IMI2 GA853989 - ERA4TB

European Regimen Accelerator for Tuberculosis

WP1 – Data and Pipeline Management

D1.6 Availability of existing preclinical and clinical TB datasets – Interim Report

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Abstract

This document covers the current status on the availability of legacy clinical and preclinical datasets generated prior to the existence of the ERA4TB Consortium or in parallel, that have been made available

to ERA4TB partners. This report also covers the tools/technologies available or in development to make this data available to ERA4TB beneficiaries, including future or forecasted activities on this topic

Further progress or developments surrounding this subject matter will be reported as part of deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report).

1 Introduction

To support the objectives of the ERA4TB, and in addition to the data generated as part of the asset progression pipeline within this project, both legacy clinical and preclinical data will be acquired from

various sources and made available to authorised partners with ERA4TB, most notably data consumer partners such the data modelling work package (**WP5**).

All legacy data that has been received by C-Path (WP1) to date and in the future, are processed to conform to the expected data structures for the target platform in question (e.g., DDIM and/or Data Archive). The availability of both current and future sources of legacy data will support the project by:

- Providing additional data to support Data Modelling (**WP5**), Analyses and Machine Learning efforts (**WP1**)
- Inform pipeline management of assets in cases where assessments/experiments have already been conducted (or are conducted in parallel outside of the ERA4TB platform) by the asset owner of a specific compound, and the data in question has been shared for processing.

For the purpose of clarity, and as per Section 7 of the Initial Data Management Plan (D1.2), legacy data is defined as:

- Historical “non-asset” data from external contributors
- In-Kind contributions of “non-asset” preclinical/clinical data
- In-Kind contributions of historical data from asset owner

Future procurement of new sources of legacy data (both clinical and preclinical) are expected to follow the procedures as outlined in the SOP for Data Collaboration Agreements (D1.5). Any deviations to this will be documented in deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report)

2 Clinical Data Access

2.1 TB-PACTS Database

Under funding from ERA4TB the pre-existent TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS) managed by C-Path was further enhanced and subsequently migrated to the Data Archive platform which is hosted on EU based AWS servers (hosted in Stockholm, Sweden).

The Data Archive platform has been set up to support project objective O1.7 (Preservation of clinical and preclinical data for long-term archive, secondary research, and regulatory purposes.)

The TB-PACTS database within the Data Archive supports the aggregation of clinical trial data in CDISC SDTM data structure. All approved users (both ERA4TB partners and external researchers) can access and download the aggregated datasets in both csv and SAS formats for authorised research purposes. Further details on the Data Archive platform can be found within the User Guide document.

The information below summarises the activities conducted to enable the set up and availability of TB-PACTS data to partners within ERA4TB.

Table 1. Data Archive/TB - PACTS Activity Timeline

Activity	Activity Period	Activity Contributor(s)	Additional Comments
Data Archive Installation	Jan-20	C-Path	Test instance of the Data Archive platform installed on AWS servers based in Stockholm, Sweden.
Data Archive Installation Updates/Enhancement	Mar – Nov 2020	C-Path	System updates/improvements applied and tested by C-PATH. Production version configuration completed 13th November 2020.
CDC Study 26 Data Processing	Sep-Nov 2020	C-Path	Curation, transformation, and integration of study data into TB-PACTS Data
Use Case / User Profile Consensus	Apr – Dec 2020	All	Document describing user access process and roles for DDIM and Data Archive. Document was shared cross-work package for alignment and consensus.
CDC Studies 22, 27, 28	Nov 2020 – Feb 2021	C-Path	Curation, transformation, and integration of study data into TB-PACTS Data
Data Archive Online Application portal testing/Updates	Feb-Mar 2021	C-Path	Testing updates based on user access process requirements consensus received.
Final TB-PACTS data migration	Apr-21	C-Path	Latest data migrated from US instance of TB-PACTS
ERA4TB Partner Accounts Creation	Apr-21	C-Path	Accounts created for authorised ERA4TB partners as per list provide by Synapse. Accounts set up in period 20th – 26th April
Nix-TB Study	Mar – May 2021	C-Path	Curation, transformation, and integration of study data into TB-PACTS Data
TB-PACTS Steering Committee Authorisation	May-21	C-Path	Authorisation received from TB-PACTS SC to enable fast-tracking of ERA4TB authorised members on 17th May
ERA4TB Account Activation	May-21	C-Path	All accounts activated on 18th May based on TB-PACTS SC approval being received
STREAM1 Study	Jul – Aug 21	C-Path	Curation, transformation, and integration of study data into TB-PACTS Data

2.2 Current Available Data

The table below, provides the current list of available clinical trials studies that have been standardised and integrated into the TB-PACTS database as of the date of this report. The listed studies are available to all users who have been approved access to TB-PACTS including authorised ERA4TB partners.

