IMI2 GA853989 - ERA4TB

European Regimen Accelerator for Tuberculosis

WP1 – Data and Pipeline Management

D1.12 Second Report on clinical and preclinical datasets standardized and integrated into the DDIM.

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0.1	15 March 2023	Initial Draft
0.2	24 March 2023	Definitions in Figure 1 were updated based on Section 6 in D1.11. Section 2.4 (Project Benchmarking data) was removed and included as part of 2.1.
1.0	3 April 2023	V0.2 updated with current metrics

Contents

Abstract

This document provides an overview of the data that has currently been integrated into the ERA4TB Drug Development Information Management system (DDIM).

This report focusses specifically on the integration of data into the grit42 platform, and imaging repository including metrics and potential sources of data to be integrated in the future. Information surrounding the integration of DICOM images into the XNAT platform will be reported in a future report, once actual images have been received and subsequently delivered into the XNAT platform.

Further progress or developments surrounding the continued integration of data and/or images into the DDIM will be reported as part of the deliverable D1.14 (Third Report on clinical and preclinical datasets standardized and integrated into the DDIM).

1. Introduction

To support the objectives of the ERA4TB project, data is being acquired from various sources and made available to authorized partners within ERA4TB via the Drug Development Information Management (DDIM) system, most notably data consumer partners (e.g., **WP5**). Initial details regarding the DDIM can be found within the report for the Instantiation of EU-based Drug Development Information Management system (D1.3).

The sources of data being acquired, processed, and made available within the DDIM are defined as per **Section 6** of the Updated Data Management Plan D1.11, which is currently accessible to ERA4TB partners only, and as per **Figure 1** below.

Project Pipeline Data	*Data generated by the various work packages for the relevant drug assets within the project pipeline.*
Off-Project Data	*Data generated by asset owners in parallel to the ERA4TB project activities.*
Project Benchmarking Data	*Benchmarking activities approved by the ERA4TB SC to facilitate the establishment or development of experiments/models.*
Legacy Data	*1. Historical "non-asset" data from external contributors (e.g., TB-PACTS).* *2. In-Kind contribution of "non-assets" preclinical/clinical data.* *3. Historical data from asset owners.*

Figure 1. ERA4TB Data Types/Sources

Data that has been formally received by C-Path (**WP1**) from an ERA4TB partner and/or external contributor is processed to conform to the required data structures for integration into the DDIM, specifically the grit42 data platform. The current data structures established for integration into the DDIM are described in the Standardized templates for collection and reporting of clinical and preclinical data available to consortium members –Interim report (D1.8).

The delivery and downstream processing of data to the grit42 platform within the DDIM is subject to having the relevant agreements in place which is outlined in the SOP for Data Contribution Agreements (D1.5) document which is currently accessible to ERA4TB partners only.

Upon the relevant terms being formally approved, the flow of data will follow the activities as described in **Figure 2.** In summary, the key prerequisites in integrating the relevant source of data into the grit42 platform are as follows (in order):

I. Final reported data is approved by the Asset Management Team (AMT) and Asset Owner prior to data being made available to C-Path for Gate 2 processing (NB: Gate 1 activities applies to Project Data only). A description on the scope and composition of an AMT can be found within **Section 2.2** of the Project Handbook (D8.1).
II. Issues/findings detected by C-Path during Gate 2 activities to be addressed by the relevant data contributor(s), including data re-transfer (where applicable).
III. Final transformed output and issues logs/reports generated by C-Path provided to asset owner for review/approval.
IV. Gate 2 Approval signed off by Asset Owner and C-Path

2. DDIM – grit42 Data Integration Updates

The information in this section presents the data integrated into the grit42 platform within the DDIM as of the date of this report. ERA4TB partners can find the most up to date list by accessing the Gate 2 report within the Synapse SharePoint (accessible to ERA4TB partners only) or by accessing the grit42 interface directly. Also, using the PMT (Pipeline Management Tool) tool being created by the UC3M, the ERA4TB users can track the pipeline progress which is intended to provide interactive dashboards. Further updates on the PMT tool will is made available on the deliverable D1.9 (Second Report on DDIM system availability to Consortium members).

