IMATCH INNOVATION HUB TEST PLAN

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This document has been reviewed and approved by the following signatories. Hand written signatures on the Cover Page indicate acceptance of the entire document.

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Date			

DOCUMENT CHANGE HISTORY

Section	Date	Summary of Change	Author
	November 2019	iMATCHiHub01 **Revision 01**	
All	November 2019	New Document	Stephanie Roberts (Chaucer)
4.3	June 2020	Update to Test Methodology Section	Donatela Salaj (Chaucer)

Note: This list should be started fresh each time a “Revision 00” is created (new documents). These should show the changes since the previous document where this is a new version of an existing document (e.g. for a new version of the product).

Table of Contents

1 Introduction

This plan sets out how the end to end data flow of the iMATCH Innovation Data Hub will be tested to ensure data integrity and GCP compliance during the clinical data processing pipeline for the iMATCH project.

1.1 Relevant Documents

Document Description	Document Reference Number
Data Stewardship Plan	
iMATCHWP4.1 Draft End to End Test Plan –Flowchart v0.1	
iMATCH Test Script.xlsx	

1.2 Glossary

Term	Filename
iMATCH	Innovate Manchester Advanced Therapy Centre Hub
API	Application Programming Interface
HTTPS	Hypertext Transfer Protocol Secure
SDTM	Study Data Tabulation Model
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare Products Regulatory Agency

2 Scope

2.1 In Scope

End to end testing of data processing pipeline from data collection through to data storage in the iMATCH Innovation hub. Assessment of how data integrity and quality are preserved as clinical data flows through the entire system including data transfer between the systems. This testing will be an essential aspect of validating the end to end flow of clinical data and will test that no risks arise through connection of the systems. A further aspect that will be evaluated will include data traceability requirements (Audit Trail) and integrity requirements as set out in GCP guidelines.

2.2 Out of Scope

Each of the systems are already standalone systems that are licensed by existing clients, the latest version of the systems that are being utilised by clients would have already passed a through testing and validation process that will not be repeated.

Additionally, some new technical components such as APIs have been developed by the work package 4.1 vendors in order to meet the needs of iMATCH and independent testing and validation of these new technical components was included as part of their deliverables for iMATCH and therefore would have been completed ahead of this end to end testing. Therefore, the individual testing of the technical components that have been developed independently by each vendor as a part of iMATCH are not in scope.

This test plan is only concerned with evaluating the end to end data flow, ensuring that the data processing pipeline works effectively ahead of processing patient data.

2.3 iMATCH innovation Hub Systems

System	Functionality	Company
Viedoc	Electronic Data Capture System	Viedoc
Aptus Clinical Data Management	CRO	Aptus Clinical
Nucleus	Data Collaboration Platform	Data Trial
Formedix	Data Standards Platform	Formedix

