Agenda item:	9
Attachment:	A

HRA Board Cover sheet
19 May 2021

Title of paper:	HRA Transformation Programme - Summary review of 20/21 and look forward to 21/22
Submitted by:	Ian Cook
Summary of paper:	The paper focuses on looking at progress and improvements made in 20/21 and the programme of work for 21/22 Its primary aim is to give the Board a clear understanding of the major programmes of work that will be delivered during 21/22 and in many cases continuing through to 22/23. This portfolio of activity will ultimately take the HRA to delivery of the final phase of the Transformation Programme as laid out in the original Programme Initiation Document • *Phase 1: 2011 – 2014/15: establishment, consolidation, single approval process (consultation and design)* • *Phase 2: 2015/16 – 2018/19: implementation of single approval process, comprehensive organisational restructure, Research Systems design and initial procurement, development of TOM* • **Phase 3: 2019/20 – 2022/23 – Wide scale digitalisation of service, reconfigured research review model, implementation of people strategy** It also introduces the reporting and monitoring tools that will be presented at each subsequent board meeting to offer an assurance on delivery of products and their associated benefits. The board is asked 1. Note the positive progress in 20/21 2. Endorse the programme of work for 21/22 3. Agree the proposed reporting format to future board meetings
Reason for submission:	For approval
Further information:	The paper offers a level of further detail that can also support the discussion in the earlier board seminar in considering future contributions to wider system improvements
Budget / cost implication:	Budgets already allocated to programmes and will be monitored as part of the regular reporting procedure
Dissemination:	As a part 1 paper it is a public document.
Time required:	30 mins

HRA Transformation Programme
Summary review of 20/21 and look forward to 21/22

1. Introduction

1.1. The Transformation Programme is part of a major investment in HRA capabilities that builds upon a continuous process of change and improvement which has been on-going since the HRA was established in December 2011. In simple terms this journey can be broken down into three phases

- Phase 1: 2011 – 2014/15: establishment, consolidation, single approval process (consultation and design)
- Phase 2: 2015/16 – 2018/19: implementation of single approval process, comprehensive organisational restructure, Research Systems design and initial procurement, development of TOM
- Phase 3: 2019/20 – 2022/23 – Wide scale digitalisation of service, reconfigured ethics review model, implementation of people strategy

1.2. The Transformation Programme has comprised of many constituent parts varying in scale from discrete continuous improvement activity to major programmes of work which collectively, over the three phases, will have delivered transformational change for the researcher when set against their experience pre HRA. The table below offers a summary of that journey. It does not represent the entirety of the work that has taken place but indicates the scale of change and its increasing pace over more recent years.

Ambition	2011-2014/15	2015/16-2019/20	2020/21 going forward
Systems/technology - We will have digital platforms and technologies to support our ambitions, enable researchers to deliver high quality research and provide data on the way we contribute to the knowledge base of the research community	• Development of existing IRAS with build of new workflow system (HARP) reducing admin overhead	• Completion of Member Portal for 24/7 remote access by REC members, • Long-term Investment secured for New IRAS and commenced build	• Implement 'New IRAS' which will greatly simplify, automate and speed up approvals processes and offer enhanced analytics to the wider sector and fully support research transparency
Structure - We will have an affordable review model that will continue to support the delivery of high-quality research	• Initial rationalisation of RECs completed	• Single approvals directorate set up to reflect resource and skill requirements of new streamlined processes	• Full implementation of evolved model for research approval, which is more proportionate, streamlined, user friendly and can be fully delivered remotely as required
Processes - We will have even more streamlined processes, fast track review service, an approach for student research, improved amendments processes, template model contracts	• Design and development of new Approval's process	• Delivery of a centralised governance approvals of multicentre trials • Pilot single digital application route for clinical trials • Electronic submission of amendments delivered • Full 24/7 Online booking capability available	• Fast track pilot completed and moved into BAU • All clinical trials require only one single application route through New IRAS • Reduced duplication of activity in study set-up through implementation of consistent approaches to pharmacy and technical assurance and model contracts

