Report of the implementation of a case based connectivity solution for TB diagnosis

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FIND

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Abbreviations

ADA	Adenosine Deaminase	NTP	National Tuberculosis Programme
API	Application Programming Interface	NTRL	National Testing Reference Laboratory
CDP	Connected Diagnostics Platform	PCR	Polymerase Chain Reaction
DR-TB	Drug-Resistant TB	PEPFAR	President's Emergency Plan for AIDS Relief
DST	Drug susceptibility testing	PTB	Pulmonary TB
Dx	Diagnostics	RR-TB	Rifampicin-Resistant TB
E2E	End to End	SIM	Subscriber Identity Module
EPTB	Extrapulmonary TB	SLMTA	Strengthening Laboratory Management Toward Accreditation
EQA	External Quality Assurance	SMS	Short Message Service
FIND	Foundation for Innovative New Diagnostics	SSL	Secure Socket Layer
HIS	Hospital Information System	SSM	Sputum Smear Microscopy
HIV	Human Immunodeficiency Virus	TB	Tuberculosis
HPF	High-Power Field	TLS	Transport Layer Security
IGRA	Interferon Gamma Release Assay	TPP	Target Product Profile
ISO	The International Organization for Standardization	TST	Tuberculin Skin Test
IT	Information Technology	VM	Virtual Machine
LAN	Local Area Network	WHO	World Health Organization
LPA	Line Probe Assay	WRD	WHO-approved rapid diagnostics
MDR-TB	Multidrug-Resistant TB	XDR-TB	Extensively Drug-Resistant TB

1 Executive Summary

Today, many healthcare programmes still rely on paper-based systems for managing patient diagnostics data and reporting. These systems are time consuming, inefficient and ridden with data management issues. Often results data is rekeyed from paper records into multiple systems, leading to inaccurate transcription of data and slow delivery of data into supporting systems. Where electronic diagnostic instruments are involved this can mean the manual recording of electronic data onto paper, followed by the subsequent rekeying of this data back into electronic systems. Connected diagnostics combined with a fully digital paperless system (where each step of the patient registration and diagnostic pathway is managed in an integrated fashion) can therefore save significant amounts of time, whilst driving up the quality, accuracy and immediacy of data. In addition, such digital systems can provide valuable insights into performance metrics and inform other areas of potential efficiency improvements.

To meet these challenges, FIND and others created the CDP (Connected Diagnostics Platform). CDP is intended for use in lower- and middle-income countries and is capable of capturing data on multiple infectious diseases. CDP is designed to support patient testing workflow, from patient registration, diagnosis and sample collection, to testing and result management. CDP links patient and episode data with test results generated both by connectable devices (such as the Cepheid GeneXpert™) and un-connected devices (such as the microscope). The result is a single view of all testing activity at participating sites (and their associated labs) along with test results and treatment outcomes, all linked to the patient. CDP can provide centralised reporting, as well as routing selected data into other external systems such as TB surveillance monitors. It is theoretically possible to establish a fully digital End to End process for patient testing and TB management by linking multiple, existing systems in CDP.

CDP Pilot in Viet Nam

FIND, in partnership with the National Tuberculosis Control Programme (NTCP) in Viet Nam, ran a pilot study to assess the performance of CDP, as well as the feasibility of implementing and operating such a digital process in an intended setting of use. Additionally, the CDP study was intended to provide input into the existing ‘Diagnostic Connectivity’ Target Product Profile (TPP) as well as the future ‘Data Repository and Gateway’ TPP.

Hanoi was an ideal location for the study due to its favourable infrastructure, existing use of technology and willingness to engage. The study was run in the National Lung Hospital, the Hanoi Lung Hospital and two district health centres at Hoang Mai and Hai Ba Trung. The study was active for seven weeks and took approximately 6 months to execute from the initial design phase to the final results analysis phase.

The approach

A ‘Shadow Process’ was adopted to allow FIND to assess whether CDP presented a feasible solution without interrupting the ongoing work of the NTCP in Viet Nam. This ‘Shadow Team’ consisted of individuals from the NTCP who followed the registration, diagnosis and testing of patients as they moved through the existing paper based system.

At each step in the diagnostic process, the shadow team mirrored the step by entering the data into CDP. Shadow team members were positioned at key physical locations within the hospital sites (e.g. out patients reception, laboratory reception, microscopy laboratory). Actual patient test results

were copied into CDP and linked with the CDP version of the patient's record: Xpert results were captured electronically via connectivity (using mobile data and LAN) and microscopy results were manually entered via the CDP web portal. Patients who tested positive for MTB and DR-MTB were automatically entered into existing surveillance systems VITIMES and e-TB Manager respectively.

Conclusions
The conclusion of the study is that CDP does present a viable solution, capable of digitising the patient testing workflow resulting in process efficiency and improved data access. CDP appeared to be easy to use, quick to be trained in and capable of supporting connectivity and systems integration. Areas for improvement were identified that will be used to fine tune and inform future implementation and operations.

Creating a customised version of CDP for Viet Nam, launching the service, and subsequently operating the shadow process, represented the execution of the full 'connected service development life cycle'. Consequently, enormous insights were gained into the requirements, challenges and activities that make up such an endeavour.

For various reasons the 'shadow' approach itself was not capable of providing comprehensive, end to end process improvement measurements. However, the next level of accuracy can be achieved by replacement of an existing paper process with the digital process, followed by a comparison of operational performance. Therefore, the next step for CDP and the exploitation of patient cantered connected diagnostics, is to conduct pilot studies that implement the digital process and pave the way for network wide deployments. The positive outcomes of this study prove that CDP is well positioned and capable of moving to this next step.

2 Background

2.1 Introduction

Reliable and timely diagnostic test information is of paramount importance for the proper functioning of several components of the diagnostic and treatment cascade including patient management, epidemiologic surveillance, quality assurance, laboratory operations, and technical product support.[1] Archiving test data in an accessible standardized database and enabling integration with laboratory information systems, electronic health records, and health program databases can allow laboratory diagnostic equipment to meet these broad-ranging needs. This requires device connectivity, wherein testing data and results are automatically and securely sent to repositories, translated into useful information and channelled to appropriate parties.

The transition in the management of medical records and surveillance systems, from paper-based methods, through electronic systems installed on isolated computer terminals, to systems on local area networks and, now, Internet-accessible databases with storage of data on the cloud, is an evolution that can reduce tedious and time-consuming paperwork and reduce errors. In the absence of adequate laboratory information technology infrastructure, complemented by standardised reporting solutions for screening activities and treatment follow-up, many low-resource countries have continued to use slow, error-prone paper-based recording systems. In such systems, editing

1 D Falzon et al. Digital health for the End TB Strategy: developing priority products and making them work. European Respiratory Journal 2016

and transmission of paper reports cause inherent delays and contribute to the cost, complexity and relative inaccuracy of data interpretation. [1]

According to the WHO Framework of indicators and targets for laboratory strengthening under the End TB Strategy, all sites that use WHO-recommended rapid diagnostics should be transmitting results electronically to clinicians and to information management systems using data connectivity solutions no later than 2020 (Indicator 4). Furthermore, remote monitoring via data connectivity solutions should be used to monitor key performance indicators at all sites that use WHO-recommended rapid diagnostics no later than 2020 (Indicator 9).[2] This report outlines the activities, challenges and lessons learned during the implementation of a case based connectivity solution in Viet Nam.

2.2 Challenges with existing solutions

During the last decade, several diagnostic companies have begun developing a new generation of tests for diseases of poverty such as TB and HIV, with significant support from public and philanthropic funders, including the National Institutes of Health (Bethesda, MD, USA) and the Bill & Melinda Gates Foundation (Seattle, WA, USA). The use of these new diagnostic tests has increased dramatically in the laboratories of developing countries and, more recently, in decentralised point-of-care facilities. In addition to providing rapid and accurate test results, these devices also support connectivity for remote data transfer.

A number of connectivity platforms have been developed by the manufacturers and independent companies to support the data collection from these diagnostics but many only offer support for either a single disease or are limited in terms of the models and types of diagnostic tests supported. Whilst growing in use, the number of newer connected diagnostics still only accounts for a small percentage of tests that are performed within a health system. The coverage of these tests varies considerably between countries and settings, with some countries still having only a limited number of machines based in reference laboratories. Accordingly, the challenges of paper based reporting for tests such as microscopy or culture are still present. Connecting just a subset of tests in itself could cause additional issues of data fragmentation not just between test types but also in the storage and reference of those in a digital and non-digital nature.

2 Global Laboratory Initiative (GLI). GLI Quick Guide to TB Diagnostics Connectivity. 2016. Under publication. To be available from http://stoptb.org/wg/gli/

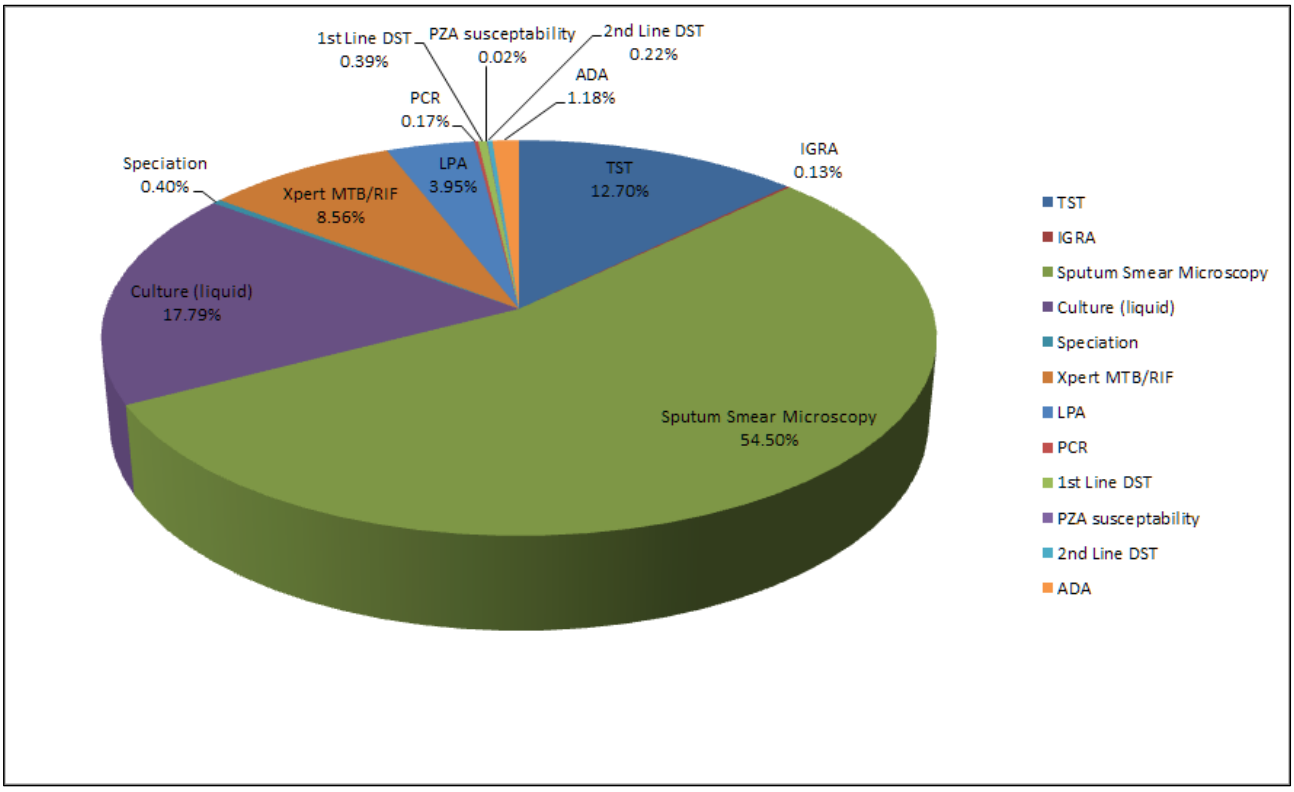


Fig 1: Breakdown of tests types performed in 2012 in South Africa - *Int J Tuberc Lung Dis* 19(2):216–222

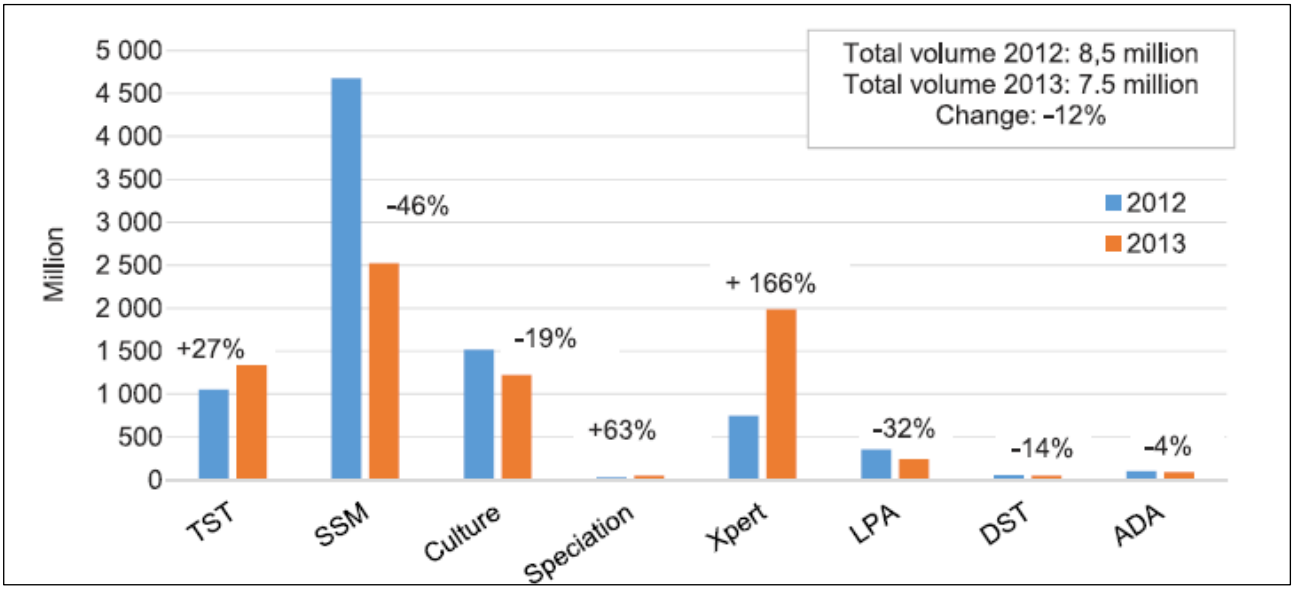


Fig 2: Volume change of tests by type 2012-2013 in South Africa - *Int J Tuberc Lung Dis* 19(2):216–222

In addition to these issues many connectivity platforms omit the patient as part of the system entity model. Rather, the functionality of these systems focusses on device monitoring, and tracking how many tests have been performed, as well as associated metrics like error rates. While beneficial, the lack of a patient entity makes it difficult to associate test results with the patient. A single patient can have multiple episodes of the disease in their lifetime, during any of one those episodes will have multiple encounters with a clinician and gives multiple samples. Simply counting tests

performed on samples without the ability to trace this at a patient level does not provide the capability to accurately assess the disease burden of a country.

2.3 FIND's Connected Diagnostics Platform

In light of the challenges above, FIND developed the Connected Diagnostics Platform (CDP) for:

1. The centralized and secure aggregation and flexible visualization and management of clinical test and device performance data from diagnostics; and
2. The digitization of diagnostic test workflows and laboratory processes from patient registration, case history, examination and reporting of samples, as well reporting of quality metrics and key performance indicators

In addition to displaying metrics regarding number of tests performed or indicators of error rates, the CDP has been designed to accommodate common laboratory testing workflows and offers the full digitization of the paper based forms that are used i.e., for patient registration, sample referral and result reporting. The concept is that the entire end to end process of the diagnostic pathway is captured in a single system, that data is easily stored and accessed for informatics purposes, and that the results can be linked back to the patient so that decisions on their care can be taken. Below is an example of the CDP workflow.

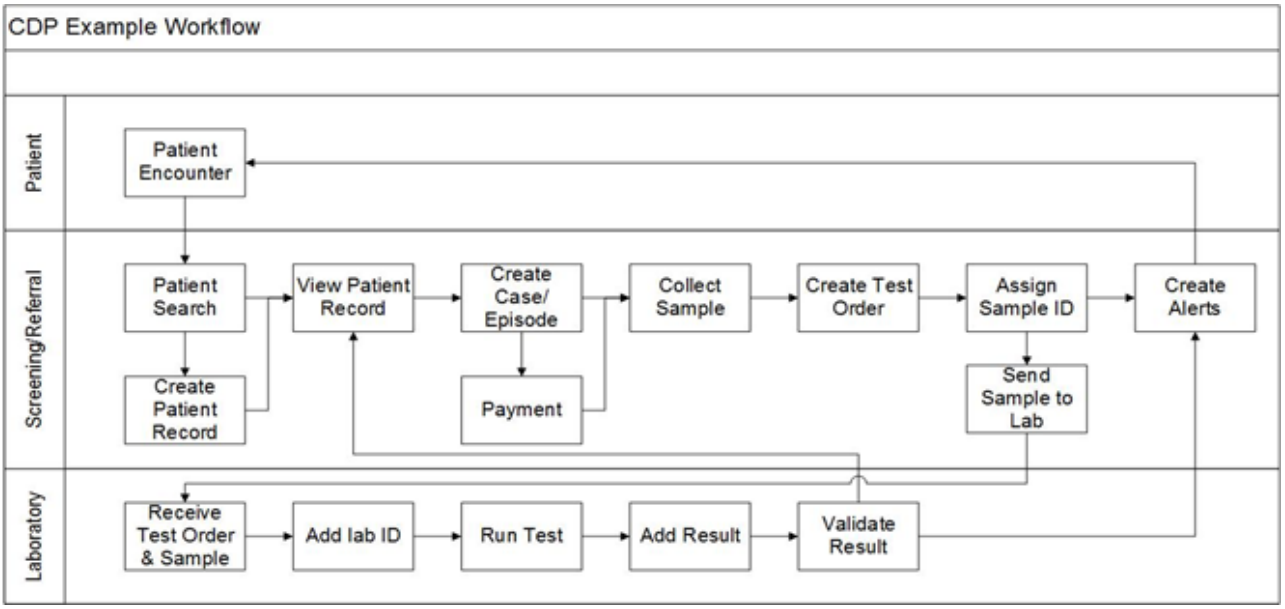


Fig 3: Example Test order workflow

CDP consists of following two major components:

1. CDP Server - a web based connectivity platform
2. CDP Bridge - a client component used for capturing and transmitting results from diagnostic devices

2.3.1 Key features of CDP server

- Web application for the capture and representation of data collected from remote diagnostics platforms, regardless of manufacturing origin and disease
- Web application can be hosted in virtual servers a.k.a. cloud hosting, or on site within the customer's own IT infrastructure

- Support for multiple languages
- Patient Electronic Medical Record
- Fully digital diagnostic testing workflow including patient registration, case/episode registration, history of previous treatment, ordering of diagnostic tests, reporting of test results, upload of x-ray files, lab manager release of results
- Alerting functions to report notifiable events via email or SMS
- Ability to alert specific users when selected conditions are met (e.g. test result available)
- Configurable user permissions management system
- Ability to connect to multiple devices via configurable 'device manifests'
- Manual results entry for offline tests e.g. microscopy
- Test referral system to other sites
- Laboratory manager review and approval of results prior to release to clinical staff
- Finance approval for test order payment
- Ability to integrate approved results automatically into integrated systems
- Multiple CSV downloads of key data, for reporting purposes
- Ability to search for patients across the entire hierarchy
- Aggregated site and devices dashboards
- Application Programming Interface (API) for data extraction to other systems

2.3.2 Key features of CDP bridge

- Interrogates the database of devices and extracts all available data
- Displays status of instruments connected
- Sends data to nominated servers according to schedules or requests by users
- Displays data queued and available to send
- Displays data previously sent
- Provides transmission reports to users and email recipients
- Caching of test and device data if internet is not available
- Able to generate dummy data for debug and testing purposes
- Provides user authentication and security
- Supports a one click installation method
- Has an automatic update mechanism allowing new versions, enhancements and bug fixes to be deployed without the need of site visits by IT staff
- Supports UTF-8 language characters and can be customised for each country of deployment
- Supports use with Windows XP computers and above

2.4 Viet Nam

FIND sought to conduct the study in Viet Nam in large part due to the organization's past and current presence in the country. FIND has been working in Viet Nam since 2007, through various clinical trials and later major projects like the UNITAID-funded EXPANDx TB project, and Center for Disease Control cooperative agreements (CDC Co Ag) under PEPFAR, in close partnership with the National Tuberculosis Control Programme and its associated facilities including NTR, Hanoi. FIND has a locally registered office in Hanoi, based at the NTP/NTRL campus

FIND has conducted a variety of studies in Viet Nam for evaluation, demonstration and implementation of newer TB diagnostics. Through the EXPANDx TB project, FIND strengthened the capacity of two labs for C&DST/ LPA for MDR-TB diagnosis and monitoring purposes and an additional two labs supported for culture for treatment monitoring purposes including training,

procurement of supplies and technical support. FIND, with CDC, has implemented a Strengthening TB laboratories towards accreditation (TB SLMTA) programme to implement quality management systems in six laboratories, and introduced quality assurance/EQA programmes for a range of TB diagnostics especially for FM microscopy, Cepheid GeneXpert™.

FIND also assessed that the country was an appropriate setting in which to conduct a study that would revolve heavily around TB diagnostic processes. WHO estimated 130,000 cases of TB in Viet Nam in 2013 (144/100.000 POP). TB is concentrated in vulnerable populations, HIV co-infected, people in congregate settings, migrants and children.

	Total Notified	New & Relapse	Retreatment Excluding Relapse	New or previous treatment history unknown			Relapse			Percentage of pulmonary cases bacteriologically confirmed
				Pulmonary Bacteriologically Confirmed	Pulmonary Clinically Diagnosed	Extra Pulmonary	Pulmonary Bacteriologically Confirmed	Pulmonary Clinically Diagnosed	Extra Pulmonary	
Viet Nam	102087	100349	1738	49938	25179	18118	7114			69

Table 1: Source WHO Global TB Report 2015

A range of diagnostic tests are used in Viet Nam for the detection of TB including Smear, Culture and GeneXpert. The number of TB/MDR-TB diagnostic facilities in country is as follows:

Test Type	Number of Facilities
TST	NIL
IGRA	2
SSM	1085 includes (707 District,,64 provincial, Satellite: 311,Central : 3)
Culture	30 facilities + 2 more in 2017
Speciation	30 facilities +2 more in 2017
Xpert	69 by Dec 2016 and 75 by End of January 2017
LPA	2 already + added 2 more in 2017
PCR	NIL
DST	2 already + added 4more in 2017
ADA	NIL

Table 2: List of Test Types

The primary method for the capture of data throughout the diagnostic process is manual entry on paper forms. All patient registration, examination requests and result reporting is conducted this way, which makes it difficult and time-consuming to track patient data, leads to risk of data errors, and results in inefficiencies and duplication of effort because simultaneous access to information is not supported.

There are however two electronic systems that are used for the recording of data once the primary paper based processes are complete.

1. VITIMES - a tool developed by NTP via Ha Thang Company (Viet Nam local software company) for the TB screening and confirmed patients. All TB suspects are registered in VITIMES regardless of diagnostic outcome.
2. e-TB manager - a tool developed by Management Sciences for Health (MSH), MA, USA for the programmatic management of TB and DR-TB cases and medicines. It is designed to provide an integrated view of cases, medicines, and other TB commodities for NTP management purposes at different levels. The system provides key information consolidated online at any level for rapid decision making and epidemiological surveillance, where interventions are needed. In the case of e-TB Manager in Viet Nam only DR-TB confirmed patients are registered in the system.

Total Country TB Facilities	Number using VITIMES	Number using e-TB Manager
1085 under NTP direct network	800	54

Table 3: TB Managements Tools, Usage

In the case of both VITIMES and e-TB Manager the entry of data happens retrospectively. The primary testing workflow is supported via the paper based forms and details are manually copied to the respective systems by users, usually on a batch basis. In some cases data entry can occur several weeks after the event being transcribed. Both VITIMES and e-TB Manager are standalone systems i.e., they are not integrated and users must login to them separately according to the desired task.

2.5 FIND/NTP Study

Previous reports on the use and benefits of connectivity platforms have focussed on the benefits once the test result is available (i.e. the ability to quickly notify clinicians of results) along with the benefits of being able to remotely monitor consumption of consumables (i.e. to prevent stock outs). In June 2016 FIND approached the Viet Nam NTP to conduct a study of the CDP. The study would follow the form of a time-limited pilot implementation of CDP to assess:

- Extent to which CDP software is ‘fit for purpose’ and its ease of use
- Feasibility and effectiveness of a fully digital workflow (test order, examination and reporting)
- Feasibility of integration to legacy based systems VITIMES and e-TB Manager
- Bottlenecks in the diagnostic processes
- Any possible reduction of loss of test orders
- Patient drop out points within the diagnostic process i.e. at finance payment
- Evidence and insights upon which to base a wider integration and rollout of CDP as well as data to support the further development of connectivity Target Product Profiles (TPPs)
- Improvements to the following performance indicators (during the workflows leading to result availability) when compared with existing manual processes:
    - Step Process Speed: Increase the speed of specific processing steps - see table (4) below
    - Transaction errors / Accuracy: Improve accuracy of data capture in test orders by mandating data entry and using controlled input choices (drop downs)

- Process Effort: Reduce the manual processing effort of data entry to VITIMES and e-TB Manager
- End to end (E2E) turnaround time (queuing) – Reduce the overall turnaround for time from encounter to clinical response

Specifically for the purpose of monitoring the Step Process Speeds the following times would be captured and compared between legacy paper based methods and the digital capabilities of CDP. For further definition please see section: '4.4 CDP entities and test order workflow'.

For an Order	the time between	New	and	Finance Approved
For an Order	the time between	Finance Approved	and	Sampled Collected
For an Order	the time between	Sampled Collected	and	In Progress
For an Order	the time between	In Progress	and	Closed
For an Order	the time between	In Progress	and	Not Financed
For a Test	the time between	New	and	Pending
For a Test	the time between	Pending	and	Received
For a Test	the time between	Received	and	In Progress
For a Test	the time between	In Progress	and	Pending Approval
For a Test	the time between	Pending Approval	and	Complete
For a Test	the time between	Received	and	Pending Approval
For a Test	the time between	Order: Finance Approved	and	Pending Approval

Table 4: Process Step Times Captured in CDP

Since CDP had not previously been used in a real world clinical setting, it was considered premature to introduce its functions and processes directly into the clinical environment. The concept of a 'Shadow Process' was therefore conceived to allow real patient diagnostic test orders to be mirrored in the CDP system with minimum disruption and risk to the business as usual management of patients - see section 0 '4.1 Shadow process'.

3 Study parameters

3.1 Overview

The study focussed on outpatient testing for tuberculosis using selected tests, as managed across four individual sites within the city of Hanoi. The requirement was to:

- Use CDP as both a connectivity platform as well as a method for providing an automated paperless testing workflow
- Automatically collect nearly real-time diagnostic data

- Provide a real-time integration with e-TB Manager and VITIMES, without the need to re-key information or log into multiple systems
- Avoid interference with the 'business as usual' testing process
- Avoid integration with production systems, in order to reduce risks and complexity

3.2 Devices / Assays

For the study period two test types were enabled on the CDP platform. One fully connected diagnostic test (Cepheid GeneXpert-™ - Sunnyvale CA) was chosen which would send test results automatically to CDP upon completion alongside a non-connected test of Sputum Smear Microscopy (SSM) which laboratory technicians would have to enter results manually within CDP using digitally recreated forms that mimic paper. Reporting of other test types such as culture or LPA was not in scope of the initial study for reasons of time, training and complexity.

3.3 Sites and site selection

For the study, four sites were chosen around the Hanoi area that represent a variety of different workflow configurations, the variables consisting of:

1. Sites with onsite testing capabilities for Xpert, microscopy or both
2. Sites with access to VITIMES, e-TB Manager or both
3. Sites that refer samples for testing to another location

Site	Xpert	SSM	VITIMES	e-TB Manager	Inbound Referral	Outbound Referral
NTP National Hospital	X	X	X	X		
Hanoi Lung Hospital	X	X	X	X	X	
Hoang Mai District Health Center	X	x	X	X		
Hai Ba Trung District Health Center		x	X	X		X - Xpert

Table 5: Study Site Configuration

3.4 Connectivity requirement

In order for test results to be automatically sent from GeneXpert devices to CDP, the ability to transmit data over a network connection was required. Prior to the study the GeneXpert machines were isolated from the internet and had no means to transmit data. Further details of the methods and challenges associated with establishing a connectivity solution for these devices is contained in section 0 '5.5 Data transmission & internet access' of this document.

3.5 Integration Requirement

In order to demonstrate the efficiencies of CDP, namely the ability to reduce process effort by automatically sending test results and other desired information to VITIMES and e-TB Manager, integration between CDP and these systems was developed for the study. Integration was originally planned for the Hospital Information Systems (HIS) too but this was taken out of scope for the study due to the fact the National Lung Hospital was midway through updating their HIS and time

restraints for the study did not permit the capture of integration requirements and design of an integration solution.

3.6 Study duration

Planning for the study started in June 2016 with several months dedicated to clarification of scope, system design and the specification of software customizations (including integration planning). This activity overlapped with a development work stream, which delivered the required software enhancements, along with a suite of quality assurance tests.

These work streams along with 'study readiness' activities, resulted in a seven week study period during which a dedicated team 'shadowed' the diagnostic testing in the chosen sites. The post study analysis period followed, during which data from the study period was assembled and analysed, and a variety of reports written.

Software development did not stop once the study period had started. Provision for continued maintenance of the code and the ability to respond to priority feedback from users (as well as resolve any 'production issues') was made. As a result three maintenance releases were made during the study period.

Further details of these activities can be found in section 6 'Project delivery'.