The data sources listed in **Sections 2.1 – 2.3** are accessible to authorized ERA4TB partners via the DDIM portal at https://ddim.era4tb.arcos.inf.uc3m.es/. Further details on the access process and availability of the DDIM to ERA4TB partners can be found within the First Report on DDIM system availability to Consortium members (D1.7) which is currently accessible to ERA4TB partners only.

2.1 Project Pipeline/Benchmarking Data

In the order of Asset, WP (Work Package) and Job ID, **Table 1** below represents the current list of project specific activities which have had their data integrated into the grit42 data platform within the DDIM. All sources have had their data Gate 2 approved by the asset owner prior to the data being integrated into the target platform. Figure 2 shows the DDIM integration steps involved in processing of different data categories as defined in Figure 1.

The Job ID for each source of integrated data represents a specific action as defined within the relevant Asset Progression Plan (APP) or Combination Progress Plan (CPP). For example, the naming convention applied to an APP job activity is as follows:

<Drug Asset>-APP<insert number>- M<insert module number>- <partner short name>-

<sequence number>*

Job ID examples:

- ERA4TB-03-APP2-M1.1-UNIPV
- ERA4TB-06-APP1-M1.1-IPL-01
- ERA4TB-06-APP1-M1.1-IPL-02

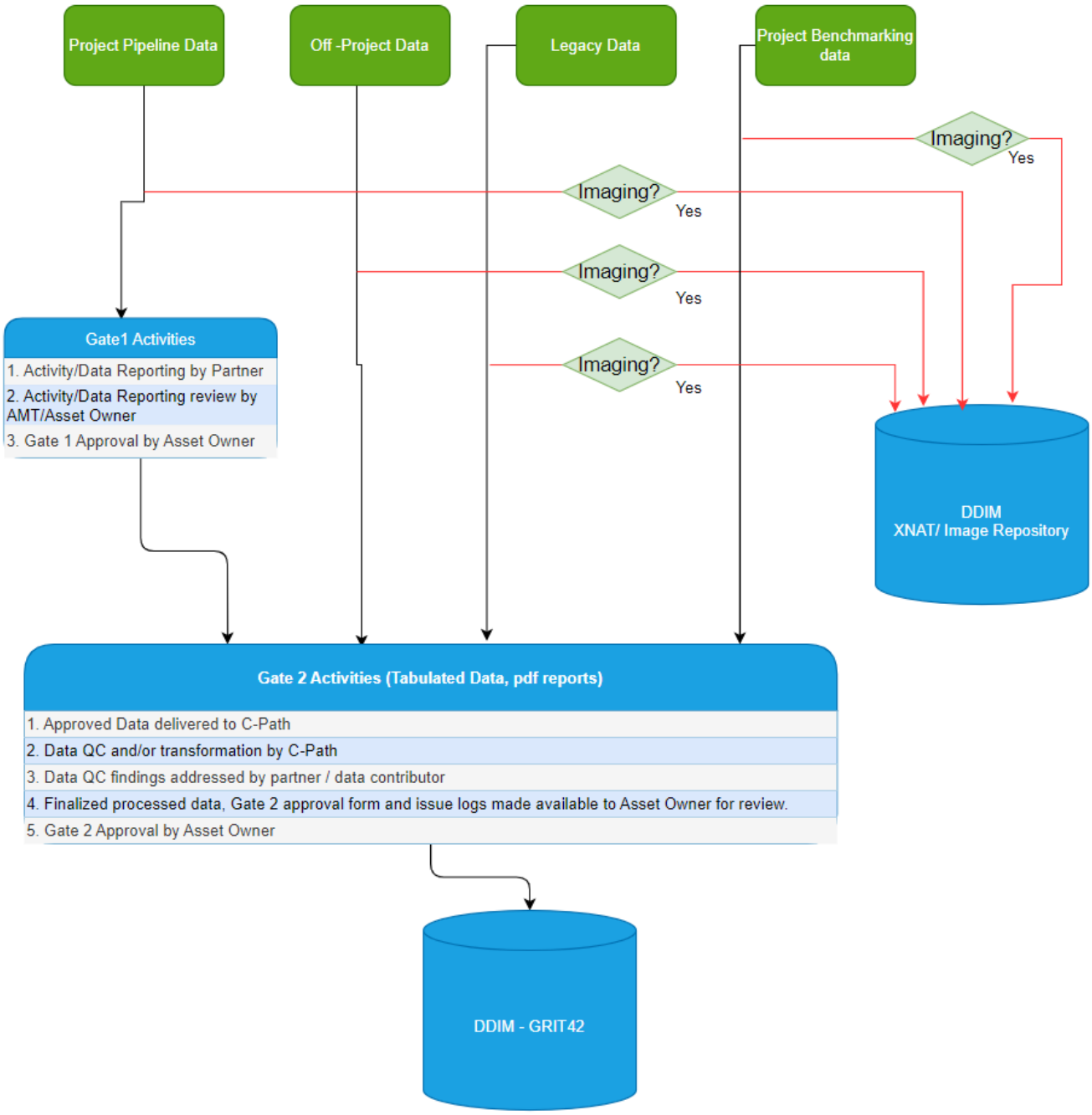

Figure 2. DDIM Data Integration Steps

**Only required if a partner is conducting multiple experiments for a single action*

Further details on the compound progression pipeline and APP's (asset progression plans) can be found within **Section 1** of the Project Handbook (D8.1).

Asset	WP	Job ID	Description	Compound(s)	Platform Delivery Date
ERA4TB-06	WP2	ERA4TB-06-APP1-M4.3.2-UNIPV	Molecular biology & biochemistry - Biochemistry - Action 12	ERA4TB-06, BM212	24-Jan-22
