NHS
Health Research Authority

Health Research Authority Business Plan 2014 / 15

Author: S. Robinson Date of Release: 07/05/2014
Version No. & Status: 1.2 Final Owner: J. Wisely Approved by: HRA Board
Supersedes Version: 0.9 Review Date: Jan 2015

Contents

1.0 The HRA: Making a Difference

The Health Research Authority (HRA) is a Special Health Authority established on 1 December 2011. Its purpose is to protect and promote the interests of patients and the public in health research. We do this by supporting and promoting a robust and efficient regulatory and governance framework in the UK.

Our vision and ambition is to develop a Health Research Authority:

- driven by our key purpose of protecting and promoting the interests of patients and the public in health research;
- underpinned by our leadership in creating a streamlined and efficient framework for the approval and management of research; and
- with success acknowledged by key stakeholders, as well as seen through improved approval times, increased numbers of research participants, and greater confidence in health research.

We will work with all the relevant partners to help create an environment where:

- greater numbers of patients and the public can and do take part in health research, and continue to feel safe when they do;
- applying to do research is simpler, and getting a decision is quicker and more predictable;
- researchers find it easier to do high-quality, ethical research;
- commissioners and providers in the NHS appreciate how health research benefits patients and staff;
- industry sees the UK as a great place to do health research;
- more money from charities and other research funders goes into carrying out research, and less into getting through unnecessary hoops before it starts; and
- clinical trials get registered and research results get published.

2.0 Our Strategic Objectives

2.1 Strategic Direction

Our overall strategic goal is to make the UK a global leader for health research.

We will work with a wide range of partners to help create an environment where more money invested in research goes into carrying out relevant, good quality research that is registered and published. To achieve this we will deliver the following strategic aims:

- Leading improvements that make it easier to conduct good quality research in the UK
- Improving efficiency and effectiveness of systems, and of advice and guidance
- Building and consolidating productive relationships with public and professional stakeholders
- Having a skilled, dedicated and motivated workforce and HRA volunteer ethics committee members
- Ensuring the HRA is managed and governed effectively, and provides value for money to the tax payer

We will help increase public participation in research by continuing to ensure it is explained well, conducted safely, and to appropriate ethical standards including registration and publication of trial results.

We have committed to a range of actions to improve transparency in health research. We require that clinical trials are registered as a condition of a favourable ethical opinion and we publish the summary and ethical opinion of health research approved by the HRA in England. The HRA recognises that transparency of research is essential so that participants and patients are protected from unnecessary research and patients benefit from improved outcomes and care informed by high quality research.

We will aim to make the approval and management of health research even simpler and more efficient to help attract global research to the UK. This, in turn, will help speed up the adoption of proven new treatments.

We will reduce bureaucracy within the framework for the approval and management of research in the UK to ensure a greater proportion of research funds are used for direct research purposes to inform improvements to patient treatments and care.

2.2 How We Do This

Streamlining Research

We have a set out an ambitious programme of work to improve the framework and processes for the approval and management of health research in the NHS. Many of the projects involve collaboration with partners, and some are led by them. We work closely with other bodies, including the NIHR (National Institute for Health Research) and MHRA (Medicines and Healthcare products Regulatory Agency), to provide proportionate and effective processes for approving research and with colleagues in the Devolved Administrations to provide a UK-wide system for research. We also promote proportionate standards within a consistent national system of research governance. Regular updates on progress are available on our website and newsletter.

Transparency

Our plans to promote transparency in research will provide important reassurances to the public, and are part of our duty to support good quality, ethical research. These include the registration of clinical trials as a formal condition of Research Ethics Committee (REC) approval (from September 2013), working with partners to understand what is meant by publication and reporting, and developing standards for publication to ensure findings are available for participants, patients and the public, researchers, clinicians and commissioners of health care.

We publish a summary and the ethical opinion of every health research project conducted in England that requires HRA ethical approval. However, for the final quarter of 2013/14, publication has been deferred until the go live of HARP.

Given the overwhelming support for our transparency agenda, we expect that the vast majority of researchers, sponsors and funders will embrace the plans. In implementing our plans we have been mindful of our ambition to make it easier to do good quality research in the UK and have set out sensible and proportionate measures to increase transparency and increase confidence in UK-based research.

Protecting the interests of the Public

The HRA has responsibility for the 69 NHS Research Ethics Committees (RECs) in England, and works with colleagues in the Devolved Administrations to provide a UK-wide service working to HRA Standard Operating Procedures (SOPs). RECs meet regularly to consider UK-wide applications for new research projects each year. The HRA is also responsible for the Gene Therapy Advisory Committee (GTAC), which reviews gene and stem cell therapy clinical trial applications from an ethical perspective.

The HRA, through its independent Confidentiality Advisory Group (CAG), provides advice about appropriate use of confidential patient information without consent in the NHS for research, and for other purposes, such as commissioning. The HRA is responsible for approving access in research and for advising the Secretary of State for purposes outside of research.

As well as protecting the public interest through our system of RECs and the CAG, the HRA now oversees TOPS (The Over-Volunteering Prevention System), to prevent healthy volunteers from taking part too often in trials of new medicines.

Working with Devolved Administrations

Whilst the HRA's remit covers England, we work closely with the devolved administrations in Scotland, Wales and Northern Ireland to provide a UK-wide ethics service and support UK-wide compatibility for the governance and management of research.

The HRA provides the Integrated Research Application System (IRAS) on behalf of partners, including the devolved administrations.

2.3 Our Business Plan 2014 /5

The objectives and goals contained in this Business Plan provide the detail of actions we will be undertaking in the forthcoming year to support the delivery of these strategic objectives and build on the considerable progress made since the HRA was established in 2011, which in turn built on the widely recognised improvement to the management of research ethics delivered through the National Research Ethics Service.

The HRA Business Planning process started in September 2013 when appraisals for all staff were completed. An instrumental part of this process was objective setting for each individual for the forthcoming year based upon each Director's and Senior Manager's understanding of the goals and objectives they would be required to achieve during 2014/15. In this way, a clear understanding of the resources and capacity required to achieve objectives was obtained. These plans are therefore built upon the clear understanding that resources are or will be (as is the case with the HRA Assessment and Approval Business Case) available.

3.0 Governance

The Health Research Authority, as a Special Health Authority, is an Arm's Length Body (ALB) of the Department of Health (DH), which operates within a framework agreement with DH and is governed by a Statutory Instrument. The HRA lays its Annual Report and Accounts before Parliament, and robust public and Parliamentary accountability

arrangements are in place between the DH and the HRA to ensure good communication and effective collaborative working between the two organisations. Monthly sponsorship and accountability meetings are held which provide a mechanism for the DH to assure itself of the HRA's delivery of its objectives.

The DH is consulting on legislation within the Care and Support Bill, which will establish the HRA as a Non-Departmental Public Body (NDPB) during 2014. NDPBs are more or less self-determining and enjoy greater independence. They are not directly part of government like a non-ministerial government department, being at a remove from both ministers and any elected assembly or parliament. Typically an NDPB would be established under statute and be accountable to Parliament rather than to Her Majesty's Government. This arrangement allows more financial independence since the government is obliged to provide funding to meet statutory obligations.

The HRA is governed by a Board that functions as a corporate decision-making body. The Board is composed of four non-executive directors (including the Chair) and two executive directors (including the Chief Executive). Four further directors attend the Board:

Chair	Professor Jonathan Montgomery
Non-Executive Directors	Sally Cheshire, Dr Allison Jeynes-Ellis, Julie Stone
Chief Executive	Dr Janet Wisely
Executive Director	Dr Shaun Griffin
Director	Debbie Corrigan
Director	Joan Kirkbride
Director	Tom Smith
Director	Ian Cook

The HRA is committed to openness and transparency with Board meetings held in public and Board papers and minutes available on the HRA website. A copy of the HRA's senior management organisational structure is provided at **Appendix 1**.

The HRA Board has established an Audit and Risk Management Committee, which meets quarterly to scrutinise audit services, risk management policy and activity, the annual governance statement, statutory annual accounts and corporate governance arrangements, providing assurance to the Board that the HRA is meeting its statutory and regulatory requirements.

To ensure the organisation operates to the highest standards of information governance, Dr. Hugh Davies, HRA Ethics Advisor, is the Caldicott Guardian and Stephen Robinson (HRA Corporate Secretary) is the board-level Senior Information Risk Owner (SIRO).

The HRA has an engagement strategy that includes a staff partnership forum and established formal feedback routes for the users of our services. The HRA has commissioned specific projects for patient and public involvement that inform the HRA public and patient involvement strategy.

The HRA is responsible for a budget of £13.6M and currently has 134 full time equivalent (fte) staff based in London, at the HRA office at Skipton House, and four offices in Bristol, Jarrow, Manchester and Nottingham.

An invaluable contribution to the HRA is made by the 1,000 committee members who voluntarily serve on the 69 national Research Ethics Committees (RECs) and the National Research Ethics Advisors' Panel (NREAP) and the 17 members of the Confidentiality Advisory Group (CAG) and who give their time freely to provide robust and independent ethical review of research proposals and advice to the HRA, research

funders, research sponsors and those responsible for managing and conducting research in the UK .

4.0 Functions

HRA's Senior Executive team have the day-to-day responsibility of managing the organisation and have specific executive responsibilities to deliver both strategic, operational and tactical objectives and functional, statutory or mandatory requirements. They are accountable, primarily through the Chief Executive, to the Board for delivery.

The HRA's Executive Management Team (EMT) comprises two executive Directors (Chief Executive and Director of Communications, Engagement and Partnerships) and four non-voting Directors namely Director of Operations, Director of Finance, Director of Business Support and Director of Quality, Standards and Information.

Each member is assigned functional responsibilities as detailed in the tables below and is responsible for developing and delivering objectives within these functional responsibilities. They are then accountable for delivery, cascading objectives to staff as appropriate and holding them to account through normal line management means.

Operations		**Finance**	**Communications, Engagement & Partnerships**
REC Operations	**Confidentiality Advice**		
Joan Kirkbride; Director of Operations		Debbie Corrigan; Director of Finance	Shaun Griffin; Director of Communications, Engagement & Partnership
Research Ethics Committees (REC) support. REC: Improvement & Quality REC Standing Operating Procedures The Over Volunteering Prevention System (TOPs) management	S251 including Confidentiality Advice Group (CAG) support CAG: Improvement & Quality CAG Standing Operating Procedures Appointing authority CAG	Financial governance incl. Standing Financial Instructions and scheme of financial delegations Financial management information Financial accounts and statutory annual accounts Budget setting and monitoring Payroll Capital planning	Strategic planning Internal communications External communications incl. Public Relations Branding Key external events Parliamentary questions Website management Partnership development Advice and Guidance

		Internal audit Estates Counter Fraud	
Business Support		**Quality, Standards & Information**	
Ian Cook; Director of Business Support		Tom Smith; Director of Quality, Standards and Information	
Human Resources (recruitment, retention, Terms & Conditions, transactions, advice, Occupational Health) Contracting & Procurement Shared Services Public and Patient Involvement Training & Development Business Support Business Intelligence Technical IT Support Travel (incl. booking)		Quality assurance Quality audit Quality improvement ISO 9001 Information Technology (The Open Service IT Platform, Video Conferencing, Infrastructure) Systems / applications maintenance support Strategic IT development Integrated Research Applications System (IRAS) and Research Ethics Database (RED) management IRAS and RED re-development HRA queries line Transparency	

In addition to the functional responsibilities that have been allocated to Directors, other key functions have been allocated as follows:

Collaboration & Development	Corporate
Janet Messer; Associate Director Collaboration & Development	Stephen Robinson; Corporate Secretary
Collaboration & Development (C&D) programme management C&D project management HRA Assessment and Approval proposals	Business planning Organisational development Board support Corporate and Information Governance Risk management Standing Orders / Scheme of Delegation Health & Safety, Business Continuity Planning, Equality & Diversity

	Freedom of Information / Complaints REC Projects (e.g. EOP) Non-Departmental Public Body transition Appointing authority RECs, CAG and NREAP

5.0 Highlights of 2013/14

Collaboration & Development Programme

The collaboration and development programme was fully initiated at the beginning of the financial year, with a number of new fixed-term posts working on a range of projects. The team was all seconded part-time alongside roles in a variety of organisations across the country. This allowed the team to bring knowledge and experience from their own settings and to explore and test proposals with their local communities and organisations. During the course of the year the team achieved significant progress, laying the ground for future developments and providing a comprehensive business case for HRA Assessment and Approval. The business case was submitted to the Department of Health on schedule in October 2013 and subsequently approved to fund the work outlined in this business and the HRA is developing detailed plans within the provided funding envelop to deliver the strategic and business planning objectives set out in this plan

- A feasibility study for a new system to simplify the research approvals system was completed. Opportunities for improved integration and interaction by research partners were identified and communicated.
- Systems for simplifying assessments for pharmacy, radiation and contracting for research studies were designed.
- Situations where poor or inconsistent quality concerns create waste or consume excessive resources were identified, and proposals were tested.
- A multi-agency steering group provided a forum for partners to contribute and share their own initiatives.

Research Ethics Committee Operation

The HRA has 69 RECs and has continued to deliver an excellent service to researchers. Following the closure of the two offices in Cambridge and Leeds in early 2013, the transition of the administrative support for the committees was implemented successfully with no disruption to service. The timelines have continued to improve and the performance within statutory timelines is excellent with good efforts being made to achieve the stretched targets. Those efforts will continue in 2014. The number of applications reviewed by full committee was 3760 in England and proportionate review applications (low risk applications through sub-committee) 1253 across the UK. The total number of applications submitted to the UK service showed the smallest percentage reduction since 2004 when SOPs were introduced in the UK. .

The type of applications which can be processed through the proportionate review service was widened and the service was enhanced with the introduction of a single national booking line which helped researchers to have their applications reviewed more quickly and again compliance with the 14 day review timeline was excellent with many applications being reviewed in less than 10 days. Applications through full committee continue to be reviewed well within the statutory 60 day target and progress has been made on the stretched target of 95% of applications reviewed within 40 days.

The quality control checking system for RECs has been refined and improved. The number of RECs going through the 3-year audit process successfully at first review has increased and where action plans have been developed compliance with submission has been 100%.

Improvements in the review of Phase 1 (Early trials with Healthy Volunteers) applications have been made including: the ability for the REC reviewing the application being able to review local site suitability through Site Specific Assessments which removed the need for a separate application for the site; a submission deadline of 7 days before the REC meeting; the establishment of a Phase 1 advertising (material used to identify healthy volunteers for studies) review system to ensure consistent and appropriate standards in the UK.

All applications reviewed through the new Gene Therapy Advisory Committee have been reviewed within the timeline targets, which represents a considerable reduction on previous timelines.

Confidentiality Advisory Group

CAG is an expert advisory group appointed by the HRA. CAG members are appointed by the HRA to provide expert and independent advice to the HRA on access to confidential patient information for medical research purposes under section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 in line with the Health Research Authority Directions 2013. This includes providing advice in relation to regulations 2, 3 (4) and 5, in line with regulation 7.

The HRA successfully recruited to and has firmly established the CAG as an independent advisory group in April 2013 when the responsibilities transferred to the HRA. A key achievement this year has been the maintenance of consistent provision of advice in a changing information landscape. The CAG has provided detailed scrutiny and robust advice against research and non-research applications, and has supported complex applications while maintaining its credibility and independence. All CAG advice and approval decisions continue to be made publicly available on the HRA website and it has strongly supported the moves towards transparency through its advice recommendations.

Well-attended stakeholder events were held at the time of CAG establishment that sought views to inform future development. Active links have been made with key stakeholders and new national bodies to encourage early consideration and collaborative working to help ensure sufficiently robust applications are submitted for consideration.

