MRC-NIHR Trials Methodology Research Partnership: Webinar recording

Validating a cloud based Electronic Data Capture solution

Presented, on behalf of the UKCRC Registered Clinical Trials Units, by:

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The slides are available below.

For any queries, please contact uktmn@nottingham.ac.uk

https://youtu.be/FakGEsvgwXM

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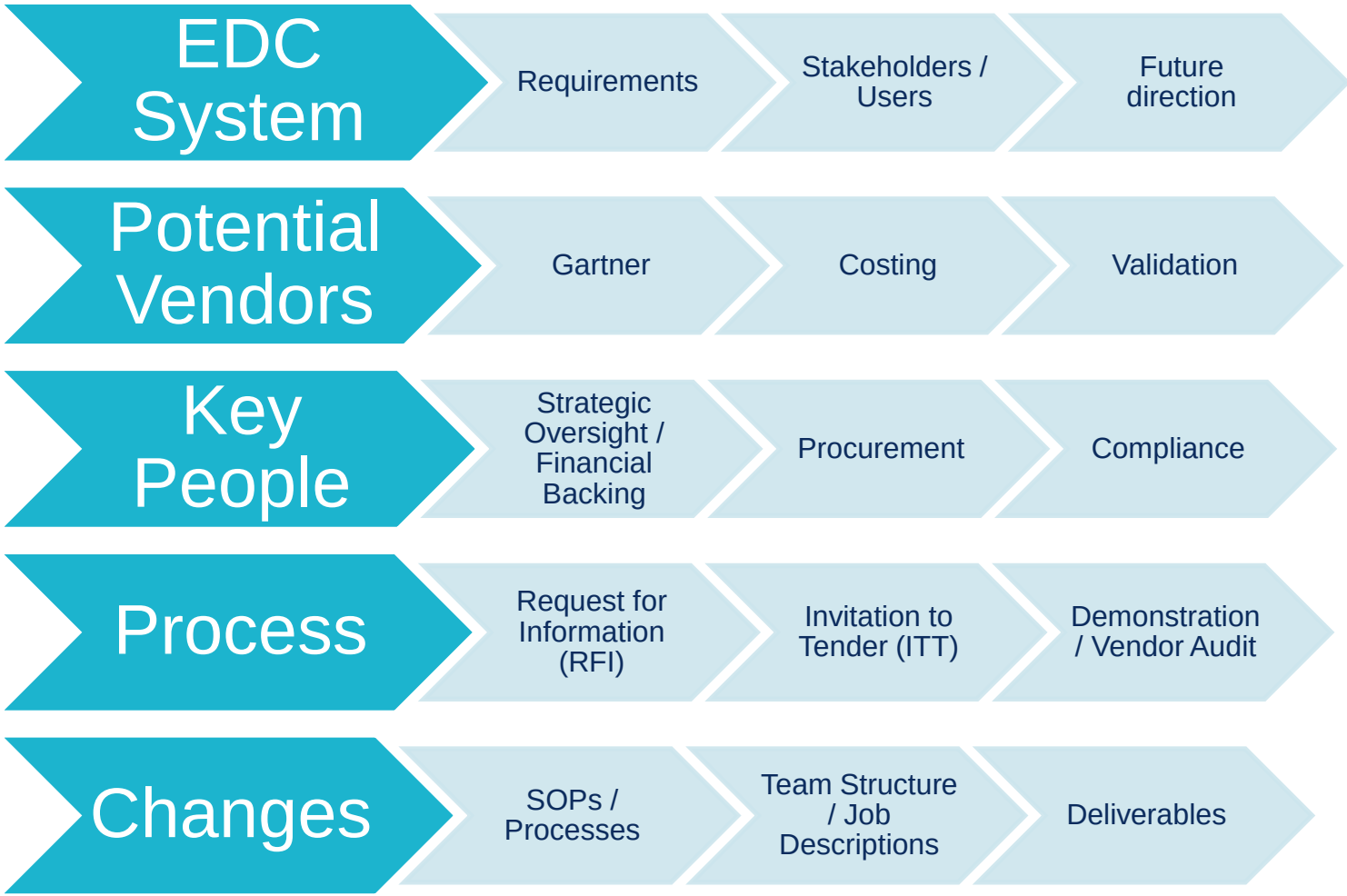
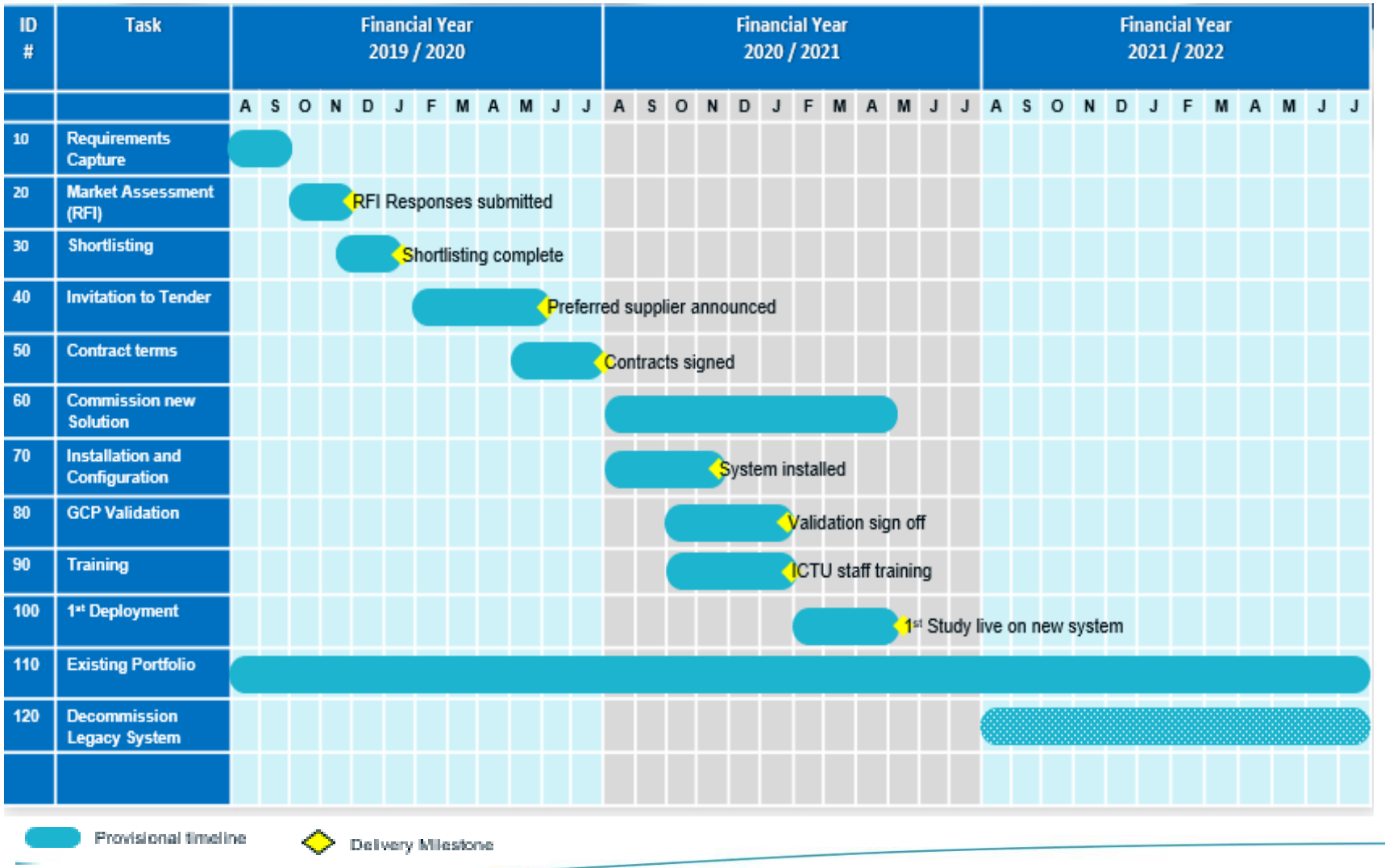
A Case Study: Computer System Validation of a Cloud Hosted System

