Application Timeline

RINTAG 9th October 2017

1. EXECUTIVE SUMMARY

In May 2017, the ODT Research Project Team presented raw data on the application process timeline to RINTAG. The majority of studies had been activated within 4 months from application. However, the timescales vary greatly between cases. An in-depth analysis has since been undertaken to identify further trends and areas for improvement. The key findings are reported in this paper.

2. RECOMMENDATION

That the data within this paper will be used to inform the lean process for ODT Research.

3. BACKGROUND

In total, the ODT Research Registry comprises a total of 39 active studies.
Application activity since January 2016:

- Approvals: 21[1]
- Live: 15

The method by which this data was gathered is outlined in Appendix 1.

4. KEY FINDINGS

- Since January 2016 the ODT/ RINTAG application process has been subject to a major overhaul. During this transition period, RINTAG has issued 21 approvals. A total of 15 studies were brought live within an average timeframe of 4 months from application.
- Changes to internal and external application processes resulted in some unforeseen delays. The primary reason for the delays was due to the review of internal NHSBT policies and RINTAG submission requirements. These delays mainly occurred in the early application stage.
- Factors outside NHSBT's control, such as changes in Health Research Authority and Research Ethics Committee requirements, were a significant contributing factor to delays. It is expected that many of the identified delays will not be repeated, since a number of corrective actions have been implemented (see Appendix 1). The application process will be further scrutinised and streamlined via the lean process.

5.1 Application Timeline

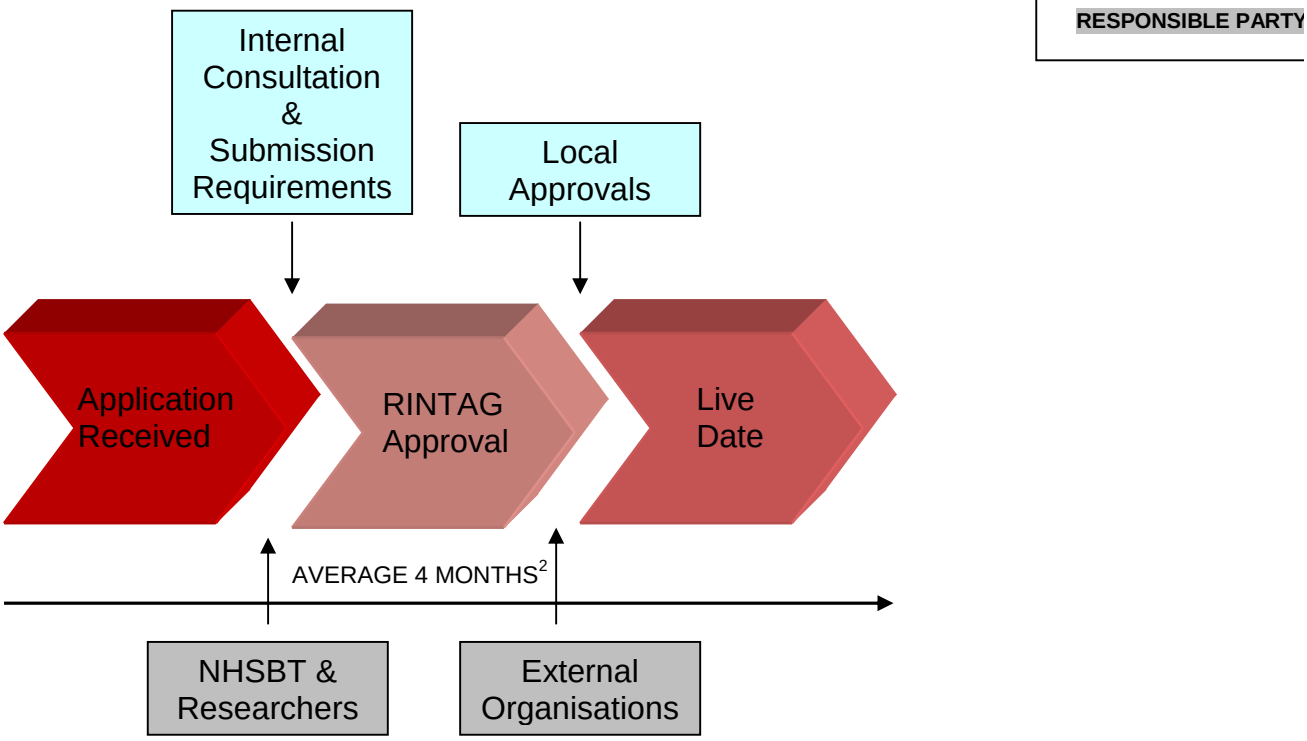
The responsibility for the primary delays (Figure 1) lies on three parties, respectively:

1. NHSBT – Internal consultation
2. Researchers – Submission requirements
3. External organisations – Local approvals

Of these, the primary delays occurred between the stage *Application Received* and *RINTAG Approval*. This is somewhat expected given that internal consultation prior to RINTAG submission aims to identify and address issues at an early stage.

