Health Research Authority

SIP Report – Mar 2018

- Overview
- Intended benefits
- Headlines
- Progress report
- Proportionality
- High level plan – *to be distributed at meeting*
- Key risks (over 12)

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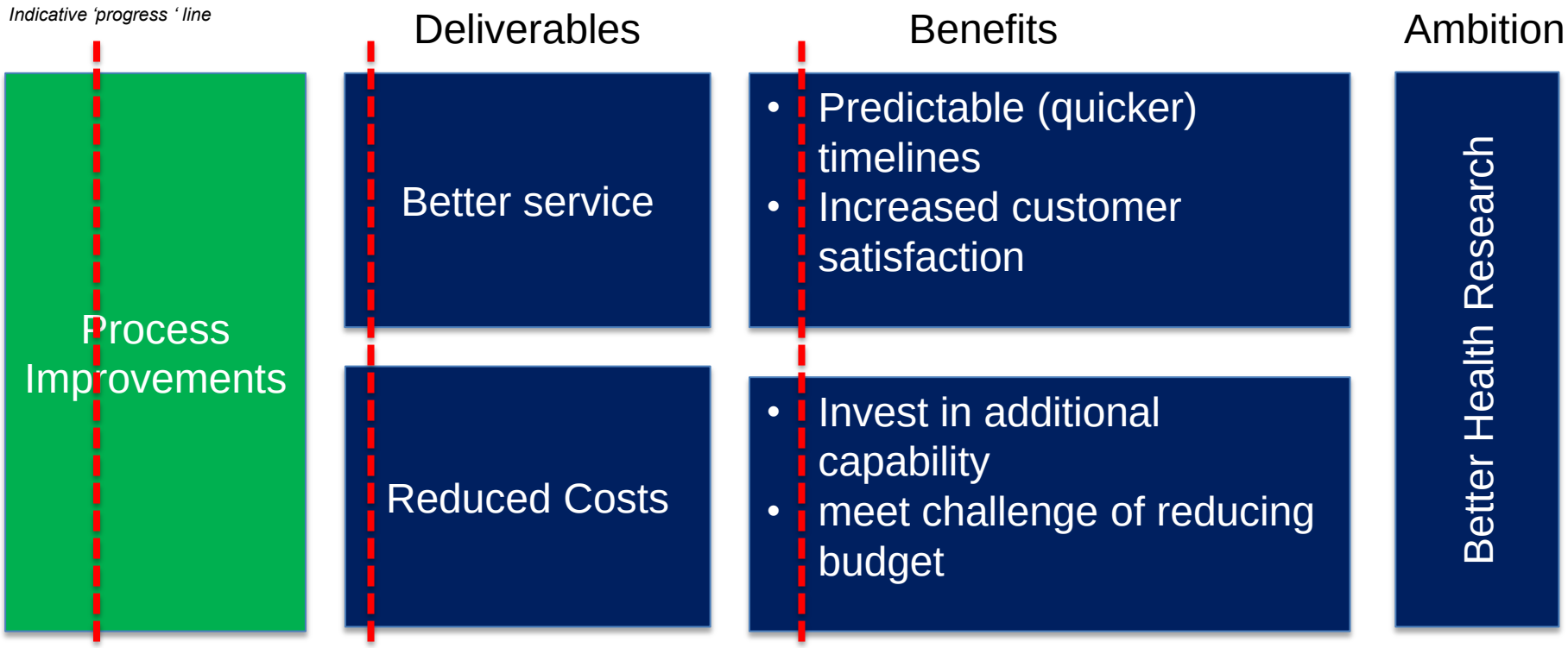
Overview

- Current focus on process improvements



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Intended Benefits (others in development)

Enhanced analytical capability which will enable data to be more effectively used in both improving operational performance and offering key intelligence to the research community
Providing transparency for researchers, stakeholders, patients and the public by offering greater access to data
A process that offers the applicant a more precise timetable to allow them to plan subsequent activity.
Less time and resource spent on re-working applications following initial submission (i.e. reduction in work needed between applicant and operational teams to get initial application to valid)
Shorter elapsed time from application to HRA Approval providing opportunity for improved speed of study set-up will improve potential for researchers to recruit to target and complete studies to schedule.
High rates of satisfaction will potentially increase attractiveness of UK as place to carry out research and enhance reputation of HRA. Sharing positive news enhances staff morale.
The application of a proportionate approach to HRA Approval (scope) will make it easier for researchers to set up studies.
Improved consistency in how Research Ethics Committees (RECs) address and consider public involvement in applications for ethical review.
Increase in the number of applicants reporting public involvement in applications for ethical review.
Improvement in the quality and relevance of the information that researchers provide on public involvement in applications for ethical review
Improved evidence base and monitoring of public involvement data.
Better experience for our customers