3 Test Objectives

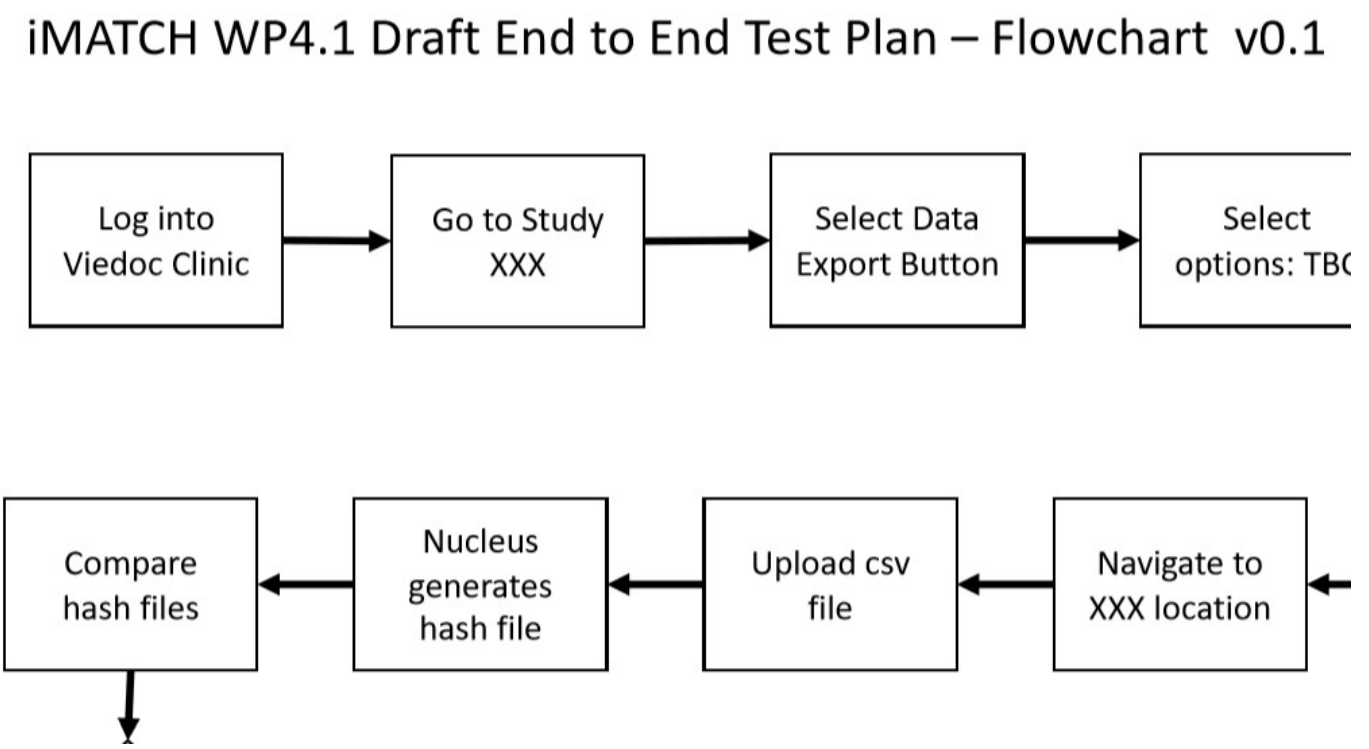
System/Process	System Detail	Test Objective	Aspects to be tested
Viedoc	Electronic Data Capture System	Data Export of raw data	Data Integrity of test study data Audit trail
Aptus Data Management	Data management department performing essential parts of the data processing	Raw Data upload to data repository	Retrieval of raw data export Hash code generation for data integrity check Upload of raw data to Nucleus Deletion of raw data from desktop
Nucleus	Clinical Data repository	Import and export of clinical data sets for storage/conversion to standards	Hash code comparison of raw data upload Storage location of raw data Edit rights of raw data file Generation of

			trigger for Formedix Audit trail
Formedix	Automated standards conversion	Data integrity following data transfer to and from Formedix Accurate standards mapping Generation of required traceability documentation (Define.XML) Removal/deletion of Clinical data	Nucleus trigger received Hash code comparison completed Standards conversion completed and define.XML SDTM file sent to Nucleus API call from Nucleus received to delete clinical data Clinical data deleted Audit Trail
Nucleus	Clinical Data Repository	Import and export of clinical data sets for storage	Retrieval of SDTM converted data set Correct permissions on SDTM data set Confirmation of data integrity of SDTM data set API call sent to Formedix for clinical data deletion following successful DI check Audit Trail generated

