NHS
Blood and Transplant

Architecture Design Blueprint

Transplant Risk and Consent (TRAC) Tool

Manuel Di Toma – Lead Technical Architect

Version 0.2

11/12/2020

Content

Approvals and Version History

Role	Name	Responsibility	Approval Date
Enterprise Architect	Bode Oluwasanmi	OTDT Ensures compliance with technology strategy	
Solution Architect	Manuel Di Toma	Ensure solution is practical and optimal from known perspectives	
Enterprise Architect	Andrew Simpson	Ensures adherence to Online Enterprise Architecture Strategy and manages Roadmap	
Business Analyst (Functional Consultant)	Matt Thorogood (Future Gov)	Requirements gathering and BRS development	
Product Owner		Ensures compliance with requirements	
Service Owner	Nic Labuschagne	Ensures guidance and documentation is in place before/during transition to BAU	
Quality	Mark Whelan (QA TA)	Ensures compliance with quality and regulatory standards	
Project Manager	Joel McGrath	Responsible for the management of the project (project governance, scheduling, stakeholder management, cost monitoring, risk management)	
Head of Business Analysis	Adam Blythe	Resource manager for BA and approval authority for BRS	
Head of Solution Architecture	Teimo Tokoro	Resource manager for SA and approval authority for ADB	
Accountable Exec	Liz Armstrong	Head of Transplant Development	
Senior Responsible Officer	John Forsythe	Medical Director for Organ Donation and Transplant	
Senior User	John Asher	Consultant Transplant & General Surgeon	
Statistical Team	Jennifer Mehew Maria Ibrahim	Principal Statistician, Statistics and Clinical Studies	

Version	Change Details	Author	Date
0.1	Initial draft	Manuel Di Toma	30/11/2020
0.2	Updated to include project feedback	Manuel Di Toma	04/01/2020

Project Overview: TRAC

Background & Drivers for Change

Over the past 10 years the number of deceased donors has increased significantly, and a record number of patients have received transplants.

The use of web-hosted clinical tools (lung & kidney) encourage patients, clinicians and other healthcare professionals to think and talk about the benefits and risks of transplantation in increasingly informed ways, improving confidence in the acceptance of marginal offers and reducing late declines of marginal offers.

This project will create lung and kidney TRAC (Transplant Risk and Consent) software tools, hosted on third-party infrastructure and linked to NHSBT web pages. The third-party supplier will then maintain the tools until NHSBT is prepared to migrate them over to local servers.

Objectives and Outcomes

- Define Architecture for the introduction of a tactical TRAC software developed and managed by a Research Centre called Winton Centre.
- Identify a strategic online forms solution to implements a Questionnaire Platform that could be used by this and other projects (e.g. Aide Memoire).
- Identification of Strategic Architecture and Design patterns for the integration of the forms platform with NHSBT systems (e.g. Statistical team, MS Power Platform and Dynamics, etc.).
- Adoption and migration to the strategic TRAC platform.

Strategic Alignment and Benefits	
Donor, customer and patient need	• Transplant Clinicians require an up-to-date tool to guide them through Transplant Risks and Patient Consent.
Business value	• NHSBT alignment with the Taking Organ Utilisation to 2020 Strategy. • Reduce the risk of litigation and reputational risks in current consent system. • Improving Transplant Outcomes (success and survivability).
Cost savings	• Minimising future CAPEX: No need to create ad-hoc solution for each future change to the TRAC process. This will be available through configuration change. • Optimising OPEX: Efficient use of internal resources (dedicated team to implement new requirements)
IT stability, perform & risks	• Identification of a Strategic forms management solution • Tactical solution is not supported as implemented pro-bono • The current form is developed in clojurescript, no skills in house to main it.