Study Start	Study End	Study Duration Days
21st November 2016	6th January 2017	47

Table 6: Study Period

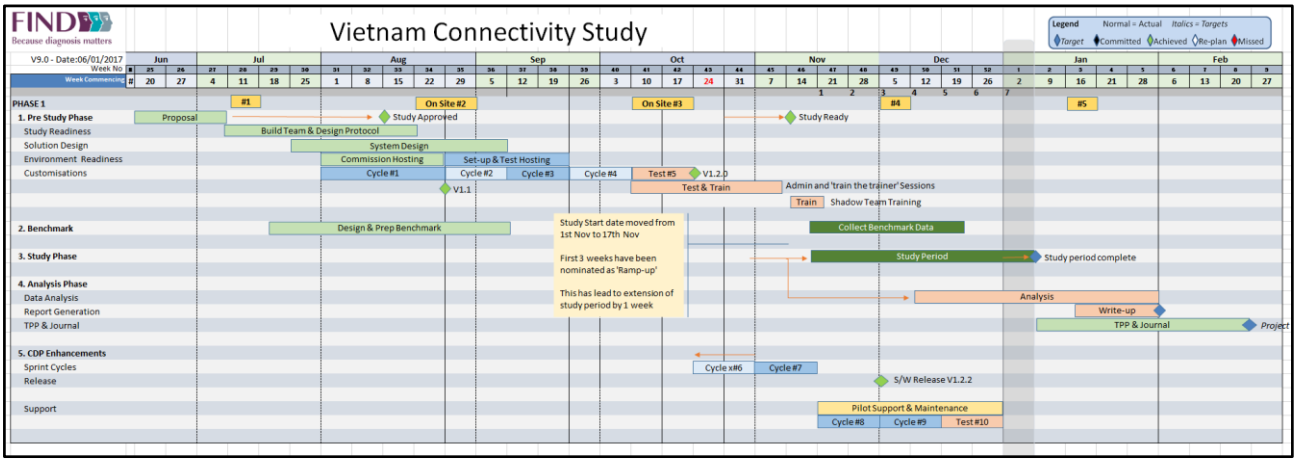


Fig 4: High level view of project work streams and timescales

3.7 Capacity building (local partners)

A pillar of the FIND Connectivity strategy is the commitment to in-country capacity building. This manifests itself in a requirement to use local skills and resources to deliver both developments and operations.

Although FIND has an office based in Hanoi a technically focussed local implementation partner was agreed to provide:

- Study planning and project management
- Selected software development

- Training and operational support

FIND chose to partner with Larion Computing (http://elarion.com/), an ISO certified company based in Viet Nam with more than 10 years' experience of providing software and consultancy services.

4 Study solutions - Processes, Resources, Workflows & Customizations

4.1 Shadow process

During the study period two separate processes were operated:

1. As-is Process - The existing legacy testing processes
2. The Shadow Process - The electronic process run in parallel with the as-is Process for comparison

The as-is processes were used for provision of health care to the patient and the electronic process was only used to generate study data.

The Shadow Process required that clinical and administrative staff were shadowed during their routine roles by additional resources (Shadow Team), who mirrored the clinical team's function using the CDP system. In this way the real world test orders could be separately processed through the CDP system, without impacting provision of clinical services to the patients.

A single set of clinical samples were used to drive the test so the number of tests and consumables required to support the study was not duplicated. Whilst the standard paper based reporting (from the existing clinical and administrative teams) was used in the as-is process, the results from the GeneXpert devices were automatically added to the CDP system using connectivity; microscopy results were manually entered by the Shadow Team into CDP via the user interface.

4.2 Shadow Team resources

In total 32 individuals were involved as part of the Shadow Team. These individuals were recruited by the NTP from existing staff and in many cases the Shadow Processing was included as part of the daily activities.

Due to the reduced volumes experienced in the Hang Mia and Hi Ba Trung sites, only one Shadow Team member was allocated to all roles, in each site.

The diagrams below show the numbers and locations of Shadow Team members in the National and Hanoi lung hospitals.

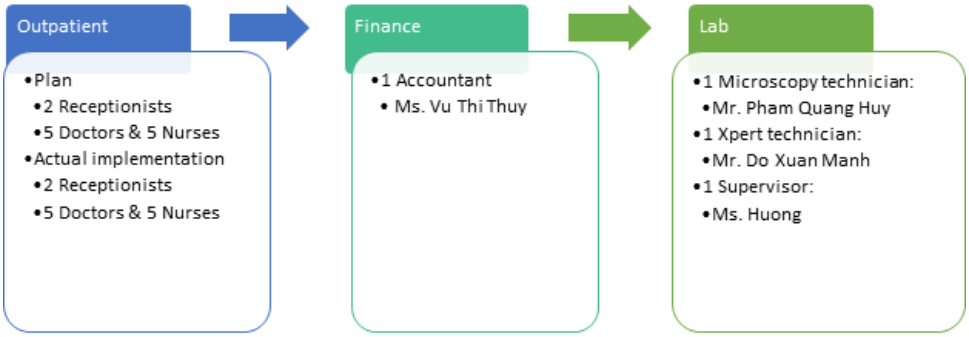


Fig 5.1: Shadow Team Resources: National Lung Hospital

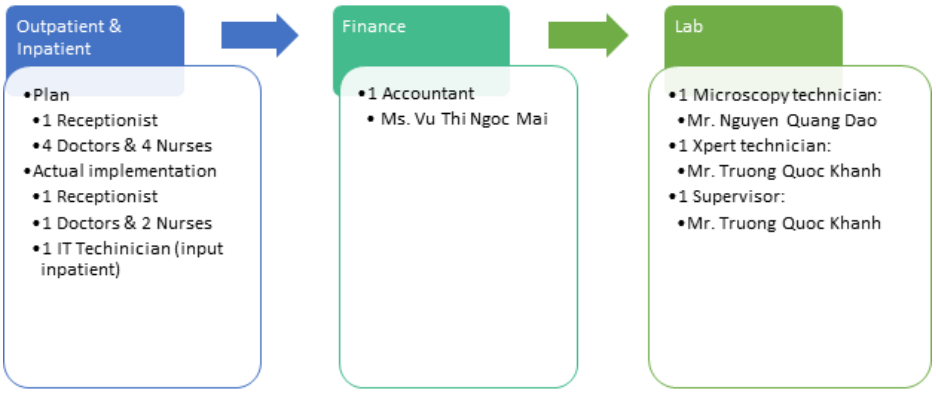


Fig 5.2: Shadow Team Resources: Hanoi Lung Hospital

4.3 Overview of the Shadow Process

The scope of the Shadow Process was restricted to registration and testing of out-patients, who were either 'presumptive TB' or 'in therapy'. The process only concerned itself with the delivery of GeneXpert and microscopy tests. The Shadow Process was completed with the approved test results which were then made available (within CDP) to the clinician. The recording of therapy, the prescription of drugs and management of treatment were outside the scope of CDP and the study. Additionally, logistics, stock management and the reporting of consumable usage was also outside the scope of the study.

See Appendix 1 for an overview of the steps carried out by the As-is process and the Shadow Team.

4.4 CDP entities and test order workflow

In addition to supporting the ability to electronically capture diagnostic results from connected testing equipment, CDP also provides the ability to support diagnostic test ordering. In order to achieve this the system captures and stores the following information:

1. **Patient**: Patient details are recorded and stored forming a patient record
2. **Episode**: A patient can be mapped to one or more episodes relating to specific supported diseases (currently TB, HIV and Ebola). Episodes record the current diagnosis, treatment history and (when closed) treatment outcome
3. **Order**: The order entity provides the ability for the user to order and monitor delivery of one or more diagnostic tests. The order behaves in a similar way to a shopping basket, in that it provides a container through which multiple tests are individually fulfilled.
4. **Tests**: A test represents the execution of a diagnostic procedure performed against a given sample. In CDP tests are categorised into two types:
    a. Linked Tests - Tests that are linked to a patient and therefore form part of the patient history
    b. Orphaned Tests - Tests that are not linked to a patient and therefore contribute to a purely sample based view of testing activity and outcomes

The testing workflow captures the status of a test order throughout its lifecycle, which consists of registration, order placement, processing, approval and results.

Orders		Tests	
New	Order has been created	New	Test has been created
Finance Approved	Order has been paid for		
Samples Collected	Samples have been collected from the patient and associated with the order	Pending	As soon as one or more Samples have been added to an order, then the tests within that order, are set to pending.
Samples Received	As soon as one of the tests in an order has a sample 'Allocated' to it, the Order is set to Samples received. This is an indication that the sample have reached Lab reception and are being handled.	Allocated	Indicates that a sample has been associated with a test
In Progress	Set when any action against any test (within the order) has been taken.	In Progress	Option status that can be used in the case of long running tests (i.e. Culture). Not used in the current system.
		Pending Approval	Results are added to the test and pending approval
Closed	Each test within the order has either completed, or has been rejected.	Complete	Tests are closed once approved

Table 8: CDP Test Order State Model

See Appendix 2 - CDP state transition model for orders and tests

4.5 Standard approach to linking GeneXpert results

One of the key features of CDP is the ability to link test results back to a patient and their case history. In a production setting the sample ID generated at the point of collection, is linked to the patient ID and is intended to follow the entire diagnostic and reporting process. In the core CDP system, linkage of GeneXpert results is specifically achieved through matching the sample ID (generated at the point of sample collection) with the sample ID entered into the GeneXpert DX software, at the point when the test is run.

Success in linking results relies on the correct sample ID being entered into the DX software. In order to reduce the possibility of linkage errors the recommended approach is to label samples by printing the sample ID as a bar code and attaching this to the sample itself. Sample IDs are then scanned into the DX software, removing the likelihood of transcription errors.

4.6 Viet Nam customization for linking GeneXpert results

Upon investigation of the existing Viet Nam process, it was noted that the DX sample ID is populated with a 'lab test number' which is obtained from the lab test register, a book that sits on the desk next to the GeneXpert devices. By convention, an identifier is constructed from the date and

the register (YYYY.lab number i.e. 2016.352) and entered into the DX software. This value is unknown to CDP and therefore could not be used for linkage. Equally we could not ask the NTP to change their process to use a CDP supplied ID. It was agreed therefore that the GeneXpert notes field would be used to store the CDP sample ID and that CDP would be modified to link on the notes field.

Label printers (Brother QL/500s) were provided for the 3 processing sites to allow the rapid printing of a label (containing the barcode) which was then attached to the paper 'test order' form. Lab techs were instructed to scan the ID into the notes field when processing the test.

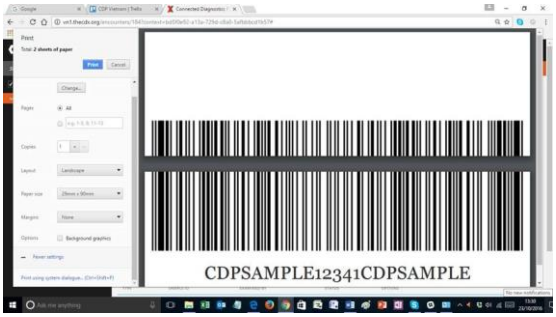


Image 1.0: CDP Bar Code

Image 1.1: Label Printer

5 Study solutions – Technology

This section describes the technology solutions built and preparations made to support the study requirements.

5.1 CDP Bridge

CDP Bridge was installed on each of the GeneXpert computers in order to automatically extract test results and send them to the CDP server. For the study the CDP Bridge was modified to accommodate the Windows XP operating system that was being used in Viet Nam. Additional consideration was given to the Dx software version being used on the GeneXpert computers to ensure the correct collection and representation of data.

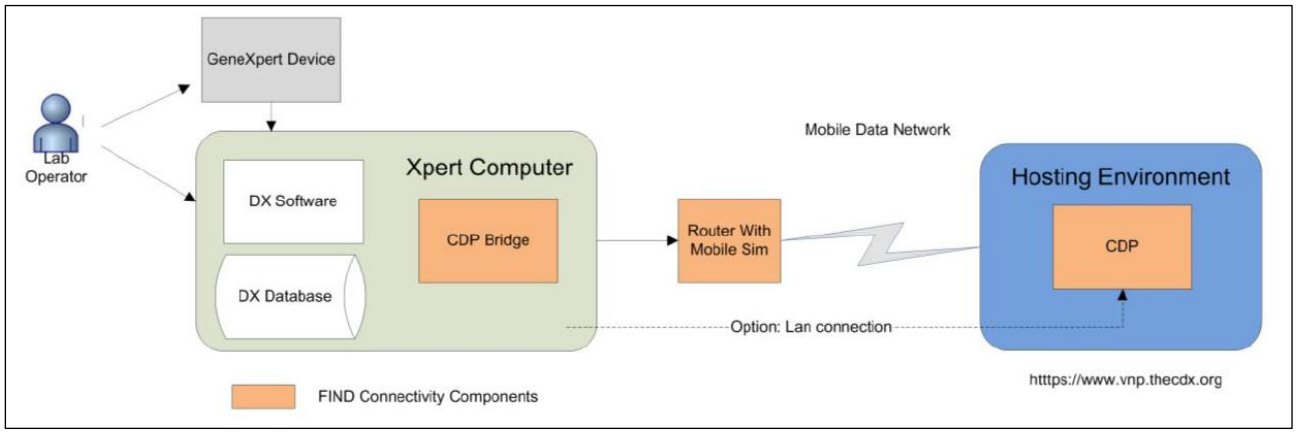


Fig 6: Function of CDP Bridge

5.1.1 Setup and configuration of CDP Bridge

Precise step by step guides detailing the installation and setup of the CDP Bridge software and the Modem (including configuring, loading specific configuration settings and start-up tests) were

delivered. The creation of these guides aimed to ensure that the correct configuration could be restored in the event of unintended changes and maintain uninterrupted continuation of the study. The guides were intended for use by the field support staff as part of deploying the connectivity solution.

5.1.2 GeneXpert data security & operational continuity

When installing CDP Bridge and in order to maintain data security throughout the study for the newly connected GeneXpert devices the following practices were implemented:

1. All GeneXpert computers were virus checked and had a firewall security review before any changes were made
2. Restore points were created on all GeneXpert computers to ensure that there would be no loss of data arising from a failed attempt to update any computer, install CDP Bridge, modify firewalls or install modem drivers
3. Virus software was also added to ensure there was little to no risk from connecting the GeneXpert computers to the internet
4. All GeneXpert computers were then verified for any potential issues, including firewall settings confirmation before being returned to service

5.2 CDP Server

5.2.1 CDP server - platform architecture

See Appendix 3 – CDP Technologies, Component Versions and Licences

5.2.2 CDP server - environments and hosting

For the study, we chose to host the CDP servers with Rackspace (www.rackspace.com) who provide secure hosting facilities under ISO/IEC 27001 Information security management and ISO 9001 Quality management controls. The hardware configuration consisted of a single server with an Intel Xeon E5-2670 processor @ 2.60GHz and 4GB RAM. The RAM was later upgraded to 8GB to address timeout issues as discussed later.

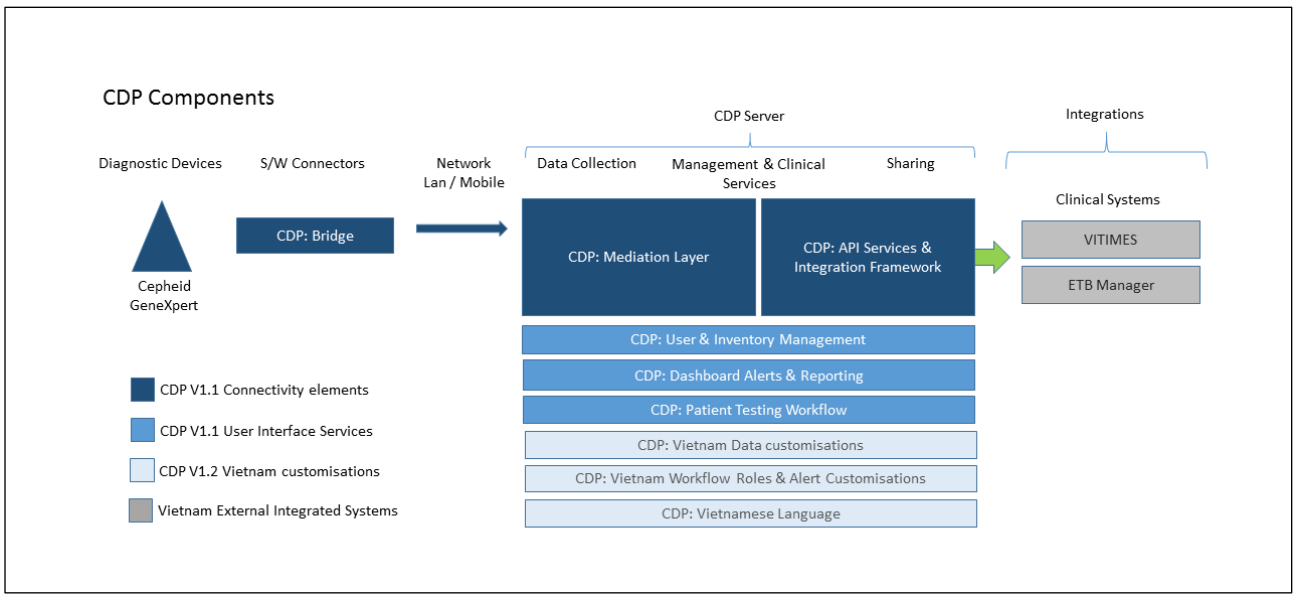


Fig 7: CDP Study Solution Components

5.3 Customizations and alignment

The core product encapsulates the full range of supported, features and functions. Core features and functions are 'generic' in nature and are presented with the expectation that customization will be required in order to align the any given implementation with the conditions and requirements of each specific installation. In order to model and support the 'Shadow Process' and create effective integration, a series of customizations of the core application were required. These included:

- Constrained Scope: HIV and Ebola episodes and testing were hidden
- Constrained Scope of Testing: culture and LPA testing options were hidden
- Language Support: Vietnamese language was implemented
- Integration solution: screen scraping for e-TB Manager and VITIMES was introduced
- Integration and alignment: business logic and capture of specific fields was introduced to support e-TB Manager and VITMES integration
- Integration and alignment with e-TB Manager
- Financial Approval: at the request of the NTP 'Financial Approval' was added to the workflow and state model (see the section below for expanded details)
- Customised Linkage of GeneXpert Results: A customised approach to linking GeneXpert tests to patients was required to minimise the impact on the existing laboratory processes (See below for more details)

5.3.1 Overview of customizations to the testing workflow

The table below calls out a selected number of customizations according to their location within the CDP frontend.

Page / Function	Customization
Create / Edit Patient	Customised Fields include: ● VITIMES/e-TB Manager Log ID ● Social Security ID ● Medical Insurance Number ● External Patient ID with dropdown options ● Region / Province and Country Drop down modifications
Create / Edit Episode	Previously Treated and outcome dropdown menu aligned with e-TB Manager
Create Order	Blood was removed as a sample type and 'Other' added as a category
Finance Approved	This step was added at the request of the NTP. In summary a TB test cannot be run unless it has been paid for first. A finance role and the ability to set a status of 'Finance approved' or Finance rejected (with reasons) was added
Submit Samples	Viet Nam was configured to allow multiple samples to be allocated at the 'order level'. Auto generation of sample ID's was disabled.
Allocate Samples and Print Sample ID	Ability to print sample ID as a barcode with CDPSAMPLE as tags (see Approach to linkage) was added
Add / Edit Results	At the user's request the ability to edit entered results (to allow for correction of mistakes) was add to CDP

Approve Results	Approve Results: no customizations required
View Results	View Results: no modifications required

Table 9: Workflow customizations

5.4 Integration to VITIMES and e-TB Manager

The modern accepted way of integrating two or more electronic systems together for the purpose of data exchange is to use Application Programming Interfaces (APIs). However, both VITIMES and e-TB Manager versions at the time did not have APIs in place so a screen scrape approach was taken in order to push information between them. Screen scraping mimics the process of a user logging in and keying data into an application via the target system's user interface.

Screen scraping is very sensitive to any changes in the target systems UI and layout. It can also suffer from poor performance and resource usage. Finally, any records written are forced to follow the process by which an operator would navigate through screens to enter the data rather than programmatically providing the data needed. However screen scraping is common place and requires next to no involvement from the owners of the target system in supporting an integration.

When integrating CDP with VITIMES and e-TB Manager the following considerations were taken:

1. **Workflow integration point**: At what point are test results from CDP sent to e-TB Manager and VITIMES. For the study the test results were added at the point at which the tests were approved by the supervisor. This however meant that there would be no order history recording in the participating systems, only a record of the outcome.
2. **Failed integrations**: The ability for CDP to retry failed integration attempts and the ability to view and download the integration log.
3. **Business rules**: The ability to include business rules and send data dependant on the outcome of the test results.
4. **Mapping of key data fields**: To ensure that data fields captured in e-TB Manager and VITIMES matched those in CDP. Several customizations were made in CDP to match mandatory fields and dropdown menus.
5. **Integration simplifications**: Implementation of a fully featured production ready integration was not a requirement of the study. Therefore a number of simplifications were made to limit the complexity and effort required to build the integration.
6. **Foreign keys**: When a record is written to a participating system the key identifier for that record is retrieved from the target system and stored in CDP. This allows for reconciliation between systems.

5.5 Data transmission & internet access

In order for data to be transmitted (from the GeneXpert devices in the study) to the CDP server, each participating GeneXpert computer requires internet connectivity that can provide an IP connection into CDP. This can happen in two ways:

1. Via institution LAN or Wi-Fi connection which provides a connection to CDP via the internet
2. Via cellular data connection which requires a mobile terminal, dongle, Mi-Fi or router, with an appropriate SIM card.

Prior to the NTP CDP study, none of the GeneXpert machines had previously been connected to the internet, which meant that connecting these devices to any existing LAN/WLAN network, presented resourcing issues, such as dependency on IT support from a local institution.

Due to time and resource constraints from NTP IT staff, the existing fixed line internet connectivity was not a feasible option to be able to deliver the solution within the agreed timescales of the study. FIND opted to utilise mobile cellular network products for the connectivity solution proposal for the NTP study sites, opting to use local in-country SIM Cards over international roaming SIM cards.

See Appendix 4 – Cellular Modem Product Selection, Mobile Operators and Site Surveys

5.6 Site environmental factors

- The following describes the various technical environmental factors that were taken into consideration when providing connectivity to the study sites.
- **The Cepheid GeneXpert model:** How many GeneXpert units were available per each Dx software configuration and how they were physically connected were noted.
- **Cepheid Dx Software version:** Dx PC software revisions can impact the support of the CDP Bridge client application. During the study the computers' Dx Software versions were Dx v4.3 & v4.4.
- **Computer System type:** To provide to a suitable connectivity solution for any existing "GeneXpert LAN connectivity" or "Computer hosted Dx Software" the type of computer system setup hosting the Cepheid Dx Software has to be taken into account.
- **Computer Operating System:** The computer operating systems used to host the Cepheid Dx Software can impact overall compatibility, performance and security of the solution.
- **Computer Antivirus & Firewall Security system:** It was important to understand the security status and malware protection of a computer system prior to performing any new software installations.
- **Virus & Malware:** FIND ensured the systems were clean of viruses and malware, to prevent data loss through malicious or rogue computer software.
- **Firewall Security Systems:** The Dx computer system must be verified for any existing firewall system installed, either locally or on the network side. If the operating system is end of life, such as Windows XP, it is recommended that a very strict firewall policy should be enabled to restrict all internet traffic to and from the computer.
- **Power outlets:** During the site visits it is important to understand the existence of a power source. In some instances it is recommended to install appliance surge protection on any IT equipment installed, which protects the appliance from unstable power grid surges which could potentially break the IT equipment.
- **Availability of local IT Support:** The availability of institution IT support is an important factor during a connectivity installation.

6 Project delivery

Delivery of a connectivity service requires assembling a complex set of technologies to support both people and systems, in executing a full set of end to end (E2E) processes.

A definition of E2E - To be successful, connectivity service delivery projects need to address the full E2E requirement, where E2E is defined as:

- **Full user journey and entity life cycle -** All users and entities in a system have a life cycle of their own, for example tests can be Created, Processed, Closed or Rejected.
- **Top to bottom technology** - E2E Processes will drive transactions up and down the entirety of a solution's technology stack. In integrated systems it is not good enough to simply understand the data exchange between systems or components. An understanding of how data transforms over time is essential in understanding the behaviour of the E2E system.
- **The full project life cycle -** The E2E project life cycle starts with capturing an idea and ends (in the case of the study) with retiring the system and completion of a (post launch) benefits realization exercise. An E2E project plan, for instance, must identify and account for the requirements of all phases of the project.

To achieve this the study project team adopted the following principles:

1. **E2E Entity Modelling -** This involved identifying and modelling all entities involved in provision of the Shadow Process namely:
   - People: Customers and Suppliers (a.k.a. Actors) that interact with the service
   - Resources: Physical resources such as diagnostic devices, cartridges, etc.
   - Virtual Resources: e.g. Mobile data bundles, per user licences
   - Entities: e.g. Patient, Episode, Order
   - Life cycle and state transitions: An effective system needs to correctly model how entities change over time and encapsulate the correct behaviours that govern the transition from one status to another
   - Services: Individual services (either constructed as part of the project or externally sourced) that are consumed as part of the operations of E2E service (i.e. SMS gateway to support text alerts)
   - Processes: sequences of tasks, actions and automations that consume resources and services whilst moving entities through their lifecycles

   In this way the full requirement of the system was captured.

2. **User centric -** The approach taken was to lead with people and process, not technology. The technical solution was built on the clinical requirement. Development of the clinical requirement put the user at the centre of analysis.

3. **Focus on adoption -** Time was allocated to the familiarisation, ramp-up and normalization of the process. Equally, provisions were made for sponsoring adoption and the continuous implementation of service improvements throughout the operational period.

6.1 Team structure and organization

The project team consisted of a multi-disciplinary, geographically dispersed group of people covering technical and non-technical roles across both development and operational domains.

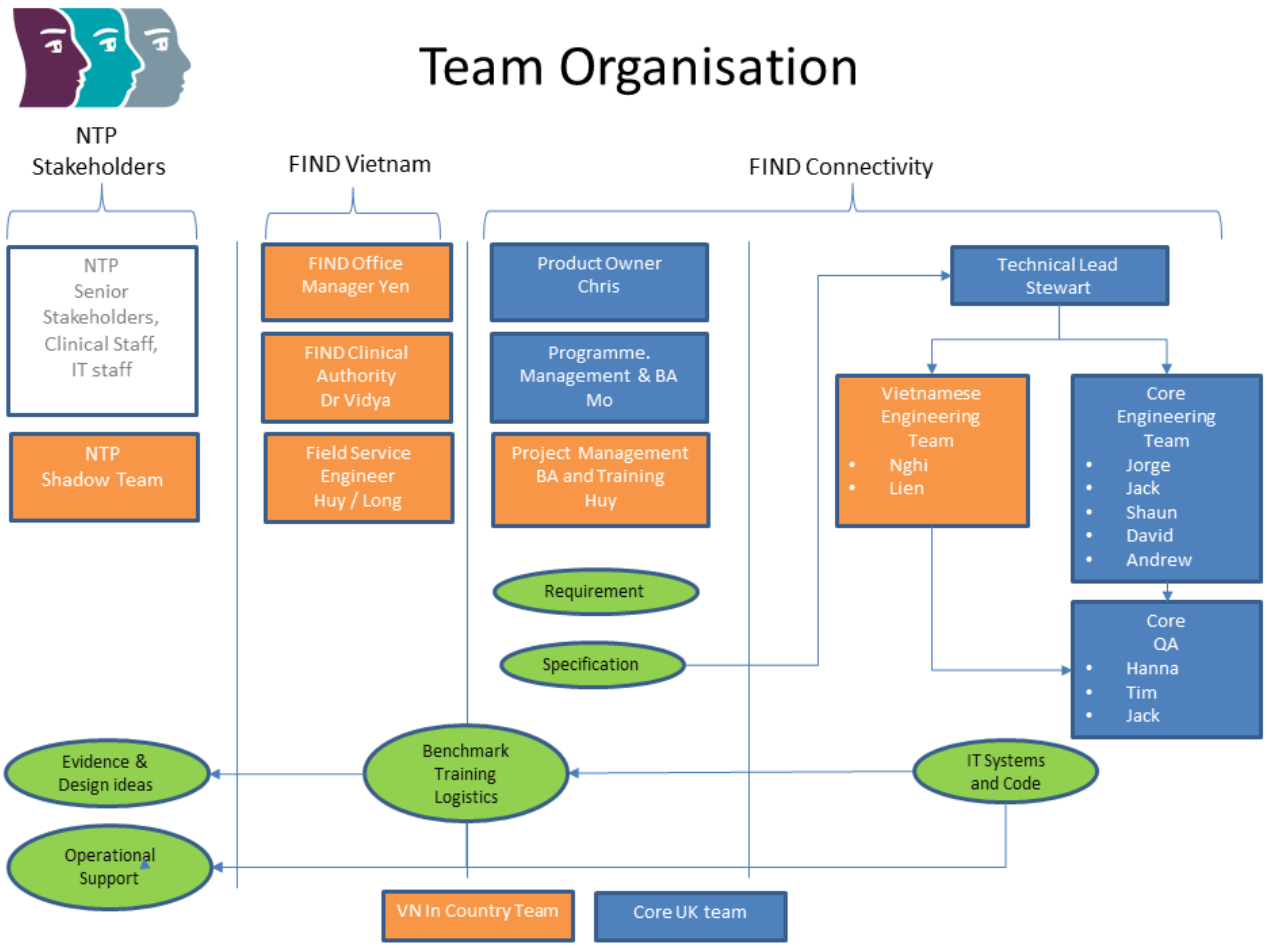


Fig 7: Project team structure

In line with the objective to 'support the building of local capacity', and also driven by the practical constraints of language, time-zones and distance, the decision was taken to establish the concept of a Core Team (mostly based in the UK) and an in-country team based in Viet Nam. The accountabilities were distributed as follows:

Core Team: To operate as the core product owner and systems integrator, accountable for the CDP product, changes to CDP core functionality, programme management, reporting to FIND and other project sponsors, and the delivery of Quality Assurance

VN Team: In country, customer facing team, accountable for relationship management with the NTP, project management of daily tasks in-conjunction with the hospitals and labs, provision of field service support, collection of requirements for input into the core team and technical development of the following key Viet Nam customizations:

- Translation and multilingual framework
- Integration and integration framework
- Bug fixing and technical debt

6.1.1 Resource providers

The workforce was drawn from a number of organizations listed below:

- FIND Connectivity Team: Product ownership, project management, business analysis, report writing and advocacy.
- FIND Viet Nam: Providing customer relationship management, logistical support and clinical consultancy
- Blue Frontier: UK software development and IT consultancy firm providing, software and user experience development, QA and hosting
- Larion: provision of software development, in country business analysis, project management, translation and field service support
- NTP: Clinical consulting and validations, Shadow Team resourcing, project management and logistical support. Note: although drawn from existing NTP staff, the Shadow Team were considered part of the project's in-country workforce.

6.2 Agile project development

The CDP software and its various customization were developed by FIND using an Agile software development approach. Agile software development describes a set of principles for software development under which requirements and solutions evolve through the collaborative effort of self-organizing cross-functional teams. It advocates adaptive programming.

The project adopted a two week 'sprint cycle' in which a selected number of 'User stories' (a description of an atomic system feature or function) are targeted for completion. User stories are assigned to individual engineers. Once complete the story is submitted for QA review and a new story assigned. System builds are done on a fortnightly basis at a minimum and QA testing of the emerging system is continuously performed against these builds.