The advice team supporting the CAG were also effectively transitioned in the HRA with no loss of service throughout this time. The placement of CAG in the HRA has enabled greater integration of processes between the CAG and RECs so that a more streamlined service can be delivered, and SOPs have been developed to standardise the process of integration and application handling. The pre-assessment service has been developed and standardised, and an improvement plan is now in place to deliver anticipated improvements to processing timescales. Applicant feedback is now actively sought to help inform future streamlining of processes and development of priorities for the forthcoming year.

Quality Assurance

Quality Assurance achievements within the HRA include:

- The completion, on schedule, of the second three year cycle of REC accreditation audits and audits of REC Centres was achieved. The third cycle commenced in September 2013;

- The revision of the Quality Control checklist was undertaken to streamline the system, provide greater emphasis on the RECs end product – minutes and letters and to make better use of the available management information data. This is currently being piloted until March 2014 when the results of the pilot will be analysed and further modification to the checklist considered;
- Working together with NRES Operational colleagues to produce a timely analysis of appeals and increased the sampling of the targeted feedback from applicants as from January 2014. Moving forward into 2014/15 looking to revised and tailor the questions put to applicants in order to increase both levels of feedback and its effectiveness to the management teams;
- Retaining ISO9001 certification for the HRA QA department with no findings and starting the scoping work to extend certification to the whole of the HRA;
- Undertaking internal audits for NRES operations on the use of favourable with conditions and targeted audits on compliance with the RED dataset for a selected number of RECs;
- Carrying out a gap analysis on CAG, which joined the HRA in year;
- Working with the HRA Director of Operations and HRA Ethics Guidance & Strategy Manager revised the Shared ethical debate process in addressing feedback from REC Chairs and members on the shortfalls of the process. The pilot, which commenced in September 2013 and being run over 2 exercises, has three key aims: - identifying / building consensus on an issue (and the need for possible guidance to applicants and REC members), identifying issues in REC process (i.e. problems re: minutes, process) and identifying training needs for REC Chairs and members. The pilot is due to complete in May 2014; and
- Training on QC and accreditation has been completed at all five REC Centres.

Transparency

In terms of the HRA's Transparency agenda, 2013/14 saw a significant gain of approval and support when from the end of September 2013 the registration of clinical trials in a publicly accessible database became a condition of the favourable ethical opinion. For all REC approvals of clinical trials moving forwards, failure to register will therefore be a breach of good research practice. Towards the end of the year, the HRA actively sought feedback on the barriers to registration of clinical trials, so that this might be advanced in the coming year with Trial Registries. In addition, work was undertaken with the medical devices sector to work through moving timelines for all registrations similarly.

The HRA has also been working closely with key stakeholders on related areas of the Transparency-related agenda where they are leading, such as ABPI and the Institute of Medicine Study / Wellcome Trust on responsible sharing of Clinical Trial Data. In addition, the HRA is leading the agenda on 'What we mean by Publication?' culminating in a workshop with stakeholders in March, where the interim results of the HRA audit on publication were shared.

Advice and Guidance

The HRA has a programme of work to provide further guidance and support and to improve accessibility in new user-friendly formats, such as online decision tools and developing a web-based version of our consent guidance. Information on the website is arranged according to the stage in the research life cycle and includes improved signposting to other sources of information.

EU CT Regulation / Working in Partnership

The text for the European Clinical Trials Regulation, which will replace the current EU Clinical Trials Directive, was agreed by the permanent representatives in each member state in December 2013. The HRA worked closely with the MHRA throughout the negotiations and we are satisfied with the position negotiated. The HRA proposals for

Approval and Assessment are compatible with the requirements of the regulations, and early implementation of these proposals will give a competitive advantage to the UK in being ready to implement the new regulations.

The Over Volunteering Prevention System (TOPs)

The HRA has assumed responsibility for the above service and mandated its use as part of a favourable ethical opinion. TOPs is a database which records the details of healthy volunteers who wish to participate in Phase 1 trials and is one of a range of measures to ensure their safety by reducing the ability to over-volunteer. The transfer to the HRA has enabled the system to be implemented UK-wide and its use is also a requirement for the MHRA accreditation of Phase 1 research sites.

Communications

During 2013/14, the HRA developed and launched a new website, restructured to help users find the information they need more readily, and is now compatible with mobile devices.

We have refined and developed the bi-monthly newsletter, and have built a database of over 1500 subscribers. The HRA has also launched on Twitter.

Media highlights have included an interview with Janet Wisely on BBC Radio 5 Live, articles in the national press and frequent coverage in specialist journals.

Improvements have been made to internal communications, in line with feedback from our staff survey, and we have made HRA News a regular weekly newsletter for staff and are in the process of using the new videoconferencing equipment to deliver frequent, direct, two-way communications with staff.

Corporate

To ensure that the HRA's management structure reflected the developing business and operational needs of the organisation, comprehensive reviews of both the Executive Management Structure and Executive Committees were undertaken resulting in refinements that have improved decision-making processes and accountability. In conjunction with this, risk management, objective setting and performance management process continue to evolve and improve. Further, internal audits on Health & Safety, Business Continuity and Information Governance concluded that the HRA is operating to a high standard.

6.0 The Government's Planning Priorities

6.1 The Government's Priorities

The HRA strategic objectives and operational plans are firmly aligned to the Government priorities for clinical research as set out in the NHS Constitution, Plan for Growth and supported again through Select Committee recommendations last year for regenerative medicine and clinical trials in the UK. The Government has set some clear priorities (see below) for delivery by the health and care system so all Health, Health-Related and Social Care bodies need to consider how their work contributes to the joint delivery of these priorities to ensure the system is aligned, consistent and works effectively through collaboration.

From the Department of Health's perspective, this year the business planning process will be aligned across its ALBs to ensure they focus on the Government's strategic objectives and fulfil the role envisaged for them by Parliament. The Department will therefore be looking to ensure that the objectives set out in the HRA Business Plan 2014/15 take into account these key priorities and further integrate these into its Corporate Plan.

Set out below is the HRA's contribution to these Government's Priorities:

6.2 HRA Alignment with the Government's Priorities

Priority One

Preventing people from dying prematurely by improving mortality rates for the big killer diseases to be the best in Europe, through improving prevention, diagnosis and treatment

The HRA's Contribution: Building upon the substantial progress already made, working to improve and streamline the systems and processes to support and improve confidence in good quality research, the HRA will actively facilitate an improvement in the speed with which research is approved and delivered to improve the understanding of disease and the development of effective treatments that will improve patient care and mortality rates. For example, a specific HRA Business Case for Assessment & Approval seeks to align the approval processes with NHS Research & Development Departments therefore minimising bureaucracy for researchers, improving the quality of research and reducing the time taken for research to be approved and delivered within the NHS. This will also include an evaluation of the success of the measures taken to not only ensure aspirations are being met but to continually improve the systems and processes.

Priority Two

Improving the standard of care throughout the system so that quality of care is considered as important as quality of treatment, through more accountability, better training, tougher inspections and more attention paid to what patients say

The HRA's Contribution: Examination of effective standards of care is an important part of the health research portfolio. By continuing to work with UK-wide partners across the research pathway to:

- Simplify processes associated with research regulation and management;
- Continue developing and disseminating agreed standards and standardised systems to support good quality research; and
- Reduce duplication and improve efficiency for sites, sponsors and regulators,

The HRA will continue to have an important and significant impact on improving standards of care. As evidence suggests that those health care organisations that are actively engaged in research have better patient outcomes than those that do not, reducing barriers to research will undoubtedly improve the quality of care. The HRA Business Case for Assessment and Approval will provide a service of significant value for the NHS releasing resources locally for direct patient care.

Priority Three

Improving treatment and care of people with dementia to be among the best in Europe through early diagnosis, better research and better support

The HRA's Contribution: The causal link to the HRA's involvement is more direct as the priority recognises that better research will improve the treatment and care of people with dementia. As well as improving systems and processes, an important part of the HRA's plans is to have an impact on the quality and relevance of research by supporting

researchers throughout the application process with enhanced and comprehensive advice and guidance so they are better able to develop robust research proposals that can meet the required criteria. Further, by pursuing an agenda of patient and public involvement and transparency in research, quality and relevance will be improved through patient involvement and availability of evidence from previously conducted trials, a critical factor that has been proven to have concrete results in other arenas.

Priority Four

Bringing the technology revolution to the NHS to help people, especially those with long term conditions, manage their health and care

The HRA's Contribution: The HRA has and continues to use technology to full advantage within the HRA remit for health research. The Integrated Research Application System (IRAS) first introduced in 2008 will be upgraded to ensure that the means by which researchers make applications takes full advantage of recent technological advances. Whilst this does not interface directly with patients, it will help improve research systems and processes which, as pointed out above, will have a direct impact on the NHS and the care it provides, especially to those with long term conditions. The HRA also recognises the potential of technology in identifying patients for research and will actively supportive initiatives by gathering evidence of effective and efficient recruitment and providing guidance to researchers and those required to approve new techniques.

Priority Five

Improving care for vulnerable older people, focusing on the role of primary care in providing integrated out of hospital care, but also looking at what can be done to improve urgent and emergency care

The HRA's Contribution: In this instance, the HRA's contribution to Priorities One, Two and Three will by default, have an effective contribution to this priority. The HRA has also recognised the potential of making research more accessible through primary care and is targeting initiatives to improve the accessibility of patients in primary care for research.

Priority Six

Demonstrating real and meaningful progress towards achieving true 'parity of esteem' between mental and physical health by March 2015

The HRA's Contribution: Underpinning the achievement of 'parity of esteem' is the understanding of mental health. Knowledge of mental health has improved significantly in both the clinical and public arenas in recent years and undoubtedly research has had a dramatic impact in supporting this improvement. All the work the HRA is planning to do to improve and streamlining systems and processes, underpinned by the delivery of continually improving, quality services that support and improve confidence in good quality relevant research can only help improve this situation further.

The HRA's support for biomedical research, including that involving the study of brains from the deceased, contributes to the priority of making improvements for those with dementia or who are likely to develop dementia. We continue to ensure that researchers using the 200 Human Tissue Authority-licensed tissue banks benefit from a streamlined process where Research Ethics Committees give generic approval for tissue collection, storage and release arrangements. Further, the training the HRA provides committee members on mental capacity to improve understanding and support to researchers is an example of the good practice the HRA pursues.

Priority Seven (DH)

Improving productivity and long term sustainability and ensuring value for money for the taxpayer

The HRA's Contribution: In keeping with previous years, the HRA will ensure that it remains within agreed revenue and capital cash and resource limits and ensure that budgets are managed throughout the organisation. Further, it will also continue to ensure that savings targets are identified year on year to help finance the delivery of key planning priorities, to maintain focus on efficiency and value for money, and to offset any emerging cost pressures. Finally, it will critically review key areas of service delivery in order to generate efficiencies / more for less such as:

- ensuring the HRA secures 'Best Value' in any shared service arrangements; and
- reviewing the estates footprint to maximise productivity and value for money.

Priority Eight (DH)

Contributing to economic growth

The HRA's Contribution: By continuing to be at the forefront of leading improvements that make it easier to conduct good quality research in the UK through and by:

- working with our partners and others to gather evidence and promote the UK as a great place to do health research;
- working with UK-wide partners across the research pathway to streamline and simplify processes associated with research regulation and management;
- developing and disseminating agreed standards and standardised systems to support good quality research, reduce duplication and improve efficiency for sites, sponsors and regulators;
- developing the role of the HRA with its partners to support the spread of public involvement in health research to ensure that research is relevant to patient priorities;
- promoting research transparency, taking proportionate and pragmatic measures to improve and measure transparency in the UK and to increase public confidence in health research and to ensure that research is not duplicated;
- Utilising modern technologies such as the Integrated Research Application System (IRAS) to streamline application and approval processes for researchers that makes the UK a more attractive place to conduct research; and
- delivering quality services and pursuing continual improvements,

As a result of these, the UK will continue be a growing major international centre for conducting health-related research and therefore be able to attract significant additional investment thus contributing to economic growth.

Priority Nine (DH)

Implementing social care reform

The HRA's Contribution: The HRA will have additional responsibilities for research in adult social care as it becomes a Non-Departmental Public Body, subject to legislation expected late 2014. This will see the HRA take responsibility for the National Social Care Research Ethics Committee and enable the HRA to look at the interfaces for research across the health and social care settings. Although not a direct part of the social care reforms, the greater integration and streamlining of research across the health and social care settings will be important and have the potential to provide greater opportunity for more patients to have access to research by including outcomes across the social care spectrum.

Priority Ten (DH)

Developing the resilience of DH and the wider health and care system by:

i. Focusing on improved delivery and performance
The HRA's Contribution: The HRA intends to produce timely, accurate and relevant Management Information for a range of 'audiences' including the Department of Health Sponsors, its Board and wider stakeholders and the public to demonstrate its performance and effectiveness in key national, organisational, operational and corporate activities.

ii. Working together to build a sense of common purpose
The HRA's Contribution: The HRA plans to develop and implement a comprehensive stakeholder engagement plan that ensures broad government and stakeholder support for the HRA's agenda and work with others to gather evidence and promote the UK as a great place to do health research. It also contributes to resilience by working in collaboration with the Department and its ALBs and other partners to embed incident response and business continuity planning to facilitate speedy and efficient disaster recovery, particularly during significant system-wide and organisational change programmes.

7.0 Aiming High for 2014/15

The HRA's planning priorities for 2014/15 are:

A. Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research *(Systems & Process Improvement)*;
B. Delivering Quality Services and Pursuing Continual Improvement *(Delivery and Quality Assurance of Existing Services)*;
C. Leading in Partnership;
D. Strengthening Organisational Capability, being Efficient and Effective; and
E. Delivering Best Value.

A. Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research

Collaboration and Development Projects

A UK-wide Collaboration and Development group of stakeholders has been established to oversee the scoping, development and implementation of projects where the HRA will provide a platform for a wide range of organisations to work collectively together to deliver change within the research environment.

Our goals are to:

- continue working with UK-wide partners across the research pathway to streamline and simplify processes associated with research regulation and management;
- continue developing and disseminating agreed standards and standardised systems to support good quality ethical research, reduce duplication and improve efficiency for sites, sponsors and regulators; and
- evaluate the success of the measures taken to support good quality ethical research in improving confidence in UK health research.

We will seek to achieve this by:

- supporting implementation of a UK-wide process for protocol amendments;
- supporting funders in identifying opportunities to improve the ability of others to rely on relevant assurances about funding and peer review;
- developing, testing and implementing templates and guidance on protocols for different study types to allow sponsors and researchers to reduce the number of questions that need to be completed in IRAS;
- collaborating with others in agreeing data standards for information shared across the research life cycle e.g. study identifiers and titles;
- refining and implementing guidance on sponsor responsibilities following consultation;
- assessing and considering options for implementation of standards for competency of researchers; and
- identifying opportunities to reduce duplication relating to progress reporting for researchers.

So that:

we support the improvement of the quality of research sponsorship and management of research and deliver further improvements within the approvals pathway that deliver efficiencies for researchers and reviewers.

HRA Streamlining of Assessment and Approval

The HRA Assessment and Approval will provide a single system for all studies in England, replacing the current separate systems for ethical review and NHS permissions with an integrated process and single approval that provides assurance to organisations hosting research. This will significantly reduce the complexity of the approvals process for academic and industry research.

Our goal is to:

- complete the detailed planning and implement HRA Assessment and Approval in line with the business case submitted to streamline the assessment and approval of research in the NHS through greater coordination and efficiency across those with established roles including NIHR CRN and local Trust R&D Departments.

Which we will seek to achieve by:

- coordinating detailed planning, in collaboration with relevant stakeholders where appropriate;
- undertaking recruitment of required resources in accordance with plans;
- implementing change management, communication and engagement plans;
- planning, developing and implementing the necessary Information Systems (including HARP and IRAS) to support the different stages of implementation, ensuring relevant interfaces with partner systems are maintained; and
- implementing new functions, processes, tools and guidance in accordance with phased plan.

