DMID – eTMF V1.1

Project Charter

v1.1 – February 18, 2021

VERSION HISTORY

Version	Author	Revised	Description of Change
1.0	A.M. Lucas	2021-02-05	Initial Version
1.1	Laura Lacy	2021-02-18	Final for Signature

TABLE OF CONTENTS

1 INTRODUCTION 3

2 PROJECT OVERVIEW 3

3 SCOPE 3

3.1 High-Level Requirements 3

3.2 Major Deliverables 4

3.3 Out of Scope 5

4 PROJECT ORGANIZATION 5

4.1 Governance 6

4.2 Change Control Process 6

5 ESTIMATED LEVEL OF EFFORT 7

6 ASSUMPTIONS, CONSTRAINTS, RISKS 7

7 NIAID-EDRMS-QA-010-F01 INITIATION OF VALIDATION EFFORT 9

7.1 Validation Overview and Purpose 9

7.2 Resourcing 9

7.3 Timelines and Responsibility 9

7.4 Validation Package Checklist 9

APPROVAL 10

1 INTRODUCTION

The Project Charter formally authorizes a project, describes the business need for the project and the product to be created by the project. It provides the project manager with the authority to apply up to a certain level of organizational resources to project activities. It is created during the Initiating Phase of the project.

2 PROJECT OVERVIEW

This project is for the development of the *Division of Microbiology and Infectious Disease* (***DMID***) *electronic Trial Master File* (***eTMF***) System on the *National Institute of Allergy and Infectious Diseases* (***NIAID***) *Validated Electronic Document and Records Management System* (***VEDRMS***).

The project repository for this version is located at: ***https://edrms.niaid.nih.gov/livelink/llisapi.dll/Properties/111726566***

3 SCOPE

Because the DMID eTMF System will be used to collect and manage information generated during clinical trials that will ultimately contribute to submission made to regulatory agencies throughout the world, the DMID eTMF System must be validated. See Section 7 *Validation Overview and Purpose* for additional information.

High level tasks, deliverables, and responsible parties are shown in **Table 1.** A preliminary detailed list of project deliverables are specified in the ***DMID – eTMF V1.1 - Deliverable Inventory (*****Deliverable Inventory**) located in the **Project Repository | 02 Management** folder (***https://edrms.niaid.nih.gov/livelink/llisapi.dll/Properties/111725887***).

Table 1: High-Level Tasks, Deliverables, Responsible Parties

ID	Task | Deliverable	Primary Responsibility
1	Collection and analysis of requirements | Requirements Document	BPIMB & DMID
2	Design and Construction of the DMID eTMF System | Design Document	BPIMB
3	*Installation Qualification* (***IQ***) and *Operational Qualification* (***OQ***) testing | IQ & OQ Test Scripts	BPIMB
4	Develop and revise Division procedures and documentation required to integrate use of the DMID eTMF System into DMID activities | *Standard Operating Procedures* (***SOPs***)	DMID
5	Compliance with Regulatory Requirements | Validation Plan	BPIMB
6	*Performance Qualification* (***PQ***) testing | PQ Test *S*cripts	DMID
7	Deploy the DMID eTMF System and rollout to DMID staff	BPIMB & DMID

3.1 HIGH-LEVEL REQUIREMENTS

High-level business requirements are enumerated in **Table 2: High-Level Requirements**.

Table 2: High-Level Requirements

ID	Requirement Description
BUS-001	Secure repository for eTMF documents with role-based access control.
BUS-002	Compliant with relevant regulatory and *Computer System Validation* (***CSV***) guidelines and requirements.
BUS-003	The DMID eTMF System and the *Quality Management System* (***QMS***) under which it is built and operated must be ready for inspection at any time by relevant regulatory agencies.
BUS-004	The ability to import TMFs from the CRO system into the DMID eTMF while maintaining metadata

3.2 MAJOR DELIVERABLES

The following table presents the major deliverables that the project's product, service, or result must meet in order for the project objectives to be satisfied.

Table 3: Major Product Deliverables

Major Product Deliverable	Deliverable Description
Document Repository	Validated electronic document repository to house trial master file final documents
Web Interface	Web interface to set up new eTMF file structure for individual protocols to allow the addition of final trial master file documentation.
Workflow Process	N/A

Table 4: Major EPLC Deliverables

Major EPLC Deliverable	Deliverable Description
Project Charter	Formally authorizes the project, describes the business need for the project and the product to be created by the project.
Project Timeline	Shows the project timeline and the person(s) responsible for each task
User Requirements Specifications	Defines the functional, non-functional, and technical requirements for the system.
CIS Model	The Community Information Security (CIS) model that describes which groups have access to files and folders in the repository.
Design Specification Document	Provides a detailed list of the functions that the system is expected to perform and the software and system architecture elements that are needed to fulfill the requirements.
Test script	Provides a set of instructions that will be performed on the system to test that the system functions as expected

Major EPLC Deliverable	Deliverable Description
Requirements Traceability Matrix	Traces the relationship between high-level requirements, detailed design and functional requirements, and the detailed test plan and test cases. The matrix permits tracking from requirements to testing, and from testing to requirements, helping to ensure that all the requirements are fulfilled.
User Acceptance Testing (UAT)	Performed by the customer before the system enters production to verify that the system meets the business needs listed in the User Requirements Specifications.
Job Aid	Documents the approach for ensuring that end users learn how to use the final product.