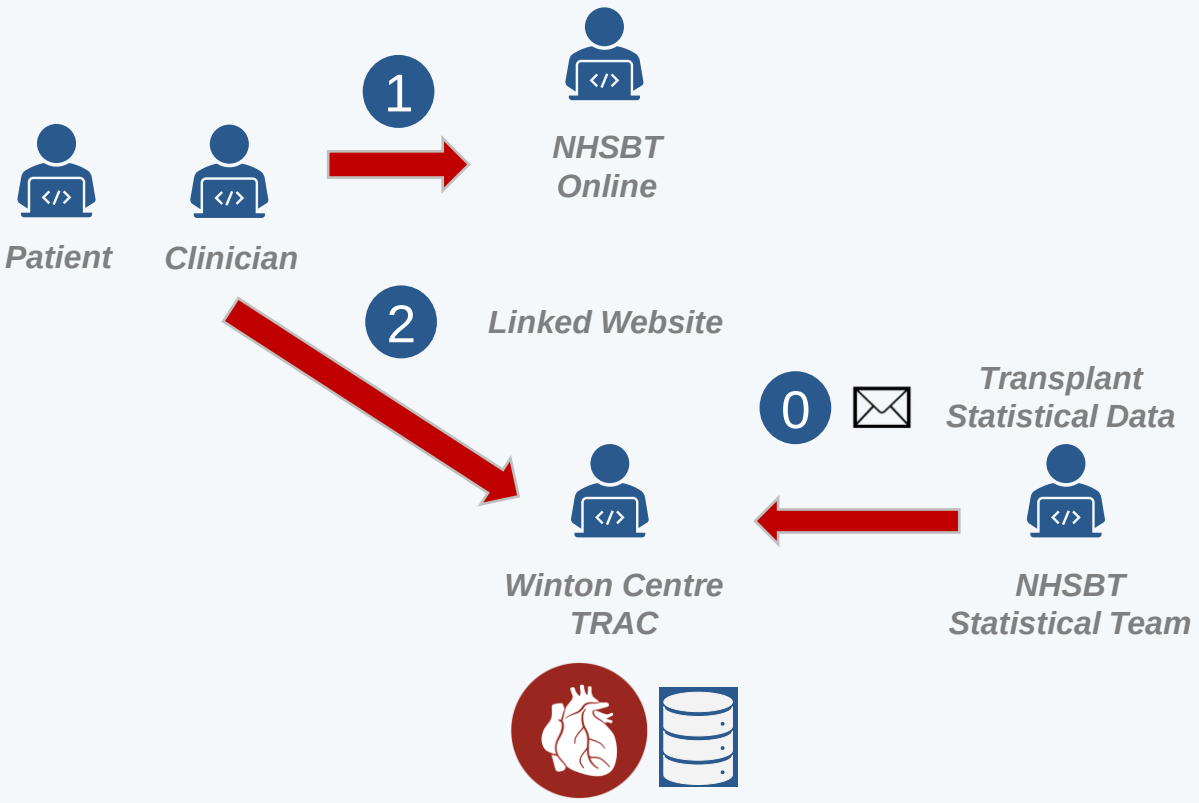
Costs	2020	2021	Yr3-5	Total
Change	£12K	£200K	£0	£0K
Run	0	£5K	£5K	£5K
Maintain	**0**	**£0 (internal only)**	**£0 (internal only)**	**£0 (internal only)**
Total	£K	£K	£K	£K

Delivery	
Proposed next stage	**Test**
Cost to progress to next stage	£200K (external)
Delivery Approach	Waterfall
Project Timeline	**GoLive – March 2021**

Confidence	
Business	**M**
Technology	**H**
Impact	**M**
Delivery	**M**

1 – Business Context

Business Context Diagram – TRAC (Tactical)



Narrative

Scope of Phase 1

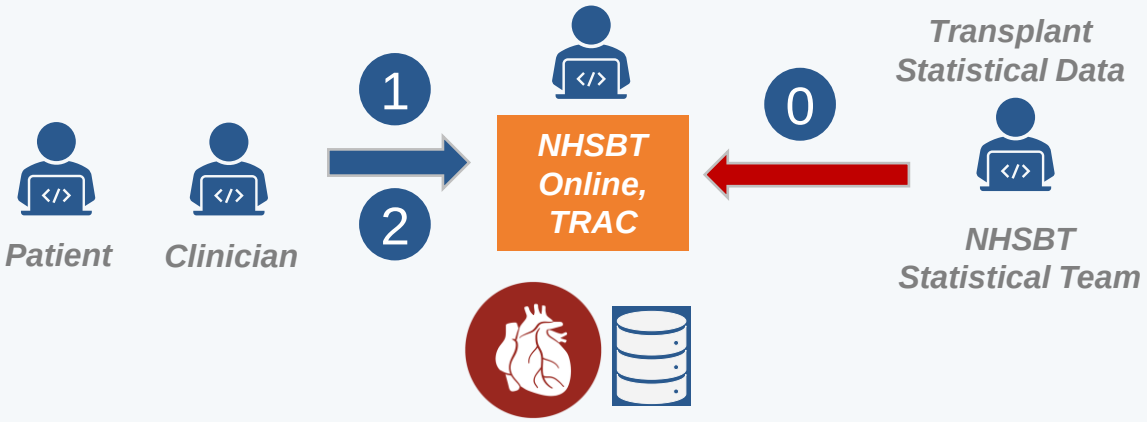
0- Transplants Statistical Data is sent to the Winton Centre and uploaded in the TRAC Tool.