So that:

we remove unnecessary duplication and delay within the approvals pathway in the UK, so that timelines are improved and more predictable.

Research Support and Governance Policy

Our goals are to:

- develop a new UK wide policy for health and social care in the UK; and
- develop guidance, advice, tools and training to implement the new policy framework.

Which we will seek to achieve by:

- considering and consulting on principles to underpin the revision of the policy framework, including assessment of risks of research and risks to the successful delivery of research in the UK;
- working in collaboration with the Devolved Administrations to ensure UK-wide application of the policy, which identifies where the policy can be aligned and explains and manages where legislation or local requirements requires different but coordinated approaches; and
- drafting and issuing for consultation the revised policy framework to support research in the NHS, as the HRA becomes a NDPB.

So that:

the UK has a policy framework that is proportionate and reflective of the risks in research, so as to provide a framework that supports good quality research in the UK and facilitates the NHS achieving the ambition in the NHS constitution to have all patients provided with the opportunity to participate in research.

Integrated Research Application System (IRAS)

IRAS (Integrated Research Application System) is a web-based application system through which researchers can input their information relating to their research projects only once so that multiple applications for approvals to the various regulatory bodies and IRAS partners can be submitted.

Our goals are to:

- ensure IRAS's continued availability for HRA and Partners; and
- secure the development of a replacement system.

Which we will seek to achieve by:

- undertaking regular meetings with IRAS Partners to address key issues and maintain Risk Register; and
- delivering, on behalf of IRAS Partners, a replacement to agreed timetable (dependent on procurement options) during 2015/16.

So that:

IRAS (or the replacement application system) continues to be provided 24-7 and meets the needs of researchers and the IRAS partners by creating an environment where applying to do research is simpler and makes the UK a more attractive place to do research.

HRA Assessment Review Portal (HARP)

The Research Ethics Database (RED) is a database application delivered through a password protected web interface. It is designed to support the management and administration of the research ethics review by a Research Ethics Committee (REC) within the UK Health Departments Research Ethics Service. The database also supports committee management and contains details about REC members. Throughout the year, work has been undertaken to replace the system with an updated improved system called the HRA Assessment Review Portal (HARP).

Our goal is to:

- ensure a successful Research Ethics Database (RED) to HARP migration and subsequently to ensure continued availability for HRA and Devolved Administrations.

Which we will seek to achieve by:

- overseeing successful HARP go-live in 2014/15; and
- working with colleagues at NIHR CRN to provide coordinated IS systems in England, and with colleagues in the Devolved Administrations to maintain UK-wide compatibility.

So that:

the database system is available 24-7 and meets the operational requirements UK-wide.

Research Transparency

The HRA has a role to promote transparency in health research, and has already taken active pragmatic and proportionate steps to deliver in this role, including making the registration of clinical trials a condition of the REC favourable opinion. This is a developing agenda where our goals are to:

- continue to promote research transparency, taking proportionate and pragmatic measures to improve and measure transparency in the UK and to increase public confidence in health research;
- continue to raise awareness and support for the HRA's transparency agenda and report on its effectiveness; and
- launch and ensure dissemination and support for future transparency initiatives either led by or supported by the HRA.

Which we will seek to achieve by:

- further defining registration requirements for studies approved by RECs;
- undertaking an audit on compliance, one year on from Sep 2013 changes that mandated registration for clinical trials;
- undertaking an audit of publications from REC approved studies;
- specifically leading on ‘What is meant by Publication, and for what purpose and audiences?’;
- developing standards for publication/reporting, and considering how the HRA can implement and monitor compliance;
- working with others to promote transparency, including access to data and tissue where others are the more appropriate lead; and
- working with partners to widen the transparency of research within UK.

So that:

the UK has proportionate and pragmatic measures in place to ensure the registration and publication of research.

B. Delivering Quality Services and Pursuing Continual Improvement

Develop and Scope Baseline Metrics for the HRA Assessment and Approval

Our goal is to:

- develop trusted metrics with defined targets to measure the effectiveness of the single system for approval of all studies in England (*see above*).

Which we will seek to achieve by:

- establishing baselines for HRA Assessment and Approval components including validation timelines, accuracy of meeting target for approval set at validation and approval timelines;
- exploring with others, including the MHRA, how components of approvals outside the HRA remit can be further coordinated to determine metrics for all regulatory approvals;
- working with Trusts to determine baselines and metrics for the time from HRA target approval, HRA approval and site initiation visits;
- working with others, including funders to understand the status of applications when funding is awarded and released and look at how the UK can start to map out timelines through from funding, protocol development and approvals through HRA systems; and
- continuing to look for measures to demonstrate efficiency not just in terms of timelines but also wider efficiencies as resources are released from current wasteful duplication of review and approval of research.

So that:

not only the immediate Impact and benefits can be objectively measured but that future direction and strategy can be further developed to provide additional focus for more improvements, significantly contributing to making the UK an attractive place to do research.

HRA National Operational Roles

Our goal is to:

- ensure a UK-wide operational framework and delivery within the appropriate legislation, policy and operational standards.

Which we will seek to achieve by:

- Chairing the UK operations group, through which HRA standard operating procedures are monitored and maintained;
- Chairing and providing secretariat support to the UK Ethics Committee Authority;
- Chairing and providing secretariat support for the Four Nations meetings;
- transitioning the Social Care REC into the HRA; and
- considering the impact of and responding to the implementation of the EU Clinical Trials Regulation.

So that:

the UK continues to have an agreed framework for research that meets policy and legislative requirements.

Development of Quality Assurance Management Processes / ISO 9001

Our goal is to:

- ensure all functions and services provided within and by the HRA are of a high quality and quality checked;

Which we will seek to achieve by:

- widening the Internal Quality Audit function within HRA by 2015;
- maintaining HRA ISO9001 Certification (August 2015 external audit); and
- developing and holding the document management system for HRA Policies and Procedures, by March 2015.

So that:

we can deliver quality services and demonstrate the quality so as to build confidence in health research in the UK and the HRA.

Research Ethics Committee Operations

Our goal is to:

- continue to provide an efficient, responsive, proportionate, effective and robust Research Ethics Committee operation.

Which we will seek to achieve by:

- managing the requirement for clinical trial registration, including requests for deferral;
- reviewing staffing establishment as a result of implementation of new developments;
- implementing electronic review of applications;
- improving timelines for review of applications to RECs;
- implementing the second stage pilot of early assessment and pre-committee review; and
- rolling out proportionate information for the proportionate review.

So that:

applicants continue to be satisfied with the service we provide and our commitment to continual improvement, and participants can take assurance from our role to protect their interests.

Confidentiality Advice Group (CAG)

Our goal is to:

- continue providing independent, efficient, responsive, proportionate, effective and robust advice on access to patient identifiable data without consent for research and non-research purposes.

Which we will seek to achieve by:

- improving timelines for studies using recognised methodologies;
- implementing the use of HARP for recording CAG application data (research applications only);
- maintaining provision of early advice to stakeholders to improve the quality of applications;
- managing any relevant legal and policy changes impacting on CAG remit to ensure they are fully considered, implemented and communicated within processes and advice;
- developing existing guidance and develop productive relationships with key collaborators in the information and research fields to ensure CAG advice remains accurate, responsive and credible;
- proactively supporting, developing and maintaining effective communications with relevant external stakeholders to improve the quality of applications (this includes training activities we carry out); and
- reviewing the feasibility of CAG providing advice on non s251 aspects in broader IG environments within HRAs work towards ISO accreditation.

So that:

we continue to provide appropriate and relevant advice on access to confidential data that is in the interests of, and maintains the confidence of, patients and the public.

Working with our Partners

Our goal is to:

- formally agree and document how we work with partner organisations.

Which we will seek to achieve by:

- publishing tailored Memoranda of Understanding; and
- explaining the relationship between the HRA and other organisations through the publications of joint statements and other communications as required.

So that:

our partners, the research community and the public understand the basis on which we work together and collaborate to make the UK a better place to conduct research

Learning through Evaluation

Our goal is to:

- ensure the HRA supports and maximizes the opportunities to research and evaluate how we manage research in the UK.

Which we will seek to achieve by:

- continuing to support and provide expert contribution to identified projects, including statistical quality and protocol evaluation;
- pilot and evaluation of service improvements to maximize effectiveness; and
- continuing to monitor overseas developments.

So that:

we underpin improvement and development of our services by evaluation and understanding of their impact.

The Over-volunteering Prevention System (TOPS)

Our goal is to:

- protect healthy volunteers from the risks of over volunteering, and industry from the risks to research integrity from over volunteering

Which we will seek to achieve by:

- continuing to manage the recording of healthy volunteers' participation in Phase 1 research on TOPS;
- supporting the management and improvement of the TOPs database; and
- ensuring TOPs website accurately reflects the HRA brand.

So that:

the UK can ensure healthy volunteers entering in to Phase 1 studies are not putting themselves are risk through over-volunteering.

The HRA Website

Our goals are to:

- ensure the website is up-to-date, accurate and reflects the HRA's key messages; and
- ensure website content reflects the breadth and depth of existing and new initiatives for which the HRA is responsible, or supports those of others.

Which we will seek to achieve by:

- ensuring we manage website content accurately and in a timely way;
- ensuring the website and newsletters regularly reflects progress of HRA plans and proposals so that shows demonstrable progress; and
- continuing to monitor how people use the website.

So that:

the HRA website is seen as a comprehensive and accessible service which enhances the reputation and authority of the HRA.

Guidance and Advice

Our goals are to:

- improve HRA advice as provided through our email services
- review existing decision tools and if required revise or add to the decision tools portfolio:
- develop guidance and resources for the research community (in collaboration with others).
- review acceptance of the web-based version of consent and participant information sheet guidance
- update and develop advice and guidance in response to organisational, policy, legislation and process changes, as required

Which we will seek to achieve by:

- review timelines and performance of advice provided by email; learning from these reviews to improve standard operating processes and workflows for the handling of queries;
- monitoring and responding to trends in queries by developing standard responses and improve guidance;
- surveying users of decision tools and web-based information sheet guidance; review for trends in requests for further advice after using these resources; and
- working with others internally and externally to provide guidance that is consistent and up to date and which effectively signposts further information, reducing unnecessary duplication.

So that:

the advice and guidance provided by the HRA is relevant, accurate and accessible to support the improvement of quality of research, research applications and research review.

Training

Our goal is:

- to support the improvement the quality of applications and application review for health research in the UK.

Which we will seek to achieve by:

- maintaining a comprehensive training programme for our volunteer committee members;
- providing training and / or training material to researchers and others; and
- reviewing and considering future options for training courses for students and supervisors.

So that:

the HRA maximizes the value from the investment in training by providing relevant and accessible training opportunities and sharing as appropriate training material to be used by others.

C. Leading in Partnership

Communications

Our goal is to:

- ensure communications are effective to ensure we work together within our organisation and externally to support effective leadership.

Which we will seek to achieve by:

- refine and refresh our communications strategies and plans;
- provide opportunities for engagement including the HRA forum stakeholder event (s);
- ensuring our approach to communicating change reflects good practice and demonstrates we have acted on staff feedback;
- effectively positioning CAG in a changing data landscape; and
- surveying staff and stakeholders to inform our strategic approach.

So that:

the communications from HRA are effective and professional to support the HRA leadership roles and enhance the reputation of HRA.

Public Involvement

Our goals are to:

- further develop the HRA into an effective 'involving' organisation;
- embed public involvement into the core business of the HRA; and
- develop the role of the HRA with its partners to support the spread of public involvement in health research.

Which we will seek to achieve by:

- developing capacity to support public involvement;
- reviewing resource requirements needed to support involvement in our own work and the work we do to promote public involvement more widely;
- reviewing business plans to identify all areas of work where public involvement would add value and where public involvement can be promoted as part of our influencing work with research communities;
- promoting and supporting the spread of public involvement in health research with a view to this becoming the rule and not the exception. Also working with partners, including the National Institute for Health Research (NIHR), to exert our influence on those who conduct, fund and manage health research to understand the benefits of public involvement for health research; and
- ensuring action we take to promote public involvement will not increase the regulatory burden on the research community.

So that:

the HRA effectively and appropriately involves patients and the public in developing and implementing plans and proposals, and uses its influence on others to support effective public involvement in health research.

Stakeholder Management and Engagement

Our goals are to:

- implement the stakeholder engagement strategic plan; and
- ensure broad government and stakeholder support for the HRA's agenda.

Which we will seek to achieve by:

- continuing to seek comment on plans and proposals to maintain engagement;
- consulting as appropriate on changes to policies or processes; and
- conducting a perception audit of key opinion leader stakeholders.

So that:

the HRA continues to be seen as an organisation that engages and listens so that the plans and proposals it develops are relevant and effective.

Supporting the UK's Position on Global Research

Our goal is to:

- continue working with key stakeholders to gather evidence and promote the UK as a great place to do quality health research.

Which we will seek to achieve by:

- working with key stakeholders to develop metrics that are comparable and understandable in a global setting; and
- taking opportunities to promote the UK as a great place to do quality health research, providing information and examples to others as well as supporting and presenting at local and national events.

So that:

the UK is a great place to do quality health research, and the evidence is there to demonstrate it and build confidence in the proposition.

D. Strengthening Organisational Capability; Being Efficient and Effective

Organisational Development

Our goals are to:

- develop and manage a programme of work to further embed organisational values and increase staff engagement;
- ensure that the HRA's workforce has the necessary capacity, skills and knowledge to deliver the functions required of it;
- support continued effectiveness of the Board and HRA Teams; and
- manage change well.

We will achieve this by:

- devising and implementing an Organisational Development Strategy and associated workforce plan;
- delivering bespoke facilitation and team building training;

- developing and delivering a detailed change management programme implemented on time;
- undertaking successful recruitment to have staff with appropriate skills in place;
- building strong teams; and
- maintaining an effective learning and development training plan.

So that:

the HRA is an organisation that has the people, structures and values that ensure it is able to deliver effectively, and command respect and authority in its leadership role for health research.

Non-Departmental Public Body (NDPB) Status

Our goal is to:

- implement a new organisational design and structure that caters for all the requirements of becoming a Non-Departmental Public Body (NDPB).

Which we will seek to achieve by:

- conducting the transition within the appropriate legal and regulatory frameworks;
- implementing the Governance framework to ensure legality and efficacy;
- effectively communicate and manage changes in accordance with organisational values; and
- aligned structures to the organisational strategy and business plan.

So that:

the HRA is able to continue to deliver its business plans through transition and is ready to receive the additional responsibilities as a NDPB.

Shared Services

Our goal is to:

- ensure the HRA continues to secures ‘Best Value’ in any shared service arrangement.

Which we will seek to achieve by:

- in accordance with the Governments’ Strategic Plan for Next Generation Shared Services (NGSS) for implementing, operating and managing a more effective programme of back office shared services across departments and arm’s-length bodies (ALBs), consider a move to their ISSC1 shared service option for Payroll, F&A and HR; and
- effectively project managing the transfer of current service from NHS Shared Business Services (SBS) and NHS Business Services Authority (BSA) as appropriate to the ISSC 1 by April 2015.

So that:

the HRA works effectively within the Government provided framework for shared services.

Management Information (MI)

Our goal is to:

- produce timely, accurate and relevant MI for a range of 'audiences' including Sponsor, our Board and Executive Committees to reflect performance and trends in key operational and corporate activities.

Which we will seek to achieve by:

- producing a quarterly high level KPI (Key Performance Indicators) and Performance Assurance Report (a copy is included at Appendix C) from monthly returns which contains comprehensive and relevant performance information including key HR data such as staff turnover, and sickness; and
- undertaking an assessment of the data (by relevant management teams) and agreeing to the mitigating actions required to address areas of concern as well as celebrating areas of good performance.