Imperial College defacto electronic data capture (EDC) software for CTIMP trials in sustaining support with provider

Several discussions with current provider to understand their future roadmap for current software.

Recommended market review of Clinical Trial software undertaken to ensure that the next version of EDC software used is fit for purpose for at least the next 5 year


EDC System
Requirements
Stakeholders / Users
Future direction
Potential Vendors
Gartner
Costing
Validation
Key People
Strategic Oversight / Financial Backing
Procurement
Compliance
Process
Request for Information (RFI)
Invitation to Tender (ITT)
Demonstration / Vendor Audit
Changes
SOPs / Processes
Team Structure / Job Descriptions
Deliverables


ID #
Task
Financial Year 2019 / 2020
Financial Year 2020 / 2021
Financial Year 2021 / 2022
A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J
10 Requirements Capture
20 Market Assessment (RFI)
RFI Responses submitted
30 Shortlisting
Shortlisting complete
40 Invitation to Tender
Preferred supplier announced
50 Contract terms
Contracts signed
60 Commission new Solution
70 Installation and Configuration
System installed
80 GCP Validation
Validation sign off
90 Training
ICTU staff training
100 1st Deployment
1st Study live on new system
110 Existing Portfolio
120 Decommission Legacy System
Provisional timeline
Delivery Milestone

Procurement Process

Stage 1 – Request For Information (RFI)