6.3 Project roles

See Appendix 5 – Project Roles and Ceremonies

6.4 Collaboration tools

See Appendix 6 – Collaboration Tools

6.5 Testing & quality assurance

6.5.1 V-Model Approach - Principles

Quality assurance (QA) for the study was based on the (Verification and Validation) V-Model Approach in which the left hand side of the V represents the specification of the system at increasing levels of detail and the right hand side of the V represents the validation of these parts in increasing levels of integration.

The V model Demands that:

- Verification is always against requirements and validation is always against the real world or the user needs
- Each phase in the development cycle should be directly associated with a testing phase
- Corresponding testing phase of the development phase is planned in parallel

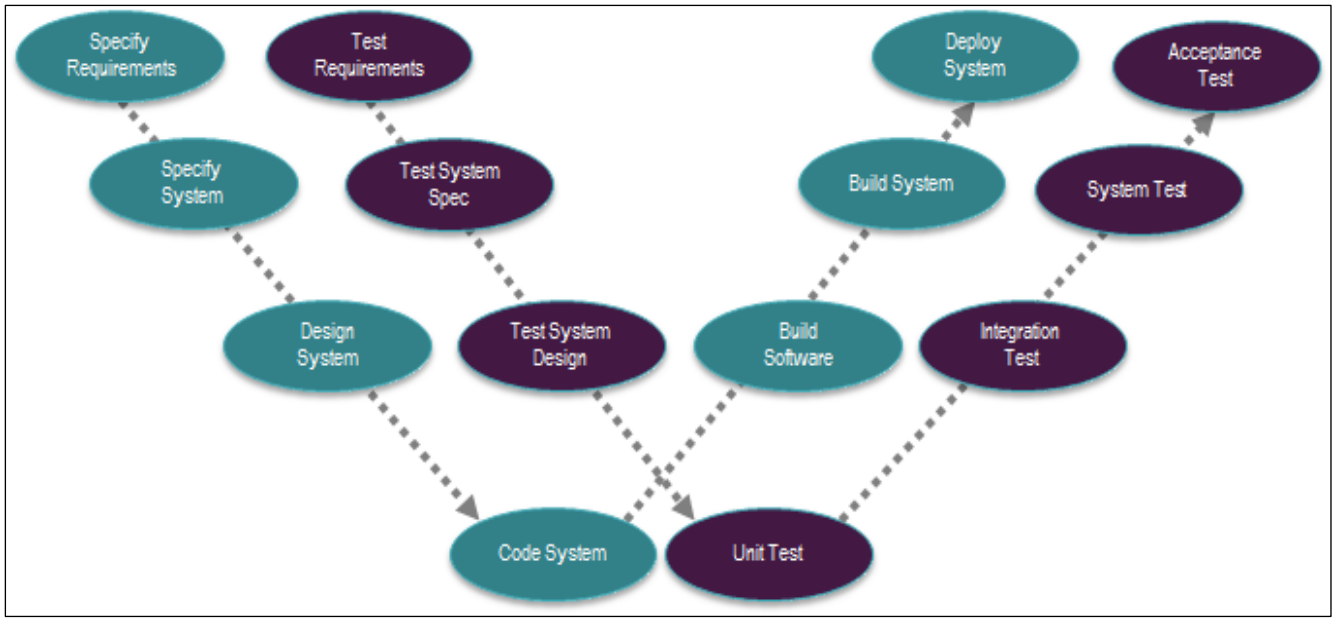


Fig 8: The V model for Quality Assurance

6.5.2 V-Model as applied to CDP

In applying the V model to a connectivity project, it is essential that an E2E view is taken of the entire service, in this way the ability of people and processes to operate is tested as much as specific technical components. This approach inevitably results in an extensive and wide ranging collection of QA activities which require careful coordination to ensure that tests are valid and to avoid regression going unnoticed. QA test resources were commissioned to manage both the creation of a test strategy, as well as delivery of specific testing exercises. Despite the short life span of the service (7 weeks) the following testing activities were necessary to assure the quality of the project.

See Appendix 7 – CDP Testing Activities

6.6 Deployment

6.6.1 CDP Bridge deployment

CDP Bridge deployment in Viet Nam depended on internet connectivity to enable transmission of test results from GeneXpert & Dx software, to the CDP Server. The connectivity between CDP Bridge and CDP Server is protected and secured by SSL encryption (TLS v1.0), which allows for secure transmission over many different internet connectivity transports, such as LAN, Wi-Fi, Wi-Fi Hotspots or Cellular, without the concern of data theft or vulnerability.

The computers running the GeneXpert Dx software packages are notoriously situated in medical laboratories or other locations without internet connectivity. We know that the current NTP GeneXpert installations, installed by Cepheid's regional support partners, were not connected to the internet and lacked any antivirus software or firewall.

Early survey results told us that all of the GeneXpert Dx computers were running Windows XP and in the early stages of CDP Bridge development was not supported. Windows XP is no longer supported by Microsoft, similarly most vendors have stopped all development supporting Windows XP.

Deployment of the CDP Bridge was initiated by first enabling internet connectivity to the GeneXpert workstations, utilising this connectivity to download the CDP Bridge 1-Click software installer from a hosted website.

Whilst FIND technical staff conducted the deployments of CDP Bridge, this one click method was utilized in development to support non-technical resources in the future.

6.6.2 CDP server deployment

The deployment of the CDP server was managed by the utilization of a 'Container Management' platform called Docker. A Docker container wraps up a piece of software in a complete file system that contains everything it needs to run: code, runtime, system tools and system libraries – everything that needs to be installed on the server. By encapsulating and isolating everything in a container, this guarantees that the container will always run the same, regardless of the environment it is running in.

For years virtual machines (VMs) were seen as the status quo for packaging and running applications. Containers and VMs seem similar, but containers utilise a different architectural approach. VMs require a full operating system (OS) inside of each VM in order to run the service inside of it. Each virtual machine includes the application, the necessary binaries and libraries and an entire guest operating system - all of which may be tens of GBs in size. Containers have similar resource isolation and allocation benefits as virtual machines but their architectural approach allows them to be much more portable and efficient. Containers include the application and all of its dependencies, but share the kernel with other containers. They run as an isolated process in the user space on the host operating system. For more information on containers and Docker please visit https://www.docker.com/

6.7 Readiness

In order to start the study period key service components were evaluated for a level of so called 'readiness'. This state of readiness was reviewed via Go / No Go meetings that focussed on the key deliverables in each area. Below are selected service areas along with a description of the solutions implemented, in order for them to achieve readiness.

6.7.1 Maintenance release process

Throughout the study period regular updates of the code were made to either:

- Implement fixes to known issues
- Response to technical support items
- Implement requested enhancements
- Resolve technical debt (optimizations and refactor of code to proactively maintain operations)

See Appendix 8 – Maintenance Releases

6.7.2 Study Support and Escalation Process

A tiered model was adopted to provide study support where each tier is defined as follows:

Tier 1	User facing support including onsite field support from the VN team. Accountability; to be the first point of contact for user related queries, problems and complaints, and provide immediate resolution (if possible) or escalate to tier 2.
Tier 2	Provides in country technical support, support call triage and tier 3 escalation (as required). This role was performed by the in county VN team, within the user's time zone. The resolution of an issue can sometimes require the coordination of changes across a number of different tier 3 providers. It is therefore the responsibility of the tier2 support to coordinate problem resolution and resolve any disputes regarding solutions and individual accountabilities.
Tier 3	Individual system level support by owners of the participating systems. CDP support was provided by the UK Core development team (Blue Frontier); e-TB and VITIMES support was provided by the NTP IT team.

Table 10: Support Tiers

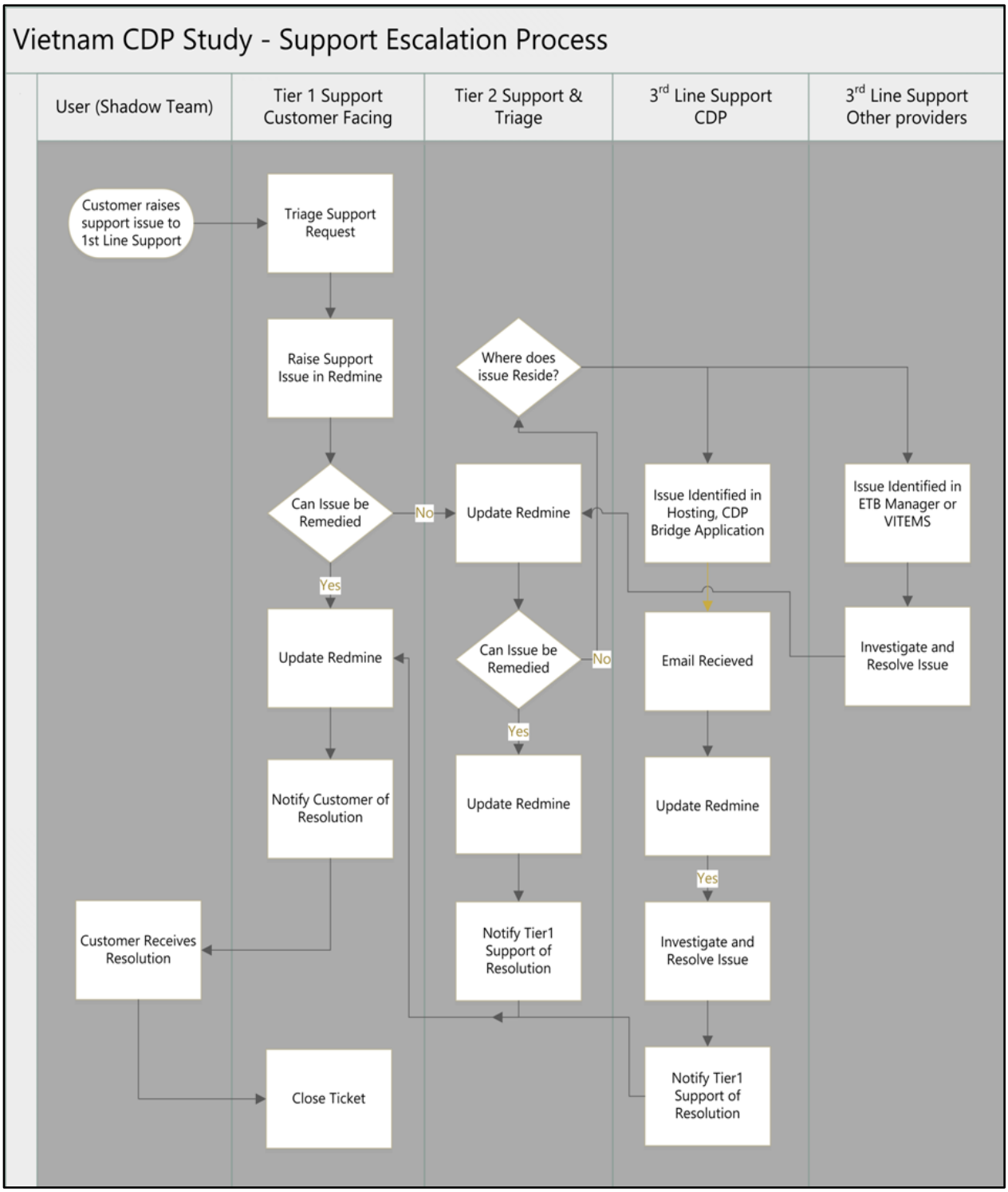


Fig 9: Support and escalation process

See Appendix 9 – Support Components and Owners

6.7.3 Data privacy policy

Although the study process did not change the actual 'business as usual' processing of patients, the study did involve collecting and handling Patient Identifiable Information (PII). The items listed below were used to address the need to assure data security.

Data Security

- Encrypted CDP database: The CDP Bridge uses SQLite to store data prior to transmission. This database is encrypted
- Encrypted data transmission using SSL: Secure Socket Layer is used to provide encryption, authentication and to prevent interference

CDP Security Policies

- CDP is hosted by Rackspace who provide secure hosting facilities under ISO/IEC 27001 Information security management and ISO 9001 Quality management controls
- FIND's CDP development and operational staff are governed by the project's security policies that have been prepared using ISO/IEC 27001 Information security management.
- Access to CDP Bridge and its database is via username and password
- Since the bridge is installed on the GeneXpert computer, it can only be accessed by clinical staff with authorised access to the lab locations

The ISO standards and policies were used to:

- Maintain a register of project staff
- Control system access
- Provide 'training and education' regarding data security to all registered users

Staff were trained in how to handle sensitive data an implementation Seafile (a self-hosted secure file sharing application) was set-up for storage of all sensitive data. There have been to date, no reported breaches of security.

6.7.4 Study team readiness

Study team readiness was achieved through provision of the following:

- Clinical review: A number of clinical reviews
- Equipment procurement and installation: equipment to support the Shadow Team included provision of barcode label printers and a cellular wireless router to allow staff to connect via a web browser to CDP in locations with no hospital Wi-Fi connection
- Approved budget and Shadow Team recruitment: The NTP assembled the Shadow Team, allocating existing staff to Shadow Team roles
- CDP Production Configuration: This involved creating the sites, devices, roles and users on the production system
- Shadow team training: 1 days' worth of training was provided including hands on testing as well as printed material

6.7.5 Connectivity readiness

Connectivity readiness was achieved through provision of the following:

- Site assessment conducted and best performing operator SIM installed at study sites
- CDP Bridge Client Software configured per computer operating system environment
- Firewall optimization completed and IP & URL filtering configurations up to date

- Email reporting is tested and working for each site installation
- Testing of the E2E system is conducted and is successful in proving a robust & reliable connectivity between client and CDP server
- SIM data allowances verified as active for 30 or more days and with appropriate bundles
- Computer training materials are available for installation, support and debugging efforts
- Remote management is active on local Dx computers via TeamViewer for remote support

7 Study data

This calls out data collected via CDP during the study period. This data has been derived from the CDP data store and provides a view on the volumes of activity captured by the Shadow Team during this period. Access to the source data can be made available on request to the authors.

7.1 Diagnostic test volumes

The charts below show the total volumes of tests entered in CDP during the study period.

Study Volumes	Numbers	Percentage
Total Microscopy Tests	3378	91.59%
Total Xpert Tests	310	8.41%
Total Tests	3688	

Fig 10.1: Order volumes by test type

The chart below shows the total volume of Microscopy and GeneXpert tests during the study period individual test site.

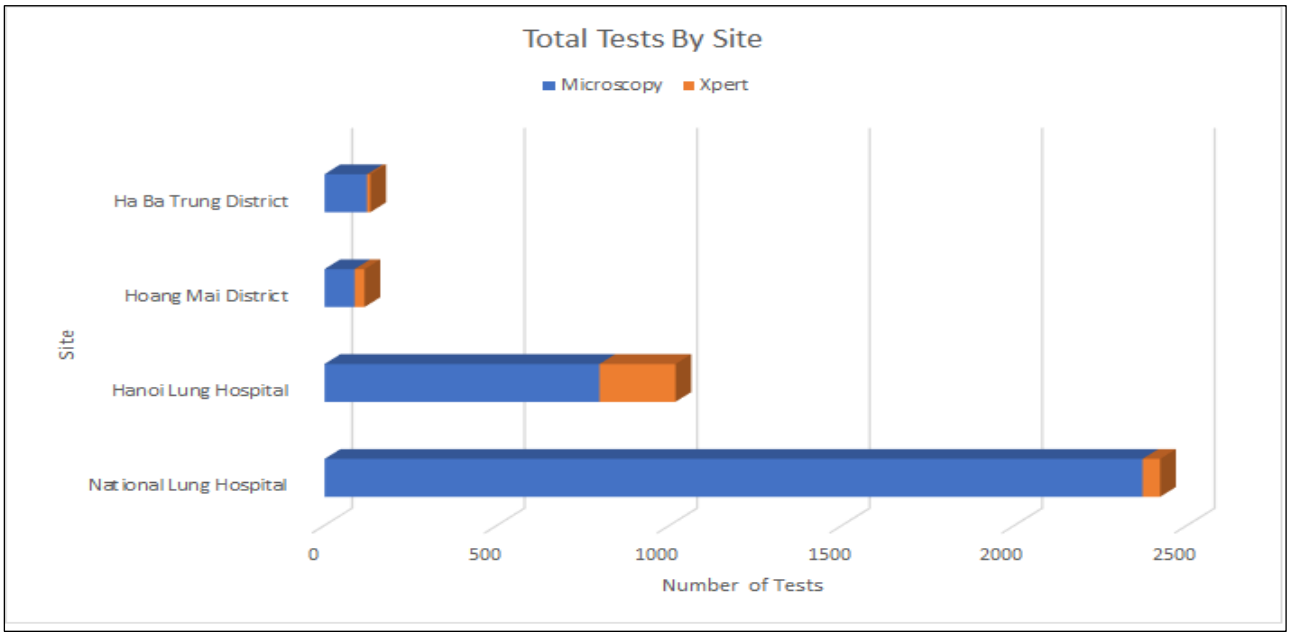


Fig 10.2: Order volumes by site

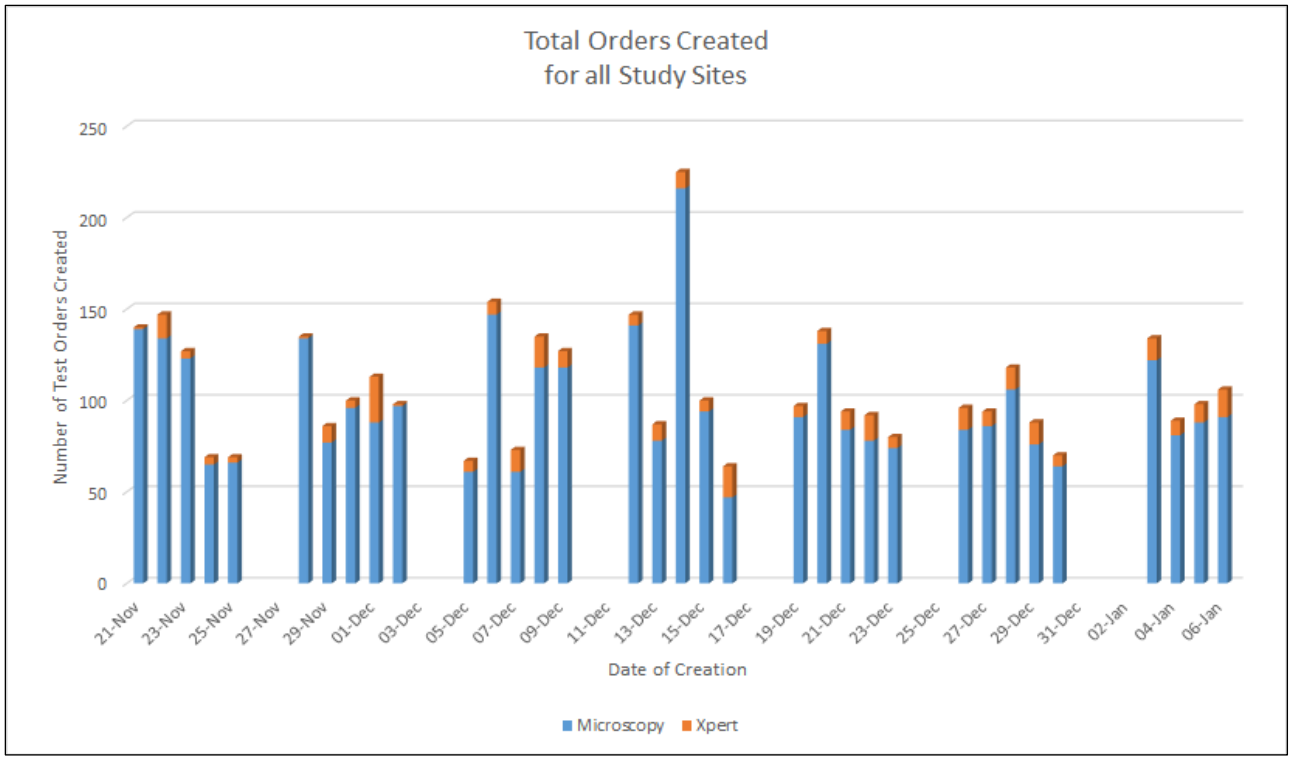


Fig 11.1: Total orders created for all sites

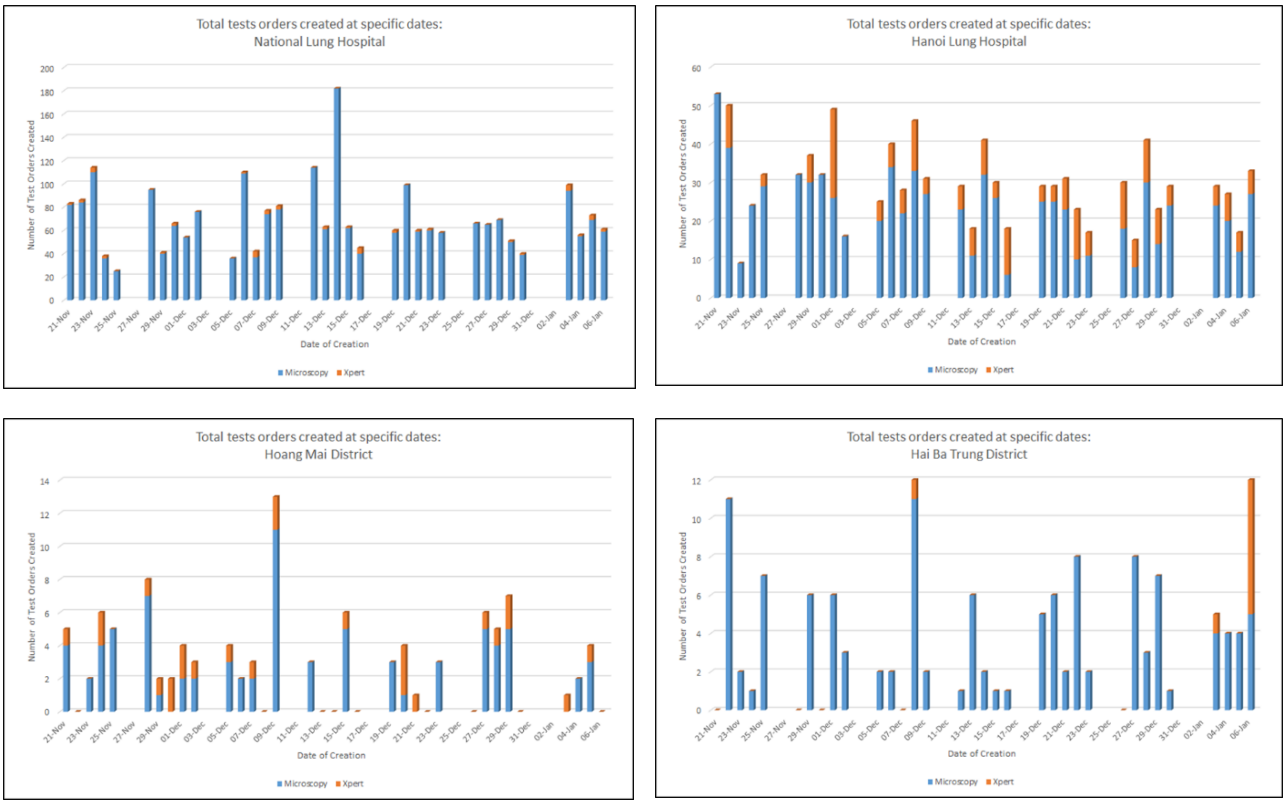


Fig 11.2: Total orders created by individual sites

7.2 Patient registrations and profile

The chart below show the number of patients registered per day by the Shadow Team, on the CDP system.

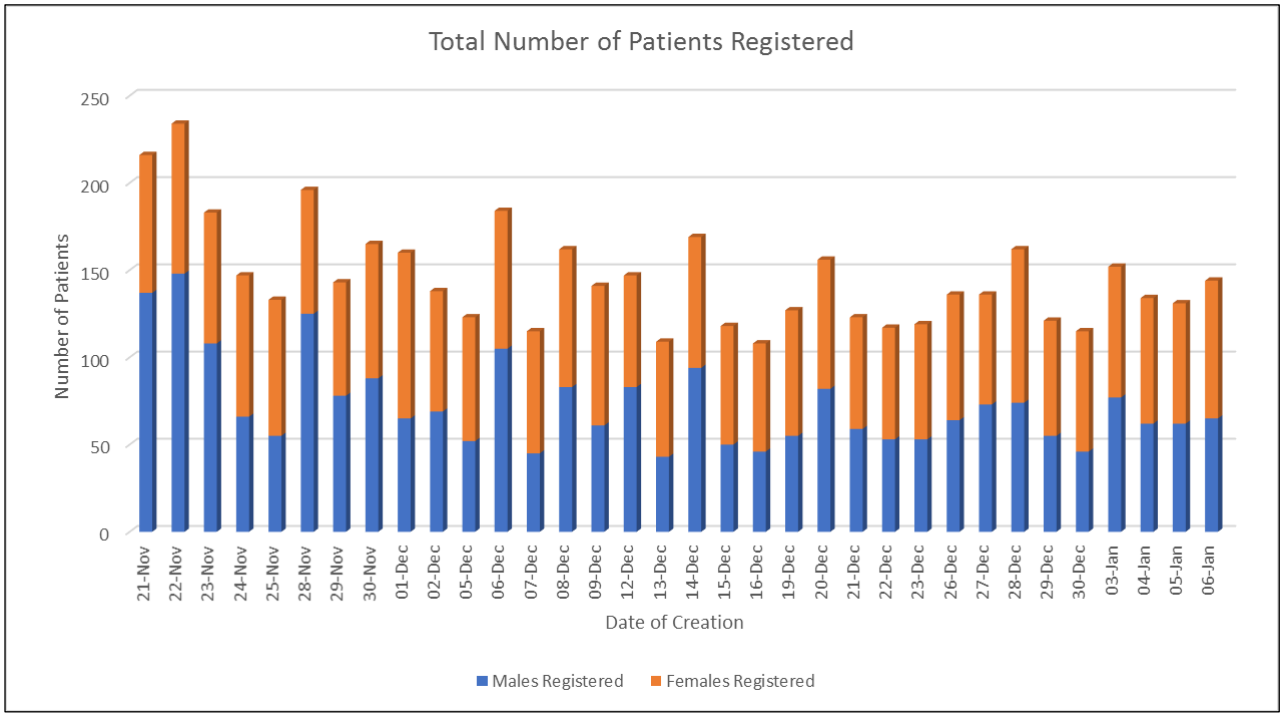


Fig 12: Patients Registered by Date

7.2.1 Duplicate patient entries

It was observed that a high number of patient entries appear to be duplicated by the Shadow Team.

Duplicate Patients	Number	Percentage of All Patients
Total Number of Patients	3644	n/a
Number of Duplicated Patients*	276	7.6%

Table 11.1: Duplicate Patient Entries

*Duplicated Patients were defined as two or more patient entries having matching Names, Gender Type, Age and First Line of Addresses.

7.2.2 Previous treatment history

The chart below shows the previous treatment history of patients captured in CDP. Please note that the percentage figures are a percentage of unique patients entered in the system. That is to say that duplicate patient entries have been removed.

Episode 'Previous History of TB' Status		
Total Number of Patients*	*3645*	*100%*
Number of Unique Patients*	*3368*	*92.4%*
Number of 'New' Patients**	*2484*	*73.8%*
Number of 'Previously Treated' Patients ***	*5*	*0.1%*
Number of 'Unknown Previous History' Patients ****	*236*	*7.0%*
Number of Patients with No Episode in CDP	*643*	*19.1%*

Table (11.2) - Episode 'Previous History' status

* *Filter for Patients with unique name, age, and address*
** *Number of patients with a value of 'New', recorded in their episode under 'Previous History of TB'*
*** *Number of patients with a value of 'Previously Treated', recorded in their episode under 'Previous History of TB'*
**** *Number of patients with a value for 'Previous History' of 'Unknown Previous history', recorded in their episode Percentages are calculated as the % of unique patients*
Percentages are calculated as a percentage of unique patients

Regarding patients with 'No episode'

If a patient has no episode then the indication is that there no reason to diagnose TB (presumptive or otherwise). There are a number of reasons why a patient may be registered in CDP but not have an Open Episode. The common reasons are:

- They have no previous TB history and on examination were not diagnosed as presumptive, therefore no episode was raised.
- They are duplicated entries and the episode is raised against another record.
- The process started by the Shadow Team failed to shadow the patient beyond that point

7.2.3 Multiple orders

The following set of metrics indicates the case where patients have been tested more than once during the study period. This includes patients who were tested by both GenXpert and microscopy or had repeat GeneXpert or microscopy tests ordered for them. Percentages are presented as percentage of unique patients.

Patient Testing Profile		
Total Number of Unique Patients	*3368*	100%
Number of Patients Not Tested	*707*	*21.0%*
Number of Patients Tested Once	*2243*	*66.6%*

Number of Patients Tested Twice	*370*	*11.0%*
Number of Patients Tested Thrice	*25*	*0.7%*
Number of Patients Tested Four times	*9*	*0.3%*
Number of Patients Tested Five and more Times	*14*	*0.4%*

Table 11.3: Multiple orders per patient

*Note: a test order cannot be created for a patient which doesn't have an open episode.

Of the patients registered 21% were not tested, however 19.1% of patients registered did not have an episode created under their name. It can be deduced therefore that in the Shadow Process 1.9% of patients diagnosed with TB (presumptive or otherwise) failed to have diagnostic tests ordered for them.

8 Other study activity & performance

8.1 Connectivity transmission performance

In order to identify the efficiency and reliability of the connectivity solution, and more specifically the CDP Bridge application on the host machines the transmission performance of each GeneXpert machine during the study was monitored. The lead time of a transmission is determined by finding the duration (in minutes) between a GeneXpert test ending and the test being received by CDP itself. The intended transmission window for any test run on a GeneXpert device is between $GX\ End\ Time$and $GX\ End\ Time\ +\ CDP\ Bridge\ interval\ (minutes)$

The CDP Bridge interval throughout the study was 30 minutes. All tests with a lead time of greater than 30 minutes missed the intended transmission window, this signifies the first stage of a potential outage.
Overall there 720 trackable transmissions during the study period, this does not include transmissions on the 22nd and 23rd, these were days in which historical transmissions were run. Historical lead times are outside the study and cannot be measured.

Of these trackable transmissions 74 missed their intended transmission window (10.3%), and 36 (or 5%) missed the second transmission window.