Ambition	2011-2014/15	2015/16-2019/20	2020/21 going forward
Culture - We will stay true to our values in how we do our work and will continue to build an inclusive culture, we will support our staff and volunteers in working in different ways	• Development of HRA values (with staff) • Establishment of staff forum • Public involvement strategy produced • Building a single HRA identity	• Set up of Joint Negotiating Committee (JNC) with UNISON • Increased engagement with volunteers through greater senior management visibility • Public Involvement Panel set-up	• Set up of volunteers panel to work collaboratively on evolving model for research approval • EDI & People strategy completed and implemented, supporting move towards a more diverse workforce and volunteer group
People - We will have valued volunteers and staff and a more diverse and digitally enabled workforce	• Transitioning to a single employer model	• Increased investment in business IT • Establishment of specific service in Approvals directorate to support volunteers	• Fully digitally equipped workforce and volunteer group to effectively deliver services from anywhere • Full automation of all low-level transactional tasks • Greater flexibility in how and where services are delivered by our staff and volunteers
Estates - Our estates will enhance a collaborative and technologically mature operational approach, moving to Government hubs and aligning with government estates strategy	• Reduction in number of offices from 6 to 5	• Began move to Government hubs • Estate's strategy produced	• IT improvements and move to government hubs delivers target footprint reduction • Estates strategy fully delivered

1.3. There is a clear plan of work for phase 3 which comprises of a number of programmes and projects which are being managed as a 'portfolio' (**Annex A** outlines the overall approach to change being applied). Although we are reaching the end of this part of the journey, the next 18 months represents a significant period of improvement and change which will see the delivery of real and tangible benefits to the wider research system as a result of our investment in the necessary system and people capabilities along w the learning gained during the pandemic

Note: there will be a more detailed exploration of these benefits and the associated researcher experience in the earlier seminar session

1.4. This report offers both a look forward to 21/22 and a look back on progress made during 20/21. It also contains, in **Annex B**, the proposed model for future reporting to the board which aims to give a concise and focussed summary of progress against plan

2. Progress during 20/21

2.1. Much of the focus in 20/21 has been securing the necessary resource and capability and in ensuring the learning that has resulted from delivering services during the pandemic will be capitalised on.

2.2. 20/21 saw the successful outcome of the bid to the Department of Health and Social Care Investment Committee for the Research Systems Programme (and the subsequent award of the contract which will support system build, delivery and go-

live), the securing of funding to support the Ethics Review, Research Transparency and Streamlining Data Driven Research programmes.

2.3. Work has continued to move forward on new IRAS (including CWoW and the new IRAS website), the fast-track pilot has been delivered and a report with associated recommendations has been made on a revised model for ethics review. The new digital operating model to support the long-term development and support of IRAS was launched.

2.4. The roll out of Pharmacy and Radiation Technical Assurances and development of further Model contracts has continued, with a particular focus on UK-wide working. These processes are focussed on reducing duplication in the NHS and reducing the burden of study set-up in the NHS.

2.5. An Equality, Diversity and Inclusion Strategy was completed, a framework for the People Strategy delivered and work on future ways of working has begun (taking the learning from delivering a service remotely).

2.6. Two office moves have been successfully completed and with it the overall estates footprint has been reduced. Technology successfully enabled home working and plans for a greater exploitation of Office 365 are in place as is extended use of the Employee Service Record system both of which will move the HRA further towards digitalisation.

2.7. The table below highlights a number of system/process enhancements that have delivered tangible benefits to the Research Regulatory process.

Product	Benefit
Online booking of applications	Bookings can be self-service when it suits applicants
Electronic submission of amendments	Quicker and easier to submit amendments
Continued roll out of combined review with MHRA	Simplified streamlined application service and single decision
All learning resources and activity delivered online for members and with researcher access to the LMS	Expansion of access to learning resources
Collaborative development of learning resources relating to innovative trial designs	Supporting adoption of innovative trials
Successful piloting of Fast Track REC	Paving the way for implementing as ongoing service
Virtual meetings/electronic paperwork	Significant savings in time and cost (staff, volunteers and researchers)

3. Look forward to 21/22

3.1. The short summary tables below represent the key elements of the major programmes of work which make up the portfolio for 21/22 and the intended key deliverables and milestones planned for the same year (these are all included in 21/22 business plan).

3.2. To be included in this portfolio of activity will be the work related to the two major collaboration exercises being led by Department of Health and Social Care; **Recovery, Resilience and Growth (RRG) and Find, Recruit and Follow-up (FRF)** work is in progress to ensure coherence and connection with the work of HRA outlined below.

