

INITIATION OF VALIDATION EFFORT FORM

1 VALIDATION OVERVIEW AND PURPOSE

System Name	DMID Electronic Trial Master File (eTMF)	
EDRMS Project Name	DMID eTMF Repository	
Is validation Needed for this system?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If No, please provide an explanation		
What is the purpose of the validation?	Validation is required to have final trial master file documents stored prior to regulatory submission.	

2 RESOURCING

Name or Designee (Company)/Title	N/A	Individuals	Contact Information (Email Addresses)
System Owner(s)	<input type="checkbox"/>	John Beigel	jbeigel@niaid.nih.gov
BPIMB Management	<input type="checkbox"/>	Matt Eisenberg Jim Saadvandi	matthew.eisenberg@nih.gov jamshid.saadvandi@nih.gov
Project Management	<input type="checkbox"/>	Anne Marie Lucas	anne.lucas@nih.gov
Project Development	<input type="checkbox"/>	John Simon Shadi Bashir David Chen Anubhav Vij	john.simon@nih.gov shady.bashir@nih.gov weichei.chen@nih.gov anubhav.vij@nih.gov
Operations	<input type="checkbox"/>	Jorge Montalvo	jorge.montalvo@nih.gov
Technical and Engineering Support	<input type="checkbox"/>	Mahesh Pinnameni	mahesh.pinnameni@nih.gov
Quality Assurance	<input type="checkbox"/>	Carlos Perez-Santiago Christina Nazario Berrios	carlos.perez-santiago2@nih.gov cristina.nazarioberrios@nih.gov

3 TIMELINES AND RESPONSIBILITY

Phase	Target Completion Date	Responsibility
Planning	4/15/2021	Anne Marie Lucas
Analysis	5/31/2021	Anne Marie Lucas

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Phase	Target Completion Date	Responsibility
Design	5/31/2021	Shadi Bashir, John Simon, David Chen, Anubhav Vij
Construction	6/18/2021	Shadi Bashir, John Simon, David Chen, Anubhav Vij
Quality Assurance	6/28/2021	Carlos Perez-Santiago, Cristina Nazario Berrios
Deploy	7/7/2021	Jorge Montalvo
Operations	Indefinite	Jorge Montalvo
Decommission	N/A	N/A

4 VALIDATION PACKAGE CHECKLIST

Phase	Deliverable	Deliverable Needed for This Validation Effort?	
Planning	Business Needs Statement	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Project Charter	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Initial Risk Assessment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Project Management Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Change Control Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Configuration Management Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Deployment Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Quality Management Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Security Plan	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	Test Plan	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	UAT Test Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Training Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Risk Management Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Validation Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Analysis	User Requirements Specifications	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

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Phase	Deliverable	Deliverable Needed for This Validation Effort?	
	Functional Specifications	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Requirements Traceability Matrix	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Design	Software Design Specification	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Hardware Design Specification	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	Community, Information, Security (CIS) Model	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Test Plan	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	Installation Qualification (IQ) Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Operation Qualification (OQ) Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Performance Qualification (PQ) Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Construction	Code Review Report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Test Scripts or Test Cases	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Quality Assurance	Test Summary Report	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	Installation Qualification (IQ) Report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Operational Qualification (OQ) Report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Performance Qualification (PQ) Report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
	Final Validation Summary Report	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Deploy	Training Plan	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	Training Log	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
	System Release Memo	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Operations	Operations & Maintenance Plan	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Decommission	Decommission Plan	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

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APPROVAL

The undersigned acknowledge that they have reviewed the DMID – eTMF V1.0 – Initiation of Validation Effort Form 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:

Name: Anne Marie Lucas
Title: Project Manager
Role: Project Manager

Signature:

Name: Sophia Mutamba
Title: Quality Manager
Role: Quality Manager