1- Patient and Clinician discuss pro and cons of undertaking Transplant surgery. NHSBT site offers some information on transplant.

2- On NHSBT website there is a link to the Winton Centre TRAC Tool. Clinician uses the TRAC tool together with the patient to explain pro, cons of transplant and statistical evidence of what can happen.

Existing
Modify
New

Business Context Diagram – TRAC (Strategic)



Narrative

Scope of Phase 2

0- Transplants Statistical Data is sent to the NHSBT TRAC Tool.

1- Patient and Clinician discuss pro and cons of undertaking Transplant surgery. NHSBT site offers some information on transplant.

2- On NHSBT website clinician uses the TRAC tool together with the patient to explain pro, cons of transplant and statistical evidence of what can happen.

- Existing
- Modify
- New

Scope (Phase 1 - Tactical) – Capabilities/Requirements & NFR

Phase Objectives

Over the past 10 years the number of deceased donors has increased significantly, and a record number of patients have received transplants. Donor demographics have changed over time and increasingly marginal organs are being offered. Donors are older, more overweight and with higher co-morbidity compared with donors from years past. Changes to donor demographics and hence an increase in marginal organ offers (higher- risk donors) have contributed to challenges with regards to organ acceptance and organ utilisation. There has been a recorded decrease in organ utilisation and deceased donor transplants. Additionally, litigation and reputational risks in current consent system continue to be prevalent.

These web-hosted clinical tools (lung & kidney) encourage patients, clinicians and other healthcare professionals to think and talk about the benefits and risks of transplantation in increasingly informed ways, improving confidence in the acceptance of marginal offers and reducing late declines of marginal offers.

ID	Category	Description
1	**Kidney Transplant Evaluation**	Returns transplant success rates based on several factors like (age, pre-existing condition, etc.)
2	**Lung Transplant Evaluation**	Returns transplant success rates based on several factors like (age, pre-existing condition, etc.)
3	**Kidney Transplant Evaluation**	Returns rates of other outcomes (waiting for transplant, removed from list, patient died) based on several factors like (age, pre-existing condition, etc.)
4	**Lung Transplant Evaluation**	Returns rates of other outcomes (waiting for transplant, removed from list, patient died) based on several factors like (age, pre-existing condition, etc.)

NFR Category	NFRs
NFR	**Up to 30000 requests a month**

Scope (Phase 2 - Strategic) – Capabilities/Requirements & NFR

Phase Objectives
The phase 1 solution is re-implemented by NHSBT using a technology stack that can be supported. The existing organs will be migrated to the new solution and additional organs will be supported (e.g. Liver, Heart, Pancreas).

ID	Category	Description
1	**Kidney Transplant Evaluation**	Returns transplant success rates based on several factors like (age, pre-existing condition, etc.)
2	**Lung Transplant Evaluation**	Returns transplant success rates based on several factors like (age, pre-existing condition, etc.)
3	**Other Organs (e.g. Liver, Heart, Pancreas)**	As above