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Headlines

- Programme remains green
- Joined up validation rolled across HRA For English led studies at English REC's
- Testing beginning on
  - 'Ready for review threshold' (ensuring that applications are of a suitable quality standard i.e. completeness, consistency and legal compliance) and
  - 'Approvals finalisation' (single communication around further information requests as a result of REC review and HRA Assessment)
- Initial report on 'proportionality' received
- Effective progress made in Corporate SIP projects
- Benefit realisation plan nearing completion – aim for sign off in April
- Key risk remains around internal resourcing

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Service Improvement Programme	Date: 14th March 18	Budget: 97.2k Forecast outturn:110k	RAG

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Workstream	Status	Commentary
HRA Approval - Integrated Process		Initial testing of Threshold paperwork about to begin. Joined up validation rolled out across HRA for English led studies at English RECs. Wales to pilot Wales led studies at Wales REC. Scotland to pilot English led studies at Scottish REC. NI considering options
HRA Approval - Proportionality		Initial proportionality report received by Transformation Board ***(further detail on following slide)*** Single site pilot report to March Transformation Board
HRA Approval - Get it right first time		Verification Tool in development due in IRAS 5.8 release in April 2018. Webinars aimed at applicants being delivered
HRA Approval - Amendments		Scoping paper prepared but group not yet convened. Some resource now identified via bank.
PIER: Effective public involvement in the ethical review process leading to more favourable opinions and improved health research		Public Involvement Guidance begin developed for applicants (how evidencing PI can support favourable ethical opinion). Developing PI standards (in development of consent process and participant info sheets) which if met will guarantee a key requirement of ethical review being met
Corporate: Development of an effective and efficient corporate support and infrastructure model that results in a business model that secures the best value 'mix' of in-house, third party and shared ALB resourcing.		Employee Record – Self – Service being rolled out Discovery phase on best model for facilities and office support completed Consultation around proposed changes to Corp Sec and Corp Finance nearing completion
Customer Support: Delivering an integrated approach to managing the customer relationship, ensuring that all queries are managed effectively and that feedback is effectively used in improving service provision		In discovery phase – report due end of March 2018 (pushed back from February)
Analytics:	N/A	Now part of Research System Programme

SIP - Proportionality

The following initial recommendations were considered at February Transformation Board related to studies that could be taken out of HRA approval

- ***Staff Research*** *– it is recommended that we continue to see staff research in assessment but continue to explore a more proportionate approach with academic led funded research involving senior NHS members of staff.*
- ***Anonymised tissue/ tissue and data/ data only studies*** *– it was recommended that the work currently undertaken on the Research Tissue Bank/Research Database project would hopefully lead to many of these studies not requiring review at the individual project level where the tissue/data was drawn from a reviewed bank/database but that we might want to continue to review studies undertaken by individual clinicians with appropriate clarity provided in the scope document. In the interim we propose no change.*
- ***Premises*** *– guidance to be clearer that studies which only involve the use of NHS premises are out of scope.*
- ***NHS sponsored single site studies*** *– recommendation pending review of pilot work recently completed in this area.*
- *Work initiated to review if* ***very low risk studies which have no ethical issues*** *can be confirmed as such by desk assessment and removed from PR*

Further work will be carried out by the project team before any final recommendations are brought back to the Transformation Board

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Risks

Risk Description	Timing	Inherent Likelihood Score	Inherent Impact Score	Inherent Risk Score	Risk Owner	Controls and Mitigations	Action Owner	Residual Likelihood Score	Residual Impact Score	Residual Risk score	Trend	Target Residual Risk Score
Risk: Insufficient 'people' resource to deliver service improvement programme **Cause:** Resources being directed to maintaining BAU as agreed as business priority and time taken to fill vacancies in current establishment **Effect:** Will hinder speed of implementing change and realising benefits	Medium-term	4	4	16	JM	RM1: identify back fill resource to ensure necessary capability is freed up (use of SIP budget and reserves) RM2: Ensure SIP requirements are clearly detailed and part of an agreed resource management process	Leadership Team	4	4	16	↓↑	8
Risk: UK wide compatability adversly affected **Cause:** Unable to reach agreement regarding SIP proposals which impact on UK wide working, 4N do not have resource to implement agreed changes **Effect:** UK wide relationships damaged and unable to deliver cross country compatability to the detriment of researchers working across UK boarders	Medium-term	4	4	16	TA	RM1: Strong relationships in place RM2: UK wide compatability programme to improve cross border working and agree proposals RM3: MC appointed to UK wide post to facilitate improvements and compatability across the DAs RM4: Additional 4 Nations meeting held to discuss SIP proposals RM5: SIP PID shared with DAs 01/08 4 Nations meeting RM6: MC updated 4Ns on 12/10/17 about some of the SIP Integrated Processes that will impact compatibility. RM7: SIP discussion at 4N policy meeting 28/11/2017. RM8: SIP discussion at 4N policy leads meeting 01/02/2018. Scotland wish to be kept informed and have opportunity to engage. Wales keen to engage once HRA style process rolled out in Wales.	JM	3	4	12	↓↑	8

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