Table 2. TB-PACTS Clinical Studies List

Contributor	Study ID	Study Short Name	Study Title	Treatment Regimen
British Medical Research Council	TB-1025	MRC East African 2nd Study (T) 1972	A Short-Course (6-Month) Treatment in Pulmonary Tuberculosis, East African 2nd Study (T) 1972	Isoniazid, Rifampicin, Pyrazinamide, Streptomycin, Thiacetazone
British Medical Research Council	TB-1026	MRC East African 4th Study (X) 1976	Controlled Clinical Trial of 5 Short-Course (4-Month) Chemotherapy Regimens in Pulmonary Tuberculosis, East African 4th Study (X) 1976	Isoniazid, Rifampicin, Pyrazinamide, Streptomycin
British Medical Research Council	TB-1027	MRC East African 1st Study (R) 1970	Controlled Clinical Trial of 4 Short-Course (6-Month) Regimens of Chemotherapy for Treatment of Pulmonary Tuberculosis, East African Investigation (R) 1970	Isoniazid, Rifampicin, Pyrazinamide, Streptomycin, Thiacetazone
British Medical Research Council	TB-1028	MRC Hong Kong 2nd Short Course 1974	Controlled Trial of 6-Month and 8-Month Regimens in the Treatment of Pulmonary Tuberculosis, Hong Kong 2nd Short Course Investigation 1974	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, Streptomycin
British Medical Research Council	TB-1029	MRC Hong Kong 3rd Short Course 1977	Third Study of Short-Course Chemotherapy in the Treatment of Pulmonary Tuberculosis in Hong Kong, 1977	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, Streptomycin
British Medical Research Council	TB-1030	Jindani Nunn Enarsen 1998	Two 8-month regimens of chemotherapy for treatment of newly diagnosed pulmonary tuberculosis: international multicentre randomised trial	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Case Western Reserve University	TB-1024	Johnson2009_01009	Tuberculosis Treatment Shortening Trial	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Case Western Reserve University	TB-1031	Johnson2006_01553	Early Bactericidal Activity of Linezolid, Gatifloxacin, Levofloxacin, Isoniazid (INH) and Moxifloxacin in HIV Negative Adults with Initial Episodes of Sputum Smear-Positive Pulmonary Tuberculosis	Moxifloxacin, Gatifloxacin, Levofloxacin, Isoniazid

Contributor	Study ID	Study Short Name	Study Title	Treatment Regimen
TB Alliance	TB-1003	PA-824 EBA Low Dose	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis (CL-010)	PA-824 50-200 mg
TB Alliance	TB-1005	TMC207 EBA	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis (TMC207-CL001)	TMC207
TB Alliance	TB-1007	PA-824 EBA High Dose	PA-824-CL-007: Phase IIa Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis	PA-824 200-1200 mg
TB Alliance	TB-1008	NC-001-J-M-Pa-Z	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis With(J-M-Pa-Z) (NC-001)	TMC207, PA-824, Pyrazinamide, Moxifloxacin
TB Alliance	TB-1011	NC-002-M-Pa-Z	Evaluation of 8 Weeks of Treatment with the Combination of Moxifloxacin, PA-824 and Pyrazinamide in Patients with Drug Sensitive and Multi Drug-Resistant Pulmonary Tuberculosis (TB) (NC-002)	Moxifloxacin, PA-824, Pyrazinamide
TB Alliance	TB-1014	NC-003-C-J-Pa-Z	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis with Clofazimine (C)-TMC207 (J)-PA-824 (Pa)-Pyrazinamide (Z) (NC-003)	TMC207, PA-824, Pyrazinamide, Clofazimine
TB Alliance	TB-1015	NC-005	A Phase 2 to Evaluate the Efficacy, Safety and Tolerability of Combinations of Bedaquiline, Moxifloxacin, PA-824 and Pyrazinamide in Adult Subjects with Drug-Sensitive or Multi Drug-Resistant Pulmonary Tuberculosis. (NC-005)	PA-824, Bedaquiline, Moxifloxacin, Pyrazinamide, Isoniazid, Rifampicin, Ethambutol
TB Alliance	TB-1018	Nix-TB-(B-L-Pa)	A Phase 3 Study Assessing the Safety and Efficacy of Bedaquiline Plus PA-824 Plus Linezolid in Subjects with Drug Resistant Pulmonary Tuberculosis	Bedaquiline, Pretomanid, Linezolid