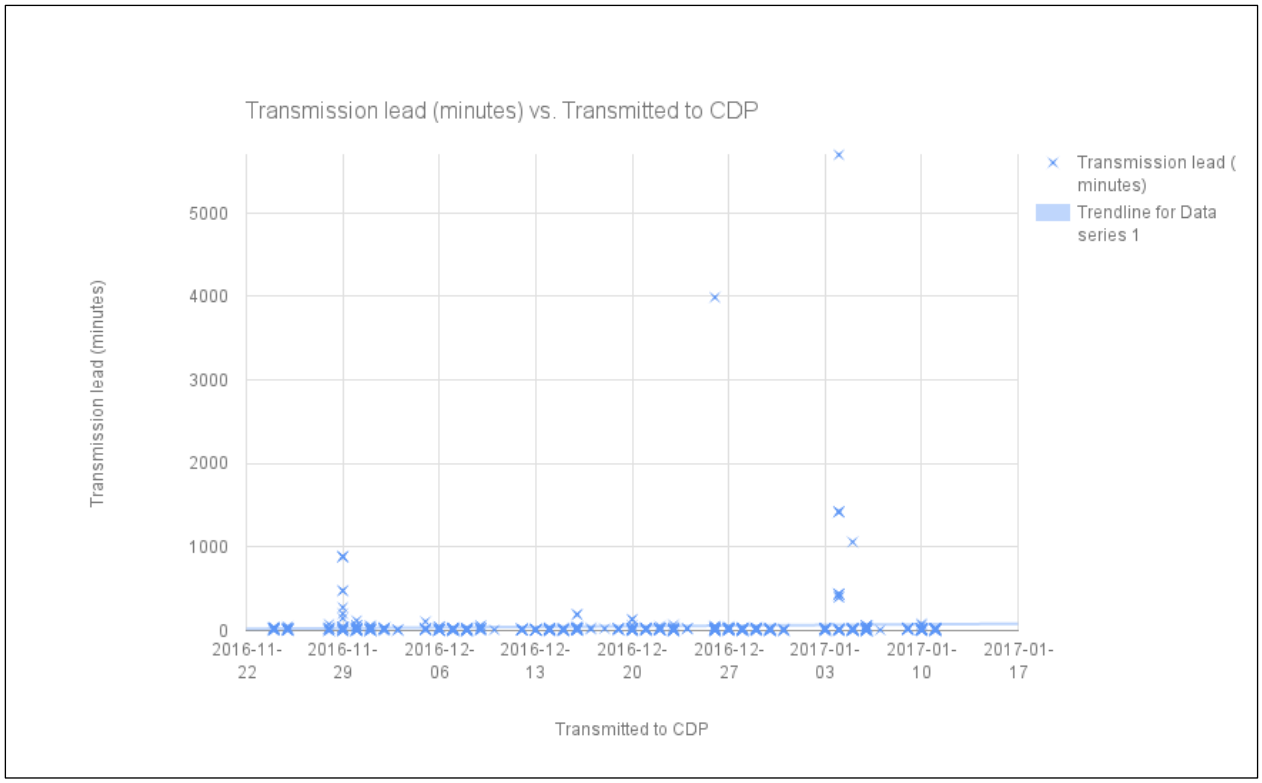


Fig 13: Connectivity transmission times

The above graph is skewed by outlying incidents which pushed a small number of lead times up to several days in some cases. (See anomaly table for details). GeneXpert tests themselves take on average 1 hour and 39 minutes (or 98.75 minutes) to finish, over the course of the study 95% of tests were transmitted within an hour of the test finishing on the GeneXpert device in the lab (2 CDP Bridge intervals).

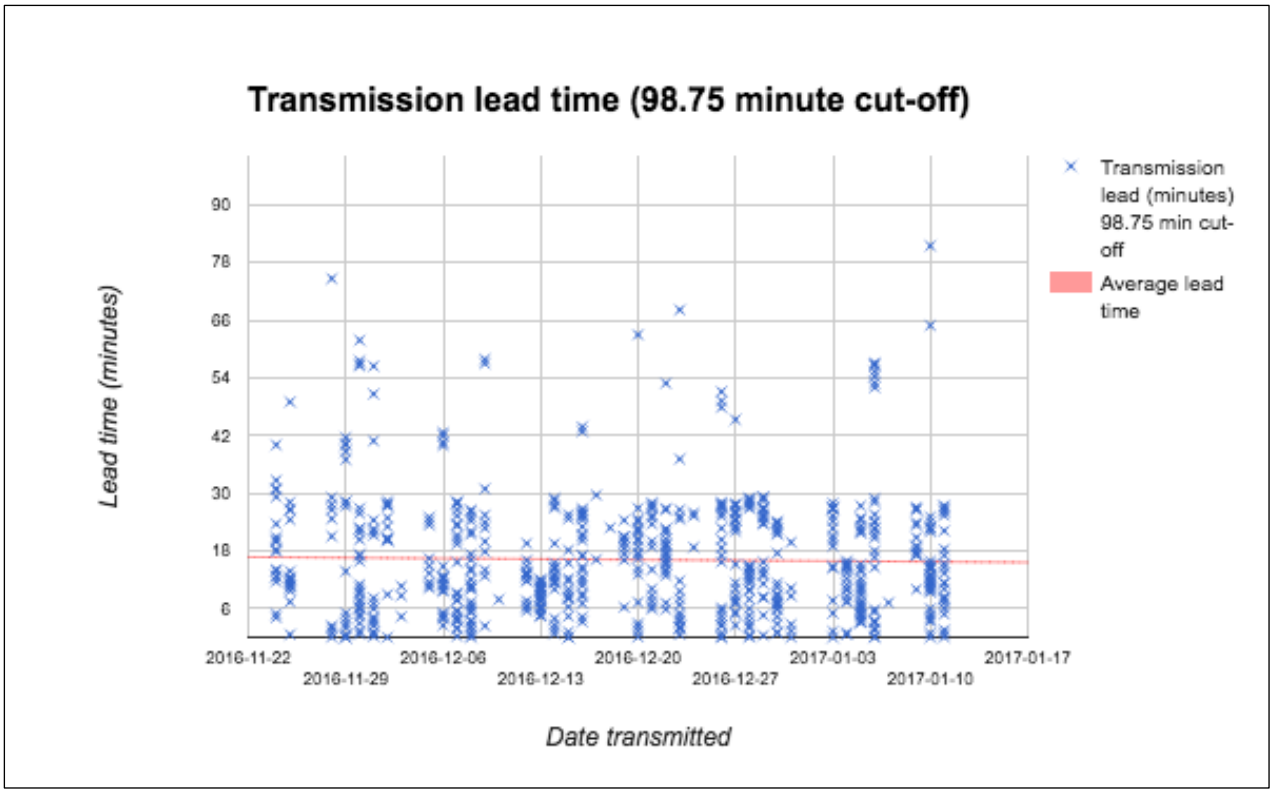


Fig 14: Connectivity transmission times

The above graph shows the transmissions within the maximum transmission window that was defined. The majority of transmissions are submitted within the 30 minute window, and the average lead time is under 18 minutes. Only 6.4% (44 transmissions out of 690) missed the intended transmission window for this period.

8.2 Identified incidents

The table below shows periods of 'outage' that have been calculated based on the time between the last received email report and the next successful transmission. The lead times for this transmission is also displayed.

	Possible start	Possible end	Outage period (hours)	Last transmission ID	Lead time (hours)	Site
Incident 1	11/28/2016 10:09:00	11/29/2016 9:00:40	22.86 hours	27744	14.72 hours	Hanoi Lung Hospital
Incident 2	11/29/2016 10:51:26	11/29/2016 14:21:25	3.50 hours	27753	3.37 hours	Hoang Mai District
Incident 3	11/29/2016 20:00:32	11/29/2016 20:30:36	.5 hours	27765	4.61 hours	Hanoi Lung Hospital
Incident 4	12/5/2016 11:21:26	12/5/2016 14:21:20	3.00 hours	27831	1.79 hours	Hoang Mai District
Incident 5	12/16/2016 12:49:25	12/16/2016 16:26:31	3.62 hours	28018	3.27 hours	Hanoi Lung Hospital
Incident 6	12/20/2016 15:23:05	12/20/2016 18:22:49	3.00 hours	28056	2.23 hours	National Lung Hospital

Incident 7	1/4/2017 14:16:55	1/4/2017 23:44:50	9.47 hours	28281	7.31 hours	National Lung Hospital
Incident 8	1/4/2017 15:19:04	1/5/2017 9:15:55	17.95 hours	28289	17.68 hours	Hanoi Lung Hospital
		Total	**63.90 hours**			

Table 12: Connectivity Incidents

These incidents should be linkable to actions taken within the study by the operations team. Out of the 3,168 hours (1,056 hours across 3 sites) that the study was running only 63.90 hours were offline. This is around 2% of study time. This number can be further reduced by looking at the operational time of the site and excluding this from the incident period.

See Appendix 10 – Incident Resolutions

8.3 Hosting

The hosted services from Rackspace performed well. The study suffered no unscheduled downtime on the virtual servers resulting from the hosted infrastructure. Performance was acceptable within the time period of the study, though additional RAM was added as the study progressed (see section 0 '9.8.5 Gateway 504 timeout and performance'). This was due to the requirements of the application rather than any contention in the environment.

PING is a network utility for measuring round trip times between servers. A 'Ping is sent from the originating server and echoed back by the destination server. The round trip Ping time gives an indication of network health, the successful return of a ping gives an indication of availability of the destination server – a large and protected period of lost pings suggest that the server is unavailable.

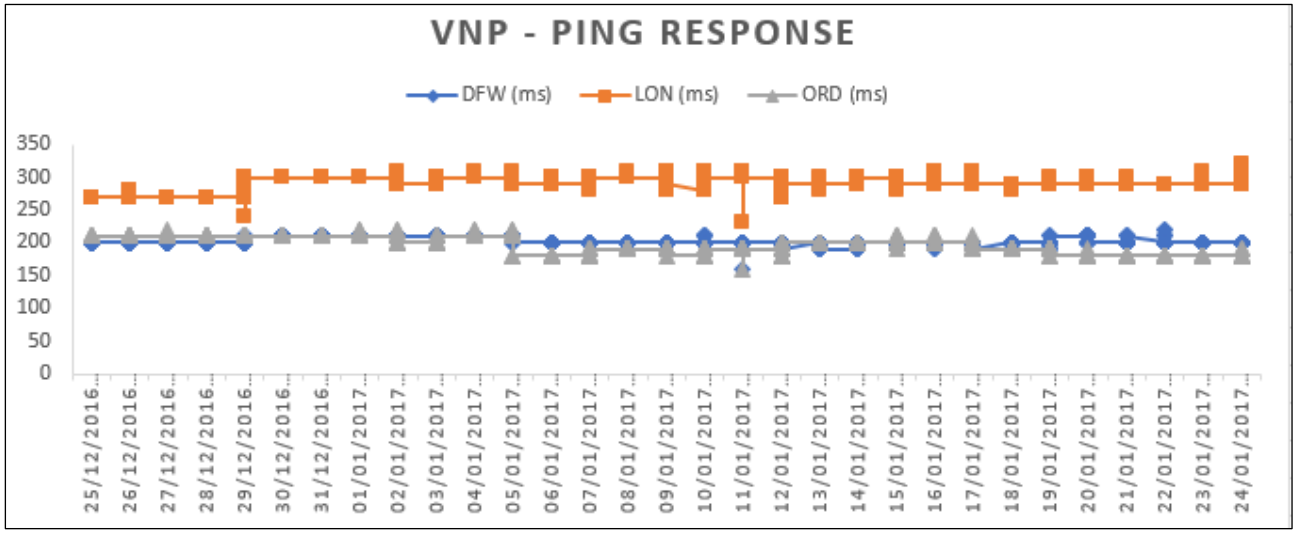


Fig 15: Server response as indicated by the PING* time.

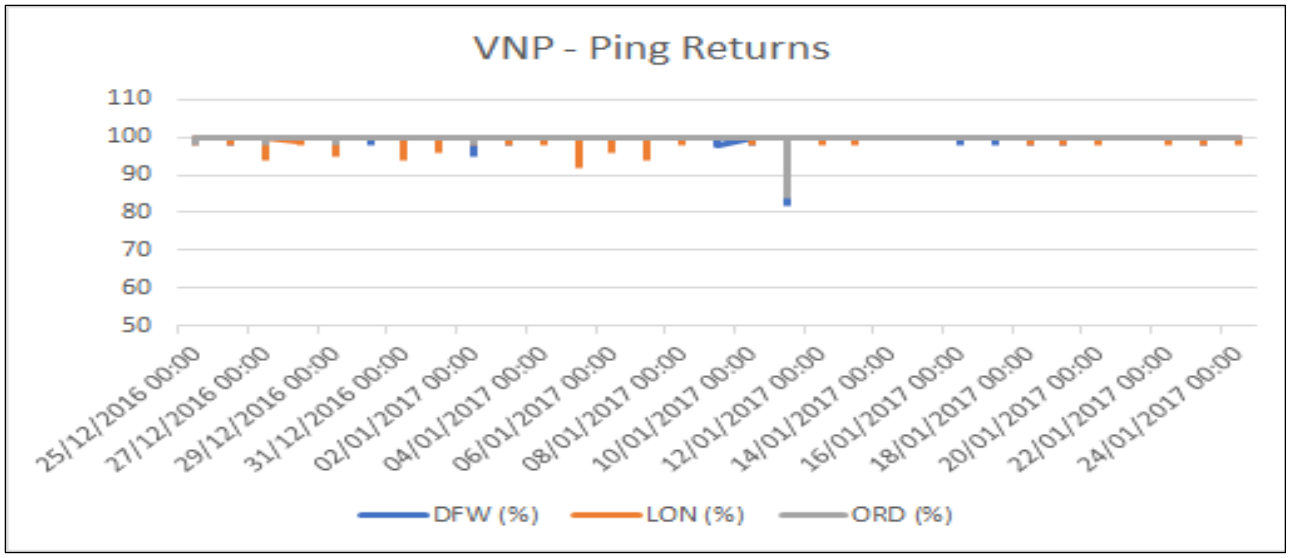


Fig 16: Availability of the Viet Nam Service as measured by the % returns of PING

Note: The originating servers for the Ping tests are as follows:

- DFW - Dallas Fort Worth US
- LON - London UK
- ORD - Chicago US

8.4 Shadow Process support

8.4.1 Support activity

Daily operational meetings were held to raise and monitor resolution of support issues. The table below shows the number of support items raised by category.

Category	Incidences	Percentage
Alerts	1	2%
API	2	5%
Connectivity	13	31%
Data export	1	2%
Data Reconciliation	3	7%
Devices	3	7%
GX Reporter	2	5%
Integration	1	2%
Result Linkage	1	2%
Shadow Process	6	14%
System	3	7%
Test Flow - Test Order	2	5%
Test Orders	4	10%

Fig 17: Distribution of support calls

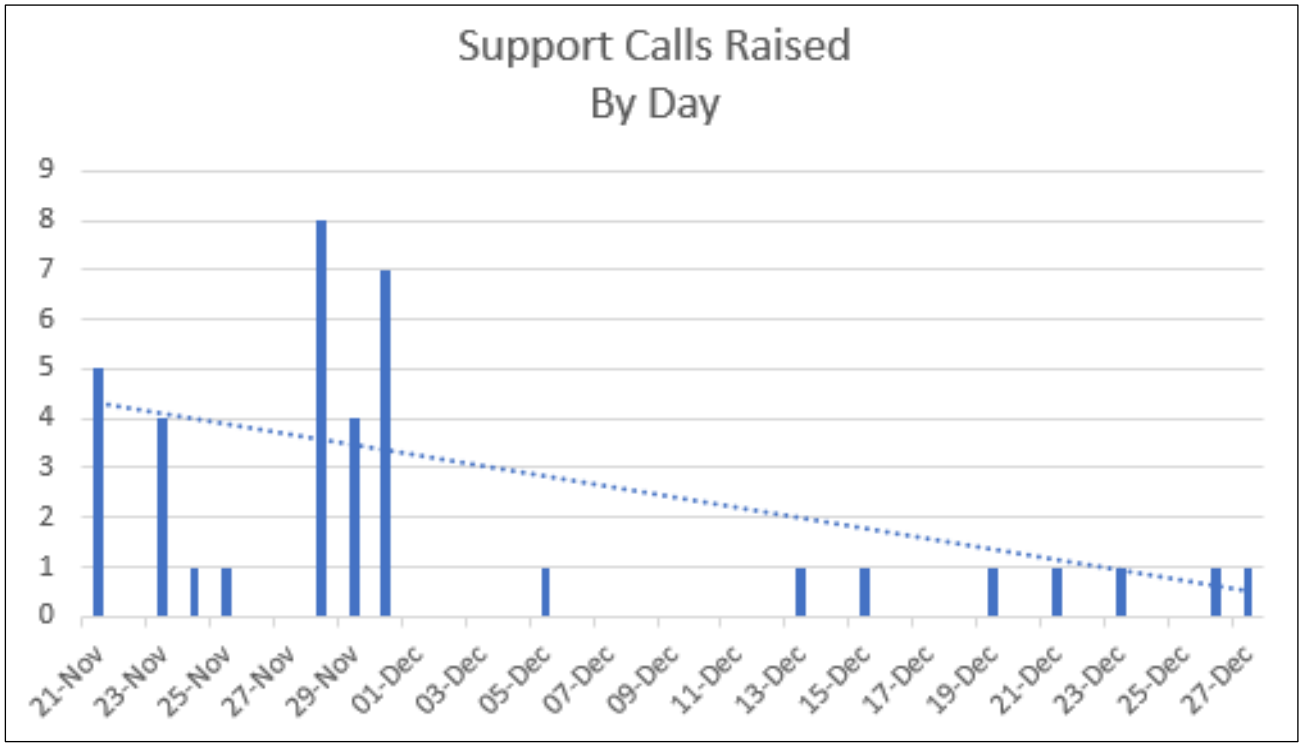


Fig 18: Support calls over time

After an initial flurry of support activity the profile settled down to a low level of issues being raised. The majority of these issues were related to either connectivity or the Shadow Process.

8.4.2 Technical issues versus procedural issues

In this chart support issues have been classified as follows:

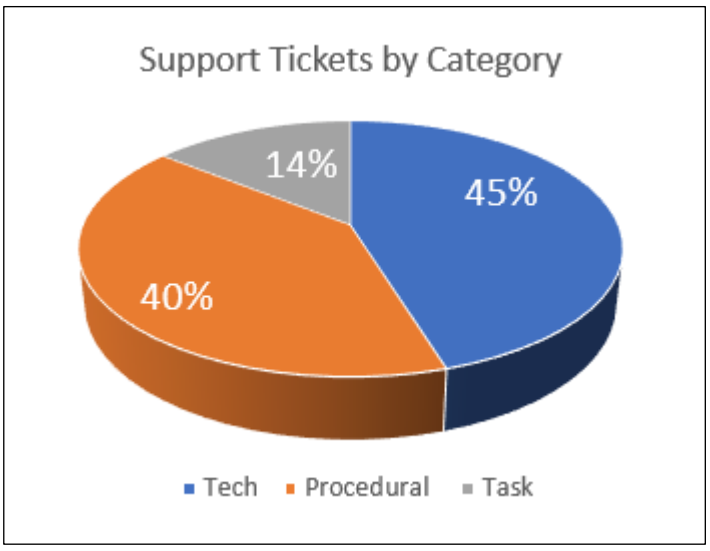


Fig 19: Support tickets by category

Technical: Issues whose root cause is in software, hardware or network functionality including problems that have been resolved by modifying either technical components (i.e. configuration changes, re-starting services) or by updating code.

Procedural: Issues that are caused by human behaviour (i.e. switching modems off overnight) or via non-compliance with processes (i.e. attempting to link results after the result has been transmitted).

Tasks: Support calls queries or questions that have resulted in tasks to be performed.

9 Observations and lessons learnt

9.1 Feedback

Feedback was collected from both the technical teams and Shadow Team, in order to inform and the steer future developments, as well as measure the quality of the launched product. High priority feedback and issues were addressed continuously throughout the study period. The feedback presented here should inform future developments and product evolution.

9.1.1 Technical team feedback

Technical feedback and improvement suggestions were collected from the Viet Nam support team at the end of the study period. Feedback covered requests for improved user interface responsiveness, improved control over user access and more configurable alert messaging. No high priority or blocking issues were raised.

A retrospective meeting was held with the core development team, to identify 'technical debt' (internal refactor and optimizations, invisible to the user) and additional improvements to both the system and the project approach. During a period of 1.5 days specific areas of the service were examined by presenting the team with the following questions:

- What went well?
- Things we can improve?
- Technical Debt?

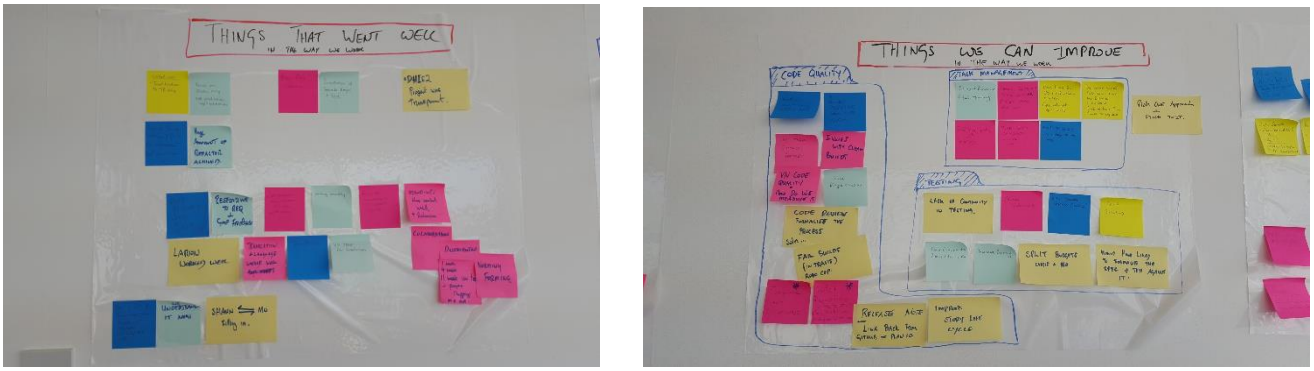


Image 2: Selected outputs from tech team retrospective

Feedback was captured, validated, categorized and de-duplicated. Where appropriate, system related suggestions were added to the agile 'Product Backlog' for future consideration. In total over 90 feedback items were raised by both Viet Nam and Core teams.

Category	Items Raised
Test Orders	13
CDP Bridge	12
Test Results	8
Patients	6
System	6
User Experience	6
Core System	5
Roles	5
Test Flow	5
Devices	4
Total	**70**

Fig 20: Feedback by category

A total of 63 known issues were captured contributing to an ongoing maintenance and bug fixing burden. This is typical of all modern web based systems and serves as a reminder that provision must be made, 'post launch' for ongoing support, maintenance and testing.

Priority	Issue Count
High	4
Normal	45
Low	14
Total	63

Fig 21: Known issues by priority

9.1.2 Shadow Team feedback

Feedback from the Shadow Team was collected in two ways:

1. **Questionnaire**: At the end of the study period the Shadow Team was presented with a questionnaire polling their opinions on system usage training and visions for the future. High-level results are shown below.

2. **Interviews**: During the first week of December 2016 a visit was paid by FIND, to the study's participating sites, to collect initial feedback and observations. The study had been running for a couple of weeks at this point so users and participants would have had enough time to familiarise themselves with the new processes and technology.

Shadow staff feedback summary

Responses to the questionnaire showed an overwhelming preference for using a computer based system with only 1 of the 27 Shadow Team members reporting that they preferred using paper. Workflow automation and preventing rekeying of information were cited as the key benefits of a digital system.

The ‘Bipolar Response’ section of the questionnaire attempted to measure people's reaction to the CDP website by positioning their response to various aspects of the service i.e. ‘Web site navigation’ between two poles, for i.e. ‘Easy or Difficult. The results are presented below:

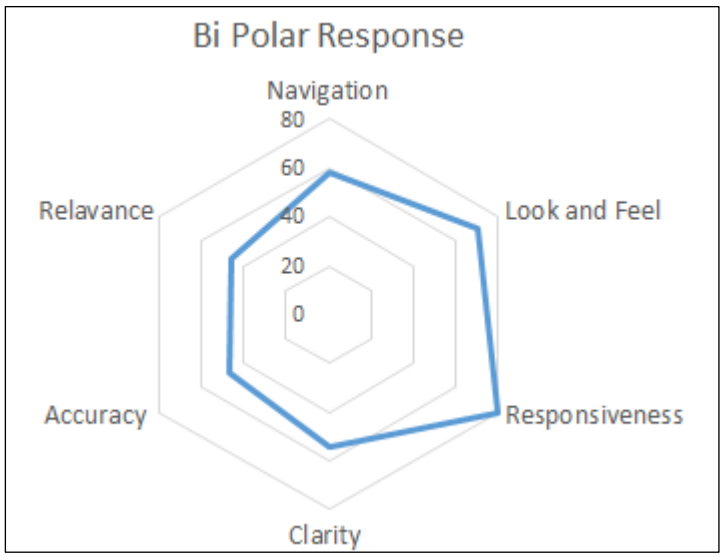


Fig 22: CDP bi polar response results

CDP scored well in terms of its responsiveness and look and feel. These results back-up users comments that they generally found CDP easy to work with. Although navigation and clarity were rated as good there is clearly room for improvements. The product backlog contains plenty of specific improvements suggestions that can be easily implemented in the future.

The lower scores in ‘relevance’ and ‘accuracy’ are seen as a reflection of the fundamental issues with Shadow Process approach and the difficulties experienced in driving shadow transactions through the E2E process. It is a reflection of comments such as:

- *Some of the Shadow Team complaining and angry at having to do the data entry to CDP as complaining they have too much work – 20% - generally older staff that complain*
- *Doctors don’t really care about the results as they see this as just a study*

These sentiments were far from universal and the attitude to the process and the quality of its adoption, clearly increased during the study period (as is concluded in section 0 '9.2 Operations’).

Importance of change management

These results serve to remind us of the importance of communication and organizational change management, and the role it has to play in ensuring that the workforce understand the relevance of what they are doing. Although the training was rated as satisfactory and that the Shadow Team universally felt they could easily train others in their job, the direction, vision and purpose of the study, was perhaps not so clearly understood.

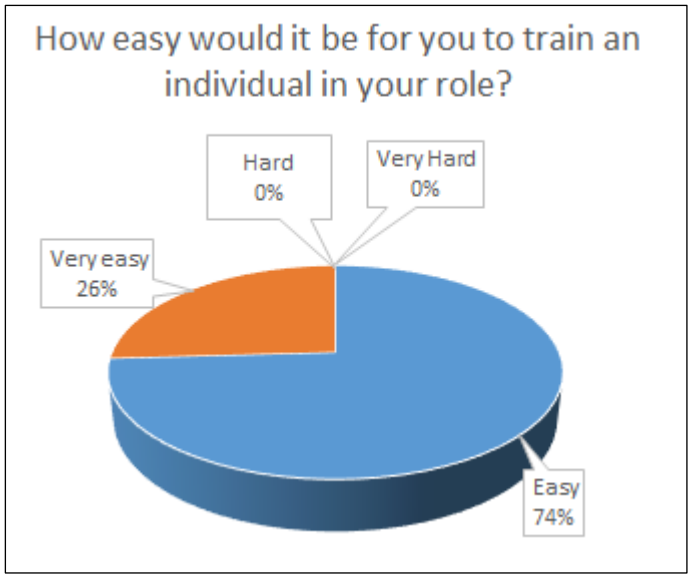


Fig 23: Questionnaire response - ease of training Results

Any deployment at scale needs to take the workforce with it towards a shared end goal. Provision and focus must therefore be made towards regular communications as part of a coordinated change management plan.

9.1.3 Patient ID

When registering a new patient in CDP a unique sequential ID number was assigned to the patient. CDP does have an option of manual entry of an ID number but for the purposes of study a new CDP originated ID was assigned. This ID was unique to the study and did not replace the actual patient ID. Further interaction with the patient throughout the different departments would have normally be referenced only by the patient name on paper records which has the risk of duplication. The study showed that a unique patient ID was desirable as once the patient was registered in CDP, other departments were asking specifically for the CDP reference number as the search for the unique record was much easier. It was also witnessed that this ID number was also being recorded on the legacy paper based forms to make the searching for patients easier. As this was not part of the training protocol we can conclude that the presence of a unique ID number that can be found and referenced from any part of the diagnostic pathway is valuable as the user's adopted this into their legacy workflows by themselves.

9.1.4 Additional patient data

The patient registration functionality of CDP allows the capture of additional information about the patient. For study purposes the option to additionally capture alternative addresses, email, phone numbers and an alias was provided. These data fields can be used for various purposes in the management of patients and TB such as contact tracing, patient notifications and epidemiology. During the study however it was noted that this information was not being populated against the patients being registered in CDP. Upon enquiry the users responsible for the patient registration in CDP commented that as these fields were not being captured on the legacy paper records then they were not being entered into CDP either.

Further to this a number of patients (n=8) in the Hanoi Lung Hospital were asked if they would be prepared to provide additional information (specifically mobile phone and email) upon registration if it meant that results could sent to them once their sample had been taken and they didn't have to

remain in or return to the hospital for their results. All patients responded positively, many with the question of if this could be done during their current visit. One patient asked if there was a cost for this service. When asked if they would be willing to pay for this the answer was neutral based on the potential cost. Further studies into patient willingness to provide additional information, based on benefit to the hospital and patient are ideas for the future.

9.1.5 Ease of use

CDP users within the study were each given training for a period of a half day. During the study visit the users were asked how easy the platform was to navigate and use. Without exception all responded positively towards CDP stating that it was very easy. Some users that were interviewed had used a computer previously but said that usage on a daily basis for them was not common. We found that even users with very little exposure to computers were able to quickly and easily navigate the system.

Although only trained for their specific roles we observed that on many occasions if a member of another team was absent then cover was offered by another CDP user. Without providing additional training from the study perspective it seems that users were training each other on how their specific function should operate. All users were asked if they thought the half day training was sufficient to which all replied yes. Additionally they all felt that they, after just a few days usage, would be able to train other users.

9.1.6 User confusion

The following are areas that confused some of the users

- User/site Segregation - During the study the users were setup so that visibility and data access were given to all users for all sites participating in the study. In a production environment we would expect that users would only be given permissions to access data from their own site unless they were in a regional supervisory position or similar. CDP has the ability to offer this but it was noted that users expected this to be as standard. There were no issues from users having this ability within the study but it was more an issue of expectation that permissions would be restricted for them.
- Multiple sample IDs - The CDP configuration used for the study offered the ability for multiple tests to be ordered as part of the same order i.e. GeneXpert and microscopy. For each of these tests it is possible to specify a different sample and indeed a different sample ID. Whilst this is common in some diagnostic algorithms this approach isn't adopted in Viet Nam and the normal practice is that one test order would only contain one sample and one ID.

9.1.7 Workflow and adaptation of use

The workflow in CDP follows the diagnostic pathway from a process and departmental view. Within the Hanoi Lung Hospital, once patients are registered they are required to provide payment for the TB test. We observed that the finance department, whilst trained simply to search for individual patient records in CDP to process payment against the test order, would frequently compile and sort a list of all patients registered on a particular day (most register in the morning) to see if any were still to present at the payment desk. When asked about this they used CDP to ensure that all patient payments had been processed before they concluded that no additional payments had to be processed. If any were outstanding they went to search for the patient to prompt them to pay. This was seen as encouraging and could be just a small effort to reduce any patients breaking the workflow and potentially dropping out of the process.