Title: Research Systems Programme
Summary: The new system will significantly speed up the UK life sciences regulatory approvals process and improve the researcher user experience to exceed competitor and modern standards to bring benefits to the lives of patients and the broader public. The new system will enhance the UK-wide approval system by simplifying, automating and increasing transparency. It will provide the HRA and devolved administration colleagues with an efficient and effective workflow which automates low skill administrative tasks. It will provide a modern, intuitive experience for making applications to all bodies to which such applications need to be made.

Key deliverables/milestones 2021/22	Date
1. New single identity gateway release allowing continued interoperability with NIHR	Jun 21
2. Launch a new wrap-around website for the Integrated Research Application System providing relevant guidance and signposting throughout the research journey.	Mar 22
3. Develop HRA Analytics and Customer Relationship Management strategies and implementation plans.	Dec 21
4. New Integrated Research Application System – ongoing development including quarterly releases starting in June 2021 continuing through to March 2023	Jun 21 – Mar 23

Title: Combined Ways of Working (CWOW)
Summary: The Combined Ways of Working (CWoW) programme will provide a single application route and will streamline the process for reviewing clinical trials. It is designed to retain elements of alignment that facilitate multi-country trials, while maximising UK sovereign flexibilities.

Key deliverables/milestones 2021/22	Date
1. All Clinical Trial submissions to be via combined review process	Jan 22

Title: Research (Ethics) Review
Summary: This programme will deliver an evolved model for research approval and support which is more proportionate, streamlined and user friendly for researchers and research sponsors, and supports good practice in research.

Key deliverables/milestones 2021/22	Date
1. Designing and rolling out a fast-track (15-day) ethics review service for global and phase I clinical trials, in pilot form (then transfer to BAU)	Jun 21
2. Developing a revised model for research ethics review.	Mar 22

Title: Streamlining Data Driven Research
Summary: Developers and data researchers are not always aware of the approvals AI or data driven research and technologies require. Where the required approvals are known, developers and researchers find the current processes hard to understand and difficult to navigate. Current processes do not support a smooth pathway from application to outcome. By September 2022, we will have delivered a world-class system for the approval of data driven research technologies, designed around developers and researchers.

Key deliverables/milestones 2021/22	Date
1. Conducting user and stakeholder analysis.	Sep 21
2. Redesigning our processes for the review of research involving AI and data-driven technologies to increase efficiency and effectiveness.	Sep 21
3. Starting the iterative development of a new technology platform to simplify the process for applicants and HRA staff.	Dec 21

Title: Research Transparency
Summary: The programme will deliver our vision for research transparency 'that trusted information from health and social care research studies is publicly available for the benefit of all'. by working with stakeholders across the research system, patients, and the public to make transparency easy, make transparency the norm and make information public.

Key deliverables/milestones 2021/22	Date
1. 1st Annual Report	Aug 21
2. Develop our digital systems to enable all clinical trials of medicinal products to be registered in a UK registry before a study begins.	Dec 21
3. Publish a tool in the new IRAS website to enable the public to see approved research studies and their findings	Mar 22