So that:

the HRA is able to make decisions and develop plans based on accurate management information, and to demonstrate delivery against objectives through relevant and transparent key performance indicators.

Estates Efficiency

Our goal is to:

- review the estates footprint to evaluate options to maximise productivity and value for money.

Which we will seek to achieve by:

- producing a report that details options for office accommodation based on 'ways of working' models (geographical location, specific office layouts and ways of working) that meet on-going and future operational requirements as well as remaining affordable and takes into account the current lease and cost profile.

So that:

we meet our requirements as a public body to make best use of public funds.

Transparent Governance and Compliance

Our goals are to:

- continue to promote organisational visibility and openness; and
- operating within all statutory and regulatory requirements.

Which we will seek to achieve by:

- publishing Board agenda and papers on the HRA website;
- operating to a policy of publishing all information unless legislative restrictions apply;
- scheduling and managing business effectively through the HRA Board and its committees;
- ensuring compliance with the signed Public and Parliamentary Accountability protocol between the Department and HRA;
- operating within the required standards of information governance ensuring that personal and business critical data is protected and is readily available for use when required, risks to information assets are appropriately managed with proportionate

technical, procedural, physical and personal controls applied and that assurance is obtained by conducting regular risk assessments against known and emerging risks such as cyber security and changes in the legal and regulatory environment;
- managing complaints according to HRA policies;
- providing timely responses to requests under Freedom of Information;
- ensuring compliance with equality and diversity legislation by publishing data on progress made and the results of our REC member equality survey; and
- ensuring compliance with health and safety legislation.

So that:

we work in a fully transparent way at all times, in line with our organisational values and our expectations of others.

Business Continuity and Disaster Recovery

Our goals are to:

- embed the Incident Response and Business Continuity Plans; and
- ensure IT Disaster Recovery and Business Continuity during significant change programme i.e. during the replacement of RED and IRAS.

Which we will seek to achieve by:

- undertaking training for Directors and Senior Managers;
- conducting a detailed review of existing capabilities; and
- risk assessing transition arrangements and effectively mitigating identified high impact/ probability risks.

So that:

the HRA takes all steps to protect key services from factors that may be out of the direct control of the HRA.

E. Delivering Best Value

Financial Balance and Budgeting

Our goals are to:

- ensure that the HRA remains within agreed revenue, capital cash and resource limits and to ensure that budgets are managed throughout the organisation.

Which we will seek to achieve by having:

- published a Financial Plan for 2014/15 and agreed budgets in place by the 1 May 2014;
- a Strategic 5 year financial plan published and agreed;
- financial reports produced within 4 working days and overall financial position reported to the EMT on a monthly basis and Board bi monthly; and
- forecasts produced from September at the latest and reviewed monthly thereafter with close partnering between the finance partner and the service lead.

So that:

the HRA meets its requirements as a public body to making best use of public funds at all times.

Savings

Our goal is to:

- to ensure savings targets are identified for 2014/15 and beyond to invest in further improvements, to maintain focus on efficiency and value for money and to offset any emerging cost pressures.

Which we will seek to achieve by:

- identifying and agreeing savings targets include in the Financial Plan;
- producing Monitoring Reports as part of the financial reporting cycle;
- ensuring that all procurement of goods and services achieves best value for the tax payer, whilst adhering to agreed efficiency controls; and
- project managing during 2014/15 the migration of finance and accounting services and payroll to new shared service arrangements as a minimum to deliver savings for the 2015/16 cycle.

So that:

the HRA is able to use all resources to very best effect.

Productivity

Our goal is to:

- to critically review key areas of service delivery in order to generate efficiencies and more for less.

Which we will seek to achieve by:

- identifying an agreed number of service areas for review, the processes for which will be critically reviewed in order to streamline, reduce duplication and waste, and maximise use of technology; and
- publishing a plan of work by July 2014 that links with the plans for roll out of the quality management system.

So that:

the HRA is continually reviewing and identifying opportunities to improve productivity so as to ensure all resources are used to best effect.

Procurement

Our goal is to:

- continually secure the best value out of goods and services that are procured by the HRA

Which we will seek to achieve by:

- producing a Procurement Strategy and associated pipeline for 2014/15 which contributes to related government priorities e.g. sustainability, centralisation and a greater use of SMEs
- making the best use of available government frameworks
- ensuring adequate organisational controls are in place to effectively manage non-staff spend

So that:

the HRA can demonstrate its ability to effectively and economically manage its procurement activity.

8.0 Measuring our Success

The HRA Board reviews progress against delivery of objectives quarterly with the HRA Executive Management Team (EMT) reviewing progress bi-monthly, and the Senior Management Committees (SMCs) monthly. To support these processes, a performance management framework has been developed to report progress against each objective. A separate performance report forms the basis of the formal HRA sponsor meetings with the DH.

The HRA has a set of operational measures that it monitors closely to determine and demonstrate progress against key objectives. Each director is responsible for managing and measuring performance against objectives and will have detailed metrics to inform the reports made through for scrutiny by the Executive Team and Board. The HRA recognises that these measures can form a core component on an overall indicator but that success in many areas is much more than a simple quantitative measure, success is that the HRA has delivered and that that delivery has led to tangible improvement that has been realised and valued by stakeholders including patients and the public, researchers, others involved in the regulation and management of research in the UK and other key stakeholders and opinion leaders. So we are truly making judgements about our ultimate ambition to make the UK a great place to do health research and to build patient confidence in health research.

The HRA has set out key performance indicators for each high level business objective, together with the component measures that will be used to make judgements on the successful improvement and delivery of these indicators.

Individual staff objectives that complement and reflect these organisational objectives are developed during the Appraisal process and monitored during regular 1-1s between staff and line managers.

A. Performance Dashboard

The HRA's Key Performance Indicators are under continual review and refinement but the priority portfolio for 2014/15 currently consists of the following:

A	Improving and Streamlining Systems and Processes to Support and Improve Confidence in Health Research			
	KPI		**Method of Measurement**	**Target or output**
1	Year on year improvement of HRA performance measures for operational functions including REC and CAG	a	Performance metrics collected from internal systems	95% of applications to full research ethics committee meetings to receive final decision within 40 calendar days 95% of applications to research ethics proportionate review service to receive decision within 14 calendar days 95% of amendments, on approved applications, submitted to research ethics committees to receive a decision within 28 calendar days 100% of GTAC applications to be receive a decision in 60 days CAG/CAT - 75% of full applications to be completed in 60 days 75% of proportionate review applications to be completed in 30 days 75% of amendments to be completed in 30 days Test Improvements in performance against outputs from satisfaction audits and annual perception audit
		b	Measure number of operational complaints pursued for learning	Detail changes and improvements made as a result
2	Year on year Improvement in transparency in health research	a	Publishing of research summaries, REC Decisions and Summary of Opinions	By Mar 2015 to have published 70% of research summaries Publish 100% of summary of REC decisions and opinions
		b	Increasing number and visibility of HRA registers and audit tools that demonstrate the level of good conduct of research in the UK	Audit of clinical trials applications to assess registration compliance Publish HRA register of requests to defer registration of clinical trials Audit on publication rates from applications submitted to REC's Test improvements in performance against satisfaction in public confidence and Industry confidence in UK competiveness for clinical trials
3	Year on year improvement on system provision and reputation	a	That key systems are available and accessible to levels as detailed in relevant SLA's	IRAS HARP Web TOPS Open Service
		b	Deliver new systems and system improvements according to agreed project plans and ensuring value for money	To demonstrate value for money Test improvements in performance against reported user satisfaction from satisfaction audits and annual perception audit

B	Delivering Quality Services and Pursuing Continual Improvement			
	KPI		**Method of Measurement**	**Target or output**
1	HRA's ensures that all improvements to performance metrics are matched in improvement in user satisfaction and a wider perception of improvement	a	Annual perception audit	Year one to establish baseline from stakeholder views
		b	Evaluation of Collaboration & Development Programme	To determine effectiveness and value of the outputs of the projects within the programme
		c	Experience of patients and the public involved in HRA activity	To determine improvements in level of satisfaction of quality of involvement
		d	Quality Assurance (QA) Surveys and Audits	Includes the capture of routine feedback from all applicants to RECs
2	HRA provides a high quality advice and guidance service in accessible format to its customers	a	Ongoing provision of effective tools and formal guidance and that agreed revisions and new tools are delivered within defined project timetable	Tools and guidance offered is enhanced and welcomed by stakeholders and satisfaction is measured through the satisfaction audits and annual perception audits
		b	Response times to requests for advice	90% of requests for advice met in 4 working days
3	HRA continues to deliver and improve the high quality REC and CAG services	a	REC Audit action plans completed	100% of 'final' audit action plans completed and submitted within timeframes and actions accepted by QA 50% of committees to receive full accreditation at first audit
		b	Opportunities for further improvement are identified and delivered according to agreed and published timescales	To demonstrate continued improvement in all services This includes the collection of routine and targeted feedback from applicants to REC and CAG through the QA user survey
		c	All services are effective, efficient and represent good value for money	The operational services continue to deliver savings year on year through continued improvement
4	Successful implementation of a UK wide policy framework for research which is recognised as supporting the HRA strategic objectives on making it easier to do good quality research and maintaining public confidence in research	a	Feedback on individual projects including public engagement, ahead of formal consultation to enable and ensure buy-in. Effective formal consultation process	Delivery is welcomed by all key stakeholders and adopted UK wide
		b	Create a common language and understanding within research regulation, governance and compliance of quality, risks and standards and seek researcher feedback on how this leads to improved understanding of the requirements for regulation and governance	Metrics with defined targets that measure the effectiveness of a single system for all studies in England

C	Leading in Partnership			
	KPI		**Method of Measurement**	**Target or output**
1	Develop and scope baseline metrics for the HRA Assessment and Approval	a	Implementing A and A according to agreed phasing and timelines in the detailed project plans	Programme implementation plan
		b	Determine baseline timeline across full integrated approval pathway to final approval	Establishing baselines for HRA A and A components
				Exploring components of approvals outside the HRA remit
				Working with Trusts to determine baselines and metrics for the time from HRA target approval, HRA approval and site initiation visits
				Understand the status of applications when funding is awarded and released and start to map out timelines
				Continuing to look for measures to demonstrate efficiency
2	The HRA will effectively communicate using a range of communication tools	a	The success of an annual stakeholder event which will comprise of key figures within the health research field	Event evaluation reaches a satisfaction level of 80%
		b	Number of stakeholder newsletters issued	Delivered to planned timescales, quality judged through perception and satisfaction audits
		c	Website audit to demonstrate improved website user satisfaction	Website analytics - % website user satisfaction 70% of users find what they are looking for Website analytics show website used effectively % Perception audit – baseline established for year one
		d	Positive coverage in media	70% media coverage positive or neutral about the HRA 100% of media enquiries answered in journalist deadline
3	The HRA effectively and appropriately involves patients and the public in developing and implementing plans and proposals, and uses its influence on others to support effective public involvement in health research.	a	Working with others to agree standards on public involvement in Health Research	Reach agreement on standards and principles for effective involvement in the development of research design
		b	Monitor current practice and % of involvement recorded in applications submitted through IRAS	% increase in number of applications that have clearly involved patients and the public in their development. Repeating previous survey to identify levels and trends
		c	Value and support lay members on ethics committees and continue to offer access to induction, training and mentor support	Maintain number of lay members on committees Numbers attending Induction training, and feedback on relevance and value of the training Numbers provided with additional individual support
		d	Ensuring patient and public involvement in HRA events and other work as appropriate	Year on year increase for opportunities of involvement which is recognised as valuable in perception and satisfaction audit

	KPI		Method of Measurement	Target or output
4	The HRA continues to be seen as an organisation that engages and listens so that the plans and proposals it develops are relevant and effective.	a	Measure number of plans and proposals that went out for consultation	Determine baseline for 14/15 Satisfaction with the opportunities determined through satisfaction audits and annual perception audit

D	Strengthening Organisational Capability, being Efficient and Effective			
	KPI		**Method of Measurement**	**Target or output**
1	The HRA continues to be an organisation that has structures and values that ensure it is able to deliver effectively, and command respect and authority in its leadership role for health research.	a	The delivery of OD and Workforce plan to maintain effectiveness against an expanding agenda	Plan is delivered and meets requirements of organisations purpose and functions
		b	Structures and values are good value for money	Cost of structure meets organisational requirements and is within agreed budget
2	The HRA is able to make decisions and develop plans based on accurate timely management information, and to demonstrate delivery against objectives through relevant and transparent key performance indicators.	a	Production of KPI's with agreed measures and targets	Completed March 2014
		b	The speed by which it can collect, collate, analyse and produce necessary performance reports	Produce a quarterly KPI report (final version within 4 weeks from end of reporting period) for the board and monthly (within 7 working days from end of reporting period) for Executive Management Team (EMT)
3	The HRA maximizes the value from the investment in training by providing relevant and accessible training opportunities and sharing as appropriate training material to be used by others	a	The take up of offered training places to HRA volunteers, researchers and staff	85% of available training places are taken up
		b	The evaluation score for each training course	To achieve at least 80% satisfaction for each training course. If not achieved investigation completed to ensure improvements can be made
4	Staff are well motivated and are well supported to achieve their objectives	a	Responses from annual staff survey	Improvement in targeted areas of staff survey

	KPI		Method of Measurement	Target or output
5	We work in a fully transparent way at all times, in line with our organisational values and our expectations of others.	a	Time it takes to process FOI's and Complaints	Responding to complaints within 25 working days (Quarterly report) 100% of all FOI requests (valid and invalid) acknowledged and additional clarification sought within 10 working days (Quarterly report) 100% of valid FOI requests to receive final response within 20 working days of receipt (where qualified exemption does not apply) (Quarterly report) 100% of valid FOI requests where qualified exemption applies, and a public interest test may be required, to receive a final response within 40 working days of receipt
		b	Monitor REC membership and demonstrate greater diversity in REC member profile so there is greater alignment with that of the general population	Profile data
		c	Public availability of organisational data as determined by Government and in lines with our values to be transparent	100% published on web

E	Delivering Best Value			
	KPI		**Method of Measurement**	**Target or output**
1	The HRA meets its requirements as a public body in making best use of public funds at all times.	a	Meeting formal reporting requirements	Financial plan 2014/15 published and agreed budgets in place by the 1st May 2014. Strategic 5 year financial plan published and agreed Financial reports produced within 4 working days and overall financial position reported to the EMT on a monthly basis and Board bi monthly Forecasts are produced from September at the latest and reviewed monthly thereafter Publish financial data in accordance with data transparency on a monthly basis
		b	Reduction in key areas of non-staff spend	Demonstrate reduction in spend in the following areas: - Travel and Accommodation per head count - Office Supplies per head count - Office Accommodation per head count
2	The HRA is able to use all resources to very best effect.	a	Meeting efficiency targets	Cash releasing savings plans to be cover a minimum of 3 years plus achievement against these savings to be included in the report to the Board on a monthly basis with commentary and action plans where necessary
		c	Sickness absence rates	Maintaining sickness rates for both long term and short term at 2.5% or below

The year-end Dashboard for 2013/14 is included in the Appendix.

B. Risk Management

Each objective in this Plan is also subject to risk evaluation and review. Risks are captured and reviewed by each Directorate with supporting work plans and actions to mitigate risks developed as appropriate. Risks are escalated in line with the HRA Risk Management Policy for resolution via the Corporate Risk Register and managed through integrated risk and performance management processes. The Corporate Risk Register is reviewed quarterly at Board, Audit Committee and/or Executive level and forms a key element of the HRA corporate assurance framework.

9.0 Financial Plans

Revenue

The HRA is required to plan for a balanced income and expenditure position. A summary of the plan is provided in the table below. Further detail can be found in appendix B.