4 Test Approach

4.1 Key Principles

4.2 Test Process Flow

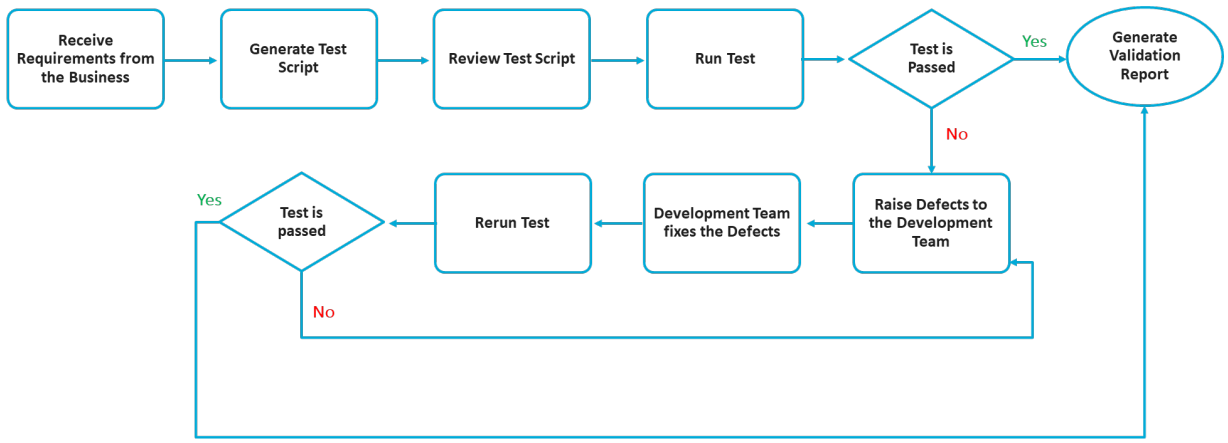


4.3 Test Methodology

Detail of script

A detailed test script will capture the above testing flow. The process is split into small test cases to ensure all aspects are covered. The test will be run as many times needed to have all steps passed. In the case that a step fails the whole test will fail and a defect will be raised associated to the specific step which has failed. Details of why the step was failed will be included on the related column of the test script (Actual Result). For each test run (in case a defect is identified, and the test is run more than once) a word document will be generated where screenshots of each step will be included as proving documentation. Once the whole test is passed successfully, a validation report will be written which will provide track of all test runs, any defect raised as well as supporting documentation.

Testing Flow



People involved Paul Blaney, Darren, Stephanie Roberts,

5 Test Deliverables

List of deliverable test documents:

- **Test Script:** Document which includes a set of instructions that will be performed on the system under test to test that the system functions as expected.
- **Validation Report:** A summary report of findings and results of the testing done. The report consists of outcomes that will later on be assessed for complete validation. Specifically, the report will include all test cases performed, including whether those test cases passed without issue. All deviations reported, including how those deviations were resolved.

6 Testing Criteria

6.1 Pass / Fail Criteria

6.1.1 Pass : Data Integrity is preserved

- Hash codes match
- Source Data is deleted when required
- Data reaches destination and corresponds to CRF
- Raw to SDTM data conversion is transparent and repeatable
- Data has appropriate access rights associated
- End to end Audit trail is generated and complete

6.1.2 Fail: Data Integrity is not preserved

- Hash codes don't match
- Source Data is not deleted when required
- Data does not reach destination and corresponds to CRF
- Raw to SDTM data conversion is not transparent and repeatable
- Data does not have appropriate access rights associated
- End to end Audit trail cannot be generated or is incomplete

6.2 Entry Criteria

- Test Script development
- Proper and adequate test data/ test files
- Environment Set up
- Trained and available resources

6.3 Exit Criteria

- Test Script updated with results
- Defects Report
- Validation Report Signed off

6.4 Suspension / Resumption Criteria

Suspension of the testing process will take place when there is a need to fix a defect. A defect will be raised when the data integrity is not preserved based on the failing criteria stated above in section 6.1.2.

7 Defect Management

Defects will be managed in accordance with SOP. All defects will be raised to the development team followed by supporting evidence on why the defect was identified. Once the development team confirm that the issue has been fixed, a new testing round will be performed by the testers to verify that the bug has been fixed. If this is the case the defect will be closed, and details will be included in the validation report at the end of testing process.

8 Test Environment, Resource and Data Requirements

8.1 Test Environment

Testing will be performed in the 4 systems (Viedoc, Nucleus, Formedix and Aptus Data Management) to ensure integrity in the data flow.

8.2 Test Data (test files)*

Details of any test data or files required to execute testing;

Copy of the latest OVSTAR build- nearly representative of the final OVSTAR build
4 visits worth
Single patient
Medical history, Demography, TIL infusion data

*The files mentioned above were not provided during iMATCH as the OVSTAR trial was not initiated.

9 Risk Management

9.1 Dependencies, Risks and Assumptions

- Prerequisite Entry Criteria is not met
- Test data is unavailable on time or proves to be inadequate

9.2 Contingency Plans

- Prerequisites that must be met before Load Testing can start will be defined
- Will ensure a full set of suitable and protected test data is available
- Will indicate what is required and will verify suitability of test data

10 Appendices

Test Script

Test Name	Step No.	Pre-requisites	Test Step Description	Exp
Viedoc Clinic Sign-in success	Step 1	Browser installed	Open up Google Chrome Browser	Bro
	Step 2		Navigate to Viedoc Clinic login page: https://www.viedoc.com/products/viedoc-clinic/	We
	Step 3	Valid credentials required	On the login page insert credentials and click log in	Use
Data Export of raw data from Viedoc	Step 1		Navigate to Study "XXX"	Stu
	Step 2		Select data export button	Da
	Step 3		Select options "XXX" and click on "Export Data"	Da