ERA4TB-03	WP2	ERA4TB-03-APP2-M1.1-UNIPV	Standard Extracellular assays (capacity n > 1000)	ERA4TB-03, Bedaquiline	24-Jan-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M1.3.3-IPL	Alternative in vitro assays - Artificial Caseum Assay (ACA)	ERA4TB-06, Isoniazid	15-Apr-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M1.3.3-UHC	Alternative in vitro assays - Artificial Caseum Assay (ACA)	ERA4TB-06, Rifampicin, Clofazimine, Isoniazid, Moxifloxacin, Linezolid	15-Apr-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M2.1.1-IPP	Frequency of Resistance assays - Standard in vitro fluctuation analysis (FA)	ERA4TB-06, Rifampicin	19-Apr-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M1.1-UNIZAR	Standard Extracellular assays (capacity n > 1000) - Action 6	ERA4TB-06	21-Apr-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M1.3.2-UNIPD	Alternative in vitro assays - Ex vivo human model of infection based on Granuloma Like Structures (GLSs) - Action 1	ERA4TB-06, Moxifloxacin, Isoniazid, Linezolid	02-Jun-22
ERA4TB-03	WP2	ERA4TB-03-APP2-M2.1-UNIPV	Frequency of Resistance assays	ERA4TB-03, Bedaquiline	23-Jun-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M4.3.1-UNIPD	Molecular biology & biochemistry - Molecular biology	ERA4TB-06	21-Jul-22
ERA4TB-06	WP2	ERA4TB-06-APP1-M4.3.1-UNIPV	Molecular biology & biochemistry - Molecular biology	ERA4TB-06	21-Jul-22
ERA4TB-06	WP2	ERA4TB-06-APP2-M3.1-UNIZAR	Standard Extracellular assays	ERA4TB-06, Isoniazid	06-Oct-22
ERA4TB-03	WP2	ERA4TB-03-APP2-M4.2-FZB	Drug resistance, genomics & evolution assays	ERA4TB-03, Bedaquiline Fumarate.	07-Oct-22
ERA4TB-03	WP2	ERA4TB-03-APP3-M1-UNIZAR	In vitro activity against Mycobacterium tuberculosis	ERA4TB-03, Isoniazid	10-Oct-22
ERA4TB-03	WP2	ERA4TB-03-APP3-M1-FZB	In vitro activity against Mycobacterium tuberculosis	ERA4TB-03, Isoniazid	12-Oct-22
ERA4TB-04	WP2	ERA4TB-04 -APP3-M2.1-IPP	Frequency of Resistance Assays	ERA4TB-04, Rifampicin	09-Nov-22
ERA4TB-04	WP2	ERA4TB-04 -APP3-M4.1-IPP	Omics technologies	ERA4TB-04	09-Nov-22