Prioritised Business plan 2014/15

Planning Priorities	Note	Cost analysis 2014/15
		(£'000)
A. Improving & Streamlining Systems and Processes to support and improve confidence in health research		5,430
B. Delivering quality services and pursuing continual improvement		7,007
C. Leading in partnership		162
D. Strengthening organisational capability, being efficient and effecive		640
E. Delivering best value		206
		13,444

Notes
All costs are stated as full cost and equivalent to GIA funding
All direct, indirect and overhead costs of support services have been aligned to each function
Devolved administration funding and associated costs shown in separate table in appendix

The table below sets out our planned costs for 2014/15 by function. It is important to stress that health research is not legal without ethics approval or approval from CAG as appropriate. Additionally, associated applications to undertake research in the UK cannot be made without IRAS and the application system we operate.

The HRA receives income from two main sources. The majority comes from grant in aid (GIA) provided via the DH (£13,444k), with the balance (£0.22k) coming from undertaking activities by agreement with the Devolved Administrations. The table below also highlights how that income is deployed. On becoming an NDPB the HRA will assume responsibility for the policy framework underpinning the national research governance framework (currently DH Policy). The planning assumption is that additional GIA will be provided to complete the detailed planning and implementation of HRA Assessment and Approval as set out in the business case submitted to DH. The income and expenditure position therefore reflects new costs associated with HRA Assessment and Approval as set out in the business case.

Prioritised Business plan 2014/15

Functions provided - all core business and captured in the Care Bill	Note	Cost analysis 2014/15 Statutory function	Other commitment	Ministerial priority
		(£'000)	(£'000)	(£'000)
RECs, Ethical review	1	6,926		
Approvals for processing confidential information relating to patients	1	429		
Training, guidance and advice	2		391	
Quality Assurance to support ethical review	3		223	
IRAS and systems to support ethical review	4		960	
Co-ordination and standardisation of practice relating to regulation of health and social care research.	5			4515
		7,355	**1,574**	**4,515**

13,444

Notes

All costs are stated as full cost and equivalent to GIA funding

All direct, indirect and overhead costs of support services have been aligned to each function

Devolved administration funding and associated costs shown in separate table in appendix

1. Research is not legal without ethics approval or appropriate approvals from CAG. The costs presented here include national research ethics panel, as well as support service costs

2. Training supports our core business and includes training for volunteer REC members, researchers and patients and the public.

3. Quality assurance is part of our core business and part of the wider remit in the care bill to ensure quality and standards of both the review itself and the research governance and research processes.

4. Applications for health research cannot be made in the UK without IRAS and the applications system HARP.

5. Business Case costs submitted to DH

The income and expenditure position also includes planned efficiency savings of £840k (equivalent to 9% of our current expenditure base), £535k are to offset some of the costs of HRA Assessment and Approval, the remainder are to ensure affordability of service delivery within the approved financial envelope and to fund cost pressures identified in the table below. Action is planned for the forthcoming year to further drive down costs on travel through investments made during 2013/14 to install and deploy video conferencing technology, efficient use of estate, further shared service efficiencies and to ensure value is achieved through contracts for mobile technologies and storage. The HRA is identifying savings now in preparation for 2015/16.

Cost pressures identified and funded from efficiencies

Description	2014/15 Plan £000s
IT service contract costs	78
Incremental drift	55
Pay inflation @ 1%	55
Non pay inflation @ c1%	47
VAT on agency staff	70
Total Cost pressures funded through efficiencies	**305**
Efficiencies identified to part fund HRA Assessment & Approval 14/15	535
Total Cost pressures funded through efficiencies	840
% of 13/14 expenditure plan	**9%**

Capital

During 2014/15, the HRA is planning to build on the capital investment programmes initiated in 2013/14 with the further development of the replacement system for IRAS, continued development of the database application system (HARP), developments to the TOPS and modest investments in video-conferencing. The plans are set out below for 2014/15.

Capital plans

Description of investment	2014/15 Plan £000s	2015/16 Initial plans £000s
HARP developments	110	70
IRAS	400	250
TOPS	35	4
Video conferencing	5	5
Total capital investment plan	550	329

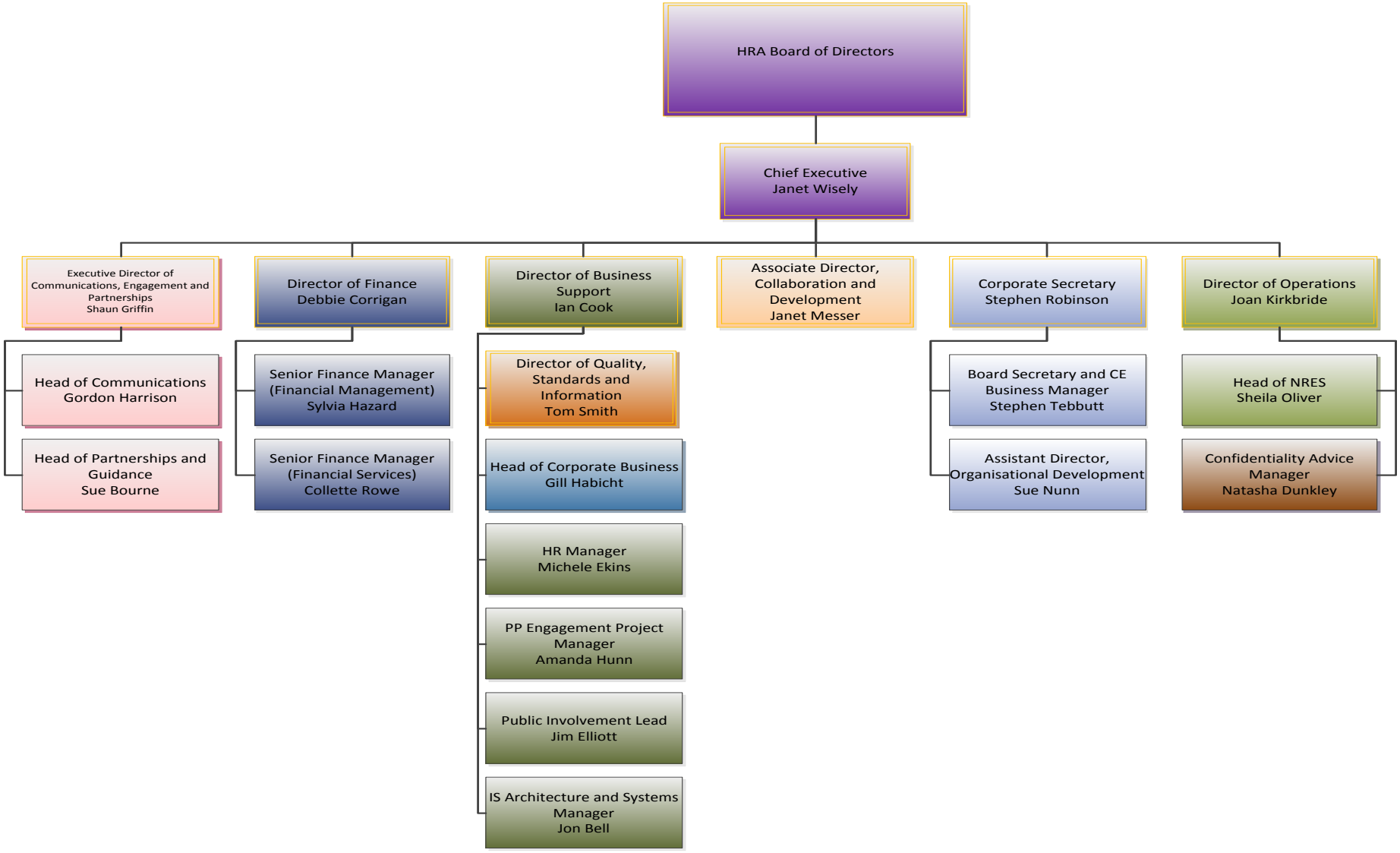
10.0 Glossary

ALB	Arm's Length Body of the Department of Health
BSA	NHS Business Services Authority
C&D	Collaboration and Development Programme and Projects
CAG	Confidentiality Advisory Group
Clinical Trials Regulations	The Medicines for Human Use (Clinical Trials) Regulations 2004
CSO	Civil Society Organisation
DH	Department of Health
EMT	Executive Management Team
EOP	Ethical Officer Pilot
EU Directive	Directive 2001/20 EC of the European Parliament and the Council of the European Union relating to the implementation of good clinical practice in the conduct of clinical trials of medicinal products for human use
GAfREC	Governance Arrangements for Research Ethics Committees
GIA	Grant in Aid
GTAC	Gene Therapy Advisory Committee
HARP	HRA Assessment Review Portal – the replacement for RED
HFEA	Human Fertilisation and Embryology Authority
HRA	Health Research Authority (Special Health Authority established from 1 December 2011)
HTA	Human Tissue Authority
INVOLVE	INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. INVOLVE is funded by and is part of the NIHR
IRAS	Integrated Research Application System, the online application system used to apply for most permissions and approvals for research in health and social care in the UK (www.myresearchproject.org.uk)
ITT	Invitation to Tender
MHRA	Medicines and Healthcare products Regulatory Agency. MHRA (Medicines) is the competent authority for the UK in relation to the EU Directive and the Clinical Trials Regulations. MHRA (Devices) is the competent authority for the UK in relation to the Medical Devices Regulations 2002

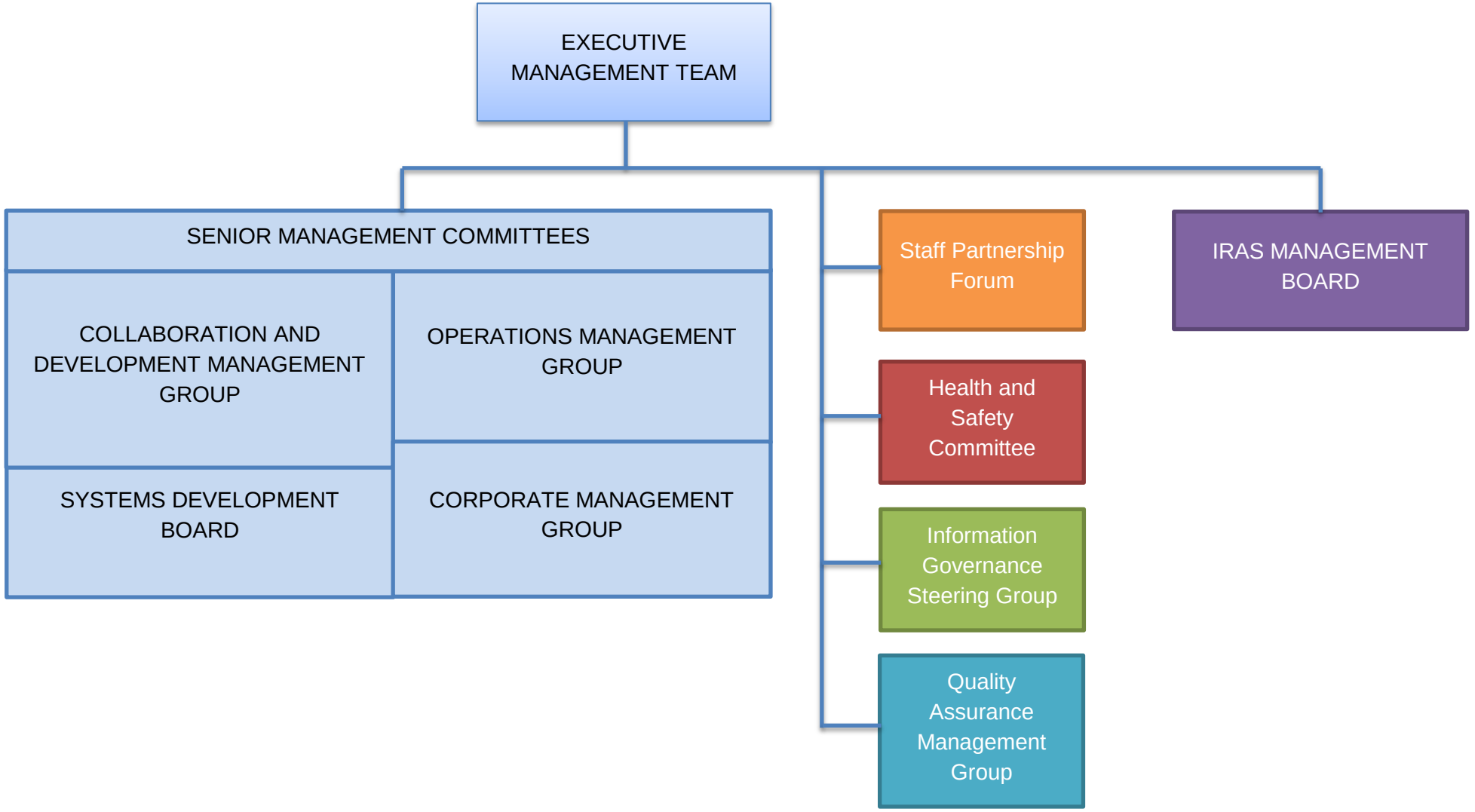
MoU	Memorandum of Understanding
NDPB	Non-Departmental Public Body
NIGB	National Information Governance Board for Health and Social Care
NIHR	National Institute for Health Research
NREAP	National Research Ethics Advisors' Panel
NRES	National Research Ethics Service
PCoE	Procurement Centre of Expertise
RED	Research Ethics Database used by administrators to manage research applications
REC	A Research Ethics Committee established in any part of the UK in accordance with GAfREC and/or recognised by the under the Clinical Trials Regulations
ShED	Shared Ethical Debate
SOPs	The Standard Operating Procedures for Research Ethics Committees
SPF	Staff Partnership Forum
Sponsor	The individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study
TOPS	The Over-Volunteering Prevention System
UKECA	United Kingdom Ethics Committee Authority

11.0 Appendix

A1. Senior Management Structure



A2. Executive Committee Structure



B. Financial Plan Detail

Financial plan detail
2014/15 Business plan by cost category

Revenue costs ***(classed as Admin revenue departmental expenditure limit DEL)***

	2013/14	2014/15
	Plan	Plan
	£000s	£000s
Admin Expenditure		
Pay	5,274	8,329
Temporary Staff/Contract Services	469	500
Consultancy Services	0	0
Other e.g. stationery, travel etc	3,904	4,772
Audit Fees	38	50
Total Admin Expenditure	**9,685**	**13,651**
Admin Income		
*Devolved Administration**		
Scotland	(116)	(108)
Wales	(66)	(62)
Northern Ireland	(38)	(37)
Total Income from Devolved Administration	(220)	(207)
Admin Income from outside NHS/DH/ALBs	(15)	0
Total Admin Income	**(235)**	**(207)**
TOTAL ADMIN NET OUTTURN and GIA	**9,450**	**13,444**

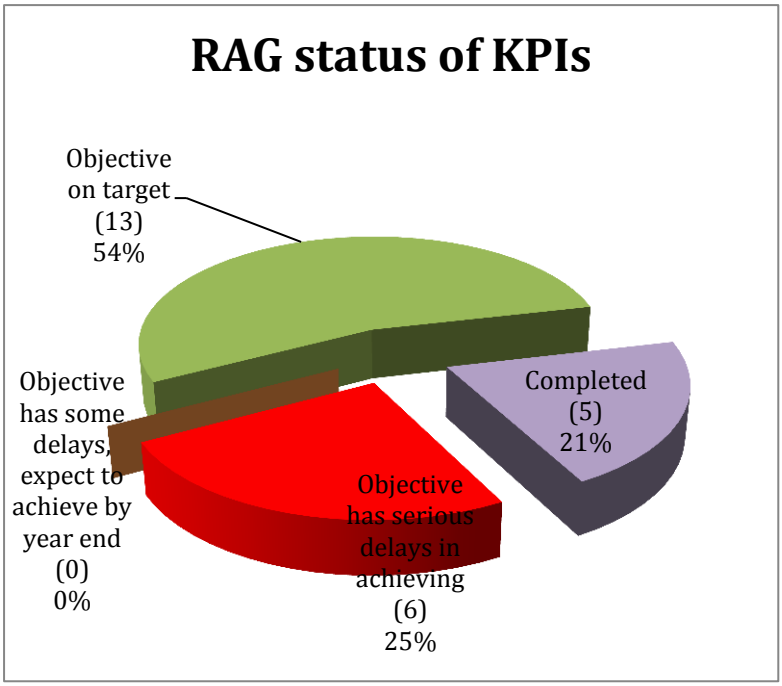
Other Revenue costs **(classed as Admin ring fenced DEL)**

