2. Subject to Clause 7.3, the Data Curator acknowledges that the Data Analyst may publish the Research Results without the consent of the Data Curator.
- 7.3. The Data Analyst shall: (a) acknowledge the use of the TB-IPD in all official publications and outputs relating to the Research Results in the manner prescribed by the Data Curator; (b) inform the Data Curator of all official publications and outputs relating to the Research Results; and (c) give the Data Contributor due attribution in all publications relating to the Research Results.

8. DATA PROTECTION

- 8.1. The Parties acknowledge that the TB-IPD Platform is intended to contain only effectively anonymised data and that the Data must not contain any Personal Data.
- 8.2. The TB-IPD Platform will pool individual patient data which is effectively anonymised. The term 'effectively anonymised' refers to data which: (i) does not relate to an identified or identifiable individual; or (ii) has been rendered anonymous in such a way that individuals are not (or are no longer) identifiable. Data held by the Data Curator within the TB-IPD shall also be stored securely so that the risk of indirect re-identification is very low. The Data Analyst shall not, and shall ensure that their Named Delegates shall not, attempt to re-identify, trace or contact any individual, or use the Data in any way that could infringe the rights of any individuals or otherwise adversely affect them.

9. DATA SECURITY

- 9.1. The Data Analyst shall notify the Data Curator without undue delay after becoming aware of any Data Breach and provide such co-operation and assistance as the Data Curator may require in connection with any Data Breach and the prevention of any unauthorised use of the Data.

10. RETURN AND DELETION OF DATA

- 10.1. The Approved Project is completed when the research stated in the Data Access Request Form is completed, or at the end of the term as defined in the Data Access Request Form.
- 10.2. On completion or termination of an Approved Project), the Data Analyst's right to use the Project Data shall automatically cease.
- 10.3. In relation to each Approved Project in respect of which the Data Analyst's right to use the Project Data has ceased, the Data Analyst shall promptly and securely delete or destroy any copies of the Project Data in its possession or under its control with the exception of the Research Results.

11. PUBLIC STATEMENTS

- 11.1. Other than as expressly required by clause 7, the Data Analyst shall not use WHO's and/or the Data Curator's name or logo in connection with the use of the Data or the Approved Project or otherwise imply that WHO and/or the Data Curator endorses the Approved Project or its use of the Data.

12. CONFIDENTIALITY

- 12.1. Each Party shall hold in confidence all Confidential Information obtained from the other Party. Neither Party shall disclose to any third party any Confidential Information in relation to the other Party save as expressly permitted by this DAA or with the prior express written permission of the other Party.
- 12.2. The provisions of Clause 12.1 shall not apply to any information which:
- (a) is or becomes public knowledge other than by breach of this Clause 12;
 - (b) is already in the possession of a Party without restriction in relation to disclosure before the date of its receipt from the other Party; or
 - (c) is received from a third party who lawfully acquired or developed it and who is under no obligation restricting its disclosure.
- 12.3. A Party may disclose Confidential Information in relation to the other Party:
- (a) except as otherwise expressly stated in this DAA, to those of its officers, employees, professional advisers, parent or subsidiary companies, or agents or sub-contractors as may be reasonably necessary for the purpose of fulfilling its obligations under this DAA or, in the case of professional advisors, for use in their professional capacity, provided that before any such disclosure that Party shall make such officers, employees, professional advisers, parent or subsidiary companies, or agents or sub-contractors aware of its obligations of confidentiality under this DAA and shall at all times procure compliance by those persons with them; or

(b) where such disclosure is required by any law, court order or competent regulatory authority.

12.4. Without prejudice to the other rights of the disclosing Party, in the event of unauthorised disclosure or use of its Confidential Information occurring directly or indirectly through disclosure made to the receiving Party, the receiving Party shall (as soon as it becomes aware of the same) notify the disclosing Party of such unauthorised disclosure and use all reasonable endeavours to assist the disclosing Party in recovering and preventing the use of, dissemination, sale or other disposal of such Confidential Information.

12.5. Unless required to do so by applicable laws, neither Party shall make public the details of the terms or the operation or circumstances of termination of this DAA without the other Party's prior written consent.

13. INDEMNITY

13.1. The Data Analyst shall indemnify the Data Curator from and against all costs (including the cost of bringing or defending any legal action), damages, losses and expenses suffered or incurred by the Data Curator arising out of or in connection with any breach by the Data Analyst of its obligations under this DAA.