ERA4TB-06	WP2	ERA4TB-06-APP2-M3.1-FZB	Standard Extracellular assays	ERA4TB-06, Isoniazid	10-Dec-22
ERA4TB-01	WP2	ERA4TB-01-APP20M1.1-UNIZAR	Standard Extracellular assays (capacity n > 1000)	ERA4TB-01, Moxifloxacin, Linezolid	30-Mar-22
ERA4TB-06	WP3	ERA4TB-06-APP1-M5.1-SCI	A 1-2 log reduction in Chronic and Acute BALB/c models, respectively, at non-toxic dosing (Action 1. Acute dose ranging study in BALB/c mice)	ERA4TB-06	09-Mar-22
ERA4TB-06	WP3	ERA4TB-06 -APP1-M5.1-IPP	A 1-2 log reduction in Chronic and Acute BALB/c models, respectively, at non-toxic dosing (Action 2. Chronic dose ranging study in BALB/c mice)	ERA4TB-06	24-Mar-23
ERA4TB-06	WP6	ERA4TB-06-APP3-M8-EUROFINS	In vitro tox (non-GLP)	ERA4TB-06	04-Apr-22
ERA4TB-06	WP6	ERA4TB-06-APP1-M10-Ardena Oss	CMC: API (Non-GMP)	ERA4TB-06, Rifampicin, Clofazimine, Isoniazid, Moxifloxacin, Linezolid	04-Apr-22
ERA4TB-06	WP6	ERA4TB-06-APP1-M7-Ardena Oss	Pharma Development	ERA4TB-06	04-Apr-22
ERA4TB-06	WP6	ERA4TB-06-APP1-M9-Charles River France	In vivo tox (non-GLP)	ERA4TB-06	04-Apr-22
ERA4TB-02	WP6	ERA4TB-02-APP1-M11.1-WuXi	API-1kg API cGMP manufacture	ERA4TB-02	22-Apr-22
ERA4TB-02	WP6	ERA4TB-02-APP2-M14-Aptuit	In vivo Tox (GLP) Rats	ERA4TB-02	06-Mar-23
ERA4TB-02	WP6	ERA4TB-02-APP2-M13-Covance	In vitro Tox (GLP)	ERA4TB-02	06-Mar-23
ERA4TB-02	WP6	ERA4TB-02-APP2-M13-Covance	In vivo Tox (GLP) Minipigs	ERA4TB-02	06-Mar-23

Table 1. Project Data Integrated into DDIM – grit42

2.2 Off Project Data

As of the date of this report, no Off-Project Data has been shared by any partner/beneficiary and subsequently processed for the purposes of integration into the grit42 data platform.

2.3 Legacy Data

To 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), data received from TB Alliance for assets ERA4TB-03 and ERA4TB-06, and the data originating from the TB-PACTS database have currently been fully integrated into the grit42 platform within the DDIM. The list of these data sources which have been integrated into the DDIM can be found in **Sections 2.3.1** and **2.3.2** respectively below.

As of the time of this report, background data as per Appendix 4 of the ERA4TB Consortium Agreement has not

yet been provided by partners to C-Path except for TB Alliance. In the event of such data being provided to C-Path for processing into the DDIM, dedicated sections for these partners will be included in the third report on clinical and preclinical datasets standardized and integrated into the DDIM (deliverable D1.14)

2.3.1 TB Alliance

2.3.1.1 Clinical Data

With the exemption of clinical study data reported in **Section 2.3.2**, no additional sources of legacy clinical data have currently been supplied by TB Alliance for processing and availability into the DDIM.

2.3.1.2. Pre-Clinical Data

As per Appendix 4 of the ERA4TB Consortium Agreement, TB Alliance has thus far supplied the current list of data (**Table 2**) which have been successfully processed and made available in the grit42 platform within the DDIM.