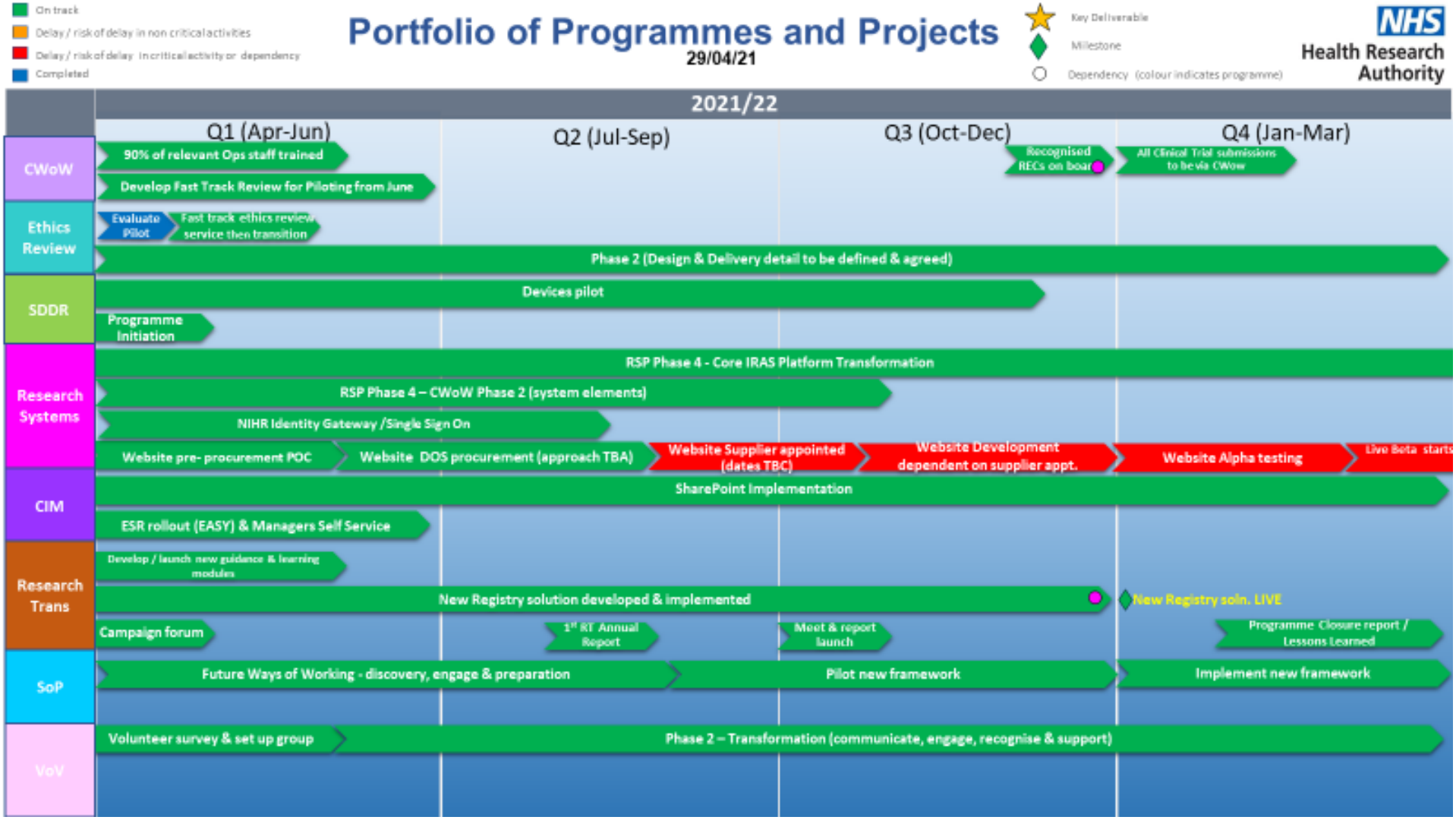
Title: Supporting our People
Summary: The purpose of the programme is for the HRA to become an inclusive and attractive organisation for staff and potential employees that lives its values, supports and empowers staff to make their best contributions, and in doing so enables the HRA to achieve its strategic aims. Our programme builds on the success of the organisation to date and aims to take it further forward and enhance this position to further meet this vision.

Key deliverables/milestones 2021/22	Date
1. Future ways of working	Pilot Nov – Jan 21
2. ED&I strategy implementation	3-year implementation to Mar 24
3. People Strategy	Mar 22

Title: Valuing our Volunteers
Summary: The Valuing our volunteers programme aims to help volunteers feel more valued, supported and part of the HRA. Some aspects of volunteer experience are being addressed through improvements to technology and documentation (Research Systems Programme) or a reduction in the 'ask' of REC members (Research Review Programme). Others need to be taken forward as part of core service delivery, based on recommendations from the Valuing our volunteers programme.