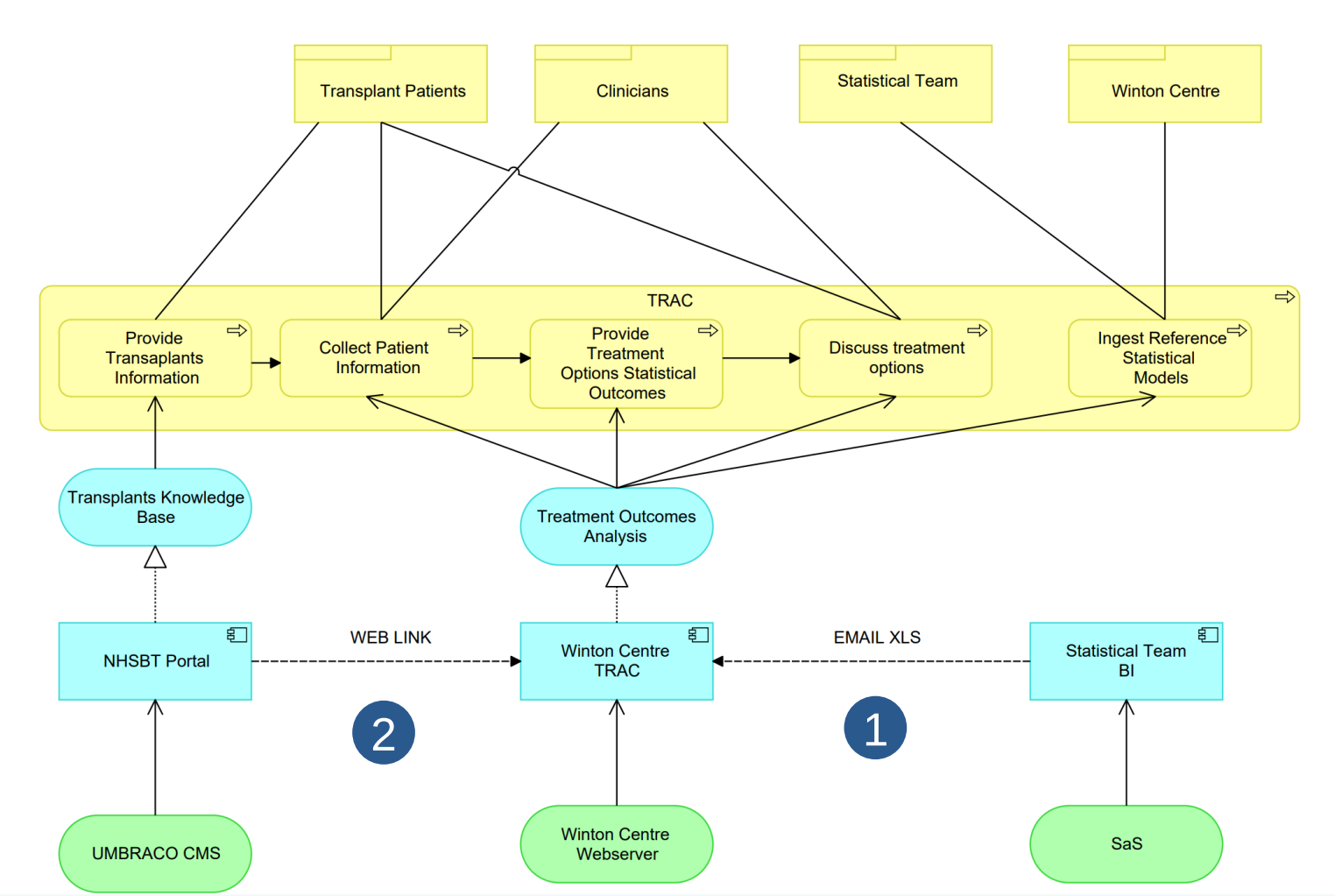
NFR Category	NFRs
Usability	• Must meet all standard NHSBT usability NFRs
Capacity & Performance	• Application screens to load in less than 5 second
Security	• Must meet all standard NHSBT security NFRs
Recoverability, reliability & availability	• 20/7/365 availability • RTO 1 hour
Regulatory and Legislative	• Must meet all NHSBT Regulatory NFRs
Maintenance and support	• Need to be on a supported platform
Other	

Scope Phase 1 – Business Areas

	Scope	Scope	
People	• Transplant Clinicians • Transplant Patients • Statistical Team • Transplant Division	• Online based UK-wide service	Locations
Process	• Pre-Transplant	• Organs Transplant	Products & Services
Data	• Lung Transplant Statistical model • Kidney Transplant Statistical model	• Phase 1 will be linking to a solution designed, built and managed outside of NHSBT.	**Out of Scope**

3 - Technology Context

Technical Context Diagram – Phase 1 (Tactical)