Task ID	Study Short Name	Descriptions	Compound(s)	Platform Delivery Date
ERA4TB-03/ ERA4TB-06-IKC (Preclinical)-TBA	NA	Stability of ERA4TB-03 & ERA4TB-06 metabolites in 7H9 medium	ERA4TB-03, ERA4TB-06	30-Nov-21

Table2. TB Alliance Background Data integrated into DDIM-grit42

2.3.2 TB-PACTS Data

The current available data from the TB-Platform for Aggregation of Clinical TB Studies (TB-PACTS) was also intended to be integrated into the DDIM for use by ERA4TB partners. This task was completed on the 17-May-2022 containing clinical data for studies as listed in **Table 3**.

This data is also accessible to authorized external researchers via the Data Archive Platform available at https://era4tb.c-path.eu/.

Task ID	Data Contributor	Study Short Name	Descriptions	Compound(s)	Platform Delivery Date
TB-1025-TBPACTS-CPATH	British Medical Research Council	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	17-May-22
TB-1026-TBPACTS-CPATH	British Medical Research Council	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	17-May-22

TB-1027-TBPACTS-CPATH	British Medical Research Council	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	17-May-22
TB-1028-TBPACTS-CPATH	British Medical Research Council	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	17-May-22
TB-1029-TBPACTS-CPATH	British Medical Research Council	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	17-May-22
TB-1030-TBPACTS-CPATH	British Medical Research Council	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	17-May-22
TB-1024-TBPACTS-CPATH	Case Western Reserve University	Johnson2009_01009	Tuberculosis Treatment Shortening Trial	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	17-May-22
TB-1031-TBPACTS-CPATH	Case Western Reserve University	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	16-May-22
TB-1020-TBPACTS-CPATH	TB Alliance	PA-824 EBA Low Dose	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis (CL-010)	PA-824 50-200 mg	25-Mar-22
TB-1003-TBPACTS-CPATH	TB Alliance	TMC207 EBA	Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis (TMC207-CL001)	TMC207	17-May-22
TB-1005-TBPACTS-CPATH	TB Alliance	PA-824 EBA High Dose	PA-824-CL-007: Phase IIa Evaluation of Early Bactericidal Activity in Pulmonary Tuberculosis	PA-824 200-1200 mg	17-May-22

TB-1007-TBPACTS-CPATH	TB Alliance	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	17-May-22
TB-1008-TBPACTS-CPATH	TB Alliance	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	17-May-22
TB-1011-TBPACTS-CPATH	TB Alliance	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	17-May-22
TB-1014-TBPACTS-CPATH	TB Alliance	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	17-May-22
TB-1015-TBPACTS-CPATH	TB Alliance	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	17-May-22
TB-1018-TBPACTS-CPATH	TB Alliance	REMOX	Controlled Comparison of Two Moxifloxacin Containing Treatment Shortening Regimens in Pulmonary Tuberculosis (REMoxTB)	Moxifloxacin, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	17-May-22
TB-1021-TBPACTS-CPATH	St. Georges University of London	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	17-May-22
TB-1001-TBPACTS-CPATH	U.S. Centers for Disease Control	TBTC Study 22	TBTC Study 22: Efficacy of Once-Weekly Rifapentine and Isoniazid in Treatment of Tuberculosis	Rifapentine and Isoniazid 1x vs. 2x/wk	17-May-22