Description	2013/14 Plan £000s	2014/15 Plan £000s
Depreciation and Amortisation	141	161
Impairments	0	
Total Admin Ring Fence DEL	141	161

c. Performance Dashboard to end March 2014

Summary dashboard

RAG status of 2013/14 Business Plan KPIs



No. of KPIs met	
bjective has serious elays in achieving	6
bjective has some elays, expect to chieve by year end	0
bjective on target	13
ompleted	5

Objective has serious delays in achieving (red)	
95% of applications to full research ethics committee meetings to receive final decision within 40 calendar days *(SOP requirement is 60 calendar days; the HRA has set stretched targets of 95% within 40 calendar days for applications going through full committee)*	75% compliance year to date cumulative figure, March 2014 (77% in Quarter 3 report) 2013/14 has seen continuing improvement in the number of applications reviewed within statutory timelines (60 calendar days) 98% of applications reviewed in 60 days (England average) *See p.23*
95% of amendments, on approved applications, to receive a decision within 28 calendar days *(SOP requirement is 35 calendar days; the HRA has set a stretched target of 28 days)*	89% compliance year to date cumulative figure, March 2014 (88% in Quarter 3 report) Individual committees have met the stretched target 98% of amendments reviewed in 35 days (England average) *See p.25*
To consolidate the HRA corporate and visual identity	Visual identity agreed; final development of guidelines/ templates almost complete but not fully adopted for use by end March 2014

Publish 50% of research summaries (from the current 15%) of applications receiving review at full committee	Owing to technical difficulties of linking the current RED (research ethics database) feed to the new website, management decision taken to hold publication until the streamlined functionality on new research ethics database (HARP) is available. With the delivery of HARP and purchase of additional modules for the HRA website, it is anticipated that research summaries will be published in Quarter 1 2014/15
Demonstrate improved website user satisfaction	User satisfaction survey still to be undertaken. Anticipate results being available before end of June 2014
Reduce S251 approval timelines in line with other approvals within HRA	Since January 2014 and the recruitment of a new staff member, there has been a reduction in processing times. The most significant increase involves review of Precedent Set review applications which has reduced by 40%. *See pp.27-28*

Objectives on target (green)	
• Create a common language and understanding within regulation, governance and compliance of quality, risks and standards; seek researcher feedback on how this leads to improved understanding of requirements for regulation and governance	A plan for the work on replacing the Research Governance Framework has been completed. A number of projects are underway, and some already completed, that will inform the principles for the new framework. These projects include seeking input from the research community, patients and the public
• Monitor REC membership and demonstrate greater diversity in REC member profile so greater alignment with that of the general population	The survey went to the HRA Executive Management Team in February and was approved with no major issues identified. The survey to be published on the HRA website shortly
• Determine baseline timeline across full integrated approval pathway to final approval	The plans for HRA Assessment and Approval have been approved and funding agreed. Initial explorations of data from NIHR benchmark returns and HRA data show no pattern in relation to timing of applications or duration of process, confirming absence of clear guidance on expectations for all parties. Future plans include whole system measurement as new systems are implemented
• Set target to reduce the timeline UK-wide	The plans for HRA Assessment and Approval have been approved and funding agreed. The plans include performance metrics that will be based not only on time to navigate the whole approval pathway, but also on predictability and consistency of timing against targets
• Reduce GTAC timelines in line with other HRA RECs *(Legal requirement is 90 calendar days; the HRA has stretched targets of 100% in 60 calendar days (previous data shows over 100 days))*	GTAC (Gene Therapy Advisory Committee) has transferred to the HRA Mean review time has reduced from 180 days to 40 days

• Maintain IRAS as an available system 24 hours a day, 7 days per week (to 99%)	100% compliance
• Maintain current 4 working days response times to requests for advice (90%) *(Quarterly report)*	For this final quarter, rather than sampling the KPI reflects 100% of the enquiries received; even with an increasing number of enquiries, the average response time was 0.38 days, or less *See p.12 for full metrics*
• 95% of applications to research ethics proportionate review service to receive decision within 14 calendar days	90% compliance year to date cumulative figure, March 2014 (97% Quarter 3 report) Proportionate sub-committee review for low-risk studies has a target of 14 days
• 100% of audit action plans from the accreditation of research ethics committees to be completed within agreed timeframes	100% compliance for quarter. *See p.26*
• Responding to complaints within 25 working days *(Half yearly report)*	89% compliance *(see p.10)*
• 100% of all FOI requests (valid and invalid) acknowledged and additional clarification sought within 10 working days *(Half yearly report)*	100% compliance *(see p.11)*
• 100% of valid FOI requests to receive final response within 20 working days of receipt (where qualified exemption does not apply) *(Half yearly report)*	100% compliance *(see p.11)*
• 100% of valid FOI requests where qualified exemption applies, and a public interest test may be required, to receive a final response within 40 working days of receipt *(Half yearly report)*	N/A – none received

Completed	
• Publish trends on number of individual applications to IRAS and individual IRAS partners, including NRES *Many IRAS partners now publish data on numbers of applications, with explanation. HRA routinely publishes management information for NRES and CAG on the website and in this report*	• Publish all REC decisions *Annual Reports for RECs in England for the period April 2012 - March 2013 formally adopted by the HRA Board on 29 October 2013 and published on HRA website*
• Determine baseline and set target to increase no. of applications through IRAS *Agreement has been achieved that HFEA (H**uman Fertilisation and Embryology Authority**) will be a new partner and*	• Develop a fit-for-purpose website *New website went live first week of October. Ongoing improvements include a consultation area and revised CAG/s251 section*

*NOMS (**National Offender Management Service**) will increase their use of IRAS rather than off-line versions. (Implementation not possible until IRAS4 developed)*	
• Publish advice from the Confidentiality Advisory Group and decisions made by the HRA on access to confidential data under Section 251 of the NHS act *Detailed CAG advice, HRA and Secretary of State approval decisions published in minutes on the HRA website*	

Section 1: Organisation metrics

FINANCE METRICS

- HRA is reporting an underspend of £937k at the end of March – £914k less than expenditure budgets and £23k more income
- 91% (£8.8million) of the annual budget has been spent
- The Better Payment Practice Code (BPPC) compliance for April to March maintained the performance levels of 97% for the number of invoices paid and 98% for value of invoices paid. This is within the 95% target set. The HRA is aiming to pay 60% of invoices within 10 days – current performance has increased slightly in March and shows 38% (34% March) on the number of invoices and 48% (39% March) based on invoice values. Performance is published on our website
- Internal team objective set: to achieve month end close in 4 days from a start point of 7 days. The finance team has worked steadily throughout the year to reduce the number of working days to complete month end to a target of 4 days. This target was achieved in February and the finance team met the agreed timetable deadlines set for the year end process

HRA Better Payment Practice Code for the period 1 April 2013 to 31 March 2014

	Number	%	Value (£)	%
0-5 Days	201	4%	661,970	15%
6-10 Days	1584	33%	1,455,661	33%
11-20 Days	2530	53%	1,864,823	42%
21-30 Days	293	6%	345,855	8%
Over 30 Days	146	3%	90,134	2%
Total	4,754	100%	4,418,443	100%
BPPC achieved	97%	97%	98%	98%

Aged Creditors at 31 March 2014

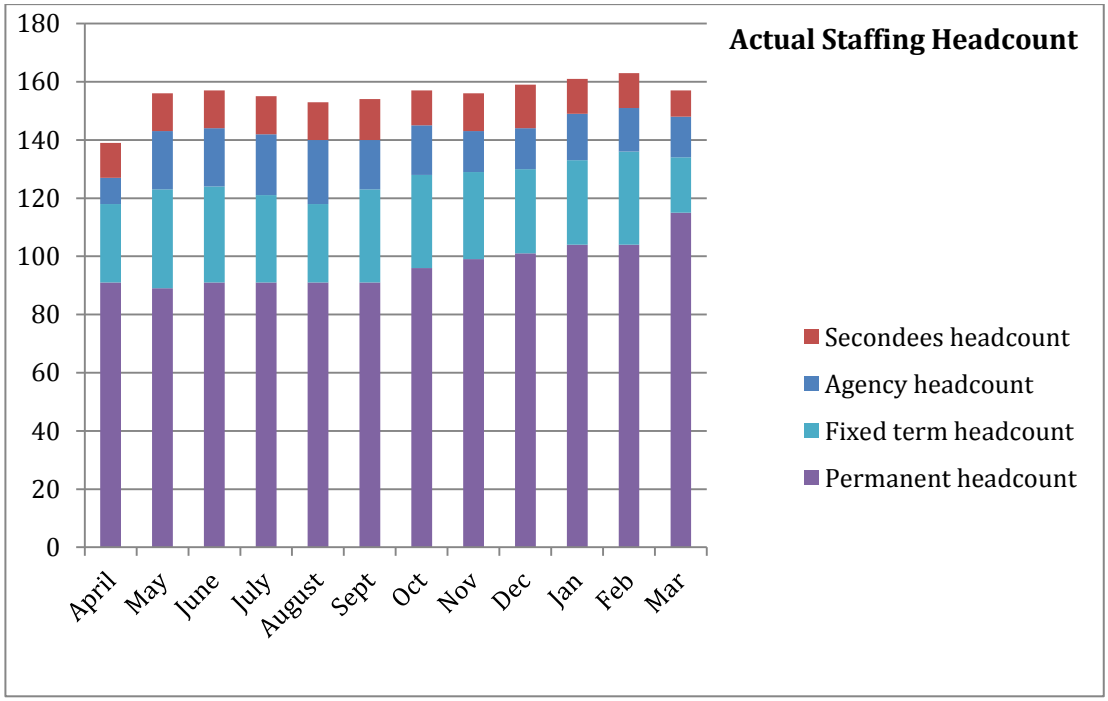
Headlines – clock start date is the invoice date (regardless of when the invoice is received in the system)

Non-NHS Trade

Only significant item in 60+ days is an invoice to Calder Conferences (£3,096), which was paid on the 1 April 2014.

	Aged Creditors – (£) amounts past due date		
	1-30 days	**31-60 days**	**60 + days**
Non NHS Trade	4,068	1,419	3,882
Non NHS Other	2,027	23	1,025
NHS	0	0	0
Total	6,096	1,443	4,907

Profile of staff headcount 2013/14



- Staff headcount for 2013-14 shows a fairly static position throughout the year to date (pay represents 64% of the costs incurred year to date)
- The HRA is continuing to work to reduce the number of agency staff employed and is implementing a staff bank which will assist with this work

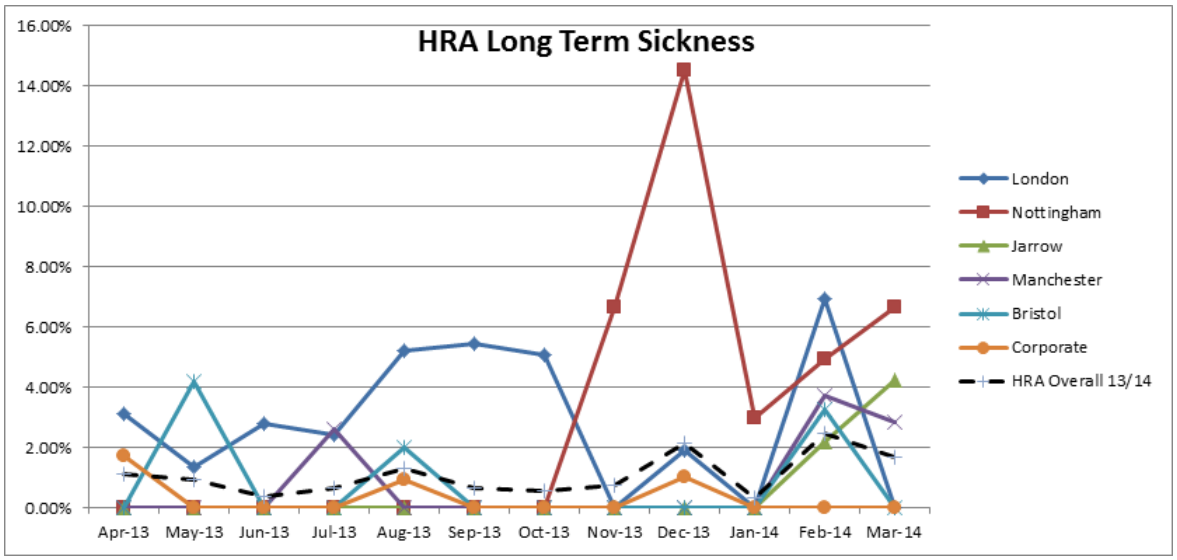
Demographic breakdown – HRA staff

(updated quarterly)

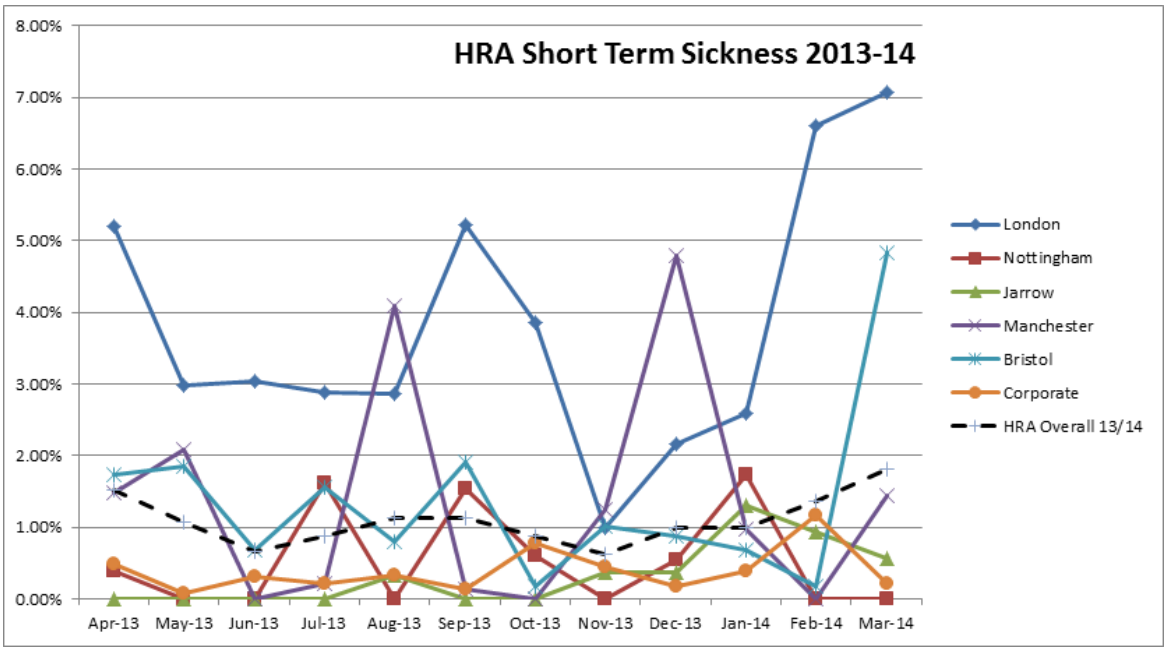
Quarter 4 Ethnicity	%
White – British / Irish	75%
White - Any other White background	4.5%
Mixed - Any other mixed background	2%
Asian or Asian British	4.5%
Black or Black British	7%
Other / Undefined	2%
Not Stated	5%
Age	**%**
<20	0%
20-30	30%
31-40	23%
41-50	25%
51-60	19%
60+	3%
Full-Time/Part Time	**%**
Full-Time	81%
Part-time	19%
Gender	**%**
Female	76%
Male	24%