- CDA/NDA
- Communication Approach
- **Functional and User Requirements**

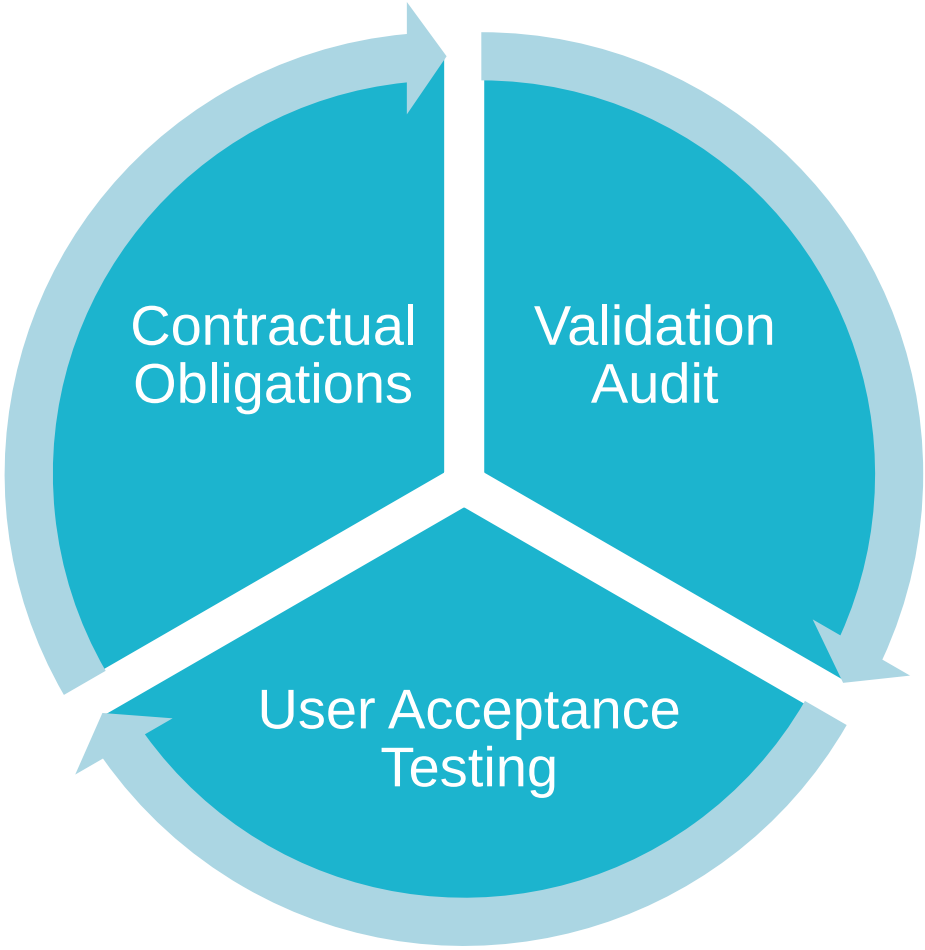
Stage 2 – Long List Selection

- Long List
- Cost – hypothetical portfolio
- **Validation / Compliance**

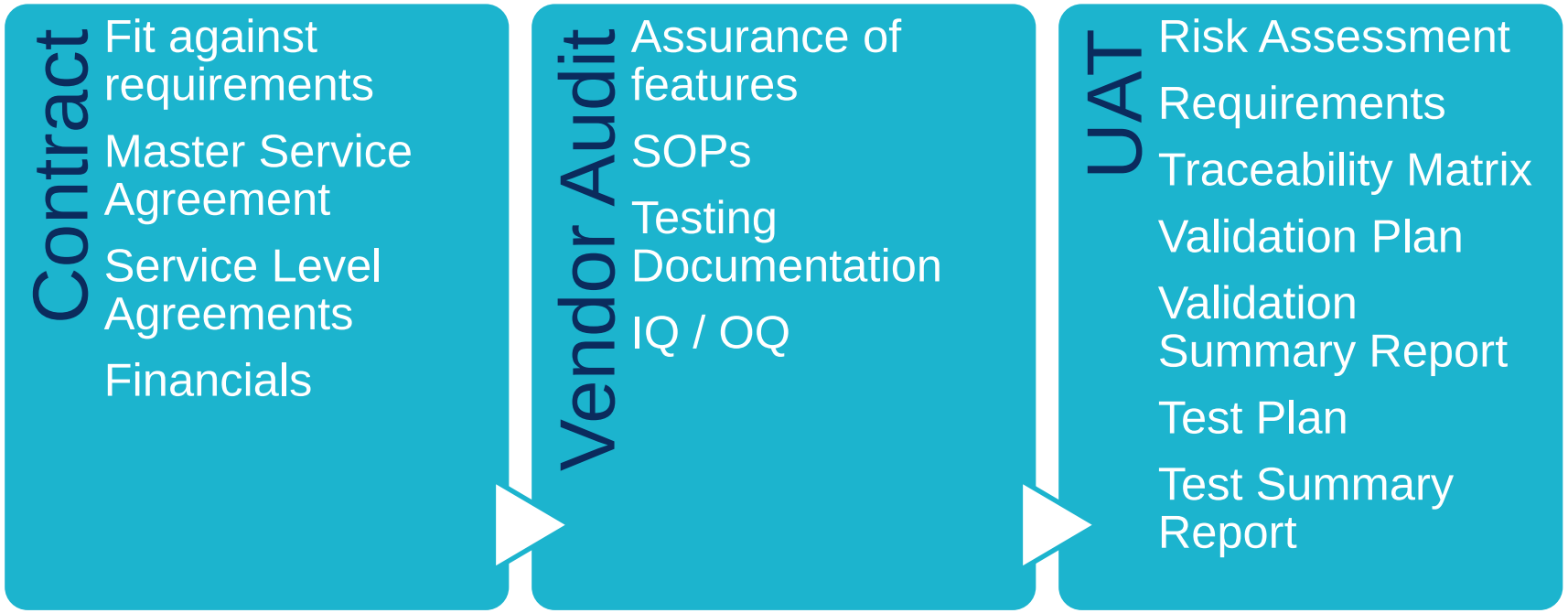
Invitation To Tender (ITT)

- Tender Question Booklet / ITT Document
- Demonstration
- **Vendor Audit**

Holistic Validation Approach



Holistic Validation Approach



Quality Assurance audits x 3 during process

Think of it as "Pizza as a Service"