3.3 OUT OF SCOPE

The following are out-of-scope for this project:

- Integration with external systems. Integration with systems like the *NIAID Clinical Management System* (***NCRMS***) may be considered for future releases.

4 PROJECT ORGANIZATION

Project stakeholders and their responsibilities are identified in **Table 5: Key Project Stakeholders**. Project team members will be assigned at appropriate times as the project progresses.

Table 5: Key Project Stakeholders

Name & Organization	Project Role	Project Responsibilities
John Beigel DMID | Associate Director for Clinical Research	Business Sponsor/Owner	Ensures that: • Requirements are satisfied by the System. • Business resources are available to support and participate in the project. • Any changes to business processes are necessary, adequate, and appropriate.
Jae Arega DMID | Supervisory Biologist	Business Owner Representative	• Acts on behalf of the Business Owner for day-to-day project activities • Primary liaison between the business and EDRMS team members.
Mike Tartakovsky Chief Information Officer, Director OCICB	System Owner	Ensures that: • The System is compatible with the NIAID technical infrastructure • The System can be adequately supported and maintained by OCICB staff. • OCICB resources are available to support and participate in the project.
Jim Saadvandi OCICB | BPIMB	System Owner Representative	Oversight of the initiation, execution, control and closure of project activities for the project. Responsible for all staff and resources with the EDRMS program.

Name & Organization	Project Role	Project Responsibilities
Anne Marie Lucas OCICB | BPIMB	Project Manager	Day-to-day management of the project and for managing the project within the approved constraints of scope, quality, time and cost, to deliver the specified requirements, deliverables and customer satisfaction.

4.1 GOVERNANCE

- The Business Owner and Business Representatives are the source of authoritative business requirements
- The Business Owner is responsible for ensuring that all other stakeholders agree with the system requirements and procedures developed during the project. Any inconsistencies or conflicts must be resolved before they affect the scope and timeline of the project
- If any business requirements conflict with other business processes or if clarification is required, the Business Owner will coordinate activities with external stakeholders
- If any business requirements create technical issues with existing functionality or interfaces or if business requirements will affect time and resource allocations, the System Owner will identify them as soon as possible and provide and impact assessment and recommendations to the Business Owner
- After the system requirements and project scope have been finalized the change control process will be used to evaluate and approve or reject changes in project scope and requirements. Both the Business Owner and System Owner must approve any issues or changes that affect the project timeline or resource commitments. Decisions will be made by consensus of the Business and System Owners

4.2 CHANGE CONTROL PROCESS

All change requests and defect tickets will be captured and managed in EDRMS's change tracking system. The Business Owner and all project team members will have read access to that system. The Project Lead will maintain and update tickets using the change control process summarized below.

- The change tracking system is the single, authoritative source of all outstanding change requests and defect tickets, collectively referred to as a Change Request (CR)
- CRs may be created because of problems identified during design, development, or testing. They may also be created because of new or changed business requirements identified by the Business Owner at any time during the project lifecycle
- The project lead evaluates new CRs to determine that sufficient information has been provided to properly address the CR, whether the issue has been previously reported, or if it is for a CR that was previously declared closed
- The Business Owner will prioritize the importance of CRs based on their business needs. Priorities may be changed at the Business Owner's discretion but the Project Lead (for the System Owner) must assess the impact of any change before the CR will be committed for implemented
- The development team prepares an impact assessment of new CRs. If a CR will affect the implementation schedule or resource allocations, the Business Owner and System Owner will collectively determine whether to alter the project scope and plan in order to address the CR. If the Business Owner and System Owner do not concur on the change the CR may be elevated to the Business Sponsor

Developers and product specialists will only work on committed CRs

5 ESTIMATED LEVEL OF EFFORT

Estimated Level of Estimates (***LOE***) for key project team members working on the project is shown in **Table 6: Phase 1 Estimated Level of Effort**.

Table 6: Phase 1 Estimated Level of Effort

Project Stage / Milestone	Deliverables	LOE (hours)
Develop Project Charter	Project Charter	10
Develop Project Schedule	Project Schedule	5
Requirements Analysis	Requirements Specifications Document CIS Model	100
Design	Design Specifications Document	20
Development	Working Software	45
QA Testing	IQ/OQ/PQ Test Scripts Requirements Traceability Matrix IQ/OQ/PQ Summary Reports	120
Production Deployment	CAB Request IQ Execution Summary Reports System Release Memo	40
Validation Documentation	Validation Plan Project Mgt. Plan QC of Test Script Summary Reports	100
Project Management	20% of Total	88
	Total Hours	**528**

6 ASSUMPTIONS, CONSTRAINTS, RISKS

This section identifies the statements believed to be true and from which a conclusion was drawn to define this project charter.