Staff sickness absence 2013/14 (year to date)

Long-term sickness:

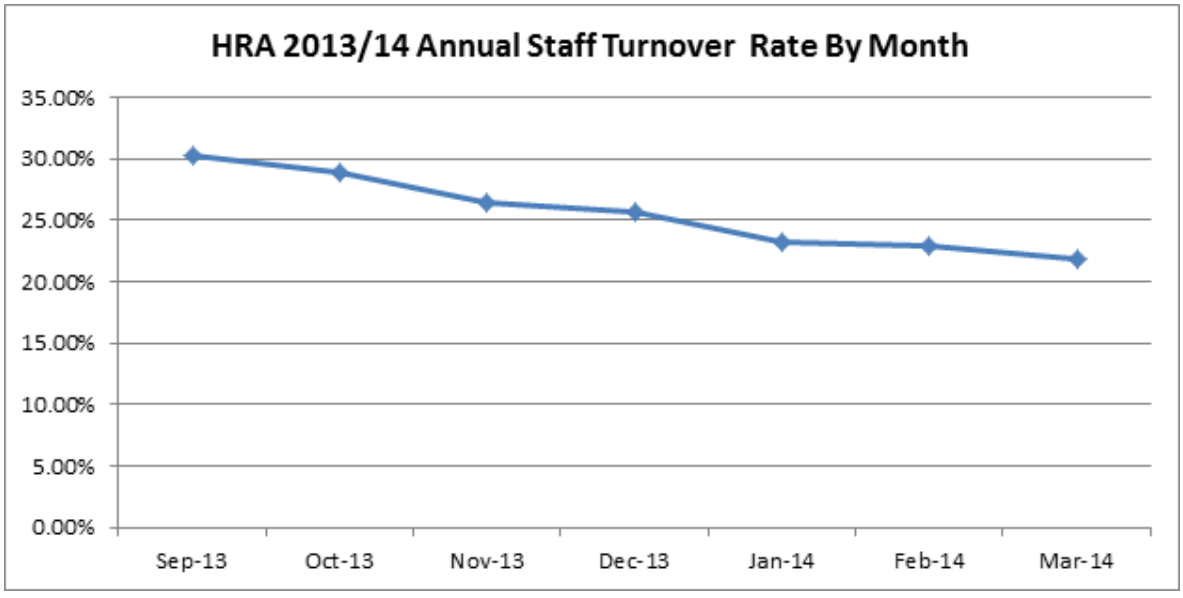


Short-term sickness:



- The combined average figure for NHS sickness absence for 2012/13 was 4.24%

Staff turnover 2013/14 (year to date)



- Includes staff on payroll only (ie excludes secondments and temporary staff)
- Annual rate is projected for months Sep 13 through to Feb 14. March 14 is actual turnover rate for period April 2013 to March 2014

Response metrics

- Target for responding to complaints, 25 working days
- Statutory target for responding to Freedom of Information (FOI) requests, 20 working days

Summary of Complaints received (April - September 2013)
(half yearly reporting)

- The HRA considers a complaint relates to the standard or quality of services provided by the HRA; divergence from procedures by staff; the behaviour of HRA staff; and the behaviour of volunteer committee members, including Research Ethics Committees (RECs), the National Research Ethics Advisors' Panel (NREAP) and the Confidentiality Advisory Group (CAG).
  (A complaint does not apply where: matters have already been thoroughly and fully investigated; legal proceedings are already underway; appeals against the decision of a REC are covered by the NRES Appeals process; behaviour of committee members are addressed under the member management policy and procedures; alleged failure by a responsible body to comply with a request under the Data Protection Act 1998 and the Freedom of Information Act 2000.)

	Apr - Sep 2013	**Oct 2013 - Mar 2014**
No. of complaints received	7	9
No. of complaints upheld	4 (1 partially)	1 (partially)
Average response time	11 days	14.8 days
No. of complaints responded to within 25 days	7	4
Categories: - Corporate - NRES - TOPS - NREAP - CAG - Other	5 2	8 1

- A total of 9 complaints were received for the 1 October 2013 to 31 March 2014 period
- One complaint was responded to and dealt with within 35 days. The complainant was kept updated regarding the status of the complaint throughout the investigation. The outcome of the investigation concluded that the complaint in fact related to a third party

Summary of FOI requests (April - September 2013)
(half yearly reporting)

	Apr - Sep 2013	Oct 2013 - March 2014
No. of FOI requests received	22	20
Average acknowledgement time	3.1 days	2.4 days
No. of FOIs acknowledged within 10 days	100%	100%
Average response time	11.2 days	8.6 days
No. of FOIs responded to within 20 days	100%	100%
No. of requests where information not held by HRA	4	1
No. of requests where Section 21 exemption applied (information available by other means)	4	
No. of request where Section 41 exemption applied (breach of confidence)	1	
No. of request where Section 43 exemption applied (commercial interests)	4	
Categories: - Corporate - NRES - TOPS - NREAP - CAG - Other	 5 11 2 1 1 2	 7 10 0 0 2 0

Response to Parliamentary Question (PQ) requests

- All PQs have been responded to within stipulated time period

No. Parliamentary Questions received per month												
Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1	1	2	2	0	1	0	1	0	0	3	1

Section 2: Queries line metrics

QUERIES LINE METRICS

- Metrics are produced on a quarterly basis – Quarter 4 position is shown below.
- For Quarters 1-3, measurement was based on a sample (first 10 queries in a day; days selected so that every month, week in the month and day in the week are covered) – the sampling procedure was established by the Quality Assurance Audit of the NRES Queries line in 2008. However, for Quarter 4, the KPI reflects 100% of the enquiries received where, even with an increasing number of enquiries, the average response time was 0.38 days, or less
- The majority of enquiries submitted to the Queries line seek advice on whether the study is research and/or research requiring ethical review. Two linked decision tools were launched by the HRA in May 2013 to assist with these types of queries
- The Queries line traffic for quarter 4, however, has continued to increase (previously a downward trend from October 2011) and has risen by 49% in comparison with the same period in 2012/13. The increased traffic may be accounted for by the decision tools, with clients seeking confirmation of the outcome of the decision tools (although it is now made clear to researchers that the decision is an authoritative source that can be relied on), or may be as a result of the launch of the new HRA website (early October) and an inability for clients to find the relevant information and thus resorting to an email enquiry

Queries per month in 2013-14									
Quarter 1		Quarter 2		Quarter 3		Quarter 4			Year Total
Apr-13	144	Jul-13	199	Oct-13	284	Jan-14	195		
May-13	160	Aug-13	174	Nov-13	268	Feb-14	234		
Jun-13	131	Sep-13	126	Dec-13	161	Mar-14	242		
	435		**499**		**713**		**671**		**2,318**
Comparison with 2012-13	-108		86		275		221		1,844
	-20%		+21%		+63%		+49%		+26%

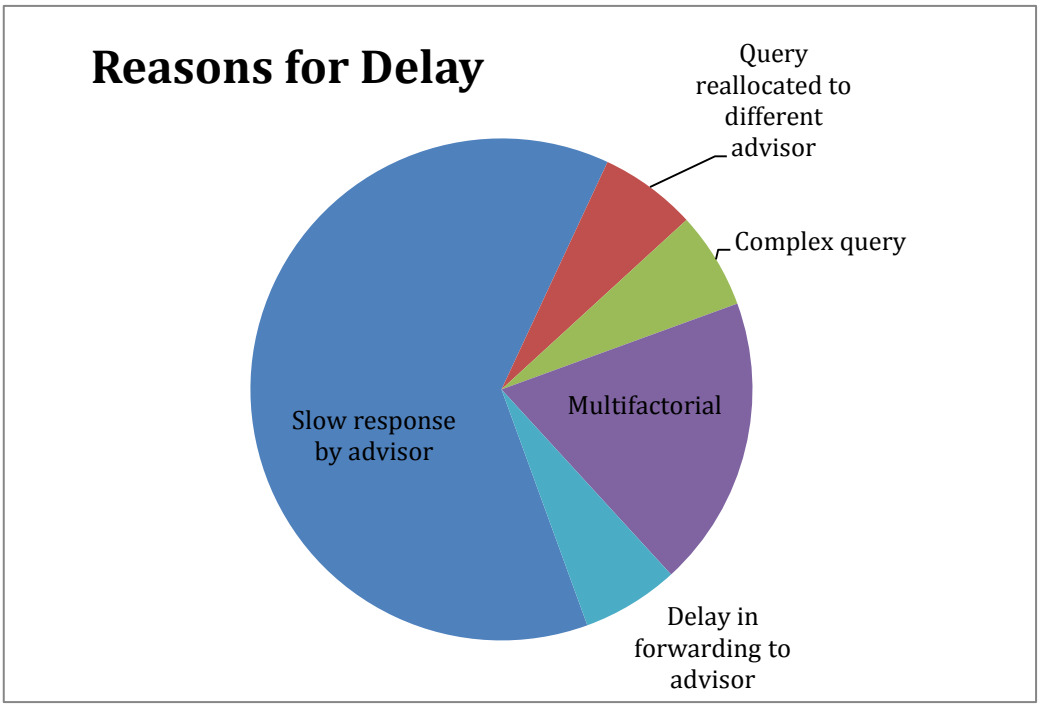
Time taken to respond to sampled queries per month 2013-14		
	% of queries responded to within 4 working days	Mean average response time
Apr-13	100%	0.9
May-13	90%	0.6
Jun-13	100%	0.5
Jul-13	100%	0.7
Aug-13	100%	1.1
Sep-13	100%	0.7
Oct -13	90%	1.0
Nov-13	70%	1.9
Dec-13	100%	0.2
Jan-14	96%	0.38
Feb-14	98%	0.32
Mar-14	99%	0.18

- The missed target, and apparent poor performance, in November 2013 was investigated. The data for the entire month was analysed and is summarised in the table below:

Summary	
Total queries	262
In target	246
Out of target	16
Percent complete within 4 days	94%
Mean average response time	1.02
Modal response time	0
Longest response time	28
Shortest response time	0

Please note: the apparent difference in the no. of queries received for November is due to the above figure indicating the total no. of enquiries received, while the figure included in the Queries per month table includes all traffic (where there may have been subsequent follow up emails from the enquirer)

- It would appear that a number of complex queries were received and a breakdown of the reasons for delay is shown below:


Reasons for Delay
Query reallocated to different advisor
Complex query
Multifactorial
Delay in forwarding to advisor
Slow response by advisor

Section 3: Systems metrics

SYSTEMS METRICS

- The HRA receives a separate IRAS helpdesk report and no major issues to note this year to date
- The HRA now receives monthly performance metrics on Open Service (DH-managed IT system)

Provision of the Integrated Research Application System (IRAS)

- 100% achievement, with IRAS available 24 hours/day, 7 days per week

Provision of website

- 100% achievement, with the current website available 24 hours/day, 7 days per week

Open Service dashboard

- Please see *Report at end of section* for the Open Service performance metrics for the period January - March 2014

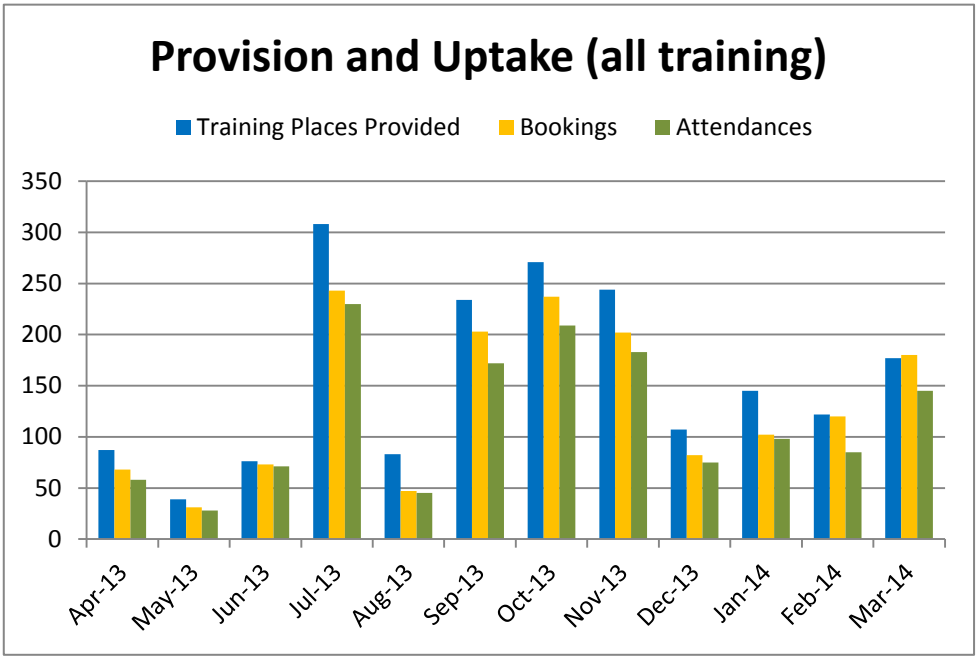
Section 4: Training

TRAINING METRICS

- 43 unique courses delivered
- 85 events provided between April - March 2014

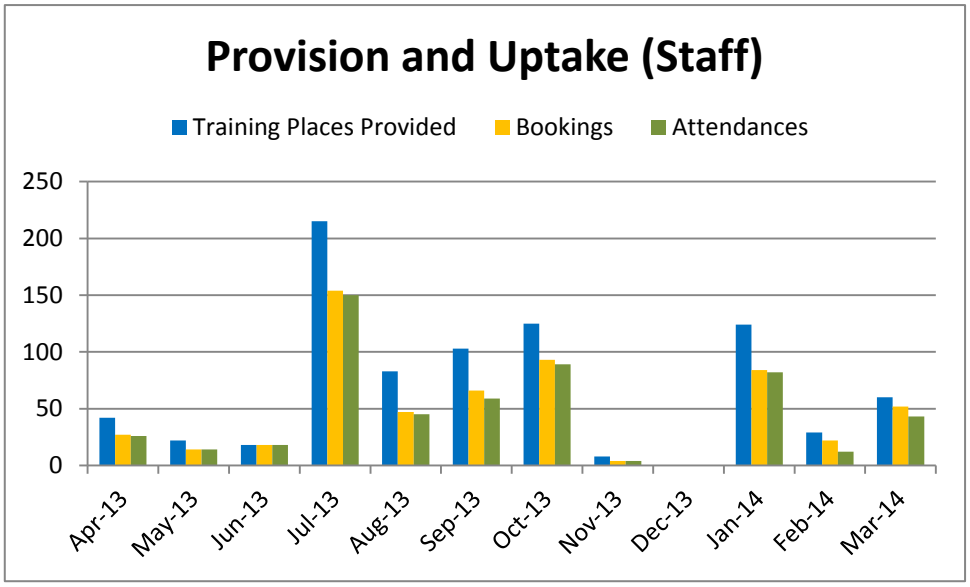
All Training:

Total Seats provided	1,893		
Total Registrations	1,588	84%	of seats provided were booked
Total Attendances	1,399	88%	of bookings were attended
		74%	of seats provided were filled