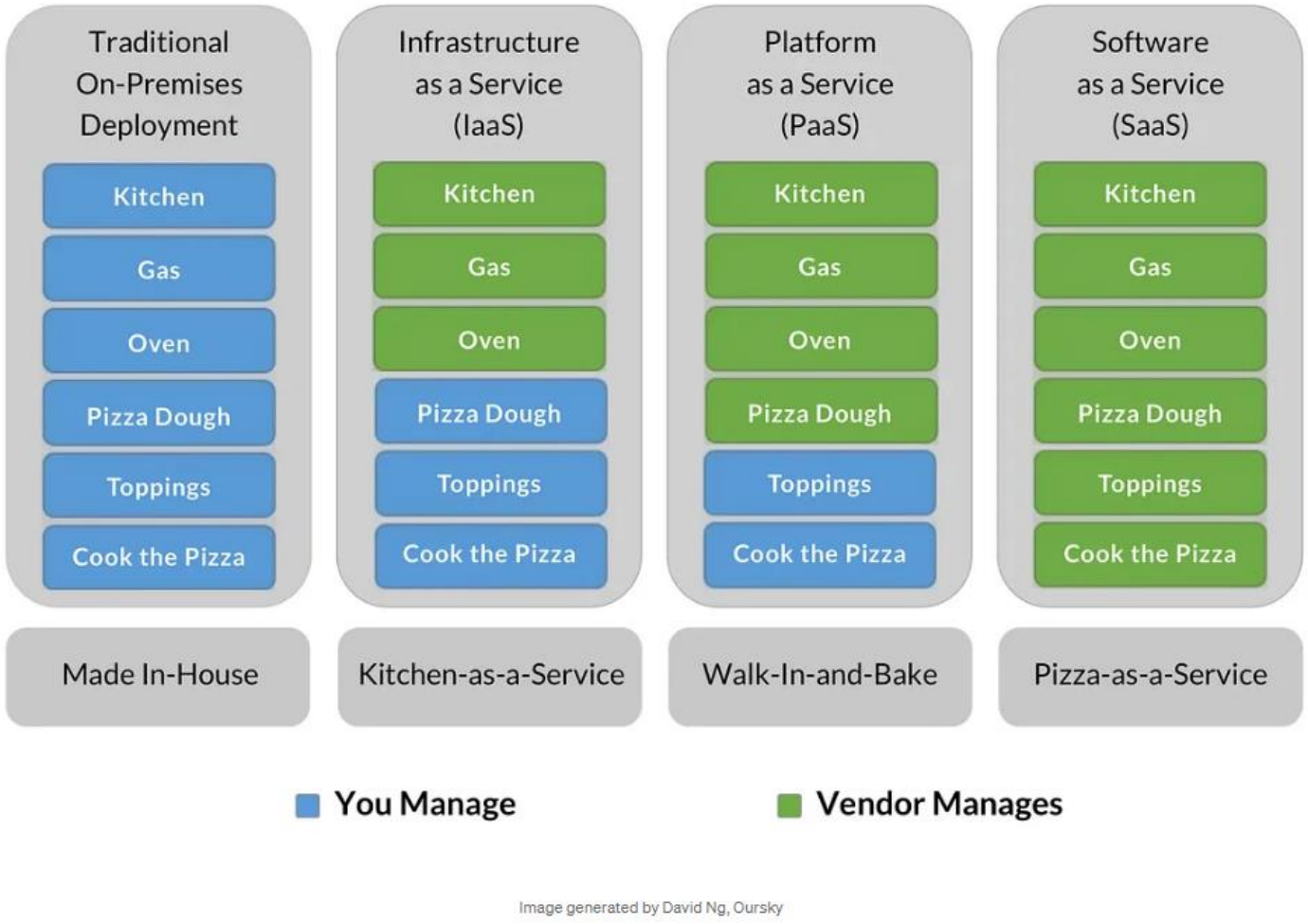


Image generated by David Ng, Oursky

Validation of Cloud Hosted Systems

Validation of System

Most vendors will provide a full validation(IQ/OQ/PQ), of their **unconfigured base** system.

The recommendation is for the Customer, to perform a full initial validation of what would be the configured system in the their environment.

Upgrades/Updates/Patches

Generally vendors will release upgrade/updates every 3-6 months and provide documentation of testing under Change Control.

The recommendation is for the Customer to use that time to do certain level of testing.
Consider is how to deal with mandatory security patches/bug fixes that are released "ASAP"

Data Integrity

Vendors should provide levels of encryption for data both at rest and in transit. But the ultimate responsibility lies with the customer.