Narrative

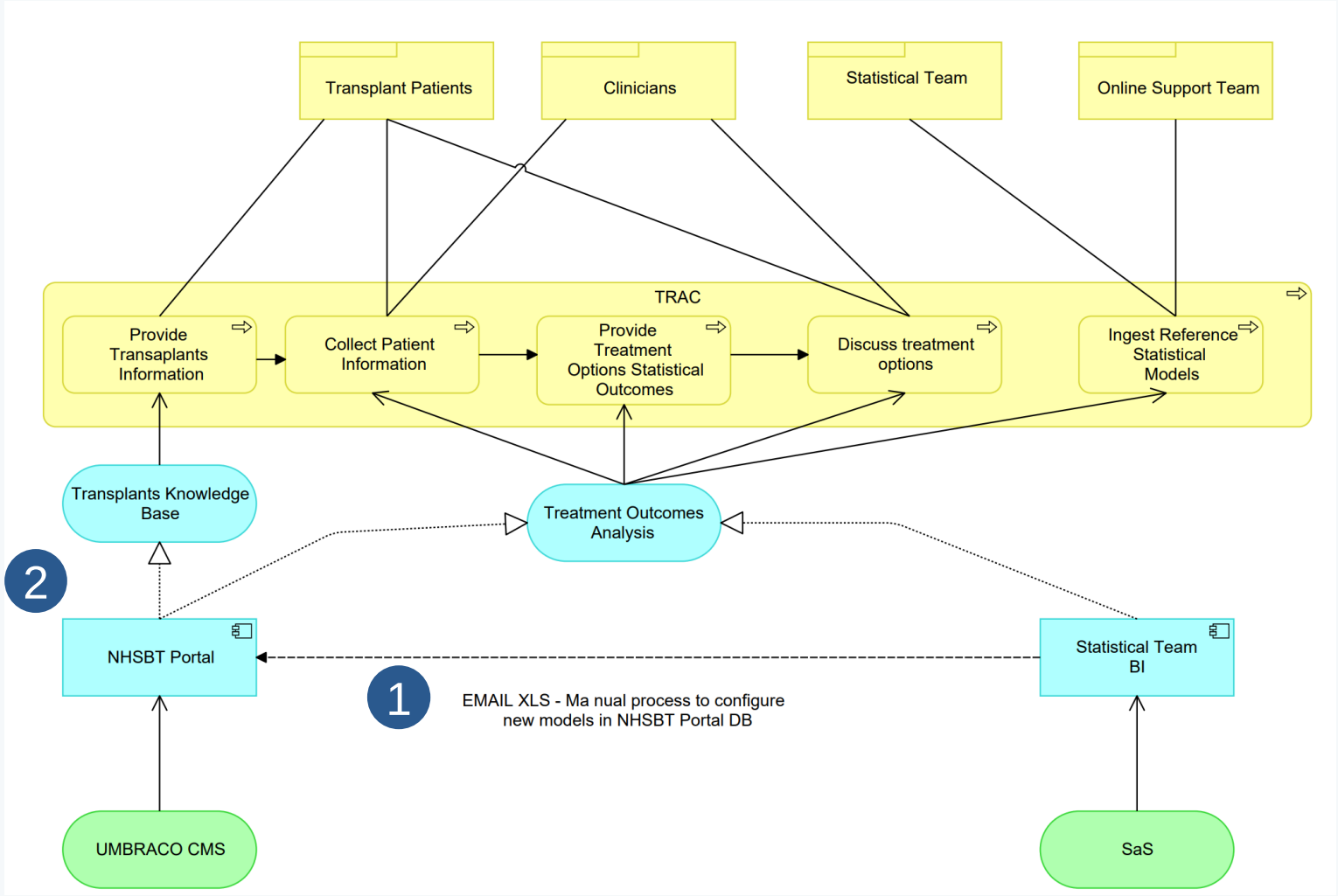
In the first phase of the TRAC project a TRAC tool is offered by the Winton Centre and NHSBT Transplant portal is linking to it.

1. Statistical Team periodically provides the Winton Centre up to date Transplant information via email (XLS attachment). Statistical Information is implemented using a CoX model. The file is processed and ingested by the Winton Centre TRAC platform.

2. A patient lands on NHSBT tool and can learn about transplants. When clicking to the TRAC web link is redirected to the Winton Centre website to use the TRAC tool. This can happen autonomously or with the support of a clinician.

NOTE: precalculated test data will be provided by Statistical team to enable TRAC testing of CoX model.

Technical Context Diagram – Phase 2 (Strategic)



Narrative

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1. Statistical Team periodically provides the Winton Centre up to date Transplant information via email (XLS attachment). The Statistical data is precalculated. The file is processed and ingested by the Winton Centre TRAC platform.

2. A patient lands on NHSBT tool and can learn about transplants. When clicking to the TRAC web link is redirected to the NHSBT TRAC tool. This can happen autonomously or with the support of a clinician. Umbraco CMS is changing to support this.