TB-1006-TBPACTS-CPATH	U.S. Centers for Disease Control	TBTC Study 27	TBTC Study 27: Moxifloxacin vs Ethambutol for TB Treatment	Moxifloxacin vs. Ethambutol	17-May-22
TB-1009-TBPACTS-CPATH	U.S. Centers for Disease Control	TBTC Study 28	TBTC Study 28: Moxifloxacin Versus Isoniazid for TB Treatment	Moxifloxacin vs. Isoniazid	17-May-22
TB-1010-TBPACTS-CPATH	U.S. Centers for Disease Control	TBTC Study 29	TBTC Study 29: Rifapentine During Intensive Phase Tuberculosis (TB) Treatment	Rifapentine 10 mg/kg, Isoniazid, Ethambutol, Pyrazinamide	17-May-22
TB-1013-TBPACTS-CPATH	U.S. Centers for Disease Control	TBTC Study 29X	TBTC Study 29: Rifapentine During Intensive Phase Tuberculosis (TB) Treatment	Rifapentine 10, 15, 20 mg/kg, Isoniazid, Ethambutol, Pyrazinamide	17-May-22
TB-1017-TBPACTS-CPATH	U.S. Centers for Disease Control	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	17-May-22
TB-1019-TBPACTS-CPATH	University College London, Vital Strategies, Inc.	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,	17-May-22
TB-1022-TBPACTS-CPATH	World Health Organization	OFLOTUB	A Controlled Trial of a 4-Month Quinolone-Containing Regimen for the Treatment of Pulmonary Tuberculosis	Gatifloxacin, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	17-May-22

Table 3. TB-PACT Data Integrated into the DDIM-grit42

2.4 Data Processing/Integration Metrics

Table 4 below provides an overview of the average Gate 2 processing duration (in business days), for various actions in Gate 2 as depicted in **Figure 2**. Gate 2 duration also includes the overall time taken by data contributing partners in following up on data corrections (i.e., data retransfers) or clarifications based on QC issues found by C-Path during the processing of the Gate 1 approved data. **Figure 3** shows the percentage of all data sources integrated into grit42 and **Figure 4** shows the number of project data integrated into the grit42 by data type.

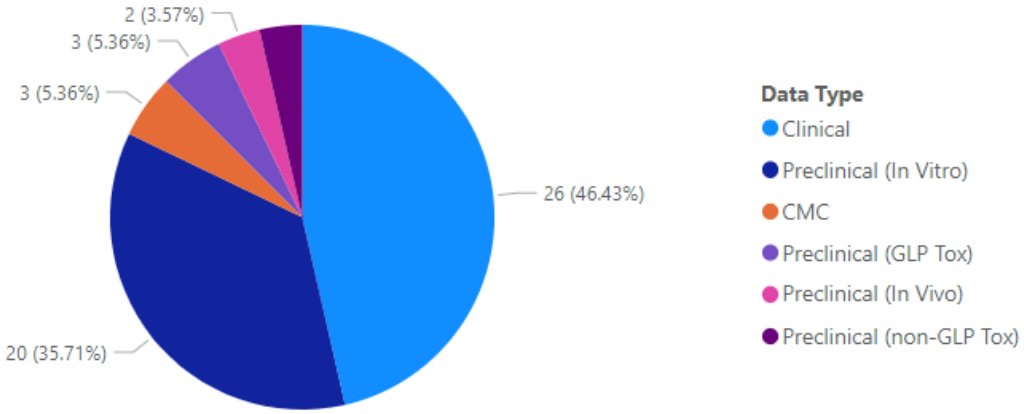

Figure 3. Overall data available in DDIM by data category percentage

Data Type	No. Data Transfers
CMC	3
Preclinical (GLP Tox)	3
Preclinical (In Vitro)	19
Preclinical (In Vivo)	2
Preclinical (non-GLP Tox)	2
Total	**29**

Figure 4. Project data in DDIM by data category

Data Type	All Sources	Project Data	Off-Project Data	Legacy Data
No. Data Transfers	56	29	0	27
Total Gate 2 Duration	6.06	7.9	0	4.22

Table 4. Overall Gate 2 Processing Metrics

3. Future Data Integration Plans

3.1 Project Pipeline/Benchmarking Data

Additional sources of project data are anticipated to be integrated into the DDIM during the course of the next twelve months. The extent of integrated data volume increase by the *Third report on clinical and preclinical*

datasets standardized and integrated into the DDIM (deliverable D1.14) will be dependent on the following factors:

- Timeliness (planned vs actual) of experiment/activity completion by designated partner.
- Reporting turnaround times by designated partners.
- Gate 1 review and Job Final Report approval turnaround times.
- Degree/extent of deviation from currently established data standards (see Deliverable D1.8)

The progress of these project pipeline jobs is being monitored with support from Synapse (WP8), and the attendance of C-Path data team members at Asset Management Team (AMT) meetings.