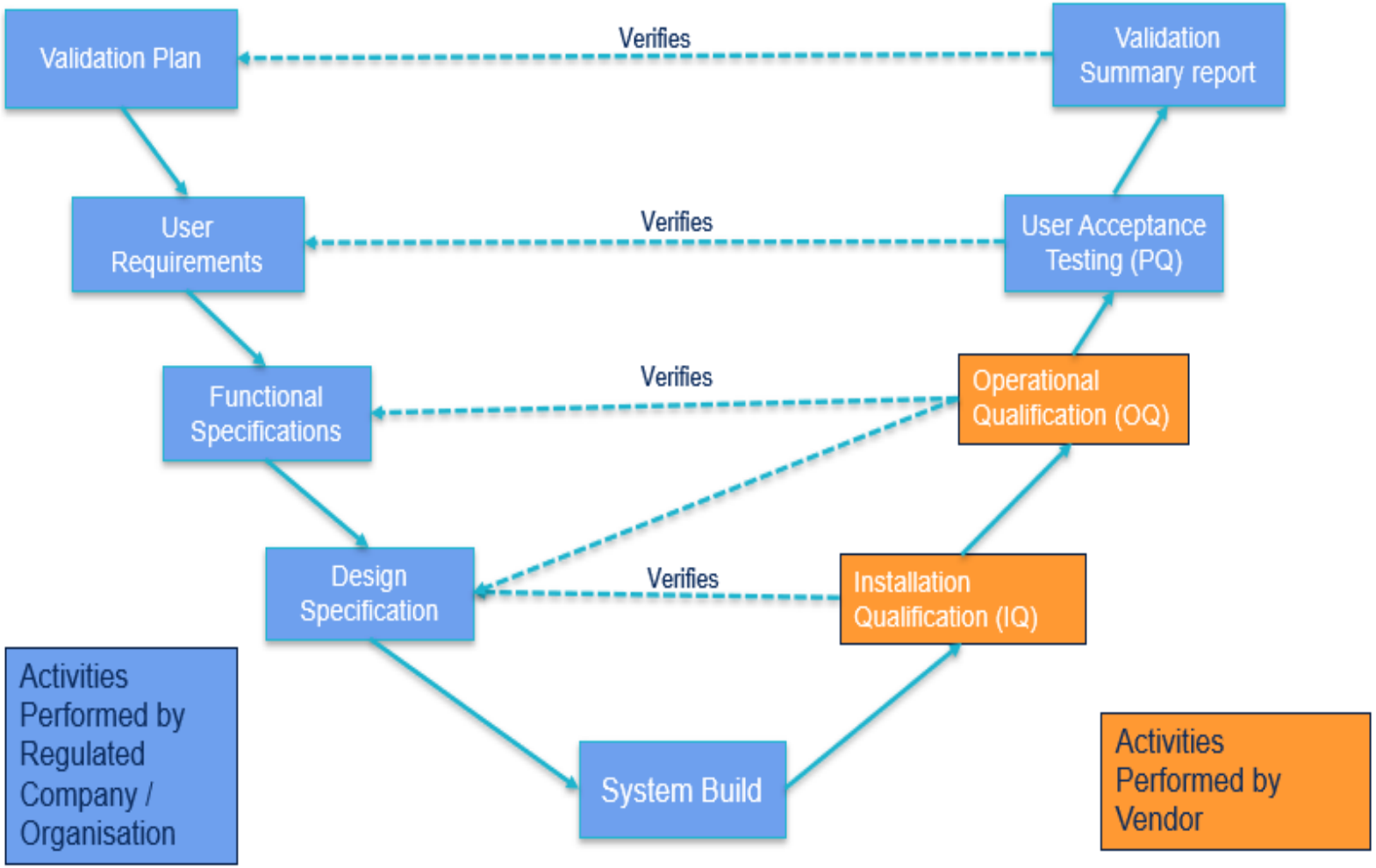
The recommendation is for the customer to incorporate data integrity tests in the initial validation and when testing upgrades.

Study Design and Build

Vendor's selling point is that the system(s) will allow study builds by simply using the systems functionalities and interface, (i.e. drag and drop style)

The recommendation would be that new studies/trials would undergo testing targeted at the newly configured components before going live.
Accompanied by SOPs/WI