Contributor	Study ID	Study Short Name	Study Title	Treatment Regimen
TB Alliance	TB-1021	REMOX	Controlled Comparison of Two Moxifloxacin Containing Treatment Shortening Regimens in Pulmonary Tuberculosis (REMoxTB)	Moxifloxacin, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
St. Georges University of London	TB-1020	RIFAQUIN	An international multicentre controlled clinical trial to evaluate high dose RIFApentine and a QUINolone in the treatment of pulmonary tuberculosis	Rifapentine, Moxifloxacin, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
U.S. Centers for Disease Control	TB-1001	TBTC Study 22	TBTC Study 22: Efficacy of Once-Weekly Rifapentine and Isoniazid in Treatment of Tuberculosis	Rifapentine and Isoniazid 1x vs. 2x/wk
U.S. Centers for Disease Control	TB-1006	TBTC Study 27	TBTC Study 27: Moxifloxacin vs Ethambutol for TB Treatment	Moxifloxacin vs. Ethambutol
U.S. Centers for Disease Control	TB-1009	TBTC Study 28	TBTC Study 28: Moxifloxacin Versus Isoniazid for TB Treatment	Moxifloxacin vs. Isoniazid
U.S. Centers for Disease Control	TB-1010	TBTC Study 29	TBTC Study 29: Rifapentine During Intensive Phase Tuberculosis (TB) Treatment	Rifapentine 10 mg/kg, Isoniazid, Ethambutol, Pyrazinamide
U.S. Centers for Disease Control	TB-1013	TBTC Study 29X	TBTC Study 29: Rifapentine During Intensive Phase Tuberculosis (TB) Treatment	Rifapentine 10, 15, 20 mg/kg, Isoniazid, Ethambutol, Pyrazinamide
U.S. Centers for Disease Control	TB-1017	TBTC Study 26	TBTC Study 26: Effectiveness and Tolerability of Weekly Rifapentine/Isoniazid for 3 Months Versus Daily Isoniazid for 9 Months for the Treatment of Latent Tuberculosis Infection	Rifapentine, Isoniazid
University College London, Vital Strategies, Inc.	TB-1019	STREAM-TB	The Evaluation of a Standard Treatment Regimen of Anti-tuberculosis Drugs for Patients With MDR-TB (STREAM)	Bedaquiline, Moxifloacin, Levofloxacin, Clofazimine, Kanamycin, Prothionamide, Isoniazid,
World Health Organization	TB-1022	OFLOTUB	A Controlled Trial of a 4-Month Quinolone-Containing Regimen for the Treatment of Pulmonary Tuberculosis	Gatifloxacin, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol

2.3 Partner Access to Data

All ERA4TB partners accounts were created by C-Path in anticipation of fast-tracking approval from the TB-PACTS Steering Committee (SC). All 176 partner accounts were made active and available to all respective users on 18th May 2021. The table below summarises the number of accounts created per partner and the percentage of users who have actively logged into the database at least once.

Access to this data is as per the current terms of the TB-PACTS database which are accepted by users prior to accessing the database in question.

Table 3. TB-PACTS Accounts per Partner

Partner	Partner Short Name	# Users Created	# Users Logged In	% Logged In
Bill and Melinda Gates Foundation	BMGF	14	4	28.57%
Bioaster Foundation de Coopération Scientifique	BAR	13	5	38.46%
Consiglio Nazionale delle Richerche	CNR	2	1	50.00%
Ecole Polytechnique Federale de Lausanne	EPFL	3	2	66.67%
Evotec	EVT	7	7	100.00%
Fondation Innovative Medicines for Tubercolusis	IM4TB	1	1	100.00%
Forschungszentrum Borstel	FZB	10	1	10.00%
GlaxoSmithKline	GSK	24	8	33.33%
ImaBiotech	IBT	4	0	0.00%
Infectious Diseases Models for Innovative Therapies	IDMIT	6	3	50.00%
Institute Pasteur de Lille Foundation	IPL	8	2	25.00%
Institute Pasteur Paris	IPP	13	3	23.08%
Instituto de Investigación Hospital Universitario La Paz	SERMAS	6	3	50.00%
Latvia Institute of Organic Synthesis	LIOS	3	0	0.00%
Public Health England-Department of Health	PHE	5	0	0.00%