[1] 12 studies via allocation scheme (generic consent). 9 studies via local removal (specific consent).

Figure 1 – Application Timeline



In addition to the above, further reasons for delay was distributed across the approvals process as following:

Stage 1: Application received

- Implementation of new application process
- Establishment of HRA process
- REC amendments
- Internal consultation (Duty Office/ NHSBT R&D/ AGs/)
- NHSBT ODT operational support
- Staffing resources – Other proposals requiring secretariat support

Stage 2: RINTAG approval

- RINTAG approval sought early and REC/ HRA/ R&D process not commenced.
- Administrative items

Stage 3: Live date

- Designated Individual (DI) support for removal of relevant material
- Local Trust approvals
- Internal consultation (Quality Assurance)
- SNOD training
- Sponsor approval, go-live date

Appendix 2. outlines corrective actions to date.

5. ACTION REQUIRED

[2] The timescales vary greatly between cases

RINTAG is asked to note:

- the findings from the audit
- that corrective action has already been taken to prevent re-occurrence for most of those issues within NHSBT's ability to influence
- the review will inform the lean process for ODT research applications

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APPENDIX 1

Methodology, and Analysis
The following timings were analysed: Date Application Received; Date of RINTAG Approval; Date of Go-Live.

Data was collated from the RINTAG database and e-mails/ correspondence held on NHSBT systems. There were no additional studies activated since the data was collated, in April 2017. Correspondence was also reviewed to identify:

- Timing of outstanding documentation received;
- NHSBT processes (operational support; QA);
- Context (new application approach; HRA process);
- RINTAG meeting dates;
- New national/ NHSBT policies

Table 1. Reasons for Delays and Corrective Action

RESPONSIBLE PARTY	NUMBER OF STUDIES	MAIN REASONS	DETAILS	CORRECTIVE ACTIONS
NHSBT	6	1. Internal Policies	DNA Animal research policy	Policy revision and internal agreements now in place.
		2. Approval Dates	Missed and/ or delayed review	Increased communication with research teams and relevant stakeholders.
			Sub-study re-submissions /	
		3. Staffing Resources	Vacant post/ sick leave	Permanent full-time post now filled.
NHSBT; Research team and; External parties	4	1. REC and HRA	Late approach to NHSBT/ REC amendments	Collaborating with the HRA to establish transplant related REC.
			HRA establishment	Shared learning with HRA staff. Education piece on transplant related proposals.
			Documentation submission	Opportunity to apply for REC in parallel with RINTAG submission.
		2. Local trust (c&c) approvals	HRA document suite review	Local approvals largely outside NHSBTs control. Increased working relations with research teams and Sponsors.
		3. Administrative items	RINTAG submission requirements	Revised submission requirements and Research Handbook developed.
			Internal consultation	

			(Quality Assurance/ Duty Office/ AGs)	
			Clinical priorities	Increased working relations with research teams and Sponsors.
			MoU amendments	
		4. Regulatory requirements	MCA/ HTA requirements	Legislative requirements largely outside NHSBTs control.
			Designated Individual (DI) support for removal	Increased guidance provided to prospective researchers.
NHSBT and Research team	3	1. Approvals	RINTAG submission requirements	Revised submission requirements and Research Handbook developed.
		2. Transportation	Confirmation of arrangements	Further guidance provided via Handbook.
		3. Final approvals	MoU and Sponsor approvals prior to going live	Largely outside NHSBTs control. Increased working relations with research teams and Sponsors.
Research team	1	1. Outstanding documents	Evidence required for submission	Early provision of guidance. Increased communication with research teams.
		2. Transport	Arrangement of appropriate transportation	
NA	1	N/A	N/A	No delays
TOTAL/ SUMMARY	**15**	**Internal review of policies and consultation.** **HRA/ REC requirements** **Local approvals.**	**Overhaul of application process.** **Submission requirements.**	**Lean Event to recommend waste reduction and delay minimisation.**