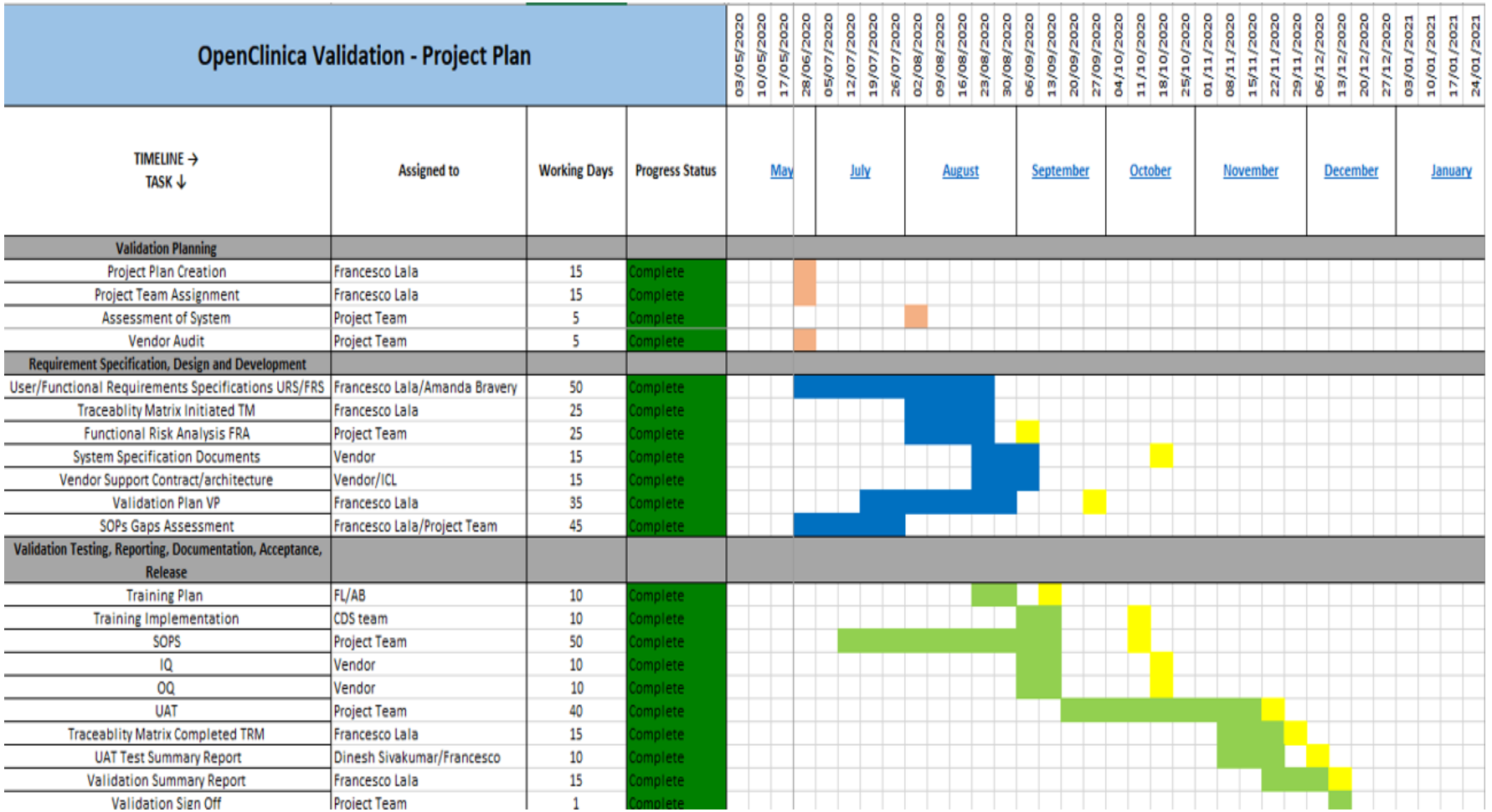
Validation Model (V-Model)



Validation Project plan

OpenClinica Validation - Project Plan

TIMELINE → TASK ↓	Assigned to	Working Days	Progress Status
Validation Planning			
Project Plan Creation	Francesco Lala	15	Complete
Project Team Assignment	Francesco Lala	15	Complete
Assessment of System	Project Team	5	Complete
Vendor Audit	Project Team	5	Complete
Requirement Specification, Design and Development			
User/Functional Requirements Specifications URS/FRS	Francesco Lala/Amanda Bravery	50	Complete
Traceablity Matrix Initiated TM	Francesco Lala	25	Complete
Functional Risk Analysis FRA	Project Team	25	Complete
System Specification Documents	Vendor	15	Complete
Vendor Support Contract/architecture	Vendor/ICL	15	Complete
Validation Plan VP	Francesco Lala	35	Complete
SOPs Gaps Assessment	Francesco Lala/Project Team	45	Complete
Validation Testing, Reporting, Documentation, Acceptance, Release			
Training Plan	FL/AB	10	Complete
Training Implementation	CDS team	10	Complete
SOPS	Project Team	50	Complete
IQ	Vendor	10	Complete
OQ	Vendor	10	Complete
UAT	Project Team	40	Complete
Traceablity Matrix Completed TRM	Francesco Lala	15	Complete
UAT Test Summary Report	Dinesh Sivakumar/Francesco	10	Complete
Validation Summary Report	Francesco Lala	15	Complete
Validation Sign Off	Project Team	1	Complete



We achieved the Validation on time!

Key to Success:

- Define the Process and Team
- Involvement of all key people
- Effective and timely communication
- Vendor co-operation
  - Defined upfront
  - ITT Demonstration
  - Vendor audit
- Documentation – prep beforehand
- SOPs
- Training for all user
- Signing of key documents

Thank You