Partner	Partner Short Name	# Users Created	# Users Logged In	% Logged In
Sciensano	SCI	2	0	0.00%
Synpase Research Partners SL	SYNAPSE	3	1	33.33%
TB Alliance	TBA	8	8	100.00%
Universidad Carlos III de Madrid	UC3M	15	5	33.33%
University of Dundee	DDU	5	0	0.00%
University of Köln	UHC	3	0	0.00%
University of Padova	UNIPD	2	0	0.00%
University of Pavia	UNIPV	4	3	75.00%
University of Zaragoza	UNIZAR	8	4	50.00%
Uppsala University	UU	7	2	28.57%
Total		**176**	**63**	**35.80%**

2.4 Future Plans/Activities

2.4.1 DDIM – grit42 Integration

To support objective O1.3 (Incorporation of historical preclinical and clinical datasets into the Drug Development Information Management (DDIM) system to help inform preclinical experiment design, model development and clinical trial design), the data from TB-PACTS will also be fully integrated into the grit42 database within the DDIM.

This activity is currently anticipated to conclude in late Q4 2021 or early Q1 2022 and will be reflected in deliverable D1.10 (First Report on clinical and preclinical datasets standardized and integrated into the DDIM).

The data from TB-PACTS is listed as background data as per Appendix 4 of the Consortium agreement. Access, and use of this data within the DDIM is as per the terms of the Consortium Agreement.

2.4.2 Background Data

The incorporation of other legacy data listed as background as per Appendix 4 of the Consortium agreement is anticipated to be processed and made available within the DDIM and/or Data Archive in the future.

Progress on this activity will be dependent on further details being received from asset owners on what type of data is available, data consumer requirements (i.e., what specific data would benefit specific analysis/modelling activities) and that the requisite agreements are in place to enable data to be available within the target platform (if applicable). Progress on this activity will be reported in deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report)

2.4.3 Other Data Sources

C-Path will be endeavouring to procure additional sources of legacy data for integration into TB-PACTS. Such sources include ERA4TB background data, UNITE4TB background data, PAN-TB data etc. The ability to process and integrate this data for the benefit of both ERA4TB partner and other TB researchers will be subject to the relevant Data Collaboration Agreement being in place. Any progress surrounding this will be reflected in deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report).

3 Preclinical Data Access

3.1 TB-APEX database

To support improved accessibility and interoperability of legacy preclinical data in standardised aggregated datasets, a new database was created by C-Path within the Data Archive platform entitled the TB-Platform for the Aggregation of Preclinical Experiment data (TB-APEX)

This effort entailed the setup of a new database, configuring the database to house data in CDISC SEND data structure. In addition, the effort included the transformation of all mouse model and hollow fibre system (HFS) data under C-Path's stewardship from source template into CDISC SEND structure prior to the data being integrated into the configured database. The table below summarises the activity timelines related to this database

Table 4. TB-APEX Activity Timeline

Activity	Activity Period	WP1 Activity Contributor(s)	Additional Comments
HFS / Mouse Model Conversion – Test Pilot	Oct – Dec 2020	C-Path	Test pilot conducted by C-Path to programmatically convert a subset of historical HFS/mouse model data held by C-Path into CDISC SEND Structure and load into TB-APEX test project area.
Creation of TB-APEX database	Nov – Dec 2020	C-Path	TB-APEX database created to hold and aggregate preclinical data in CDISC SEND structure
HFS / Mouse Model Conversion – 60 Studies	Jan – Jun 2021	C-Path	Conversion of sixty preclinical studies into CDISC SEND format
TB-APEX Data Integration Activities - 60 Studies	Jun - Jul 2021	C-Path	Integration of completed studies in CDISC SEND format into TB-APEX database
HFS / Mouse Model Conversion – Final Study	Aug – Sep 2021	C-Path	Final available study JHU-PMD-Study1`converted into CDISC SEND
TB-APEX Data Integration Activities - Final Study	Sep-21	C-Path	Final available study JHU-PMD-Study1 integrated into TB-APEX on 1st September

3.2 Available Data

The table below, provides the current list of available preclinical data that have been standardised and integrated into the TB-APEX database as of the date of this report. The listed studies will become available to authorised ERA4TB partners as per **Section 3.3**.