3.2 Off-Project Data

As mentioned in **Section 2.2** and at the time of writing this report, no details of Off-Project Data have been shared by any partner/beneficiary.

3.3 Legacy Data

A legacy MIC (Minimum Inhibitory Concentration) Data for the asset ERA4TB-01 is anticipated to be integrated into the DDIM in 2023 subject to relevant data sharing agreement being finalised with the contributor.

3.3.1 TB-APEX Data

Subject to the terms of the relevant DCA's (Data Contribution Agreement) and/or project actions which may require prioritization of current resources, it is currently anticipated that the preclinical data currently housed within the TB - platform for the Aggregation of Preclinical Experiments data (TB-APEX) will be integrated into the DDIM in Q3/Q4 2023.

This activity will bring an additional 61 preclinical studies (in CDISC SEND data format) 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).

In the interim and as of 28th January 2022, the TB-APEX data has been made accessible to authorized ERA4TB WP5 members via the Data Archive Platform available at https://era4tb.c-path.eu/.

Details regarding the TB-APEX database and its available data can be found reported in the Availability of existing preclinical and clinical TB datasets – Interim Report (D1.6) which is currently accessible to ERA4TB partners only.

3.3.2 TB-PACTS Data

An EBA (Early Bactericidal Activity) clinical study from TB Alliance is expected to be received by C-Path during 2023. Once the relevant DCA has been executed and the data has been received, this data shall initially be integrated into TB-PACTS with the potential of it also being integrated into the DDIM (subject to the terms of the DCA).

In addition, the legacy clinical trial study STAND-NC-006 (Shortening Treatment by Advancing Novel Drugs) is currently being processed by C-Path and is expected to be integrated into the TB-PACTS in Q2 2023.

3.3.3 Background Data from Asset Owners

Discussions are ongoing with asset owners to determine what historical data should be integrated into the DDIM system. It is anticipated that additional legacy data from the asset owners will be integrated into the grit42 platform on/by the Third report on clinical and preclinical datasets standardized and integrated into the DDIM (deliverable D1.14).

3.3.4 Other Potential Sources

3.3.4.1 PreDiCT- TB Data

Discussions are still ongoing regarding the prospect of bringing in-vitro and in-vivo data which emanated from the PreDiCT-TB project. Additional discussions are being arranged with key stakeholders to move this topic forward, with the long-term prospect of bringing this data into the ERATB project.

3.3.4.2 UNITE4TB Project

The Academia and Industry United Innovation and Treatment for Tuberculosis (UNITE4TB) project is a research collaboration funded under the Innovative Medicines Initiative Joint Undertaking 2 (IMI JU2) within the framework of the wider Antimicrobial Resistance Accelerator program. With C-Path operating as data management work package lead on both ERA4TB and UNITE4TB, and a selection of asset owners working on both projects also, there is the potential of the cross-sharing/availability of data. This potential will be assessed and discussed with the relevant stakeholders as the project begins to progress.

4. Conclusion/Summary

Since the production version of grit42 was implemented within the DDIM as of 24th November 2021, there has been a steady stream of data integrated into the grit42 platform within the DDIM with the current figure standing at 56 sources of data.

With the anticipated influx of data as described in **Section 3**, and in a best-case scenario, the number of data sources integrated into the DDIM on/by the third report on clinical and preclinical datasets standardized and integrated into the DDIM (deliverable D1.14) may exceed one hundred sources of data. Such an achievement is dependent on the factors and rate-limiters (including partner dependencies) that have been described throughout this report.

Further to the previous points, the Gate 2 metrics presented in Section 2.4, indicate and galvanize how adhering to a standard approach in the reporting of Project Data (as per Standardized templates for collection and reporting of clinical and preclinical data available to consortium members –Interim report (D1.8)) has facilitated the Project Data being processed and made available in a relatively short time. The continued adoption and familiarity of these standards by data generating partners, and further developments on a semi-automatic approach to data QC and transformation conducted by C-Path, may result in further improved turnaround times in the future.