Technical Scope – Phase 1 (Tactical)

	Component	Changes/Impact	Change Complexity
Application	NHSBT Portal	New Link (on a webpage)	Very Small
	Winton Centre TRAC	New Tool	
Integration	N/A		N/A
Technology	Winton Centre TRAC	Developed in clojurescript, compiling to javascript	Medium
	Umbraco	New WebPage, New Link	Very Small

Technical Scope – Phase 2 (Strategic)

	Component	Changes/Impact	Change Complexity
Application	NHSBT Portal	Implementation of TRAC Tool	Medium
Integration	N/A	N/A	N/A
Technology	Umbraco CMS	New WebPage, New Link	Very Small
	Umbraco Forms	TRAC tool implementation	Medium
	Umbraco DB	To store reference Data – assumption that will not need to be updated very often so this can be a manual process initially	Small

Principle and Design Patterns

Principle	Rationale and Impact	Level of fit
Design for Clinical & Regulatory Standards	• Statistical Reference models generated by NHSBT Statistical team	H
Cost effective and sustainable	• Re-use of the existing CMS forms capability	H
Re-use before buy, before build	• Re-use of the existing CMS forms capability	H
Data as an asset	• Data mastered in Statistical Team BI	H
Design appropriate security	• No Personal Identifiable Information exchanged in this process • Initial use of email exchange server (internal to internal) to exchange statistical models. • MFT and ETL could be introduced if necessary	H
Interoperability focused	• N/A	N/A
Put our tools in browsers	• Online based	H
Cloud first	• Uses existing Umbraco infrastructure	H

Pattern No.	Design Pattern	Description (Problem, context, solution..)	New/ Exists		
001	**Forms Based Approach**	Any solution that requires: public access, data collected following a complex flow and output presented in online form will be implemented in Umbraco forms.	Existing		

4 – IT Risk and Compliance

IT Risks, Issues, Assumption, Tech Debt & Dependencies

Type	Description	Phase	Mitigation	Impact	Prob	Proximity
Assumption	Statistical models do not need to be updated more than once every 1 year and this can be a manual process.	Both	Involving all impacted parties in the solution review, solution subject to change in phase 2.	L	L	Far
Debt	Winton Centre solution is implemented using a custom technology that cannot be supported by NHSBT.	Phase 1	NHSBT is planning a Phase 2 of the project to re-implement the solution using NHSBT controlled resources/technologies.	H	H	Near
Issue	Solution has been delivered outside NHSBT control	Phase 1	A project to onboard the solution is now in existence.	H		
Issue	NHSBT has not control on the requirements, solution for the implementation of TRAC	Phase 1	NHSBT is planning a Phase 2 of the project to re-implement the solution using NHSBT controlled resources/technologies.	H		
Issue	Statistical Models provided to Winton Centre by NHSBT changed	Both	Winton centre decided to drop 1 out of 2 organs that the solution support and focus on implementing solution for Kidney.	H		
Issue	Winton Centre is due to close in September 2021, any tool developed is not supported.	Both	Phase 2 should be addressing this issue	H	H	Near

Dependency Source	Dependency Description	Timing	Give/Get
Winton Centre	The TRAC application is implemented by the Winton Centre in Phase 1 of the solution	Feb 2021	Get
NSHBT Statistical Team	A valid set of Statistical Models for Lung and Kidney Transplant should be provided to Winton Centre	Overdue – December 2020	Give

IT Risk & Standards Assessment

Risk Area	Phase 1 Rating	Phase 2 Rating	Rationale
Design Complexity	L	M	This is a simple solution
Dependencies & contention	H	L	Tactical solution (Phase 1) out of NHSBT control and cannot be supported
Scale of Project	L	M	
Business Case Volatility	L	L	
Testing Approach / Complexity	L	L	
Delivery Implementation Approach	H	M	Project delivery is not managed buy NHSBT in Phase 1.
Patient Safety Criticality	M	M	
Named Suppliers: New? Multiple?	L	L	

Standards	Relevant	Explanation
ISO27001	Y	The system will use donor data, however this will be as existing business process.
IVDR / Medical Device	N	No, the solution is used only for reference but not to take a medical decision
NHS Interoperability Framework	N	Re-use of NHSBT forms platform
GMP Annex 11	N/A	N/A
NHSBT POL10	Y	Solution will be reviewed in context of POL10 requirements.
GDPR	Y	No PID are collected or processed.
GDS Digital Standards & Code of Practice NHS digital services manual	Y	User interface components are cloud based. Reusing existing design patterns.