Table 5. TB-APEX Preclinical Studies List

Contributor	Study ID	Experiment Type	Treatment Regiment
Baylor	HFS-100	Hollow Fiber Systems	Linezolid, Sutezolid, Tedizolid
Baylor	HFS-101	Hollow Fiber Systems	OPC
Baylor	HFS-102	Hollow Fiber Systems	OPC
Baylor	HFS-105	Hollow Fiber Systems	Sutezolid, metabolite
Baylor	HFS-107	Hollow Fiber Systems	OPC-167832 &/or Delaminid or Isoniazid, Rifampicin, Pyrazinamide
Baylor	HFS-108	Hollow Fiber Systems	OPC-167832 &/or Delaminid or Isoniazid, Rifampicin, Pyrazinamide
Baylor	HFS-109	Hollow Fiber Systems	OPC-167832 &/or Delaminid or Isoniazid, Rifampicin, Pyrazinamide
Baylor	HFS-115	Hollow Fiber Systems	Bedaquiline
Baylor	HFS-116	Hollow Fiber Systems	Bedaquiline, Delaminid, Moxifloxacin, OPC, Pretomanid, Sutezolid, Pyrazinamide, INH, RMP
Baylor	HFS-117	Hollow Fiber Systems	Bedaquiline, Delaminid, Moxifloxacin, OPC, Pretomanid, Sutezolid, Pyrazinamide, INH, RMP
Baylor	HFS-50	Hollow Fiber Systems	PA-824, Moxifloxacin, Pyrazinamide, Isoniazid, Rifampicin
Baylor	HFS-53	Hollow Fiber Systems	PA-824, Moxifloxacin, Pyrazinamide, Isoniazid, Rifampicin
Baylor	HFS-63	Hollow Fiber Systems	PA-824, Moxifloxacin, Pyrazinamide, Isoniazid, Rifampicin
Baylor	HFS-64	Hollow Fiber Systems	Sutezolid
Baylor	HFS-82	Hollow Fiber Systems	Sutezolid
Baylor	HFS-83	Hollow Fiber Systems	Sutezolid
Baylor	HFS-84	Hollow Fiber Systems	Delamanid
Baylor	HFS-86	Hollow Fiber Systems	Bedaquiline
Baylor	HFS-87	Hollow Fiber Systems	Linezolid, Sutezolid, Tedizolid
Baylor	HFS-94	Hollow Fiber Systems	Delamanid
Baylor	HFS-96	Hollow Fiber Systems	OPC
Baylor	HFS-97	Hollow Fiber Systems	Linezolid, Sutezolid, Tedizolid

Contributor	Study ID	Experiment Type	Treatment Regiment
Baylor	HFS-99	Hollow Fiber Systems	Delaminid
Colorado State University (CSU)	Gates-03	Mouse Model	Rifampin, Isoniazid, Moxifloxacin, Pyrazinamide, Ethambutol
Colorado State University (CSU)	Gates-11	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Colorado State University (CSU)	Gates-12	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Colorado State University (CSU)	Gates-17	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Colorado State University (CSU)	Gates-B	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin
Evotec	HRZE-R1	Hollow Fiber Systems	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Evotec	HRZE-R2	Hollow Fiber Systems	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Evotec	HRZE-R3	Hollow Fiber Systems	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
Evotec	PaMZ-R1	Hollow Fiber Systems	Pretomanid, Moxifloxacin, Pyrazinamide
Evotec	PaMZ-R2	Hollow Fiber Systems	Pretomanid, Moxifloxacin, Pyrazinamide
Evotec	PaMZ-R3	Hollow Fiber Systems	Pretomanid, Moxifloxacin, Pyrazinamide
Evotec	REMox-R1	Hollow Fiber Systems	Rifampicin, Ethambutol, Moxifloxacin, Pyrazinamide
Evotec	REMox-R2	Hollow Fiber Systems	Rifampicin, Ethambutol, Moxifloxacin, Pyrazinamide
Evotec	REMox-R3	Hollow Fiber Systems	Rifampicin, Ethambutol, Moxifloxacin, Pyrazinamide
Evotec	EV-LY-TBa19003	Mouse Model	Bedaquiline, Isoniazid, Linezolid, Moxifloxacin, Pretomanid, Rifampicin, Pyrazinamide
Evotec	EV-TL-PK2019	Mouse Model	Bedaquiline, Isoniazid, Linezolid, Moxifloxacin, Pretomanid, Rifampicin, Pyrazinamide