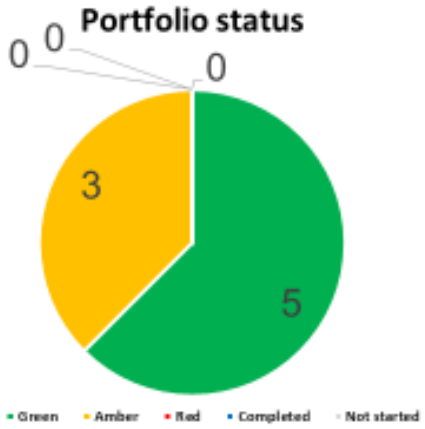
Key deliverables/milestones 2021/22	Date
Setting up a volunteers' group	Jun 21
implementing changes that act on findings from the volunteers' survey	Mar 22

Annex A - HRA Change Management


On track
Delay / risk of delay in non critical activities
Delay / risk of delay in critical activity or dependency
Completed
Portfolio of Programmes and Projects
29/04/21
Key Deliverable
Milestone
Dependency (colour indicates programme)
NHS
Health Research Authority
2021/22
Q1 (Apr-Jun)
Q2 (Jul-Sep)
Q3 (Oct-Dec)
Q4 (Jan-Mar)
CWoW
90% of relevant Ops staff trained
Develop Fast Track Review for Piloting from June
Recognised RECs on board
All Clinical Trial submissions to be via CWow
Ethics Review
Evaluate Pilot
Fast track ethics review service then transition
Phase 2 (Design & Delivery detail to be defined & agreed)
SDDR
Devices pilot
Programme Initiation
Research Systems
RSP Phase 4 - Core IRAS Platform Transformation
RSP Phase 4 – CWoW Phase 2 (system elements)
NIHR Identity Gateway /Single Sign On
Website pre- procurement POC
Website DOS procurement (approach TBA)
Website Supplier appointed (dates TBC)
Website Development dependent on supplier appt.
Website Alpha testing
Live Beta starts
CIM
SharePoint Implementation
ESR rollout (EASY) & Managers Self Service
Research Trans
Develop / launch new guidance & learning modules
New Registry solution developed & implemented
New Registry soln. LIVE
Campaign forum
1st RT Annual Report
Meet & report launch
Programme Closure report / Lessons Learned
SoP
Future Ways of Working - discovery, engage & preparation
Pilot new framework
Implement new framework
VoV
Volunteer survey & set up group
Phase 2 – Transformation (communicate, engage, recognise & support)

Title: HRA Portfolio	Overall Status	↔	Period: Apr 2021	Date: 21/4/2021	Author: C McCarthy

Portfolio status



Category status

Cost ↔	Time ↔
Risks ↔	Benefits ↔

Commentary

Significant headlines

- Ethics Review Programme – Fast Track Ethics Review Pilot complete and Post Pilot Service Commenced.
- Research Systems Programme – several roles recruited including Senior Enterprise Architect. Recruitment continuing for other roles with a DOS procurement underway for additional resourcing.
- Supporting our People – Future Ways of Working – planning underway.
- Streamlining Data Driven Research - Initial discovery launch session with external stakeholders completed.
- Research Transparency - All guidance on webpages and IRAS now updated and live.
- Valuing our Volunteers – Volunteer survey completed and BMG report of results received.
- Corporate Information Management – Recruitment underway for Programme Manager.

Forward look

- Research Review Advisory Group Initial Meeting.
- Research Systems Programme - Coforge contract drafted and signed and New IRAS website development best approach confirmed.
- Supporting our People – L&D Mental Health for Line Mangers pilot complete.
- Research Transparency - Planning for the first RT annual conference and publication of the first RT annual report.
- Streamlining Data Driven Research – Benefits workshops planned.

Benefit realisation

- Programme Manager for Benefits realisation in post.
- Ethics Review, SDDR and updates for Research Systems Programmes benefits will be presented at May PDG.
- Processes being developed for the on-going tracking and reporting of benefits realisation.

CODE	NAME	PM	SRO	BCM	STRATEGIC OBJECTIVE	FINISH DATE	COST	TIME	RISKS	BENEFITS	OVERALL RAG
P098	Ethics Review Programme	MB	JT	AT/AZ/KE	1	31/03/22	£318k				
P010	CWoW	GH	JM	CB	2	31/03/22	£382k				
X00602	Research Systems Programme	IA	KWe	MC	1/2/3	31/03/23	£7,252k				
P091	Supporting Our People	SM	KG	ME/JT	3	31/03/22	£99k				
P092	Streamlining Data Driven Research	CD	JT	EB	2	30/09/22	£2,256k				
P094	Research Transparency Implementation	CL	JT	NY	1/2	31/03/22	£323k				
P096	Valuing Our Volunteers	SM	JT	LB	1/2	31/03/22	£81k				
P049	Corporate Information Management	NU	KW	ST	3	31/03/21	£55k				