9.1.8 Value and use preference

When asked specifically if the users would prefer to continue using CDP or revert back to the legacy paper based process, all users specified their preference for CDP citing reasons of time saving compared to paper based data entry, easy search/access to patient records and test results as well as automatic reporting and alerting. It must be noted however that one user, whilst preferring the digital format raised issues of reliability especially in the event of power outages but accepted a paper based backup in during these outages would suffice. The most common comment from users in terms of value was the availability of a single data entry point with data dissemination to VITIMES and e-TB Manager happening automatically. With some users reporting that several hours per day could be attributed to data entry to these systems, the automatic sharing of data to these was seen as essential.

9.1.9 Resentment of workload

Although in most cases a member of the Shadow Team performed the necessary functions within CDP leaving the workload of the primary worker free from these tasks, there were some cases where the CDP data entry was also being conducted as an additional task on top of the primary workers day-to-day load. In a non-study environment this would not be an issue as the workers would only have to follow one set of processes rather than two. The additional tasks as part of the study were seen by some in these cases as burdensome as they didn't have time to do them.

9.1.10 Resource process bottleneck

On several occasions it was observed that test orders were being delayed at the test finance step resulting in users further down the chain being unable to complete their tasks. This was due to staff members being absent. As such we saw the ‘role covering’ scenario as explained in the ease of use section above. Auto finance configuration option was introduced as an option in case the issue could not be resolved, however this contingency was not required in the end.

9.1.11 Language selection

Although the CDP was customised for use in Viet Nam with Vietnamese language we did observe some users using it in English. When asked if they knew how to switch languages these users replied yes.

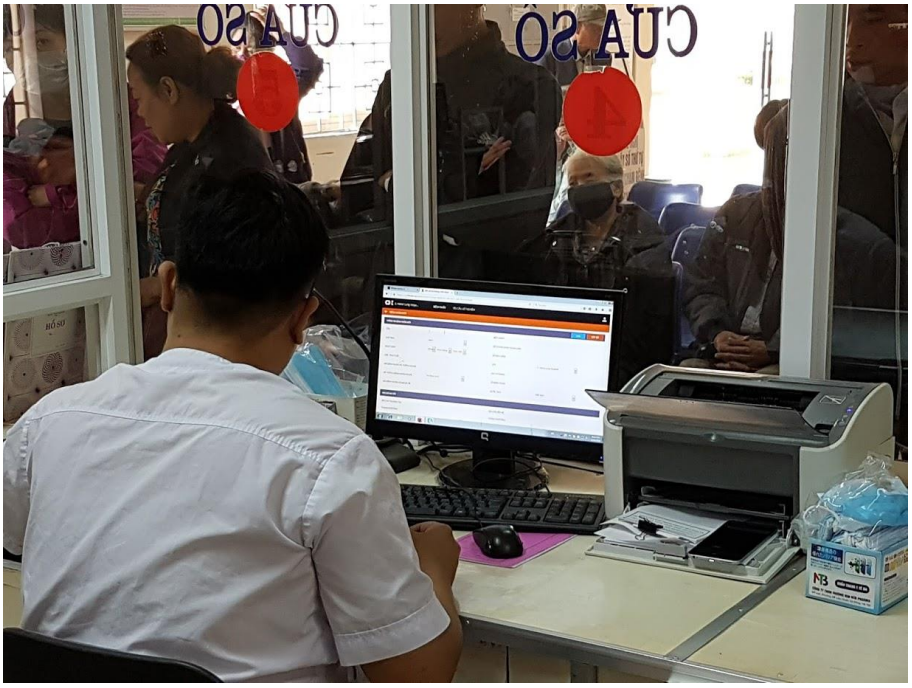


Image 3: CDP being used for patient registration

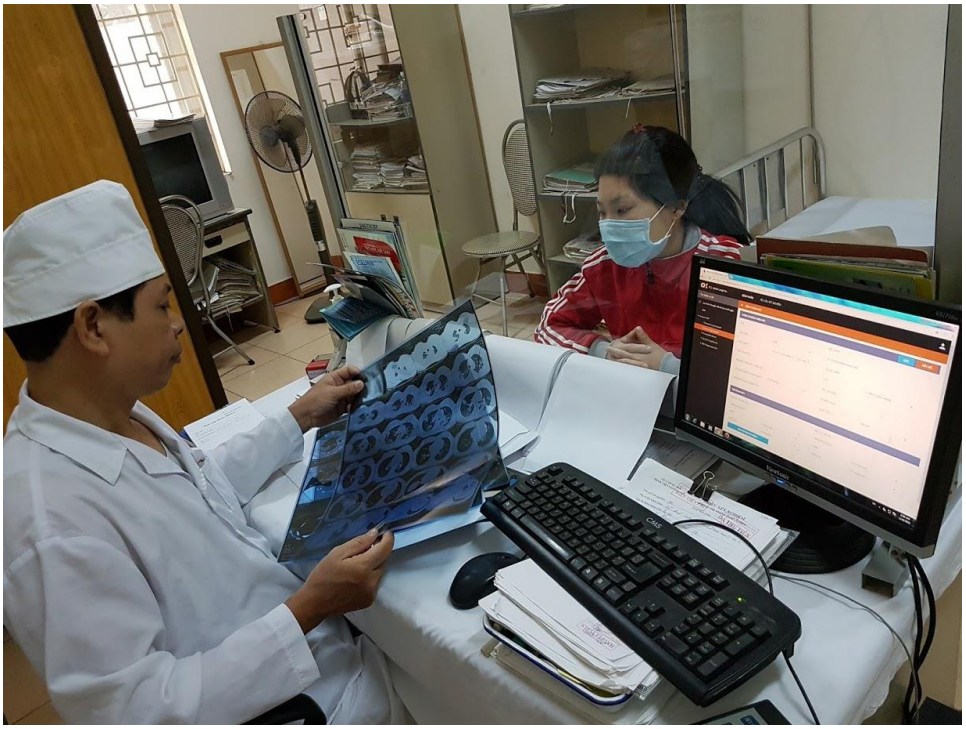


Image 4: CDP being used to access patient record

9.2 Operations

9.2.1 Percentage closed

In a production system we can expect that every order created is eventually closed; we would not expect orders to be abandoned and left incomplete. However the Shadow Process did experience a high percentage of incomplete orders. The metric '%Closed' has been used to measure the extent

to which the Shadow Process was successful in capturing the full order lifecycle.

% Closed	During Total Study Period	During First Half - 21Nov-13Dec	During 2nd Half - 14 Dec - 6 Jan
% Microscopy	55.2%	43.8%	71.2%
% GeneXpert	61.2%	45.2%	77.8%

Fig (24) - Percentage Orders Closed

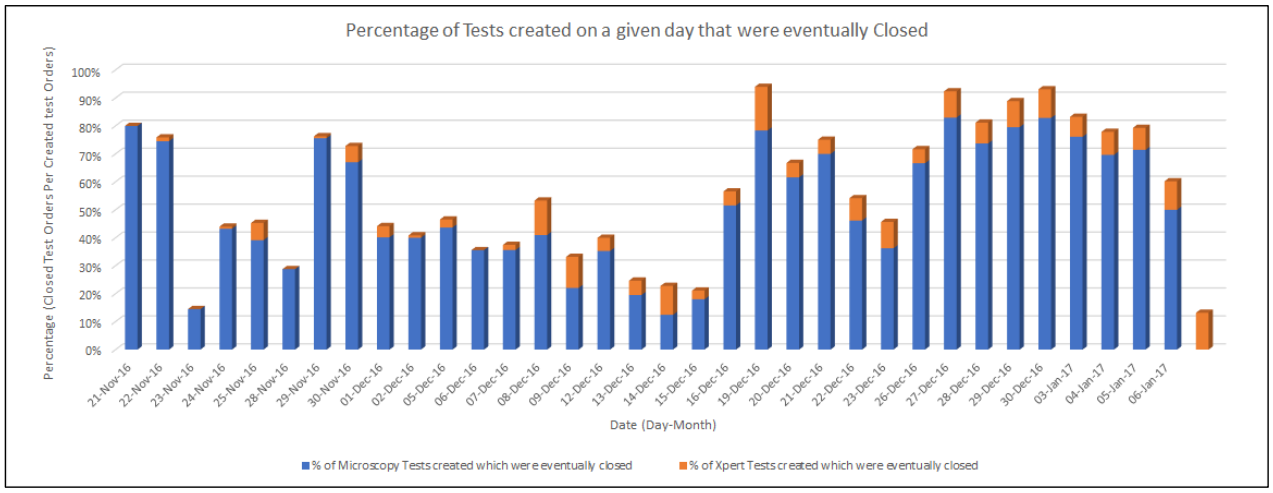


Fig 25: Percentage orders closed by day

The figures presented above show the % of orders created that were eventually closed. It is worth noting that in the state model an order cannot fail, it is only ever created, deleted or closed (See section 0 ‘4.4 CDP entities and test order workflow’).

There were several reasons why the Shadow Process can fail to complete an order; these are listed below:

- Resources were not available to complete all the orders because:
  - Individuals were unavailable due to illness or holiday (and there was no cover for certain roles)
  - Individuals were overwhelmed by volumes and did not want to delay serving patients in a queue and therefore abandoned certain orders
  - Individuals were not always dedicated to the Shadow Process and therefore prioritised other activities over processing all CDP orders
- Individuals lacked computer keyboard experience initially making them slow at data entry, causing them to skip processing all orders (This occurred during the early part of the study)
- Internet connectivity in certain locations prevented access to CDP
- Intermittent issues accessing CDP (error 504) lead to individuals abandoning certain tests

As part of the daily operations meetings the issue of %Closed was observed and service improvements recommended. Service improvement steps taken included:

- Solving internet access problems preventing some shadow staff from logging on
- Technical changes to reduce the 504 errors

- Re-allocation of resources to relieve resource constrained parts of the process
- Removal of In Patient Microscopy testing from the scope of the Hanoi hospital workload
- Prioritization of GeneXpert tests over microscopy tests

The difference between %Closed in the first part of the study compared with %Closed in the second half highlights the improvements made.

9.2.2 Process response times

In the first part of the test order process (up to the point where the result is captured in the system), it has proven hard to quantify an improvement in response times, due to the Shadow Process. It is clear that the only accurate way to measure process improvement in this area would be to conduct a direct, like-for-like comparison, between the As-is process and its replacement with an automated system.

The issues with using the Shadow Process to draw such comparisons are listed below:

- No real world incentive to complete or turnaround transactions quickly – for example if a test is approved several days after it was run there is no actual clinician waiting for the result and therefore no 'real world' pressure to turn the action around quickly
- Events that plagued the Shadow Process would not occur in the real world i.e. one would not expect illness or absence to block testing, since it is usual practice to provide resource coverage
- The Shadow Process cannot be quicker than the As-is Process– because it is shadowing each step in the real world, thus not possible for CDP to operate at a quicker pace

9.2.3 Impact of service improvements on response times

The graphs below show the average response times, as measured for the first half of the study and again for the second half. As can be seen response times have improved as a result of the service improvement interventions.

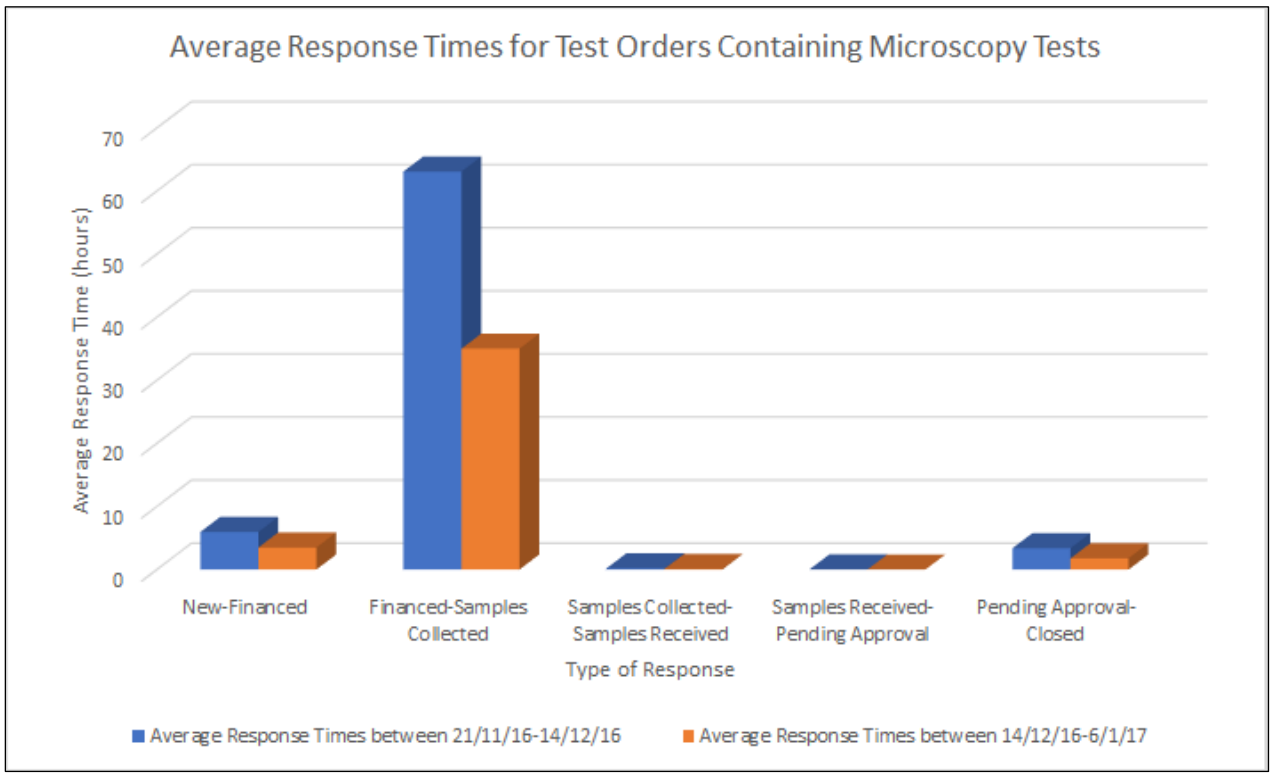


Fig 26: Microscopy response times

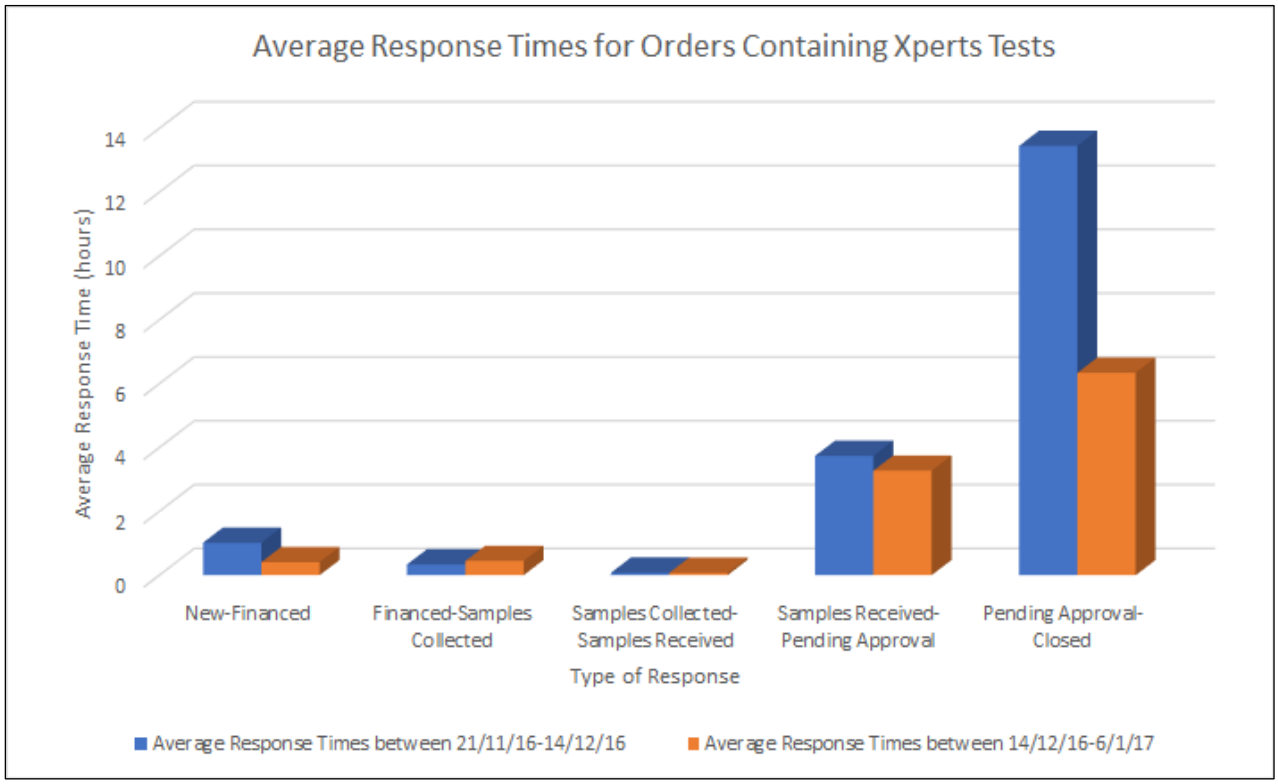


Fig 27: GeneXpert response times

It is in the later stages of the process (once the test result has been captured in the system) that the potential for major improvements through the use of CDP exist, namely:

- Results available for approval: CDP average was 18 minutes after the test completed
- Approved results available to the Clinician: available immediately
- Approved results available in VITIMES and e-TB : CDP average 13 minutes
- Production of reports (weekly, monthly, annually):Immediate according to schedule

Additionally having visibility of the progress of orders as well as the pipeline of daily work encouraged a natural modification of behaviour. Although this could not be measured empirically there were indications that efficiencies were being made including the handling of so called ‘un-happy path’ cases (cases where the process does not go so smoothly), for example:

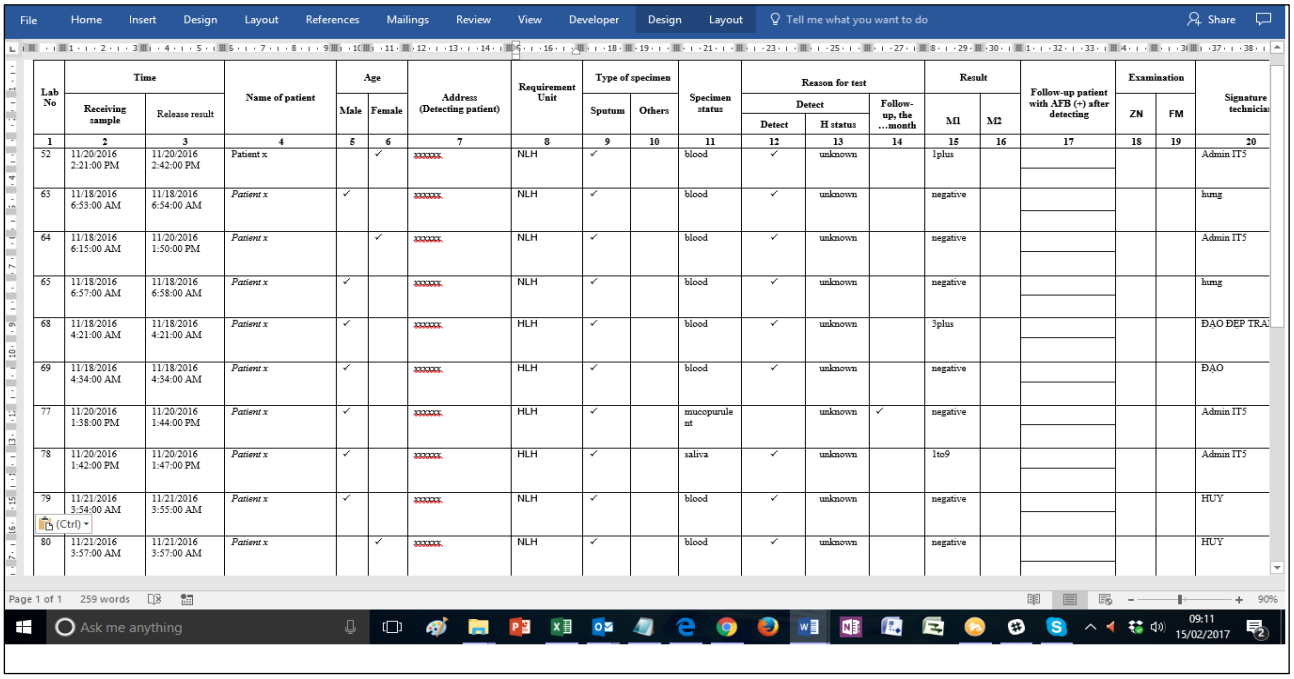
- By looking at the Finance Pending list, shadow staff started looking in the reception area for patients who had been seen by a doctor but had not yet paid for their tests
- Clinicians were able to check progress and start enquiring about delayed tests
- Remote staff in referral sites were in a position to monitor the progress of tests and be immediately alerted of results

9.2.4 Report generation, effort and response times

By way of a proof of concept the production of the following reports was semi-automated:

- Logbook of AFB direct smear microscopy
- Logbook of Xpert MTB/RIF
- M4A. REPORT OF AFB DIRECT SMEAR MICROSCOPY
- M4B2. REPORT OF XPERT MTB/RIF ACTIVITIES

To produce the reports the data was extracted from CDP using a SQL command, the quality of the output inspected and then used to drive Microsoft mail merge. This process allowed the creation of each report (approximately 15 minutes each) and required no re-keying of information. This is not the recommended production approach. However this approach has served to quickly demonstrate that the data required to drive the process was correctly collected and that this data can be easily presented in a variety of predefined, standard formats.



Lab No	Time		Name of patient	Age		Address (Detecting patient)	Requirement Unit	Type of specimen		Specimen status	Reason for test			Result		Follow-up patient with AFB (+) after detecting	Examination		Signature technicia
	Receiving sample	Release result		Male	Female			Sputum	Others		Detect	H status	Follow-up, the …month	M1	M2		ZN	FM	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
52	11/20/2016 2:21:00 PM	11/20/2016 2:42:00 PM	Patient x		✓	xxxxxx	NLH	✓		blood	✓	unknown		1plus					Admin IT5
63	11/18/2016 6:53:00 AM	11/18/2016 6:54:00 AM	Patient x	✓		xxxxxx	NLH	✓		blood	✓	unknown		negative					hung
64	11/18/2016 6:15:00 AM	11/20/2016 1:50:00 PM	Patient x		✓	xxxxxx	NLH	✓		blood	✓	unknown		negative					Admin IT5
65	11/18/2016 6:57:00 AM	11/18/2016 6:58:00 AM	Patient x	✓		xxxxxx	NLH	✓		blood	✓	unknown		negative					hung
68	11/18/2016 4:21:00 AM	11/18/2016 4:21:00 AM	Patient x	✓		xxxxxx	HLH	✓		blood	✓	unknown		3plus					ĐẠO ĐẸP TRA
69	11/18/2016 4:34:00 AM	11/18/2016 4:34:00 AM	Patient x	✓		xxxxxx	HLH	✓		blood	✓	unknown		negative					ĐẠO
77	11/20/2016 1:38:00 PM	11/20/2016 1:44:00 PM	Patient x	✓		xxxxxx	HLH	✓		mucopurule nt		unknown	✓	negative					Admin IT5
78	11/20/2016 1:42:00 PM	11/20/2016 1:47:00 PM	Patient x	✓		xxxxxx	HLH	✓		saliva	✓	unknown		1to9					Admin IT5
79	11/21/2016 3:54:00 AM	11/21/2016 3:55:00 AM	Patient x	✓		xxxxxx	NLH	✓		blood	✓	unknown		negative					HUY
80	11/21/2016 3:57:00 AM	11/21/2016 3:57:00 AM	Patient x		✓	xxxxxx	NLH	✓		blood	✓	unknown		negative					HUY

Image 5: Logbook of AFB Direct Smear Microscopy

9.2.5 Cost saving through report automation

The ability to automatically generate reports from data stored in CDP provides the ability to reduce the manual effort of reporting.

Regarding ‘Logbook of AFB direct sear microscopy’ and ‘Logbook of Xpert MTB/RIF’

The labs have to update these logbooks on a daily basis. Each day the lab staff takes between 20-40 minutes for staff to update the logbook for the day’s microscopy tests and 10 - 20 minutes for Xpert. It is estimated that this will take about a one minute per test.

During the period of study – around 3700 actual patient tests were performed. CDP had the potential therefore to save over 60 man hours of effort.

Regarding M4A. REPORT OF AFB DIRECT SMEAR MICROSCOPY & M4B2. REPORT OF XPERT MTB/RIF ACTIVITIES

These two reports are created and reported to the NTP on a quarterly basis.

It takes typically 60 minutes to manually generate each report. It has been observed that (based on NTP-guideline), all of the microscopy tests need to be updated into VITIMES which is then able to automatically generate the report as required. However, despite several provinces doing an excellent job of data entry most provinces do not enter all of their cases into the system, so they still manually create the report quarterly. CDP potentially can

improve this by ensuring that VITIMES has a complete set of data, thus removing the need for any further manual effort.

The current 'semi-automated' report generation process requires 20 – 30 minutes to generate all the above reports.

9.2.6 Report automation - Design for scalability

Numerous methods can be used to fully automate the generation of the reports to further reduce the production time. Additionally automatic scheduling, on a daily, weekly or monthly basis, can further reduce the manual overhead of report generation to zero.

Prior to investing the engineering time to fully automate the generation and scheduling of all existing paper reports, it is recommended that the full process surrounding the use of the reports is investigated with a view to process re-engineering. Such an analysis would validate to what extent reproducing the as-is paper documents is appropriate to users of a digital system. For example certain users may find a real-time on-screen report more useful than physical paper copies. External users may find an electronic data set or even an API data exchange sufficient for their needs. All opportunities should be taken to re-engineer with efficiency in mind rather that faithfully reproduce the As-is artefacts.

9.3 Linkage success and sources of linkage errors

At the start of the study a lower than expected number of 'linked GeneXpert test results' were observed. Investigations ongoing through the first four weeks of the study relieved a number of process related issues. Data from CDP was used to both observe, resolve and measure improvements, in linkage success.

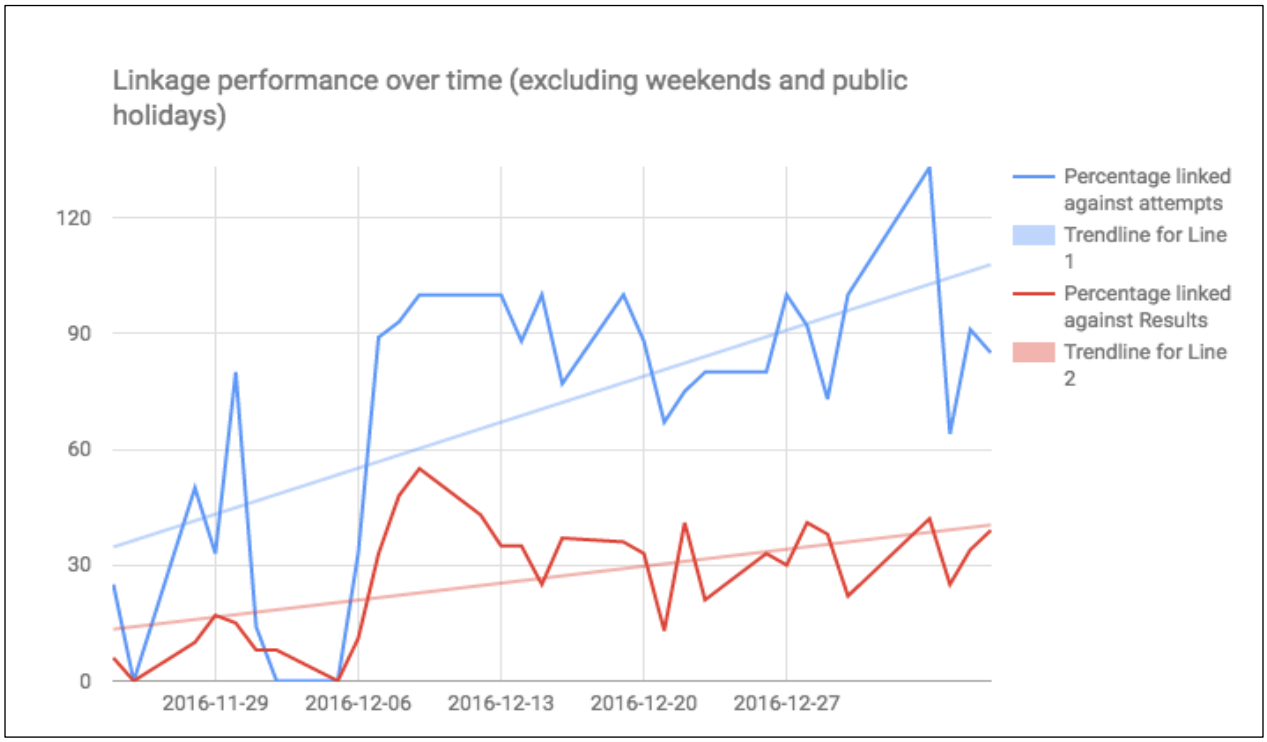


Fig 28: Percentage Linkage Attempts by Day

Time Period 24th of Nov - 6th Jan: first week of running has been removed since historical data was uploaded during this period therefore skewing the results.

The red line shows the number of successful links as a percentage of the number of GeneXpert tests ordered in CDP. This is a measure of success for the whole E2E process. There were a number of reason why tests that were ordered in CDP did not get as far as attempting to link. These are reviewed below and in section 0 '9.2.1 Percentage closed'.

The blue line shows the percentage completed orders that successfully linked results to a patient.

The trend lines show that improvements were made throughout the lifespan of the study period. Through a process of regularly operational reviews (daily meetings to review the data in CDP) and implementation of service improvement measures, the team was able to continuously improve linkage success.