Contributor	Study ID	Experiment Type	Treatment Regiment
Johns Hopkins University (JHU)	JHU-2013-Expt-3c	Mouse Model	Rifampin,Isoniazid,Pyrazinamide,Bedaquiline,Pretomanid,Linezolid, Sutezolid
Johns Hopkins University (JHU)	JHU-2014-Expt-3c	Mouse Model	Rifampin,Isoniazid,Pyrazinamide,Bedaquiline,Pretomanid,Linezolid
Johns Hopkins University (JHU)	JHU-2016-Expt-3c	Mouse Model	Bedaquiline, Pretomanid, Linezolid
Johns Hopkins University (JHU)	JHU-CFZ-Study1	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-CFZ-Study2	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-CFZ-Study3	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-CFZ-Study4	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-CFZ-Study5	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-MXF-Study1	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin
Johns Hopkins University (JHU)	JHU-MXF-Study2	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin
Johns Hopkins University (JHU)	JHU-PMD-Study1	Mouse Model	Rifampin, Pyrazinamide, Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study2	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study3	Mouse Model	Rifampin,Isoniazid,Rifapentine,Pyrazinamide,Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study4	Mouse Model	Rifampin,Isoniazid,Bedaquiline,Pyrazinamide,Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study5	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Pretomanid

Contributor	Study ID	Experiment Type	Treatment Regiment
Johns Hopkins University (JHU)	JHU-PMD-Study6	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study7	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PMD-Study8	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Pretomanid
Johns Hopkins University (JHU)	JHU-PZA-Study1	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Ethambutol
Johns Hopkins University (JHU)	JHU-REMox-Study1	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Ethambutol
Johns Hopkins University (JHU)	JHU-RPT-Study1	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Rifapentine
Johns Hopkins University (JHU)	JHU-RPT-Study2	Mouse Model	Rifampin, Isoniazid, Pyrazinamide, Moxifloxacin, Rifapentine

3.3 Partner Data Access

The availability of data listed as per **Section 3.2** to ERA4TB partners is subject to gaining the relevant data sharing agreements with the relevant data owners. Discussions with the data owners are currently ongoing.

Once all relevant agreements are achieved the database will be made available to ERA4TB authorised users via the same account created for accessing the TB-PACTS database. Access for all users is anticipated to be achieved within the next working day.

3.4 Future Plans/Activities

3.4.1 DDIM-grit42 Integration

To further support objective O1.3 (Incorporation of historical preclinical and clinical datasets into the DDIM to help inform preclinical experiment design, model development and clinical trial design), the data from TB-APEX may also be fully integrated into grit42 within the DDIM.

Progress on this activity is subject to the relevant agreements being in place and/or data pipeline priorities which may also influence resource availability. Such progress will be reflected in deliverable D1.12 (Second Report on clinical and preclinical datasets standardized and integrated into the DDIM) and/or deliverable D1.14 (Third Report on clinical and preclinical datasets standardized and integrated into the DDIM).

3.4.2 Background Data

The prospect of integrating into TB-APEX are subject to the same factors as described in **Section 2.4.2**.

3.4.3 Other Data Sources

Similar to **Section 2.4.3**, C-Path will be endeavouring to procure additional sources of legacy data for integration into TB-APEX. Any progress surrounding this will be reflected in deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report).

In addition, GSK are currently liaising with members of PredictTB in order to gain access to the preclinical data that was generated under this project. Subject to progress, this data may be integrated into TB-APEX and/or DDIM-grit42.

4. Conclusion

To conclude, as of the date of this report the ERA4TB partners currently have access to twenty-six legacy clinical trial studies with an additional sixty-one preclinical studies expected to be made available in the foreseeable future as a result of the creation of the TB-APEX database. This number (both clinical and preclinical studies) is anticipated to increase with additional sources expected to be integrated into the TB-PACTS, TB-APEX and DDIM -grit42 database during the remaining course of this project. Such details on progress will be described and reported within deliverable D1.18. (Availability of existing preclinical and clinical TB datasets – Final report).