Table 7: Assumptions

ID	Assumption
1	The folder structure, roles, permissions model, and associated business processes of DMID eTMF V1.0 will be retained.
2	Out of the box VEDRMS functionality will be utilized as much as possible. If compelling business needs arise, new workflows or custom development may be jointly considered by DMID and BPIMB.
2	A NIAID network account and *Personal Identity Verification* (***PIV***) card will be required to access the DMID eTMF System.

ID	Assumption
3	DMID will conduct PQ testing.
4	DMID will create and revise SOPs as required to integrate the DMID eTMF System into their operations.
5	DMID will coordinate and ensure Supplier support during the implementation, rollout, and operation of the eTMF. ***Suppliers*** are defined to be any external organization that works with NIAID under contracts, grants, or partnerships.
6	DMID and Supplier staff will be available to support requirements analysis and evaluation activities.

Table 8: Constraints

ID	Constraints
1	Where possible, standard Content Server functionality and configurations will be used in lieu of custom development.
2	Because of security constraints, the DMID eTMF System will only be accessible from within the NIAID network.

The table below presents the known risks which could have a major impact on the outcome of the project, and associated mitigation strategies that the business sponsor/project team will take to manage them.

Table 9: Risks

ID	Risk	Mitigation
1	**Unavailability of DMID and Supplier Staff.** Implementation of the DMID eTMF System is not the primary responsibility of DMID or Supplier staff yet their engagement and support on a timely basis is necessary for a successful project.	Ensure that DMID management supports the project, assigns sufficient priority and resources, and has adequate information to monitor its progress.
2	**Inefficient Stakeholder Coordination.** Although the Validated EDRMS is intended for use by multiple applications, each new application increases the level of coordination between stakeholders.	BPIMB Change Management processes and ongoing project reviews will ensure that sufficient communication across stakeholders exists.
3	**Impact of SOP Revisions.** DMID SOPs and business process will need to be revised in order to integrate the DMID eTMF System into their operational activities. Preparing and deploying the changes will take time and resources.	Ensure that DMID management supports the project, assigns sufficient priority and resources, and has adequate information to monitor its progress.
4	**Lack of Supplier Support.** Much of the work and activities needed to create, support, and maintain eTMFs are outsourced to external Suppliers via grants, contracts, and other means. The DMID eTMF System may require changes to Suppliers existing activities.	Ensure that DMID contracting officers and Supplier points of contact understand, coordinate, and ensure that Suppliers support the project as necessary.

NIAID-EDRMS-QA-010-F01 Initiation of Validation Effort

7 VALIDATION OVERVIEW AND PURPOSE

System Name	DMID electronic Trial Master File V1	
EDRMS Project Name	DMID eTMF V1	
Is validation Needed for this system?	☒ Yes	☐ No
If No, Please provide an explanation		
What is the purpose of the validation?	To ensure that the System complies with all known validation requirements and is fit for its intended use.	

7.1 RESOURCING

Resourcing information is provided above in **Table 5: Key Project Stakeholders**.

7.2 TIMELINES AND RESPONSIBILITY

The preliminary project timeline is provided above in **Table 10: Preliminary Milestone Schedule**.

Table 10: Preliminary Milestone Schedule

Task Name	Start	Finish
Project Charter Approved	2/3/2021	2/18/2021
Requirements Phase	3/1/2021	4/15/2021
Design Approved	5/31/2021	5/31/2021
xQ Test Scripts Approved	6/15/2021	6/15/2021
QA Readiness Review	6/18/2021	6/18/2021
Execute IQ in QA	6/21/2021	6/21/2021
Execute OQ in QA	6/28/2021	6/28/2021
Execute IQ in PROD	7/7/2021	7/7/2021
System Release Memo Issued	7/16/2021	7/16/2021

Primary resource responsibilities are provide above in **Table 5: Key Project Stakeholders**.

7.3 VALIDATION PACKAGE CHECKLIST

The Validation Package Checklist is comprised of all the deliverables specified in the Deliverable Inventory located in the **Project Repository | 02 Management** folder in the Project Repository.

APPROVAL

The undersigned acknowledge that they have reviewed the ***DMID – eTMF V1.1 - Project Charter*** and agree with the information presented within this document. Changes to this document will be coordinated with, and approved by, the undersigned, or their designated representatives.

Signature: John H. Beigel -S Digitally signed by John H. Beigel -S Date: 2021.02.21 17:33:45 -05'00' Date: Feb 21, 2021

Name: John Beigel
Title: Associate Director for Clinical Research
Role: Business Sponsor

Signature: Michael Tartakovsky -S Digitally signed by Michael Tartakovsky -S Date: 2021.02.26 09:53:45 -05'00' Date:

Name: Michael Tartakovsky
Title: NIAID, Chief Information Officer
Role: System Owner