Root Cause	Resolution
#1 CDP orders raised but not completed	
Numerous orders were raised in CDP but not all were successfully processed to completion.	These issues were addressed as part of the initiative to improve the %Closed figure (see Section 0 '9.2.1 Percentage closed').
#2 No SampleID added to the notes field	
This was caused by a mixture of individuals not understanding the process and others occasionally abandoning the step, due to workload pressures.	This issue was addressed through inclusion of a 1 pager 'cheat sheet' to remind people of the process, and the balancing of workloads and resources.
#3 Incorrect SampleID in the Notes Field	
A technical issue resulted in the linkage process being case sensitive which affected linkage.	This was remedied by code changes and was further assisted by the eventual rollout of the barcode printers.
#4 Notes added to the SampleiD field after the test was run	
This was a behavioural issue whereby, because the DX software allows results data to be updated after the test had been run, staff being resourceful with their time decided to wait until quiet periods to add SampleIDs to the notes.	This was remedied via retraining and the use of the cheat sheet. In short, once reminded of the process, operators could see that this behaviour was not appropriate. *
# 5 Multiple Tests Per Test Order	
As process adoption increased a more hidden reason for failed linkage emerged in the operational data. The symptom appeared as 'Orphaned Tests' with valid CDP SampleIDs. Investigation revealed that operators typically retry failed tests until a successful or acceptable result is achieved. Retries typically use the same sample and are logged under a single Lab Test ID. In this circumstance CDP records the 'failed' result and closes the order: any subsequent retest fails to link (and is captured as an orphan), even though a sampleID may have been added to the notes field.	The tactical resolution was to modify CDP to only link valid results. This was a quick fix however; a future enhancement would be to provide the ability to view failures and retries (with the same Patient / Sample ID)and allow the technician to submit the result they would like to link to the patient. **

Table 13: Test linkage issues and resolutions

Many of the reasons given above would not be expected to occur in a production implementation and are considered as artefacts of the Shadow Process. What is shown is that that by reviewing and acting on the data, the quality of the process can be improved.

Future Changes

Consideration should be given to the following enhancements of CDP:

- Ability to manually link orphan tests to patients
- *Ability to store an array of test results against an individual test order
- *Ability to select and store a result (as the trusted result) from an array of results
- **Synchronization of any updates made in the instrument's software (after a test result has been transmitted) with its corresponding result, in CDP

9.4 Change requests

During the study the FIND development team was on standby to fix any bugs but also to make any change requests from users. A number of software bugs were fixed but the main changes to the system during the study period are described below:

- Increased ability to search by patient name - this request was only applicable to a couple of screens used throughout the process where it was anticipated that the search would be best conducted using the CDP assigned patient ID.
- Edit Test Result - The ability to edit a submitted test result was not an option originally available to users. After several users noted that they had made mistakes during the process the ability to edit test results was extended.
- New 'Abandoned' state model for test orders - During the study bedding in period a number of tests were not processed correctly resulting in a workflow failure that wasn't resolvable e.g. a patient paying for their test but never returning to provide their sample. This was noticed by an increasing amount of tests left in a 'in progress' state over several days. The ability to abandon the test order was subsequently introduced.

9.5 Project delivery

9.5.1 Mitigation of study project risks

During the project life-span certain project risks were mitigated by removing dependencies on external suppliers. These are listed below:

Mitigation Action	Description
HIS Integration De-scoped	Integration with HIS was de-scoped due to resource constraints within the Hospital IT making commitment to this feature unsafe
Choice of Integration Solution	Integration with VITIMES and e-TB Manager was performed using 'screen scraping', therefore removing the need to commission these systems and dependencies on external IT teams
Choice of Hosting Provider	Hosting was provided by the project using external hosting providers, avoiding the lead time and expense of arranging internal hospital resources
Choice of Connectivity Solution	Connectivity was provided using mobile data procured by the project avoiding commissioning hospital network infrastructure changes

Scope of NTP Signoff	The project was free to scope technical implementation and functional approach with minimal need for clinical approval from the NTP or MOH. Although reviews were held with NTP staff, this approach reduced the risk to project milestones from delays in securing time with key stakeholders and achieving their sign-off

Table 14: Project risk mitigations

By removing these external dependencies the project was able to ensure timelines were met by setting its own priorities and focus, along with providing the required motivation.

9.5.2 Mitigation of risks when implementing at scale

Although this approach worked well for the study, any project to implement a fully integrated system cannot proceed on such a basis. The requirements, re-engineered processes and feature set for the integrated system must be guided and approved by a Clinic Governance Board (CGB).

The technical solution and supporting infrastructure must be collaboratively designed by a Technical Design Authority (TDA) consisting of representatives from all the participating systems. This is required to ensure that the behaviours of the integrated system works according to the design, and that the resources and deliverables are all provided according to a shared development plan.

It is recommended that the CGB be chaired by the NTP, and is also accountable for steering the programme.

It is recommended that the TDA should be chaired by a vendor neutral organization, operating in the role of a 'systems integrator'.

9.6 Study support

Provision of support and continuous improvement was particularly successful during the project period however an important 'lesson learnt' during the study was to ensure regular and frequent communications with the Shadow Team. Some complaints were raised by the Shadow Team that changes were made without prior notification. Although release notes, crib sheets and progress reports were issued, the following areas could have been strengthened:

1. Release notes and system changes: It is essential that all functional and UI changes are communicated in advance to the user community.
2. Adoption is supported by regular and frequent communications with the staff: it is therefore essential that regular newsletters and updates are provided to both encourage staff to improve and promote success, as well as reminding everyone that they are part of a larger system and an extended team.

9.7 Connectivity challenges

During the NTP study period, observations were made relating to provision of the connectivity service. These were captured as incidences. A list of these incidences is provided in chronological, along with the lessons learnt, in order to remedy these issues in future development.

See Appendix 11 – Connectivity Challenges & Lessons Learned

9.7.1 Virus on machines

Computer security is very important when enabling a windows based machine with internet access or connectivity. The NTP CDP Study machines should in theory have never been connected to the

internet, however it is still important to ensure that these computers which host the Cepheid Dx software solution do not pose a risk on to the Patient Identifiable Information (PII) data, which is cached locally and that could be at risk, particularly once the computer is enabled with internet access capabilities.

Viruses, new or old can seriously impact the behaviour of a computer system and cause multiple types of vulnerabilities. It is not always internet access that enables a computer to become infected. For instance, USB flash drives are extremely useful devices for transferring data but they do come with security risks, especially when dealing with a machine which does not have up to date antivirus packages and which is isolated from the internet.

The approach taken in the NTP CDP Study was to perform a full antivirus and malware scan before any work was conducted on the computer in question. The summary below details the number of viruses identified on each machine within each study site and their potential impact. In each of these instances each virus or worm was successfully cleaned from the systems. This was proven by rescanning all systems and ensuring that the machine was in a clean state.

See Appendix 12 – Virus' Identified

9.7.2 Hoang Mai Sim Swap

Between the installation of the initial SIM and the subsequent replacement at the Hoang Mai site, an escalation was raised to the program team following poor sending performance being observed, the CDP Bridge implementation was monitored remotely and was observed to be missing some of its 30 minute reporting intervals, which are in place to transmit new results to CDP. In one instance it was measured and the root cause was identified as bad network performance, 50% of service intervals were being missed due to this issue. After replacing the MobiFone SIM with the Viettel SIM card, several days of close monitoring took place and a noticeable difference was seen in the performance of the overall system.

9.7.3 Mobile operator agreement

Due to the duration of the study it wouldn't have been feasible to enter into 12 month contracts with mobile SIM providers, so PAYG (Pay As You Go) SIMs were procured instead. As a result of using PAYG SIMs, there were multiple outages of data transmission throughout the project which were caused by the SIM Cards running out of credit. Problems occurring as a result of these outages included inability for the devices to send data and most importantly, the inability to connect to the device and confirm the specifics of the outage, requiring a site visit from a member of the team to confirm the issue and 'top up' the SIM credit. 'Topping up' these SIMs required the SIM to be removed from the device and inserting it into a mobile phone, so that the on-site operator could apply the additional credit to the SIM.

9.8 Application and technology observations

This subsection calls out observations and results relating to the integration of the surveillance systems and peak time performance issues with the CDP server.

9.8.1 Integration benefits

Overall the integration with e-TB Manager and VITIMES provided stable and accurate real time updates, completely removing the need for staff to prepare inputs or rekey data. Updates occurred in the background on a record by record basis, with an average wait time of 13 minutes between test approval and system update.

It has been reported by the NTP that it normally takes 4-6 hours for two members of staff to update data into both systems per week. The time can vary according to the number of tests in each hospital. On average it takes 2-3 minutes per test to update in each system.

The NTP policy states that 'within 3 days the test result must be updated into the systems', but in real life, due to high routine workload, it takes 3-5 days from tests completing to the system being updated.

CDP can potentially provide real-time updates whilst saving between 8 -12 man hours per week in keying in data. This represents a saving of approximately 56-84 man hours during the study period.

It is estimated that to monitor for and correct (retry) any failed integrations amounts to about 20 minutes per day. With an additional 20 minutes per week to report on integration operations.

9.8.2 Integration – screen scraping

As a contingency, screen scraping worked well; there was only one outage, (of one working day) relating to an uncommunicated change in the user interface of VITIMES. This was quickly fixed by a software change to CDP. The transactions that failed during this period were recovered and successfully transmitted using the 'retry' option in CDP: no data was lost by this outage.

9.8.3 E-TB Manager Integration results

e-TB Manager Integration	
Number of RIF Detected GeneXpert Tests in CDP	*17*
Number of Attempted Transmission to e-TB Manager	*17*
Number of Successful Transmissions	*15*

Fig 29: e-TB Manager Statistics

Integration Rule: The GeneXpert Test result (and its corresponding patient information) is only written into e-TB Manager, if a GeneXpert MTB test with RIF Detection is recorded. The integration only occurs when the test has been approved in CDP.

In total, there were 17 GeneXpert Results which had RIF detection captured in CDP; 15 of these were successfully integrated into e-TB Manager, 2 failed.

One result failed because the "Social Security ID" was missing, the second failed due to a missing value for the patients age. The CMND validation is not a requirement of e-TB manager and so this constraint was removed from CDP; changes to make 'age' a mandatory field were also made.

9.8.4 VITIMES Integration results

VITIMES Manager Integration		
Total Number of Closed* Tests	*2067*	100%
Total Number of Integrated Results	*2016*	*99%*
Number of Microscopy Results Transmitted	*1846*	*91%*
Number of GeneXpert Results Transmitted	*170*	*8%*

Number of Failed Transmissions	*31*	*1.5%*

Fig 30: VITIMES Statistics (Percentages are calculated as a percentage of the Total Number of Closed Tests)

VITIMES Business rules:

- Write all microscopy and GeneXpert results to VITIMES except where drug resistance is detected
- Do not write results for failed or invalid tests
- Records are only written once orders have been approved (and therefore closed)

*Note: Once all the tests in an order have been approved then the order is 'Closed'. Not all orders raised by the Shadow Team were fully processed and therefore closed.

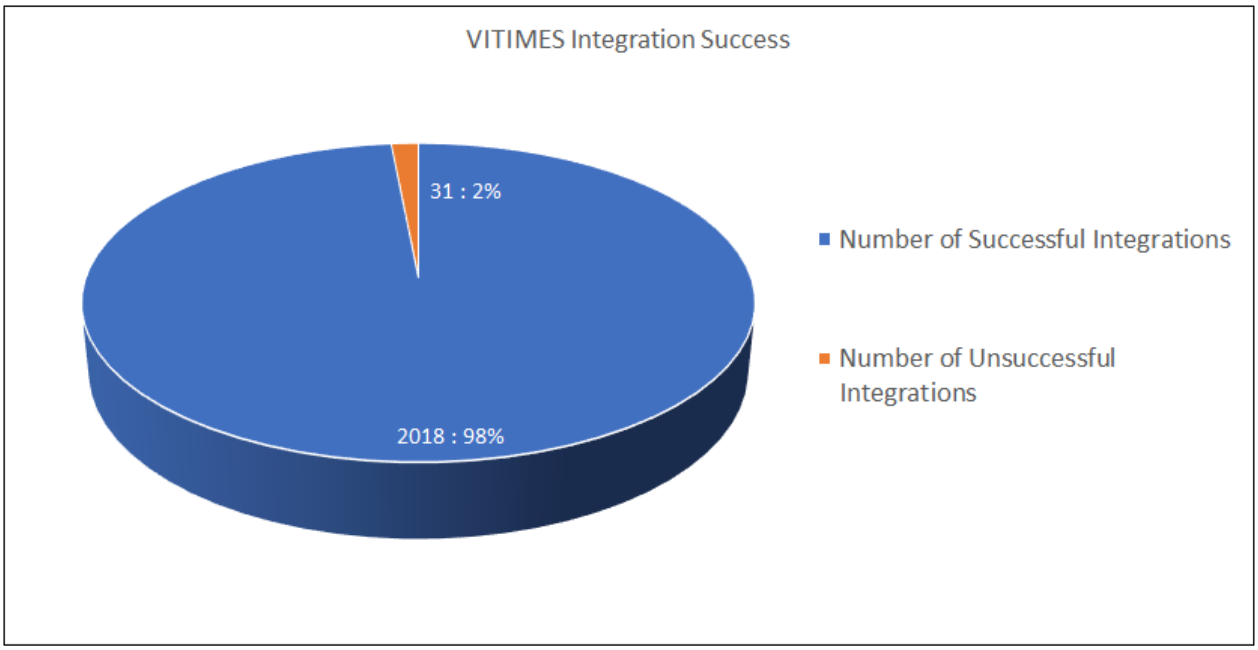


Fig 31: VITIMES integration errors

Integration errors

Investigation revealed that all the integration errors were due to missing ages in the patient registration. Making age mandatory in the patient registration process is an outstanding enhancement.

9.8.5 Gateway 504 timeout and performance

Outside of peak periods CDP's performance was regarded as acceptable, however some peak period operations were disrupted by 504 gateway timeout errors. A 504 gateway timeout error occurs when a user tries to interact with the CDP system (e.g., save a patient registration) and instead of CDP committing the change and navigating to the user to the patient page, the user receives the following message:

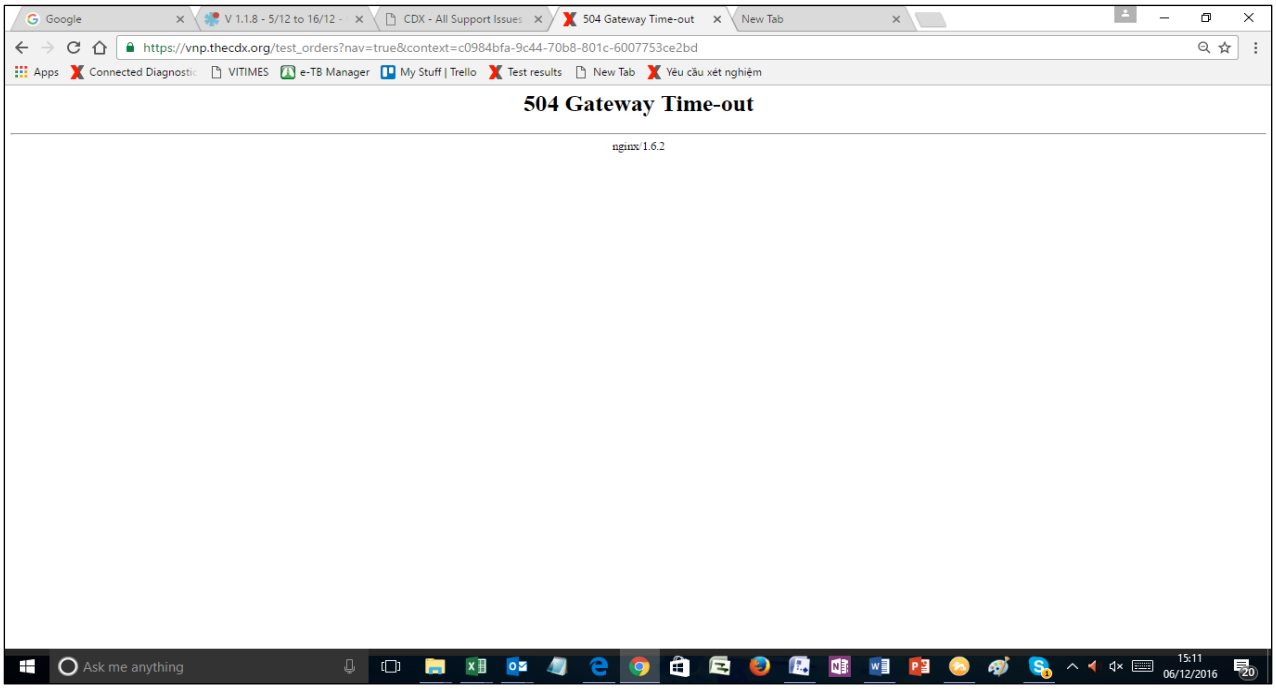


Image 6: 504 error page

504 Gateway Timeout Error Explained

When accessing the CDP service a web browser goes through the following cycle:

1. Obtain an IP address for CDP
2. Open an IP socket connection to CDP
3. Transmit data through that socket to the CDP Server
4. Receive an HTTP data stream back from the Web server in response

The 504 error occurs in the final step above and is an indication of performance timeout issues with the CDP server itself. Investigation showed that this error occurred at peak times (typically 8:30 and 9:30 in morning Vietnamese time) and was load related.

504 Gateway Resolutions

Steps taken to resolve the issue included:

- Increasing the database pool size
- Tuning the job runner worker count to 5
- Tuning web server thread count to 5
- Optimization of database performance including expansion of tuning of database indexes

Although these changes were impactful they did not completely cure the problem. For long term solution see section 0 ‘10.11 Planning for scale’.

10 Conclusions and recommendations

10.1 Real-time connectivity for case based systems

The use of connectivity to report case based data and test results requires data to be sent in as near real-time as possible. This differs from systems that are sample based in that data specific to inventory, site or operator errors is not impacted by a short delay. When using data for patient

management any small delays in the transmission of data could disrupt the workflow and skew any performance metrics being monitored. When using connectivity in case based systems it is important to have the technical capabilities and resources to monitor and rectify any connectivity issues that may arise.

10.2 Change management

Change management refers to any approach to transitioning individuals, teams, and organizations using methods intended to re-direct the use of resources, business process, budget allocations, or other modes of operation that significantly reshape a company or organization. When deploying any new technologies change management should be given consideration at the initial implementation phase and also after any analysis of data has been performed. In the case of a fully digital system the change between the legacy paper based processes and a new computer based process can be vast and will take some time for full adoption and support. Resources that have been used to a particular process for many years may provide some resistance but change ultimately needs to be led using a top down approach. Change management should also be considered following the review of data collected using new digital systems to determine if existing process are still applicable.

10.3 Data utilization

Programmatic information collected through new diagnostic technologies in real-time in low-resource settings provides an unprecedented opportunity to improve health systems and disease control. Adequate use of this information will allow proper monitoring and generation of new knowledge areas where major systems improvements are possible such as operational implementation, quality assurance for laboratories, medical management of patients, and epidemiological surveillance.

Where data is collected electronically, the vast amounts sometimes make it difficult to interpret meaning or determine necessary action requirements. Data flows are rarely linear and the abundance of data that can be made available makes it a daunting task to disseminate and use it correctly and efficiently. Data may be collected but unless utilized properly the efforts to collect are merely exercises in administration.

It is recommended that a dedicated resource is available following the implementation of any connected diagnostics project to analyse and interpret meaning to data collected as well as implement changes in process as data dictates.

10.4 Project planning

It is essential that planning for a project be conducted before any work commences and that the plan should define the ‘requirements’ in a way that can be monitored for successful delivery. Regardless of the methodologies used throughout the project, badly defined requirements will cause delays, confusion and could even cause project failure entirely. Whilst specific development activities can use an Agile approach, the strategic level plans along with expected outputs and success criteria should be known as much as possible.

It is also recommended that any project is delivered in manageable phases, whilst it be might be desirable and beneficial to overhaul everything at once this approach is not recommended for entities without considerable experience of managing large and complex IT projects. Each phase should ideally be closed, evaluated for success and lessons learnt before moving on the next phase.

Connectivity Project Framework and Connectivity Elements

The study project used the emerging FIND Connectivity project framework to assure a complete E2E project and service definition. FIND's framework draws on the best practice called out by the following standards:

Methodology	Description
Prince II	Project management methodology originally sponsored by the UK government - https://www.prince2.com/
TMForum's Frameworx	Process application and data management framework developed for the telecoms industry - https://www.tmforum.org/
BPM (Business Process Management)	Best practice method and notation for describing and managing business processes - https://en.wikipedia.org/wiki/Business_process_modeling
TOGAF ™	Methodology for analysing, designing and implementing business architectures - https://www.opengroup.org/togaf/

Table 15: Management methodologies

Although the requirements (and therefore solution) for any connectivity service tend to be unique to each individual implementation, the project framework, the essential elements, connectivity elements and required capabilities are the same. The following graphic has been created to highlight the different areas that each project should consider and plan for.

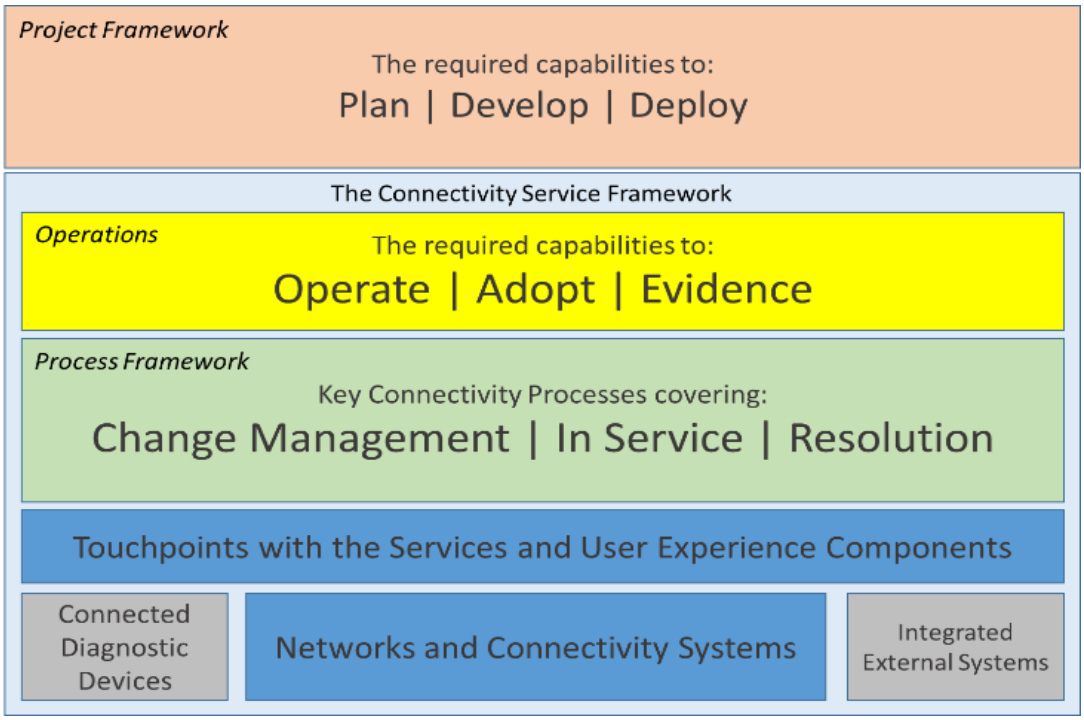


Fig 32: Level 1: Project Framework and Connectivity Service Elements

See Appendix 13 – FIND's Approach to Connectivity

10.5 Resource capabilities

As technology continues to expand its presence inside the world of healthcare and diagnostics, the need for resources to setup and maintain these also expands. Whilst we have conducted a study

into a technical platform there was also a considerable amount of resource allocated to planning, budgeting and program management. The correct resourcing for a project of this nature is essential to success. The burden of such projects should be taken by experienced but also time dedicated resources rather than those who share their commitments with other activities.

Having technical resource in country is mandatory for complex technical service issues. The ability to respond in the same time zone and speak local languages and dialects provides a more sustainable project.

10.6 User training

Whilst in the study we reported the ease of use of CDP and observed some members of the team training others on how to perform their role to cover absence etc. it is recommended that all users undergo a specific training course suited to their function and that this this training is repeated on a regular basis certainly in the adoption phase and after any change of functionality or process. The study itself did not present any problems associated to a lack of computer literacy in its user group but this should not be considered normal at large scale, especially in more rural areas of a country. The project plan for wide scale rollout of such technologies should incorporate a significant focus on the training of users to operate computers.

10.7 User communication

Not all end users had email addresses provided to them by the hospital. Communications channels varied between official email, personal email, letter, paper or face to face. Time and provisions need to be made to account for this. Ideally Ministries of health should ensure that staff have email addresses via which they can be contacted. Additionally, the option to include on screen communications and messaging on CDP could be taken.

10.8 Project budgeting

It is essential that connectivity projects be budgeted correctly, not just in terms of the sums available but also for all of the necessary activities. Many project budgets focus on the initial setup and neglect the ongoing operational support that is needed. In addition many budgets focus on tangible assets such as computers or other hardware and more often than not neglect other essential elements such as dedicated project management resource and activities relating to change management or monitoring/evaluation activities.

10.9 Software development

Whilst the core version of CDP was ready for deployment, we have demonstrated in this project that development will always be required for any software system for customization and localization. Software development within this project was aided by having local Vietnamese developers who could also provide language validation and grammatical context. When planning any project involving software it is highly advised that software development resources or provisions for them are available not just during the setup and customization phases but also throughout the entire operational periods of the solution. New requirements and enhancements will always be raised, software bugs will, despite best efforts, be found and process and metrics will inevitably arise such as a change in reporting process or additional fields in dropdown menus. Without software development resource available the risk of such software becoming out of date and unusable becomes much higher.

10.10 Agile

The agile process proved to be perfectly suited to delivering component developments, customizations, and maintenance tasks, throughout the lifespan of the project. An understanding of Agile allowed both contractors and the Viet Nam engineering resources to quickly and easily contribute to the development effort.

10.11 Planning for scale

The production implementation of any software service should include suitable E2E performance load testing and capacity planning - CDP is no exception. An appropriate 'staging environment' (that mirrors as closely as possible the production environment) should be established for this purpose.

Hardware and network capacity should be tested against volume predictions which cover, normal and peak usage, including the number of concurrent users. Representative test data and methods of driving transactions through the system, must be established. This requires not only appropriate resources and project activities to be deployed, but also requires consensus over service levels, in terms of volumes, performance and availability in order to match expectations to infrastructure and hosting costs.

10.12 Achieving scalability

Specifically for CDP the current MVP product must be enhanced to support a high availability, high performance configuration. Such a configuration should to look to implement the following:

- Front End Load Balancing
- Multiple application servers, including dynamic scaling to cope with variations in load
- Separate Database servers (possibly in master slave configuration)
- Database optimisation
- SQL query and database access optimization
- Capacity planning and modelling including optimization of system parameters such as Database pool sizes, job runner workers and web server threads, etc.
- Continues development of service components to allow separation of business logic on to separate processing units

The use of multiple instances of web application and database servers provides the additional benefit of improved redundancy and high availability operations. The recommendation is that an architectural design of a high availability, high performance implementation of CDP be developed and validated ahead of any production implementation.

10.13 Mobile networks

As the screening and diagnostic testing sites may not have regular fixed line internet connectivity available it is important be able to manage and support other means such as cellular connectivity. When looking to implement cellular connectivity it is important to capture service and coverage information from the individual sites. The service and coverage information should be gathered across all available mobile operators and used to ensure the overall service and coverage is known and the best performing cellular network can be utilized. It may even be the case that each site could use a different mobile operator, in order to provide the best performing internet connectivity solution. If these factors are not considered, the connectivity could be unreliable, suffer from poor performance and lead to incomplete workflows and distorted data.

10.14 SIM cards

Issues with mobile connectivity and associated data loss are substantially more likely when using in-country SIMs due to their limitations and the ability to only operate on a single network. The suggested method for connecting devices in the future would be to use Global Roaming SIMs. Global Roaming SIMs are unfortunately more expensive, harder to acquire and have more complex setup requirements but the benefits provided far outweigh the costs and setup, the main benefits being the availability for the SIM to use more than one in-country mobile network, additional security and control and not having to constantly credit the SIMs with data allowances.

10.15 APIs for integration

We demonstrated that a screen scraping approach was feasible for the study duration but this approach is not recommended for integration between systems for reasons of sustainability and computer resource utilization. As screen scraping effectively mimics the actions of a user to post data from one system to another: any slight change in the receiving system, e.g. an addition to a drop down menu, will break the integration. This approach is also far more intensive on the processing power on the machines as it does need to process the mimicked user activity rather than simply accepting the results directly into its own database. For any future integrations a full API for each system would need to be developed to ensure the correct and sustainable transfer of data from one system to another. As many systems are likely to be used however it is recommended that the vendor of each system is contacted and asked to provide an API to their respective systems. Another way to make this easier is to upgrade to the latest versions of any software platform being used, for example the v2.3 of e-TB Manager used in the study did not have an API available but the latest v3.0 does. If the vendor does not have or plan to develop an API to specific systems then it is recommended that the source code of these systems are acquired so that development of the APIs is possible directly.

10.16 Computer infrastructure

One of the most complex issues to accommodate during the study was the use of the Windows XP operating system on the GeneXpert computers. For various reasons of functionality and security considerations as previously mentioned it is highly advisable that all computers for GeneXpert machines be upgraded to at least Windows 7. This upgrade may require some newer computer hardware at certain sites to accommodate the higher needs of this newer and more powerful operating system.

10.17 Electricity supply stability

Although the electricity supply was stable in the study sites during the study period, consideration should be given when considering scaled deployments to those sites where power can be intermittent. Backup power supplies and surge protection is always recommended in sites where power fluctuations are commonplace but from a monitoring perspective consideration should be given to those sites where reporting may be disrupted due to power issues e.g. reports indicating last known transmission time could be extended to accommodate transmission failures.