14. LIABILITY

14.1. To the extent permitted by applicable law, the Data Curator shall not be liable to the Data Analyst for:

(a) any loss of profit, loss of business opportunity, loss of anticipated revenue or savings, loss of or damage to data and/or loss of or damage to goodwill arising out of or in connection with this DAA; or

(b) any indirect or consequential loss or damage arising out of or in connection with this DAA.

(c) To the extent permitted by applicable law, the Data Curator's total liability to the Data Analyst under or in connection with this DAA (whether such liability arises under any statute or in contract, tort (including negligence) or otherwise) shall be limited to £25,000.

15. TERM AND TERMINATION

15.1. This DAA shall commence on the date of this DAA and shall continue until terminated in accordance with the terms and conditions of this DAA.

15.2. This DAA shall automatically terminate on the date that the Data Curator ceases to operate the TB-IPD Platform on behalf of the WHO.

15.3. Either Party may terminate this DAA without cause at any time by giving at least 30 days' written notice of such termination to the other Party.

15.4. Either Party may terminate this DAA with immediate effect by giving written notice of such termination to the other Party if the other Party commits a material breach of any of the terms of this DAA and either that breach is not capable of remedy or, if the breach is capable of remedy, the other Party fails to remedy that breach within 14 days of being notified of the breach.

16. EFFECTS OF TERMINATION

16.1. The termination of this DAA shall not prejudice or affect any right of action or remedy which shall have accrued up to the date of termination.

16.2. On termination of this DAA, the Data Analyst's rights to access and use the TB-IPD Platform and the Data shall automatically cease. In particular, in respect of each Approved Project in existence as at the date of termination of this DAA, this means the Data Analyst's right to use the Project Data shall automatically cease on the date of termination of this DAA.

16.3. Clauses 1, 4 to 8 (inclusive), 11 to 14 (inclusive) and 16 to 1812.5 (inclusive) shall survive termination of this DAA and shall continue to apply as shall any other provision which by its nature is intended to survive termination.

17. **NOTICES**

17.1. Any notice required by this DAA to be given by either Party to the other shall be in writing and shall be delivered by hand or sent by recorded delivery post or e-mail to the other Party at the address set out below or otherwise notified by the other Party in accordance with this Clause 17 from time to time.

Data Curator	Data Analyst
The Dean, UCL School of Life and Medical Sciences Gower Street London WC1E 6BT Tel: +44 (0) 2076792000 Email: fphs.pa@ucl.ac.uk	[insert]

17.2. Any notice served under this DAA shall be deemed to have been received (i) if delivered by hand, immediately upon delivery during the other Party's usual business hours; (ii) if sent by recorded delivery post, two Business Days following delivery; or (iii) if sent by e-mail, when it is actually received by the recipient.

18. **GENERAL**

18.1. Neither Party shall assign, novate, sub-contract or otherwise dispose of any or all of its rights and obligations under this DAA without the prior written consent of the other Party.

18.2. A person who is not a party to this DAA shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this DAA.

18.3. This DAA, together with the documents referred to in it, constitute the entire agreement between the Parties in respect of its subject matter and supersede all previous negotiations, agreements and commitments with respect thereto.

18.4. This DAA shall not be construed as giving rise to the relationship of principal and agent (save as otherwise expressly provided herein) or partnership or joint venture.

18.5. If any provision of this DAA or the application thereof to any Party or circumstance shall be declared void, illegal or unenforceable, the remainder of this DAA shall be valid and enforceable to the extent permitted by applicable law. In such event, the Parties shall use their best efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by applicable law, achieves the purposes intended under the invalid or unenforceable provision.

18.6. No delay or failure by a Party in exercising or enforcing any right or remedy under the terms and conditions of this DAA will be deemed to be a waiver of any such right or remedy, nor will that failure operate to bar the exercise or enforcement of such right or remedy at any future time.

18.7. A change to this DAA will only be effective if it is recorded in writing and signed by an authorised representative of each of the Parties.

18.8. This DAA may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

18.9. This DAA and any dispute or claim arising out of or in connection with it or its subject matter or formation (including, without limitation, non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of England and Wales.

18.10. Each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this DAA and its subject matter or formation (including non-contractual disputes or claims).

Appendix 1

Names of Delegates of the Data Analyst granted access to Project Data