10.18 Monitoring & Evaluation

It is recommended that the entire end to end service be subject to a continuous monitoring and evaluation exercise to determine if everything is working as expected and that positive impact is being seen. The suggested categories for a connected diagnostics M&E program are:

Coverage	Increased coverage of connected diagnostics to all sites and tests
	Connectivity for all connectable devices i.e. GeneXpert, PIMA
	Digitization of Examination Requests and Test Result Report forms for other platforms
	Expansion of connectivity / digitization of all sites and facilities regardless of tests performed
	Access to relevant and actionable information for all stakeholders
Quality	Data from connected diagnostics (device and clinical) are timely, reliable and consistent
	Data from all devices is available to use within actionable time periods
	Data from devices can be relied upon and contains relevant information for action for stakeholders
	Data is consistent and does not have discrepancies
	Data is relevant for stakeholders
Impact	Data from connected diagnostics is linked and used for improved patient care and programmatic improvement
	Data is patient centric and can be used for care
	Data is used for performance indicators
	Data is analyzed, utilized and action is taken
	Data is shared where applicable for global surveillance and disease control
Sustain	Connectivity solutions are operational and services and sustainable
	Comprehensive planning is conducted
	Sufficient staff including local capacity available in all critical skill areas for programme implementation and continued operation
	Adequate planning and budgeting conducted
	Secured funding for implementation and operation

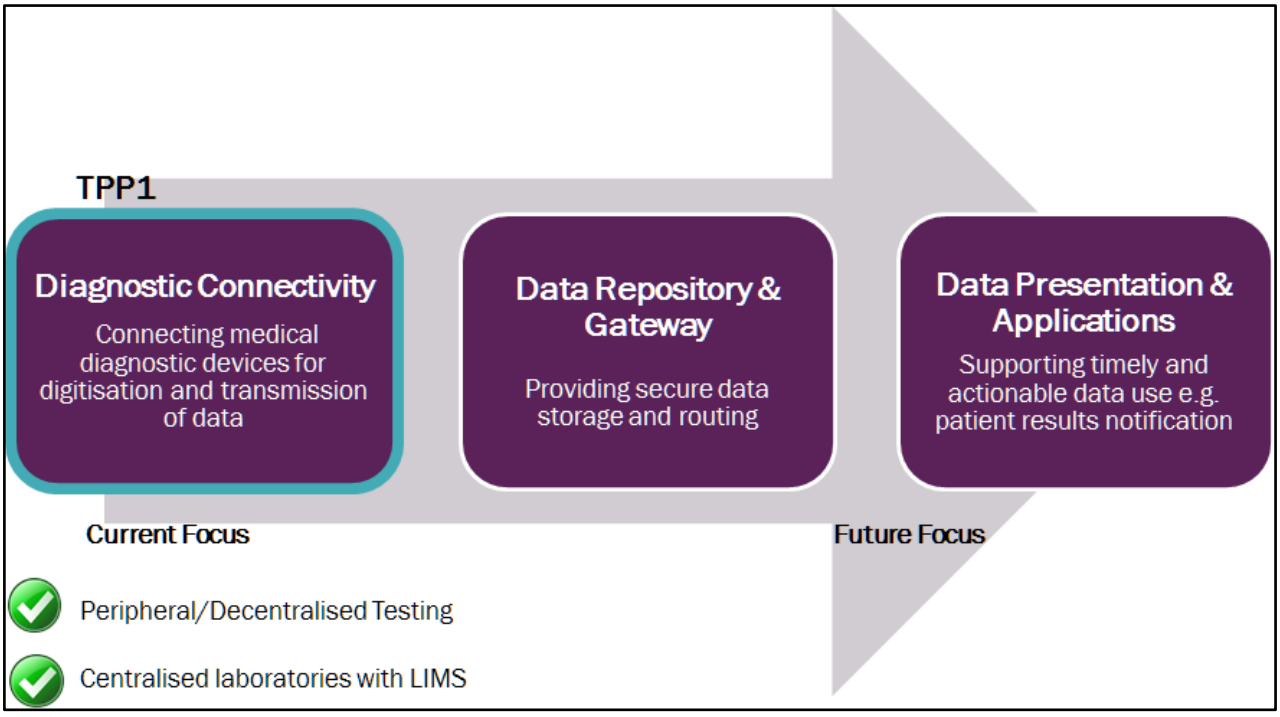
11 Project Budget

Activity/Resource	Budget $USD
FIND Staff	$128,000
Software development & Support	$141,875
Connectivity Hardware & Data	$1,750
NTP Costs	$48,125
Travel	$18,000
Total	**$337,750**

12 Inputs to Target Product Profiles (TPPs)

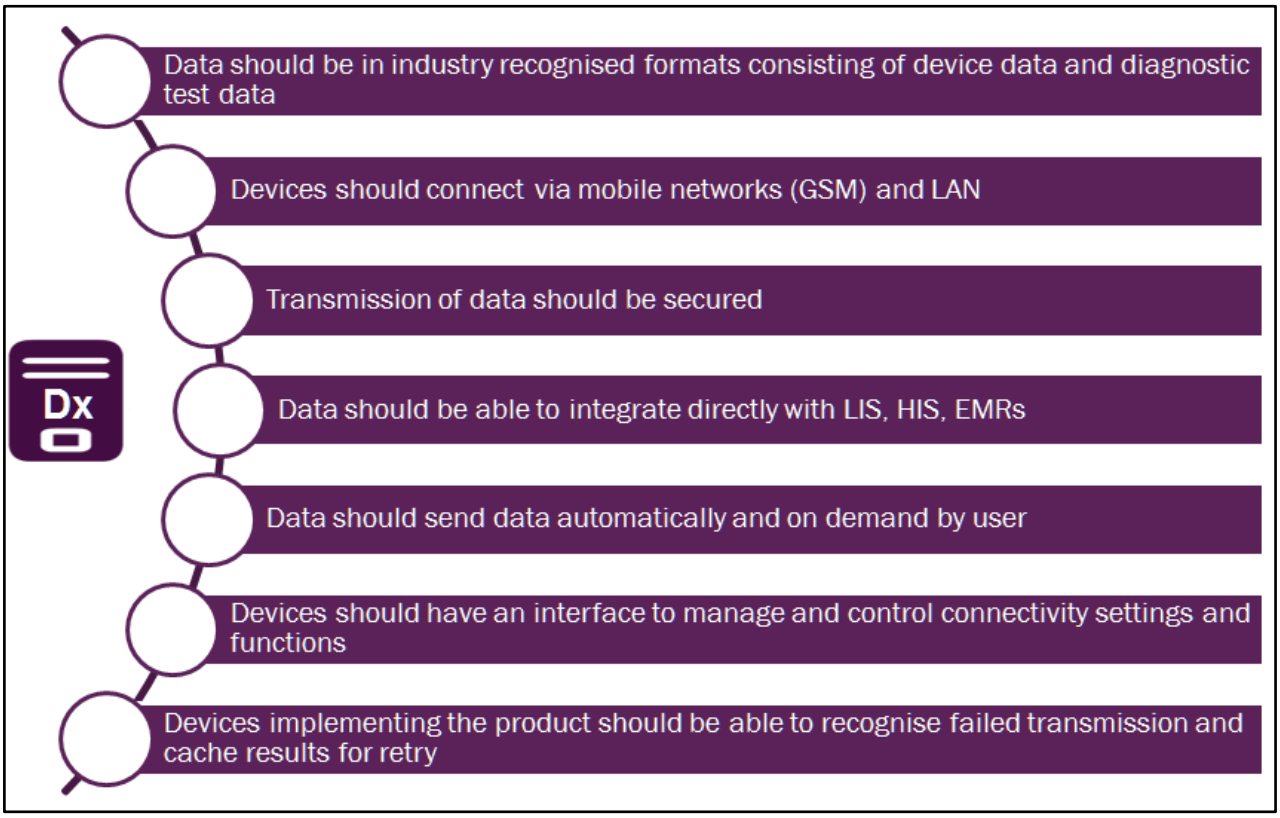
On February 25–26, 2015, the World Health Organization (WHO) and the European Respiratory Society (ERS) held a joint technical consultation on the role of digital health for TB and tobacco control in Geneva, Switzerland. Ahead of this consultation, in early 2015, WHO surveyed public views on the priority products to be focused upon during the discussions using an online questionnaire. The consultation was attended by close to 100 participants and was organised into tracks of work devoted to each of the four functions identified by the WHO conceptual framework for digital health in the TB response, namely patient care, surveillance and monitoring, programme management, and electronic learning. The programme management function was devoted to the strengthening of laboratory information systems, a critical priority for the TB manager. Each of the tracks focused on one or more digital health products selected by its members.

The characteristics of the digital health products were described using TPPs. TPPs define the features of the desired solutions in sufficient detail and transparency to stimulate more interest from potential developers. The digital health TPPs are expected to serve users at both national and global levels; they will guide developers to come up with solutions tailored to the problems faced by national TB programmes, and to steward the implementation of these new concepts, and ensure a more systematic method of collection and reporting of evidence. The choice of products and associated activities were premised upon the pressing needs and realities of TB programmes, upon existing evidence and knowledge about the effectiveness of certain digital health interventions, and the rapid advances in technologies of which potential users may be unaware.



The above graphic represents the 3 main components of a connectivity solution. The initial TPP covers only the diagnostic device. The TPP for diagnostic connectivity was published by the ERS in May 2016. The journal entry and the TPP itself can be found at: http://erj.ersjournals.com/content/erj/suppl/2016/05/26/13993003.00424-2016.DC1/ERJ-00424-2016_supplement.pdf

A selection of requirements of the diagnostic connectivity TPP are:



During this study FIND aimed to gather further information to inform any evolution of the diagnostic connectivity TPP but also to gather data to start the creation of the two remaining TPPs. The following will be put forward to the TPP working groups as optional criteria.

1. That the data presentation and applications TPP include the following:
    a. The ability to capture and manage data from all TB tests such as microscopy and not just digital platforms such as GeneXpert
    b. That all test results should be linked to patients and case records
    c. Where case management is possible - The ability to select a result for record in the scenario where multiple tests were completed with different results
    d. The ability to edit results once in the system
2. That software such as CDP Bridge that is used to extract data from diagnostic devices to send to repositories, gateways or applications be included in the diagnostic connectivity TPP and have their own subset of requirements.

13 Closing remarks and next steps

To progress from project conception, planning, development, deployment, operation and close in 7 months has been a tremendous challenge but one that proved beneficial to understand the requirements and constraints of future deployments. Whilst we conclude that the CDP performed well during the study and that a fully digital diagnostic testing solution is feasible in Viet Nam, we have seen throughout this report that a vast amount of planning and coordination is required for the project definition and development phases, that technical and operational readiness is essential but most importantly that an end to end approach must be taken throughout the entire lifecycle of the service.

Information Systems are of paramount importance to diagnostic programmes and good laboratory

practice. Such systems offer critical benefits, such as the facilitation of reporting on indicators of public health importance and on laboratory activity, as well as the integration of laboratory data with patient electronic health records. However, projects aiming to enhance information systems in low resource settings have rarely advanced beyond the pilot or demonstration stages. This is largely due to the fact that there are weaknesses along the requirements chain which are necessary for proper evaluation, implementation and functioning at large scale (within a country or a laboratory network).

Implementing and embedding new technologies of any kind involves complex processes of change at many levels. Successful implementation of change requires commitment, a roadmap, and proactive champions.

Where data are collected electronically, the vast amounts sometimes make it difficult to interpret their meaning or determine necessary action requirements. Data flows are rarely linear and the abundance of data potentially available makes it a daunting task to disseminate it correctly. It is clear that with so many fragmented data sets, a harmonized approach to data collection, storage, access and informatics is needed but these tools and technologies must be integrated into holistic, tailored eHealth solutions.

Guidance and policies are also needed for connected diagnostic solutions to truly achieve their anticipated impact. Evidence from large scale implementations are needed to catalyse adoption, standardization and impact at a global level.

At the time of report writing FIND are working with the Viet Nam NTP to plan a nationwide integrated diagnostics solution that utilizes connectivity.

14 Appendices

The following information is available in the appendices attached to this document:

Appendix	Title
Appendix 1	The Shadow Process Steps
Appendix 2	The State Transition Model
Appendix 3	Technology Components
Appendix 4	Modem Selection
Appendix 5	Project Roles and Ceremonies
Appendix 6	Collaboration Tools
Appendix 7	QA Testing Activities
Appendix 8	Maintenance Releases
Appendix 9	Support Component and Owners
Appendix 10	Incident Report and Resolutions
Appendix 11	Connectivity Challenges and Lessons Learnt
Appendix 12	Virus Detection
Appendix 13	The Connectivity Elements

Appendix 1: The Shadow Process Steps

The table below calls out the high-level steps within the scope of the study. A more detailed view of the workflow is provided in the swim-lane diagram that follows.

Department	As-Is Process Steps	Shadow Process Steps
Patient receptionist	Patient Registered by receptionist	Add Patient to CDP
Clinician	Patient Diagnosed by Clinician	Add Episode to patient Create test order and add tests
Finance Office	Process patient payment for tests	Flag Order as financially approved
Clinician (Nurse)	Collect sample and transfer to lab reception	Add SampleID and flag tests as Sample Collected
Lab Receptionist	Receive samples and direct to labs	*Set order to sample received. Print barcode and add to GeneXpert order form.
Lab Tech	Run Microscopy test	Add test result to CDP
Lab Tech	Run GeneXpert test	Scan SampleID into GeneXpert notes field before running tests
*Lab Supervisor	Review form and approve results	Review results in CDP and approve

Table (A1.1) - Shadow Process, Roles and Process Steps

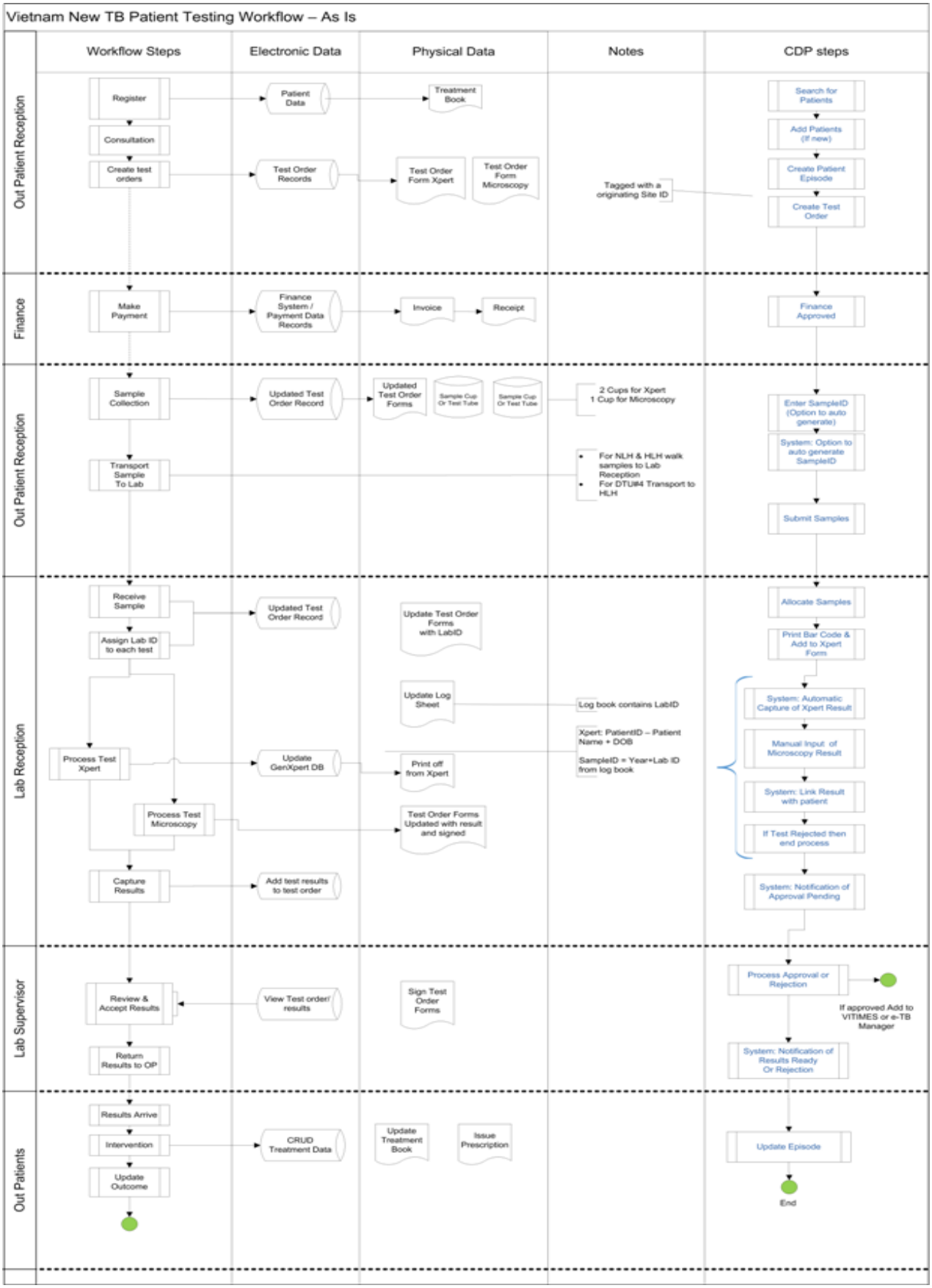


Fig (6) - Shadow Process Swim-lane

Appendix 2: State Transition Model

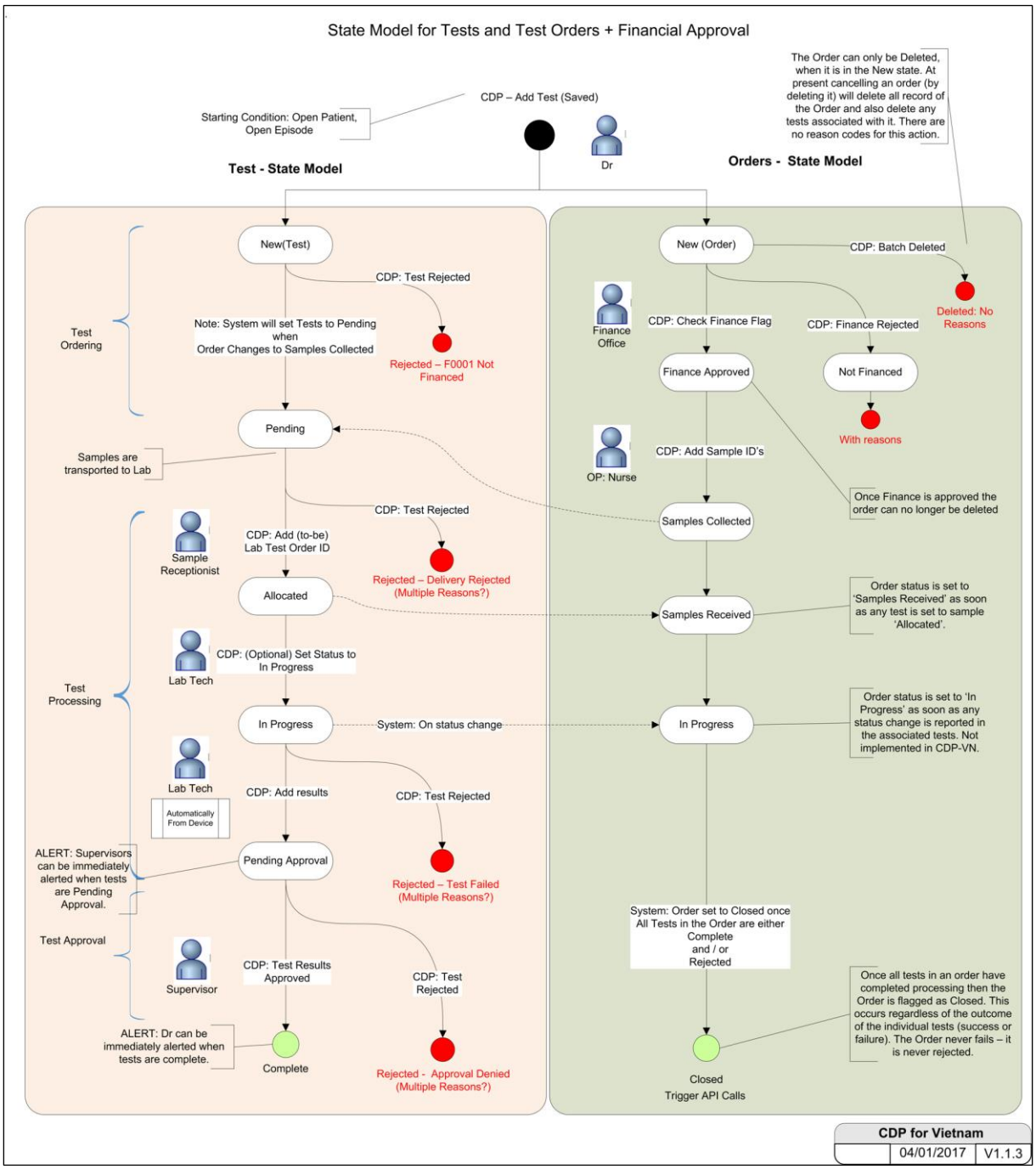


Fig (A2.1) - CDP State transition model for Orders and Tests

Appendix 3: Technology Components

The platform implemented in Viet Nam was developed using the following technologies:

- Ruby On Rails - a web application framework written in under the MIT License provides default structures for a database, a web service, and web pages. It encourages and facilitates the use of web standards such as JSON or XML for data transfer, and HTML, CSS and JavaScript for display and user interfacing. As of January 2016, it is estimated that more than 1.2 million websites are running Ruby on Rails. Some of the largest sites include Airbnb, GitHub and Yammer.
- MySQL - is an open-source relational database management system (RDBMS). In July 2013, it was the world's second most widely used RDBMS, and the most widely used open-source client–server model RDBMS. MySQL is used in many high-profile, large-scale websites, including Google, Facebook, Twitter and YouTube.
- HTML5 - is a markup language used for structuring and presenting content on the web. It is the fifth and current version of the HTML standard. HTML5 includes detailed processing models to encourage more interoperable implementations and includes features designed for low-powered devices such as smartphones and tablets.
- ReactJS - is an open-source JavaScript library providing a view for data rendered as HTML. React views are typically rendered using components that contain additional components specified as custom HTML tags. React offers a model in which subcomponents cannot directly affect enclosing components; efficient updating of the HTML document when data changes; and a clean separation between components on a modern single-page application. ReactJS is maintained by Facebook, Instagram and a community of individual developers and corporations and is currently being used on homepages such as Netflix and Airbnb.

CDP Server - Component Versions and Licenses

Component	Version	Licence
Docker	1.12.2	Apache 2.0
Ruby	2.3.1	BDSL copyrighted free software
Rails	4.2.7.1	MIT
Nginx	1.6.2	http://nginx.org/licence
MySQL	5.7	GPL
Redis	3.04	BSD
ReactJS	1.3.2	BSD

Table (A3.1) – CDP Component List

Appendix 4: Modem Selection

Cellular Modem Product Selection

A number of options to provide cellular connectivity to GeneXpert computers are available. These include:

- Mobile USB Dongles
- Wi-Fi Units
- Cellular Routers
- Mobile Phone Hotspot
- Integrated M2M Modems

The selection of one of these types was driven by the following product capabilities:

- 2G/3G band support
- SIM card specification
- LAN & Wi-Fi Capability
- Security features (Firewall, DMZ, Port Forwarding, MAC Filtering...etc)
- Mains power or battery powered
- Effort of installation

Driven by the features supported within each product's capabilities and the lack of IT support in the NTP Viet Nam study sites to enable fixed line network based connectivity, the Huawei B593s-22 cellular router was selected.

The security features of the selected Huawei router, support a fully configurable firewall and an advanced security options menu, enabling the restriction of websites accessible to reduce intrusion attempts or vulnerability of harmful viruses.

Mobile Operators

Multiple mobile network operators are available in Hanoi, Viet Nam. The networks were shortlisted according to cost, availability, performance and network coverage. These aspects can vary significantly from one operator to another, the key factors to consider during the initial operator selection were network signal strength, performance and availability.

Using recommendations from local SIM resellers in Viet Nam, bolstered by online research and evidence available from OpenSignal.com, used for signal comparison and performance benchmarking, we were able to select the prospective networks to shortlist for the site surveys.

The shortlisted networks were MobiFone and Viettel, both are known for their good performance in towns and city areas, while Vinaphone, which was not shortlisted, is recommended when considering deploying connectivity in mountainous or remote areas, however these types of geographies were not seen in the sites selected for the NTP study and so, the Vinaphone network was discounted from the list of potential mobile operators.

The figure below demonstrates 2G/3G network coverage and performance within Hanoi, Viet Nam.

The MobiFone and Viettel SIMs performance was statistically better in a majority of cases, when being compared to Vinaphone, when measuring either signal strength or data rates.

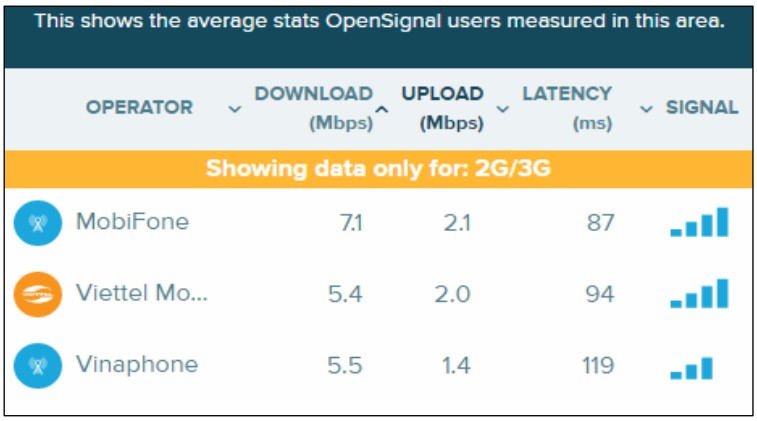


Fig (A4.1) - OpenSignal connection speeds

Mobile Operator Site Survey

The Mobile Operator Site survey aims to understand and assess the best quality mobile data service available in each NTP study location. The site surveys are conducted at the three NTP study locations, aiming to assess the signal strength, reliability & data performance of each of the mobile network providers.

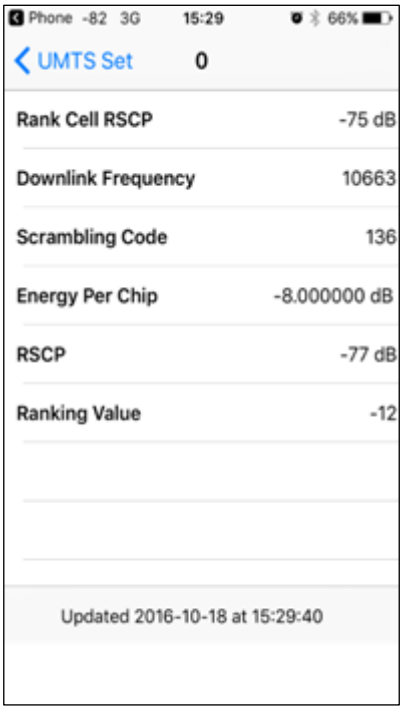
Signal Strength

Signal strength or "better coverage" does not always relate to better mobile data speeds, however it is usually the case, there are however, exceptions to the rule. When a mobile operator's network is congested, a subscriber may see low data rates and high latency in an area of good coverage (full signal), while another user on a different mobile operator may experience poorer coverage (weaker signal), but observe higher data rates when comparing to the user in good coverage conditions while in the exact same location.

Signal Measurement Collection

During the site survey we used an iPhone 6S to provide the signal information which was compared across all operators. The application used was "Field Test menu" a hidden Apple menu which is accessible by typing in *3001#12345#*and calling the number. The "Rank Cell RSCP" is recorded and stored into the survey results sheet.

Fig8c - iPhone Field Test Menu being used for signal strength testing



Mobile Data Performance

Mobile data performance is a key performance indicator we aimed to capture during the Mobile Cellular Site Surveys. A key indicator of a healthy internet connection is “low latency” and is commonly a key attribute in a reliable connectivity solution.

Low latency enables a connection to be faster in performing one single round trip time (RTT) from client to server and back to client. Accordingly, the faster the platform system can communicate data packets, errors and retransmissions back to the originator, the faster the network can send data overall.

While data networks are seen to be slow and the latency is high, more errors and connectivity issues will normally be observed. Multiple factors must be analysed before making an informed decision on which is the best network for a particular site. It is important to try and identify network congestion in the sense of an “at capacity” mobile network, which could impact CDP Bridge to cause the system to experience upload/sync issues or retries.

It is undesirable to select a heavily congested, high latency network, based solely on the cellular signal strength measured at the site. An efficient and well selected mobile operator can help to reduce the chance of data transmission problems and reduce overall round trip time, especially in notorious low/poor signal settings.

Mobile Operator Site Survey - Results

When the site surveys were conducted at the National Lung Hospital in Hanoi, a Viettel SIM exhibited slightly stronger signal strength than the Mobifone SIM, however the data transmission speeds on the Viettel network were observed to be approximately half the performance seen on Mobifone, proving that highest signal level is certainly not a good indication of data transmission speed or reliability.

Location	Speedtest.net Test Number	SIM Operator Tested	Signal Measure (dBm)	Time of Test	Downlink Speed	Uplink Speed	Ping (ms)	Server (auto)	Best Carrier
National Lung Hospital	1	Viettell	-72 RSCP	13/10/2016 14:00	9.14	1.09	70	Viettel IDC	
National Lung Hospital	2	Viettell	-72 RSCP	13/10/2016 14:01	7.74	3.08	29	Viettel IDC	
National Lung Hospital	3	Mobifone	-77 RSCP	13/10/2016 15:53	19.87	4.57	29	cmc telecom	**Mobifone**
National Lung Hospital	4	Mobifone	-77 RSCP	13/10/2016 15:55	20.3	4.59	29	cmc telecom	**Mobifone**
Ha Noi Lung Hospital	1	Viettell	-75 RSCP	18/10/2016 09:31	8.17	0.56	66	FPT Telecom	
Ha Noi Lung Hospital	2	Viettell	-75 RSCP	18/10/2016 09:34	6.24	0.49	70	FPT Telecom	
Ha Noi Lung Hospital	3	Mobifone	-79 RSCP	18/10/2016 09:39	11.04	2.56	69	MobiFone	**Mobifone**
Ha Noi Lung Hospital	4	Mobifone	-79 RSCP	18/10/2016 09:40	7.84	1.15	57	MobiFone	**Mobifone**
Hoang Mai District	1	Viettell	-71 RSCP	28/10/2016 11:01	23.18	3.54	26	Viettel IDC	**Viettell**
Hoang Mai District	2	Viettell	-71 RSCP	28/10/2016 11:02	19.3	3.39	23	Viettel IDC	**Viettell**
Hoang Mai District	3	Mobifone	-95 RSCP	28/10/2016 11:09	8.95	2.39	70	Viettel IDC	
Hoang Mai District	4	Mobifone	-95 RSCP	28/10/2016 11:11	8.23	2.03	69	Viettel IDC	

(A4.2) - Site survey results from the NTP CDP Study

The chosen networks for each test site, in accordance with the mobile operator site surveys were;

- National Lung Hospital – Mobifone
- Hanoi Lung Hospital – Mobifone
- Hoang Mai District – Viettel*

*Hoang Mai District

The initial SIM installed at the Hoang Mai District Hospital was Mobifone, which was against the site network surveys recommendation to use a Viettel operator SIM card. The local FIND staff did not have a Viettel SIM card available to install at the time the survey and installation was conducted, instead, a MobiFone SIM was installed. Upon the next visit to the Hoang Mai District study site it would be changed to Viettel SIM as per the initial recommendation.

Appendix 5: Project Roles and Ceremonies

This appendix lists the individual project roles involved in the study and the 'ceremonies' used to organise and communicate.

Project Roles

The table below lists out key project roles and their accountabilities.

Role	Comment
Service Development Project and QA	
Product Owner	Agile: Accountable for the product vision and direction as well as defining requirements, working with a roadmap (backlog) of features to champion the customer whilst prioritising the work
Project Manager	Individual accountable for delivery of project benefits, deployment of resources, reporting progress and controlling tasks and costs
Scrum Manager	Agile role: involves hosting daily meetings, ensuring team is working at it best & facilitating the agile software development process
Business Analyst	Capture requirements, analysis systems and specify solutions
Clinical Subject matter experts	Stakeholders with specific clinical expertise
E2E Process owner	Operational role responsible for support deliver and adoption of E2E processes
Quality Assurance Lead	Construction of test strategies and plans
Tester	Conducting test, reporting outcomes and raising bugs
Technical Development	
Technical Lead	Oversee coding standards and structure. Manage and direct engineering efforts
Systems Architect	Design and implementation of systems components and integration
Connectivity Lead	Accountable for data transmission and network solution design, solution delivery and operations
Software Engineer	Development of code
Network Engineer	Development installation troubleshooting and supporting connectivity
UI/UX Designer	User interface design, look and feel including navigation and usability
Infrastructure Operations and Support	
Operations Manager	Accountable for maintenance, continuity and support of systems and networks
Infrastructure Engineer	Infrastructure (Hosting servers, etc.) build, configuration, troubleshooting and support
Trainer	Development of training materials and deliver of training
Field Service Support	Onsite support and troubleshoot for process and technology
Support 1st Line 2nd Line 3rd Line	See section **Error! Reference source not found.** '**Error! Reference urce not found.**' for details of the support roles and the approach to incident escalation

Table (A5.1) - Project Roles

Project Ceremonies

To effectively manage the project the following ceremonies (meetings and assessments, etc.) were held.

Meeting	Frequency	Description
Project Team	Weekly	Held with FIND project stakeholders to review progress and provide steers
Sprint Planning	Fortnightly	Held at the start of each sprint cycle to review objectives and plan
Daily Stand-ups	Daily	Agile: To review individual's workloads for the day and any blockers. Target is 15 minute duration
Ops meetings	Daily	Review activity and support issues from the day and plan service improvement actions
Go / No Go	As required	Part of deployment these meetings ensured E2E readiness prior to decisions to start the study
War Room	As required	Term used to describe an, all hands, highest priority task, normally resolution of a show stopping issue. Can involve setting aside a room specifically for management of such an event.
De-Briefings	Following Site Visits	The NTP and FIND conducted debriefings at the end of each site visit by the core team members, to Hoi
Retrospective	One off	Agile: A retrospective was held at the end of the delivery phase with the core engineering team, in order to consider what went well, what had issues and what we would change in the future.

Table (A5.2) - Project Ceremonies

Appendix 6 – Collaboration Tools

Collaboration Tools

A number of collaborations were employed to promote communications and knowledge sharing.

Tool	Purpose	Comment
Communications		
Skype	Internet based VOIP and IM service	Invaluable tool in continuous use between all members of the team across all aspects of the delivery. Especially used for international communications.
Slack	Open source IM and communications app	User by the extended engineering team to discuss technical issues and coordinate development activities
Email	Internet based message exchange	Continuous use to exchange documents, information and raise questions
Mobile	Mobile voice and SMS communications	Continuous use, mostly for local communications.
Conference Bridge	Multi user telephony service	Rare use – mostly for senior management communications
Document Storage		
Dropbox	Internet based file sharing	Restricted access libraries used to store all project documentation
Seafile	Open source secure file sharing application	Configured and self-hosted, to provide secure file sharing of sensitive data.
Task Management and Content creation		
Redmine	Internet based task management tool	Optimised for software engineering and used to manage engineering teams work within the Agile development methodology.
Microsoft Office	Excel, Word, Visio, PowerPoint	Extensively used to create project documentation charts and reports
Balsamic	UI design tool	Used to specify and document UI developments especially during customisation of workflow
Digital Video	Mobile phone capture of digital video	Used to record software incidences, especially during development and debugging of CDP bridge provisioning
Google Doc's	Web based document creation storage and sharing tool	Occasional use for document collaboration and online questionnaire
Technical Collaboration Tools		
TeamViewer	Client software for remote control of PC's and computing devices	Extensively used in the connectivity work stream to remotely access GeneXpert computers to validate operations, resolve issues and inspect operations
Github	Open source version control and code repository.	Used to manage collaboration across all individual developers by: - Storing code - Managing versioning - Reducing the risk of merge conflicts

Table (A6.1) - Collaboration Tools

Appendix 7 : QA Testing Activities

CDP Application Testing Activities

Unit Testing	Each CDP software function is written along with a test that is executed at build time. Additionally developers test units of code before submitting them for release as part of a so called 'Release Candidate'
Smoke Testing	A smoke test consists of a limited set of key systems functions that exercise functionality within each major component of the system. When a new release candidate of CDP was built the QA function ran a smoke test to ensure that the build process had worked, that the testing environment was valid and that the release candidate was suitable for further testing
Release Testing	For each release candidate any new features were individually tested
Regression Testing	For selected releases a regression test was performed to ensure that previously working functions we still operating normally
Component Testing	Most of the QA work has been focused within this area. When large scale functionality changes were undertaken (for example: Alerts and permissions model) then end to end process tests, exercising both common cases and error or so called unhappy cases were tested.

CDP User Experience Testing Activities

Usability & User Experience Testing	This area was constantly tested during the development and study operational periods for regression and optimisation.
Compatibility	Due to limited time, compatibility testing was limited to the Chrome browser only.
Proof Reading	Several proofreading exercises were conducted in both English and Vietnamese. A final Vietnamese 'clinical language' proofread was conducted to ensure that clinical terms (unfamiliar to our translators) were correctly used.

System Testing

Workflow Testing	Major changes to the CDP platform included the addition of roles along with new states and state transitions, within the workflow. Testing of these roles and the state model, was ongoing throughout the development process.
Data Integrity & Reconciliation Testing	Data integrity was evaluated before the pilot using pre-generated test data, which was transferred through the system using CDP Bridge to transfer it to the CDP front end.
Integration Testing	Linkage of sample IDs between the CDP Bridge, CDP and e-TB Manager has been tested thoroughly in terms of sample ID validity to ensure that data remains consistent.
Performance & Load Testing	Performance and load testing was not formally conducted as there was little expectation on high loads on any part of the system during the pilot.
Vulnerability Testing	Selected vulnerability tests were conducted during the development of the code. Due to the short period of operation of the system and the continuous development effort a dedicated period of Security Testing and Penetration testing was not conducted.

Connectivity Testing

CDP Bridge Install	As a client application the process of install, upgrade, uninstall, re-install was tested against the different Microsoft operating systems encountered in the study.
Site Survey	The connectivity 'conditions' were testing, prior to (CDP Bridge installation) by conducting a site visit and by issuing a questionnaire. The site visit allowed availability of connectivity options (mobile signal, available carriers, LAN access, available ports on the computer etc…) to be inspected. The questionnaire assessed the operational conditions (ownership, support, existing hardware configuration etc..)
Installation Testing	Extensive testing of firewall configurations, compatibility of CDP Bridge with various versions of DX Software encountered, plus tuning of the firewall rules to ensure security, was performed on site as part of installing connectivity.
CDP Bridge Transmission	The ability to successfully transmit data from the study sites to CDP service, was tested through the bulk upload of existing 'historic data' and by having a period of data collection (approx. 2 weeks) ahead of the study period start.

Full E2E Testing and User Acceptance

E2E Testing	The final connectivity service is the sum total of numerous components and processes working together. Full end to end tests included full test order workflow, alerts, e-TB Manager and VITIMES integration and linkage (using fake data) was conducted. This used approximately four individuals in specific user roles, with full support from the engineering teams, and ran for a week.
Fake Data Generation	CDP bridge provides the ability to generate and transmit so called 'Fake Data' as a substitute to relying on availability of DX software and order actual tests. This is invaluable when testing data transmission, linkage and E2E testing.
Live Data Testing	It is essential in any system development (where possible) that tests are conducted using live data. For CDP anonymised GXX data were used to validate operations.
Clinical Review	Once the technical operations of the E2E service were validated a number of clinical reviews were help with subject matter experts both in FIND and the NTP to ensure alignment with clinical process and standards.
User Acceptance	Typically a service would not be launched without an appropriate period of 'User Acceptance' during which the stakeholders and users of the system would (independent of the suppliers) validate that the service both met their requirements and allowed them to perform their duties and processes. On this occasion the study itself represents the user acceptance activity.

Appendix 8: Maintenance Releases

Maintenance releases followed the same software engineering process (established for the develop phase) as follows:

- Fortnightly releases are scheduled
- Each change is captured as a Redmine ticket
- Each ticket is allocated to an engineer
- Completed components are merged into a release candidate,
- Release candidates are QA tested and deployed to production along with release notes

Version	Released	Comment
V1.2.1-RC07/RC08	24/11/2016	Combined sprints released to production
V1.2.2-RC03	01/12/2016	Maintenance
V1.2.2-RC04	08/12/2016	Maintenance
V1.2.3-RC02 (Hotfix)	12/12/2016	Maintenance
V1.2.4-RC01	19/12/2016	Release candidate merged into a single production release
V1.2.5-RC01		

Table (A8.1) - Release Events

Appendix 9: Component Owners

The table below highlights the different components and their Tier 3 support owners. It can be seen that in order to provide complete coverage, all participating systems must be represented in the escalation process.

Area	Components	Tier 3 Owner
Connectivity	Routers, Firewall Rules, Transmission Data Quality	UK Core Team – Will Mayo
Connectivity	SIMs, Data Bundles	VN Team – Huy Bui
Hosting	Hosting Environment, Availability, Security	UK BF Team – Marc Whittingham
CDP Bridge	Configuration and Operation	UK Core Team – Will Mayo
CDP Bridge Client	Software component	UK BF Team – Marc Whittingham
CDP Server	Software Component	UK BF Team – Jack Regnart
CDP Configuration	Configuration of all entities including Alerts	UK Core Team – Mo Tobin
CDP Integration	Configuration	UK Core Team – Mo Tobin
External Systems	e-TB Manager and VITIMES	NTP IT – Nam
Integration	Access to and integration with e-TB Manager and VITIMES	VN Team – Nghi Pham Minh
Shadow Process	Training Logistics and adoption	VN Team – Huy Bui
Study Analytics	Collation and analysis of study data	UK Core Team – Mo Tobin

Table (A9.1) - Component ownership

Appendix 10: Incident Report and Resolutions

Incident Resolutions

Incident 1	Description	The machine was turned off at the end of the working day. However, this was before the last test finished on the GeneXpert device. The transmission was then successfully completed at the beginning of their next working day. On further investigation it appears there was a hardware failure.
	Resolution	Cepheid hardware failure. Cepheid support contacted.
Incident 2	Description	The laptop went to sleep as it had power saving mode enabled. This stopped the CDP Bridge service from running.
	Resolution	Power saving features were disabled.
Incident 3	Description	Hard drive failure in one of the GeneXpert computers
	Resolution	Hard drive was swapped to the other machine as a secondary drive
Incident 4	Description	SIM card ran out of data
	Resolution	Investigate why the SIM is running out of data so quickly, also why the usage numbers did not match the amount on the SIM. Moved to Viettel as it was more reliable in this area. Purchased more data.
Incident 5	Description	GeneXpert computer switched off, transmissions didn't automatically start due to 'invalid internet connection'.
	Resolution	Service restarted by itself, no manual intervention.
Incident 6	Description	Unrecorded
	Resolution	This was not recorded by the Shadow Team during period of self-support.
Incident 7	Description	Unexplainable loss of results transmission despite connectivity being available
	Resolution	Service restarted
Incident 8	Description	Suspected incidence of GeneXpert computer being switched off
	Resolution	Reinforcement of process to keep computer switched on

Total outage hours	63.90 hours
Identified non-operational hours	34.13 hours
Total outage hours (after removal)	29.88 hours
% after removal	0.9%

Table (A10.1) - Connectivity Resolutions

These outage periods totalled 34.13 hours. After removing periods outside of working hours the total remaining outage hours was 29.88 hours, only 0.9% of the total study.

Appendix 11: Connectivity Challenges and Lessons Learnt

Ticket ID	Observation	Date of Issue	Lesson Learnt
2438	CDP Bridge: Add support for Microsoft XP	10/10/2016	CDP Bridge did not initially support Windows XP. Cepheid Dx Computers within the Viet Nam NTP Study sites supported Windows XP and so CDP Bridge needed adapting to certain coding frameworks. The NTP could not update their workstations OS to Windows 7, thus Windows XP development was pursued as the only means to enable the NTP study. Operating systems such as Windows XP have not had any in-life updates, support or satisfactory security protection for several years. The XP operating system is no longer supported as Microsoft ended support for Windows XP in April 8, 2014. Therefore, no further security updates or technical support is available for the Windows XP operating system. Many security vulnerabilities affect XP and connecting any Windows XP computer system to the internet could be harmful without the necessary security protection, such as an antivirus or firewall application.
2598	CDP Bridge: SSL Handshake Failure During "Device Activation" Attempt in Windows XP	02/11/2016	The Transport Layer Security (TLS) was planned for deployment on CDP prior to the NTP study start. TLS is designed to protect data being exchanged between the client and the CDP server. During the deployment of TLS security as the CDP's application layer security protocol, FIND identified that the Windows XP operating system did not support TLS v1.1 or v1.2, but only supported TLS v1.0. In the current security paradigm, TLS v1.0 is not regarded as a 100% secure protocol, hence why XP is no longer supported by most software development suites, due to the level of vulnerability. CDP was designed to support TLS v1.0 as an afterthought, however this was necessary to be able to support windows XP in the NTP Study. This defect or observation refers to the missing support for some TLS ciphers, which should have been present on the CDP servers' "ssl.conf", which is the configuration file which determines the level of acceptable cypher types which can be used to authenticate. Once the full set of TLSv1 ciphers were configured on the CDP server, device activation was successful.
2606	CDP Bridge: Bridge Service does not run in Windows 10 or Windows 7 even when	07/11/2016	*"There was an issue starting the server. Please make sure you are logged in with the administrator user"*

	run in Admin Mode (v1.0.3.865)		Error was displayed to users on Windows 7 when they attempted to start the CDP Bridge Service. The error was introduced following an update to the CDP Bridge client. At this point in the study, test coverage moved towards a focus on Windows XP and away from the initial test platform, Windows 7. This meant that this defect was not identified until several weeks of CDP Bridge deployments. Subsequently, FIND planned to perform regression testing against multiple operating systems on a concurrent basis.
2627	CDP Bridge: Email Notifications not arriving	10/11/2016	CDP Bridge test report emails that are periodically sent out upon each interval expiry (30 minutes), these email reports were found to failing to be sent out to the predefined email addresses, by the CDP Bridge application. A log collection session was conducted on the local computer system which was installed with a Huawei router, similar to those installed in the NTP study sites. The tool used to identify this issue was Wireshark, a PCAP packet logging tool. The root cause of the issue was identified as being caused by a firewall configuration issue, where the IP address of the Email Server had not been specifically allowed through. Lesson learned in this case is to ensure that all IP addresses, features and functions have been cater for at an IT level.
2639	CDP Bridge should report local system time zone	11/11/2016	CDP Bridge should report local system time zone, however the CDP Bridge application was found to report GMT-5 on-top of the existing time zone, set within the computer system environment. The root cause was found to be the application part of the conversion and transmission leg within CDP Bridge. The application protocol used to push this data to CDP is known as JSON, this area of code was found to set GMT-5. The resolution for this defect was to take the manual addition of the GMT-7 hour time zone within the JSON script, making the time neutral i.e. set it to GMT+0
2652	CDP Bridge: Bridge Attempts to Connect to MSSQL at PC Startup Before MSSQL is Available	17/11/2016	The CDP Bridge Service that runs during windows startup was found to suffer from a frequent race condition, whereby the CDP Bridge Service attempted to start, prior to the Cepheid Dx Softwares' SQL Servers initialisation. Upon encountering this race condition the user would observe the CDP Bridge Service stalled and failed to launch with an exception given in the event logs. If the service was restarted the issue would be resolved until the next restart of the computer system. The CDP Bridge Service was modified so as to have a dependency on the Microsoft SQL Server, so that the SQL

			Server was started before the CDP Bridge Service is allowed to start. The addition of the dependency resolved the issue with the race condition.
2663	CDP Bridge: Results are processed by CDP Bridge before the GeneXpert Test in Dx is completed - Impacts End Date of test	21/11/2016	Upon the identification of a new result in the Dx software, CDP Bridge loads test results into its own SQLite SQL Database. It is this component which takes the plain text gx_assay result data and encrypts each entry prior to transmission. In this observation, CDP bridge was found to transmit test results even when there was no actual "End Date" attributed to the test result entry. Upon GeneXpert test completion, the Dx software's test result would be updated with the actual "End Date", however since the SQLite database which CDP Bridges manages, has a record of this specific test result entry already being transmitted, CDP Bridge does not transmit the updated test result with the associated "End Date", which it believed had already been transmitted. Effectively, when a new test result is address into the Dx softwares database at the start of the test, CDP Bridge takes this result, transmits it and no further action is taken. This situation leads to many results being transmitted to the CDP Server without any associated result or an incomplete test. The lesson learned is to perform regression on new releases of the CDP Bridge and ensure that a test case is created to cover the scenario whereby a test result in the database which does not have any end date.
2681	INCIDENT: Connectivity Issue (Hanoi Lung Hospital and National Lung Hospital)	23/11/2016	The Mobifone SIM cards were found to be blocked in both Hanoi Lung Hospital and National Lung Hospital sites. After speaking with the Mobifone operator, local Viet Nam support staff ensured that the SIM cards were re-enabled and functional. Consumer SIM cards come with the risk that they may not be 100% reliable in the sense that different types of data bundle can exist on pre-pay SIM cards which can sometimes mean existing bundles might need to be activated manually by the user, by a simple text of supplementary service command. In future studies it is worth considering the use of international roaming SIMs, which are more manageable and have more of a seamless and configurable service.
2682	INCIDENT: Connectivity Failure with Hoang Mai Site	23/11/2016	The root cause of the Hoang Mai outage on 23-11-2016 was due to the desktop entering standby after 1 hour. The installation guide for CDP Bridge did not mention to configure the computer's power management settings so that the computer did not enter sleep mode during normal office hours. Action taken was to introduce power management configuration guidance into the installation guides.

2697	INCIDENT: Hanoi Lung Hospital (HLH) Desktop Hardware Failure (RHS Failure)	28/11/2016	The computers within the Hanoi Lung Hospital site are designated as LHS (Left Hand Side) & RHS (Right Hand Side). Back in early November, the RHS Desktop machine that hosted the Dx software was found to have an unsecured Hard Disc Drive (HDD) within the Desktop computer's chassis. This was later resolved by securing the HDD and replacing the connector, this however, indicated the desktop was in disrepair and needed to be monitored during the study as it was likely that another failure could occur. On the 28/11/2016 the RHS desktop computer failed and would not start. The local Viet Nam team were proactive in identifying a solution to overcome the issue. The solution was to move the HDD from RHS desktop and place it into the working LHS desktop computer. The LHS & RHS side GeneXpert diagnostic modules were then connected to one single desktop via an Ethernet hub. What is now the LHS desktop computer which uses the RHS's HDD. The LHS Desktops Dx Softwares previously connected GeneXpert device, required to be activated on the new configuration, so that both GeneXpert units could function on a single desktop computer, transmitting test result data to the CDP system. It was a challenge to identify the changes made to the computer systems during the reconfiguration of the two desktop computers, while observing remotely with support of local IT staff. In the future, it is recommended that more detailed reports are recorded, to enable more efficient tracking Reports of the changes made during operational phases of a study.
2698	INCIDENT: The National Lung Hospital (NLH) Huawei Router Power Supply Failed	28/11/2016	The National Lung Hospital (NLH) experienced a brief connectivity outage. The outage was related to the power supply of the Huawei router, which is installed in NLH. The power supply was damaged by what appeared to be a power surge. The NLH staff responded quickly and replaced the power supply for the router and got the site back online within 2 hours of identifying the outage. In future deployments it is recommended that a power assessment is performed during the environmental survey in order to capture the presence of existence power surge protection, used to protect the connected electronic equipment.
2714	INCIDENT: Connectivity Failure with Hanoi Lung Hospital (HLH) LHS (28-11-2016)	28/11/2016	This item is related to the outage which was referred to above, in support item #2697. During the failure of RHS (Right Hand Side), the LHS (Left Hand Side) computer was taken offline to support the maintenance work which was required to move the Hard Disc Drive (HDD) from RHS into the chassis of LHS. This is an example of how a single hardware failure on one machine, can affect another machine within the same site.

			During future studies it is important to assess the hardware reliability of the desktop or laptop machines which are used to host the Dx Software solution, hoping to reduce the need for such interventions reported in this case.
2753	INCIDENT: Connectivity Failure with Hoang Mai (Router Maintenance)	05/12/2016	The Hoang Mai site which hosted a single GeneXpert computer was identified to be performing very poorly. The site would often miss reporting periods which should occur every 30 minutes. An approach was made to remedy the poor performance at the Hoang Mai site. The plan was to update the router's firmware with newer software and to restart the router, then to confirming the firmware has been flashed successfully. Upon execution of the plan, the router was successfully updated, however, shortly after the router was updated, we found the computer went offline. The connectivity issue in Hoang Mai was resolved on 06/12/2016 3:21:25 PM Viet Nam Time. The cause was that the SIM ran out of mobile data allowance. During the site visit to remedy the issue, a different operator SIM was inserted (MCC:452/MNC:04 - Viettel Mobile) into the router. The cellular site survey indicated to use a different SIM than what was currently deployed at this site, the outcome of the cellular site survey indicated Viettel was better than MobiFone. Mobifone was not recommended due to the poor coverage that it offered in this particular area. The request to change the SIM card operator was pending resolution for some few weeks, but due to resources available and the remote nature of the Hoang Mai site, it was not possible until the occurrence of this incident. The router is now seeing signal conditions of RSCP (dBm): -68 using Viettel, vs the old MobiFone SIM was under conditions of RSCP (dBm):-82. Viettel is 14dBm better than MobiFone with regards to signal power. The lesson learned is that the data allowances need to be monitored at a program level to ensure there is clarity regarding how much data is being used on these SIMs vs how much data is required on the SIM cards, before the SIM runs out.

Table (A11.1) – Incident Log

Appendix 12: Virus Detection

Location & Specification	Virus Identified:
National Lung Hospital - CEPHEIDGR7Z9S1 Intel Core i5-2540M CPU@ 2.60GHz Dell Inc. 0K0DNP A02 GPU Intel HD Graphics 256MB RAM DDR3 1333 2084MB	**Nissan.exe -** a worm and is a type of malware that is designed to propagate and spread across networks. Worms are known to propagate using one or several of different transmission vectors like email, IRC, network shares, instant messengers (IM), and peer-to-peer (P2P) networks. They are commonly spread by USB sticks from and to computers without adequate antivirus protection which would prevent such infection. Worms do not infect files, but may carry one or more payloads, such as computer security compromise and information theft, they typically modify system settings to automatically start and restoring affected systems may require procedures other than scanning with an antivirus program.
	Win32.Flot-E.Trj - is designed to monitor what computer users are doing on the internet, in order to collect personal information. It will record the website you browser, the emails you receive and write and even the online bank account information. If those personal data is released to the third party, you will get annoying advertisements in your email box or when you surf the internet. What's worse, you may suffer property loss. Once this Win32.Flot-E.Trj infection is activated in computer, it can bring a lot of troubles to the infected system. This Trojan is designed by cyber criminals for stealing privacy from innocent PC users. When this Trojan is activated in the infected computer, it can modify the browser homepage and the Internet DNS settings without the user's approval. In this case, the confidential information such as IP address of the computer can be stolen by remote hacker. Under this circumstance, cyber hackers can take control of the infected computer remotely and secretly. In such a situation, the PC user's bank details or other personal information which saved in the computer can be leaked out to those bad guys. And the cyber criminals can use the sensitive information for illicit activity. It introduces malicious code into your machine, corrupts the OS files, and brings in spyware that sends out private information like login ID - passwords to particular destinations, causes the BSOD or Blue screen error and much more. A computer will suffer more loss, particularly if they do not notice that a computer is infected by Win32.Flot-E.Trj.
Hanoi Lung hospital RHS - Cepheid-3NC10R1 Intel Core 2 Duo CPU E7400 @2.80GHz Dell Inc. 01KD4V A01 GPU Intel 4 Series Internal Chipset 2 x 512MB RAM DDR3 1066 1024MB	**VBS:Malware-gen -** is a type of infection spread via infected USB flash drives, SD cards, phones, GPS, tablets, or in a malicious link sent through instant messaging programs and social networks. The worm may send your personal information, such as Social Security and credit card numbers, to rogue

	servers. It can disable anti-virus programs and even disable the Internet Web browser capability.
	Win32:Dorder-X [Trojan] - is a type of infection spread via infected USB flash drives, SD cards, phones, GPS, tablets, or in a malicious link sent through instant messaging programs and social networks. A healthy USB device can easily be plugged into an infected PC, where the infection is active, this will automatically create a copy of the malicious code onto the healthy USB support. Once the healthy USB is contaminated, it serves as a means of transport the infection and allows it to infect other healthy computers it comes into contact with. This family Trojan can steal your usernames and passwords by watching what you do online, they can also download other malware and stop you from visiting security-related websites. Some variants can use your PC in a denial of service (DoS) attack.
Hanoi Lung hospital LHS - Cepheid3X2BYQ1 Intel Core 2 Duo CPU E7400 @2.80GHz Dell Inc. 01KD4V A01 GPU Intel 4 Series Internal Chipset 2 x 512MB RAM DDR3 1066 1024MB	**Win32:Dorder-X [Trojan]** This type of infection spread via infected USB flash drives, SD cards, phones, GPS, tablets, or in a malicious link sent through instant messaging programs and social networks. A healthy USB device can easily be plugged into an infected PC, where the infection is active, this will automatically create a copy of the malicious code onto the healthy USB support. Once the healthy USB is contaminated, it serves as a means of transport the infection and allows it to infect other healthy computers it comes into contact with. This family Trojan can steal your usernames and passwords by watching what you do online, they can also download other malware and stop you from visiting security-related websites. Some variants can use your PC in a denial of service (DoS) attack.
Hoang Mai - Cepheid5YSWDQ1 Intel Core 2 Duo CPU E7400 @2.80GHz Dell Inc. 01KD4V A01 GPU Intel 4 Series Internal Chipset 2 x 512MB RAM DDR3 1066 1024MB	None

Appendix 13: The Connectivity Elements

FIND's approach to connectivity projects starts with consideration of the two domains:

1. **The Project Framework**: This represents the planning, development and deployment of the required service

2. **The Connectivity Service:** This is made up of the following parts:
    a. **Operations**: This represents capabilities to operate the in life service, drive adoption and gather evidence to measure success.
    b. **Process Management**: This represents the capability to manage a full suite of processes which make-up the resultant service.
    c. **Service Touch points and User Experience:** A user's experience of consuming a service is played out across a diverse range of touch points and interfaces.
    d. **Technology and diagnostic data:** This represents the core of connectivity service, namely the technologies and services that carry the diagnostic data on a bi-direction journey between source and consumer.

Further decomposition of this framework to its level 2 elements provides a comprehensive checklist of people, process and technologies, which can be used to assure the quality of any connectivity project plan and the coherent delivery of the end service.

The graphic below elaborates this framework to show the elements within each level one area that characterises diagnostic connectivity.

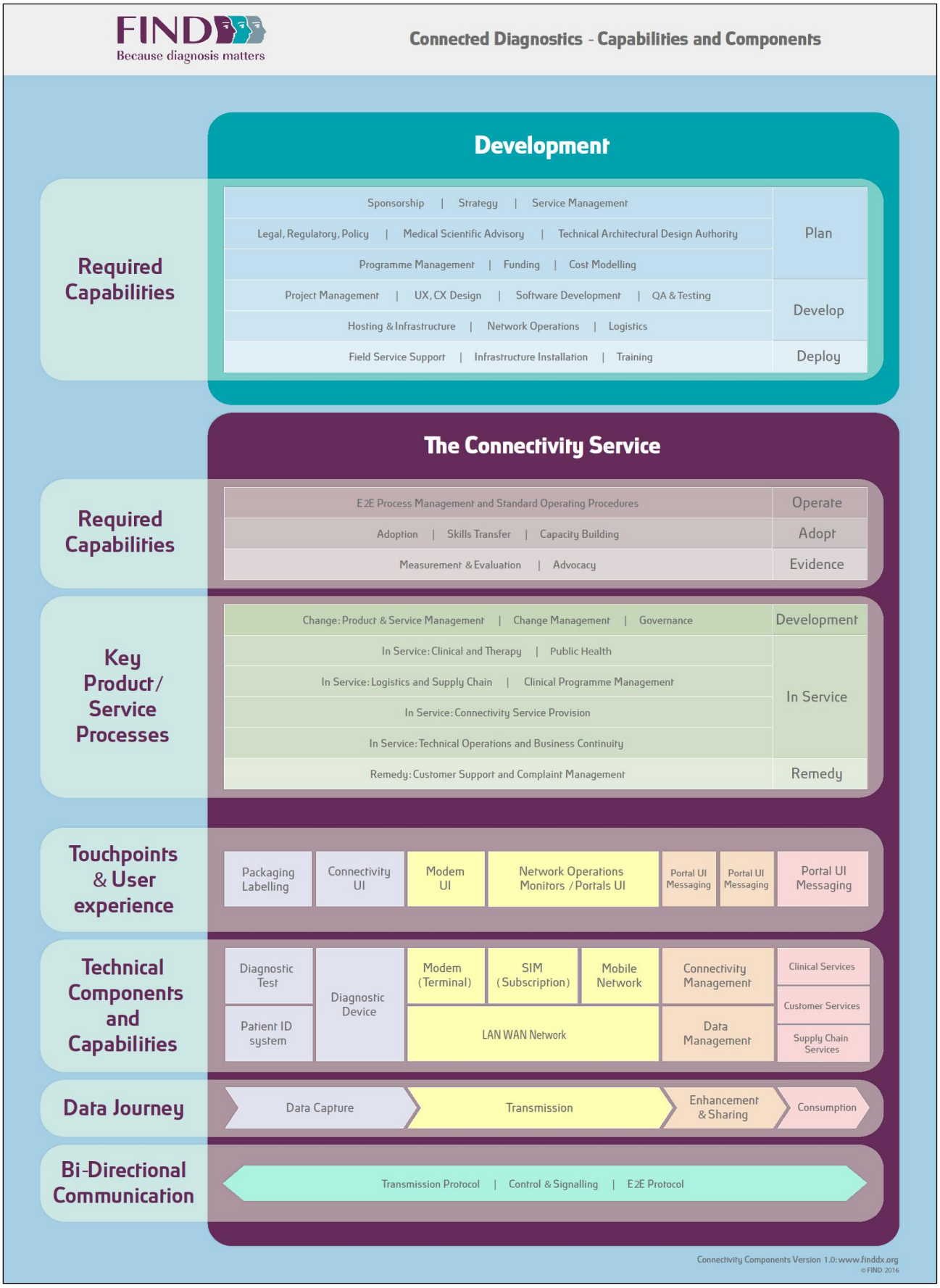


Fig (A13.1) - Level2 Connectivity Elements and Capabilities