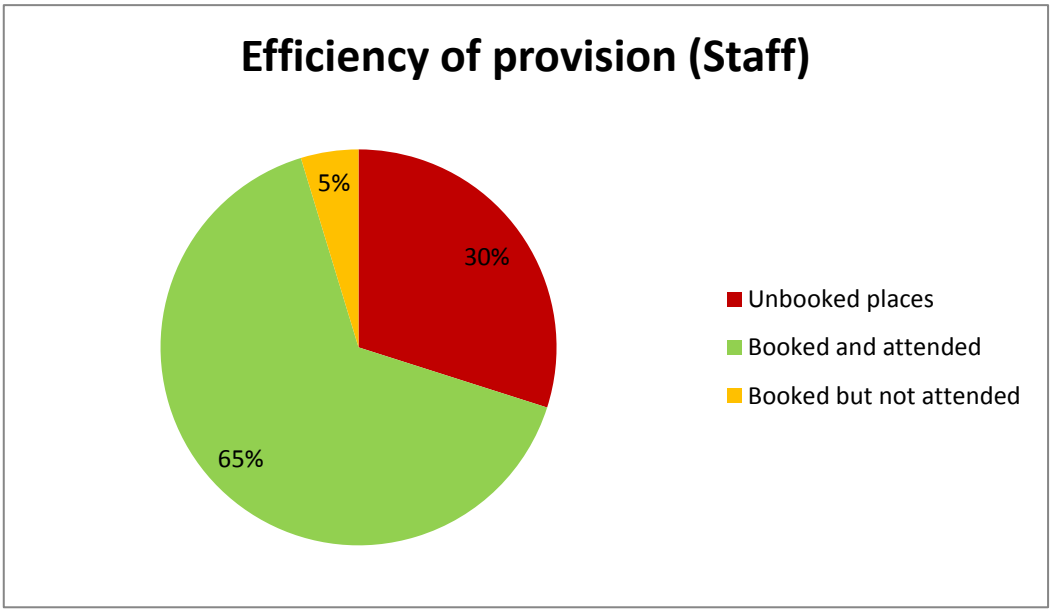


Staff Training

% of available places booked	% of bookings attended	% of available places attended
69%	96%	66%



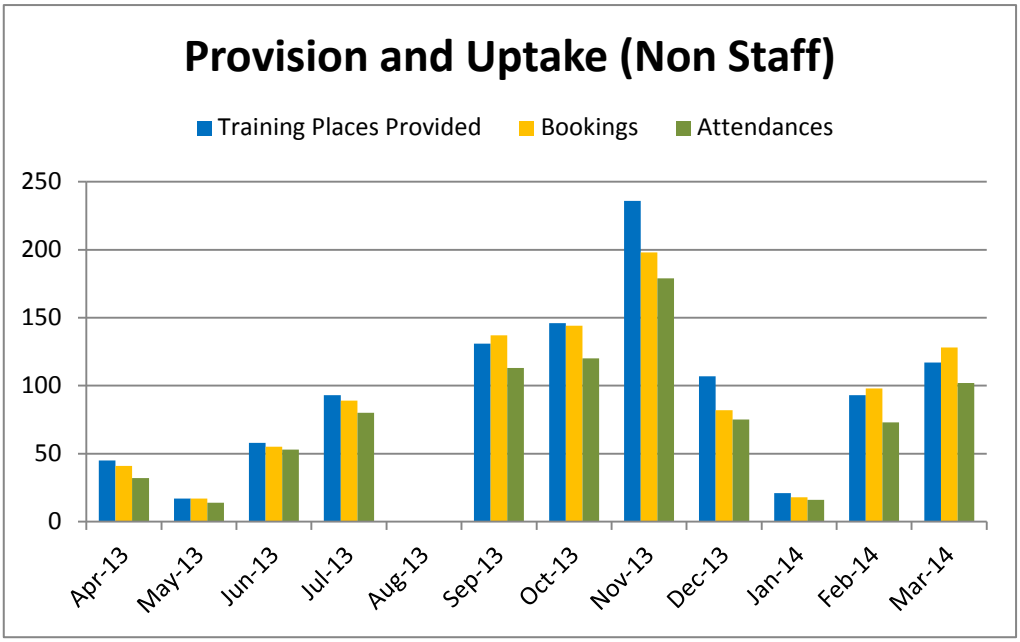
- The peak in events in July was due to a country-wide programme of appraisal training for all staff.
- There were no staff training events in December.



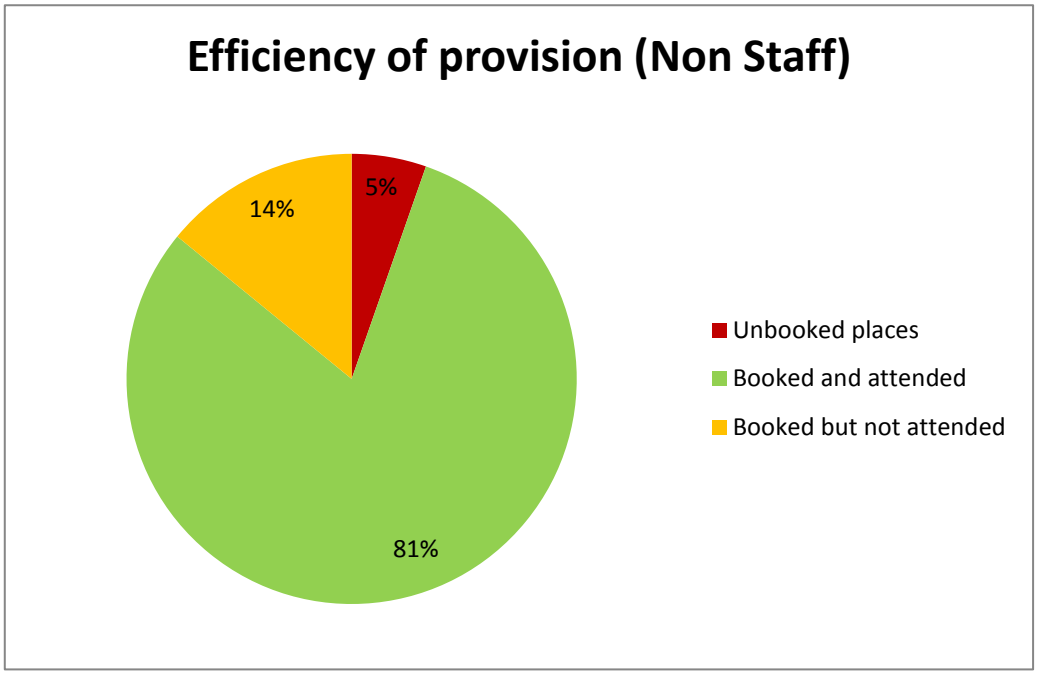
- The apparent over-provision will be explored in more detail on an event by event basis.

Non-Staff (REC Members and Research Community)

% of available places booked	% of bookings attended	% of available places attended
95%	85%	81%

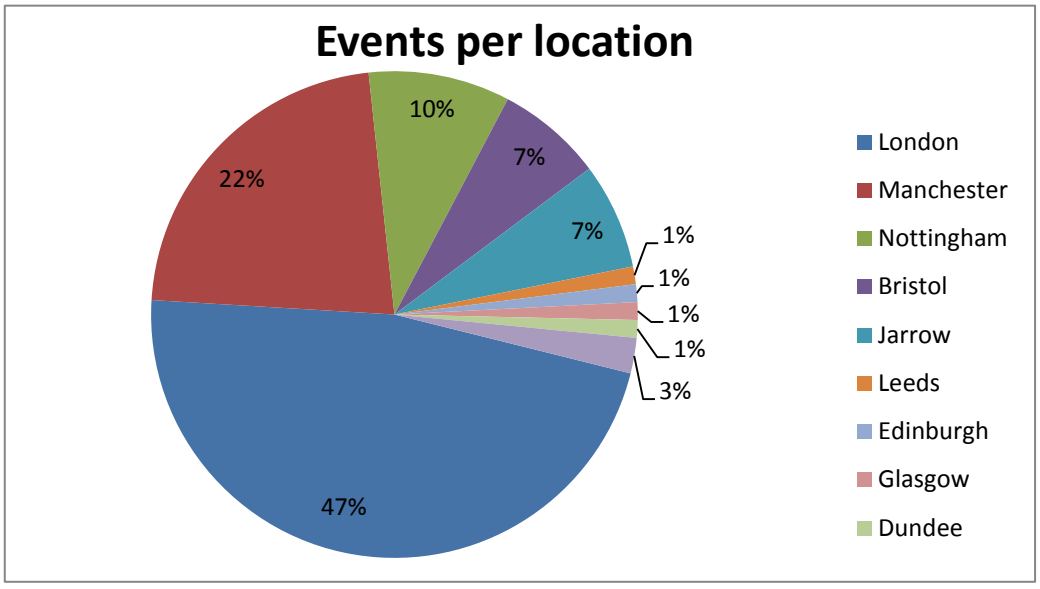


- There was no non-staff training in August



Geographical distribution of all training provided

Location	Events	Seats available	Registrations	Uptake %	Attendance figure	Bookings attended %	Bookings not attended %
London	40	931	842	90%	711	84%	16%
Manchester	19	451	380	84%	355	93%	7%
Bristol	8	134	94	70%	91	97%	3%
Jarrow	6	125	88	70%	87	99%	1%
Nottingham	6	119	57	48%	54	95%	5%
Leeds	1	58	55	95%	53	96%	4%
Edinburgh	1	26	26	100%	20	77%	23%
Glasgow	1	21	20	95%	19	95%	5%
Dundee	1	12	10	83%	9	90%	10%



- The majority of events are held in London and Manchester because those HRA offices have the largest in-house meeting rooms and are easily accessible via main rail routes

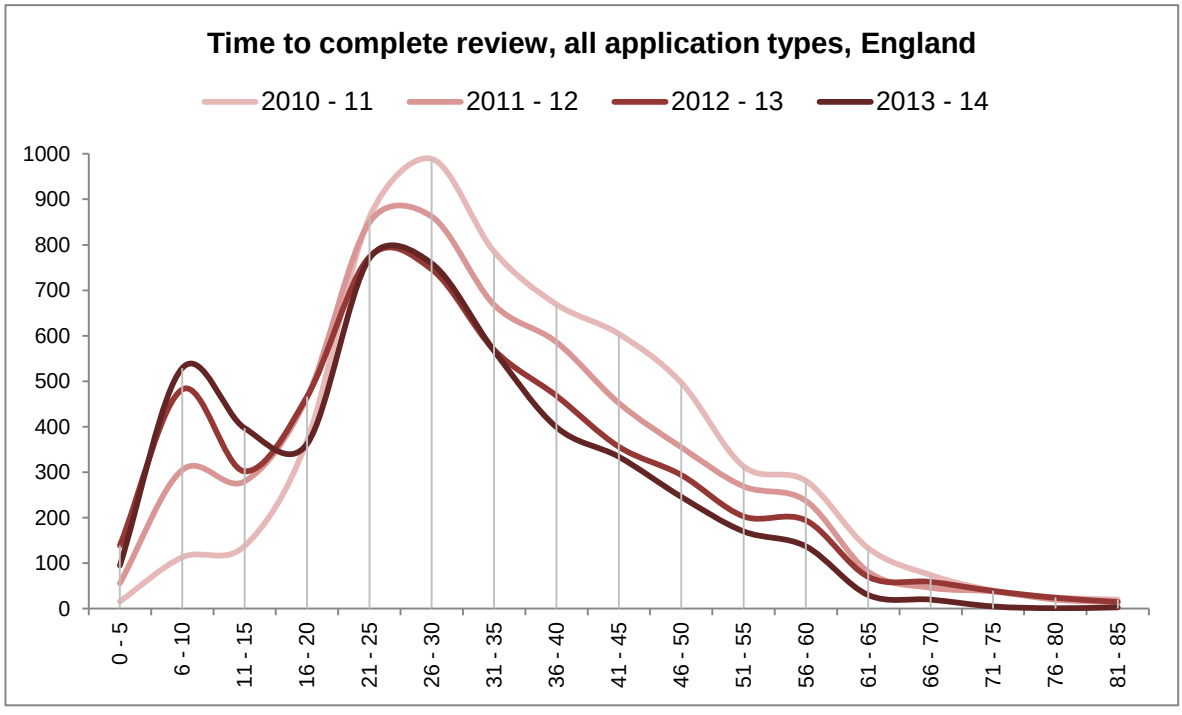
Section 5: Research Ethics Committee metrics

REC METRICS

- SOP (Standard Operating Procedure) requirement is 60 calendar days; the HRA has set stretched targets of 95% within 40 calendar days for applications going through full committee. 2013/14 has seen a continuing improvement in the number of applications reviewed within statutory timelines, despite ongoing IT issues which have seriously comprised work output on many occasions. 98% of applications reviewed in 60 days (England cumulative figure)
- Proportionate sub-committee review for low-risk studies has a target of 14 days. The cumulative figure at March 2014 is 90% compliance (England)
- GTAC (Gene Therapy Advisory Committee) has transferred to the HRA and timelines have reduced significantly. Legal requirement is 90 calendar days; the HRA has stretched targets of 100% in 60 days. Previous data was over 100 days
- Reduction of applications year-on-year has in part been due to service improvements, including database and tissue bank approvals which removed the need for individual applications, and policy changes to REC remit
- SOP requirement for amendments is 35 calendar days and the HRA has set a stretched target of 28 days. Individual committees have met the stretched target. 98% of amendments reviewed in 35 days (England cumulative figure)

Time to complete ethical review – all application types, England

(year to date)

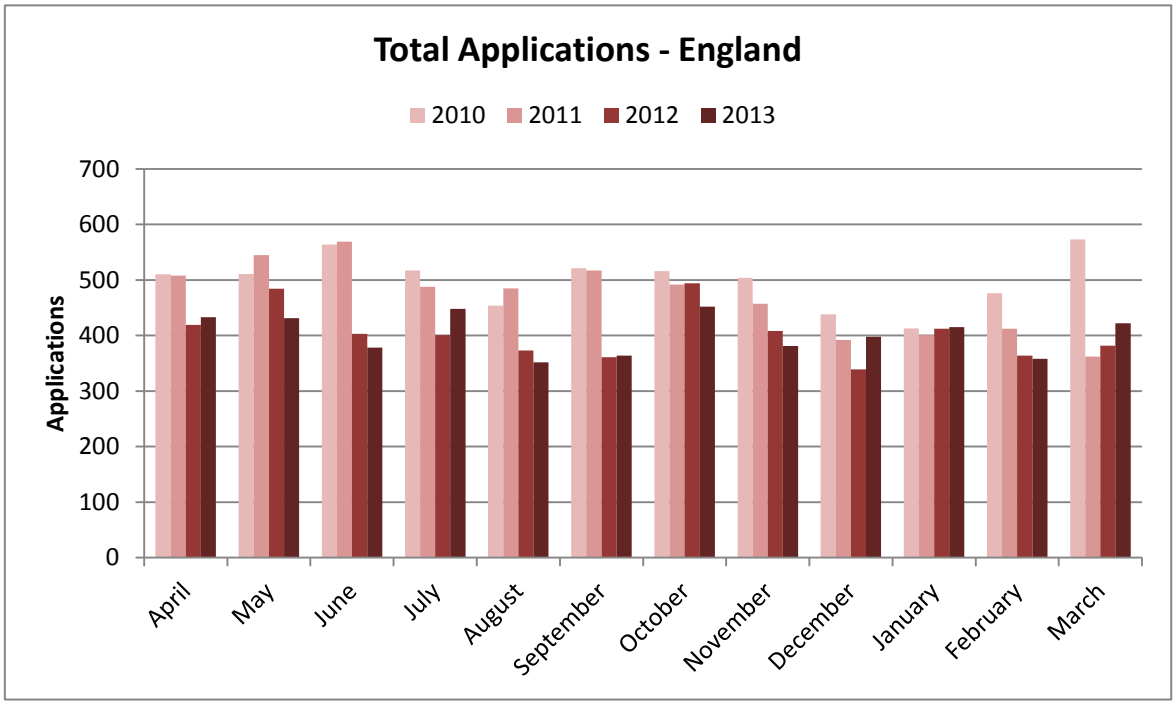


Applications to RECs in England (year to date)

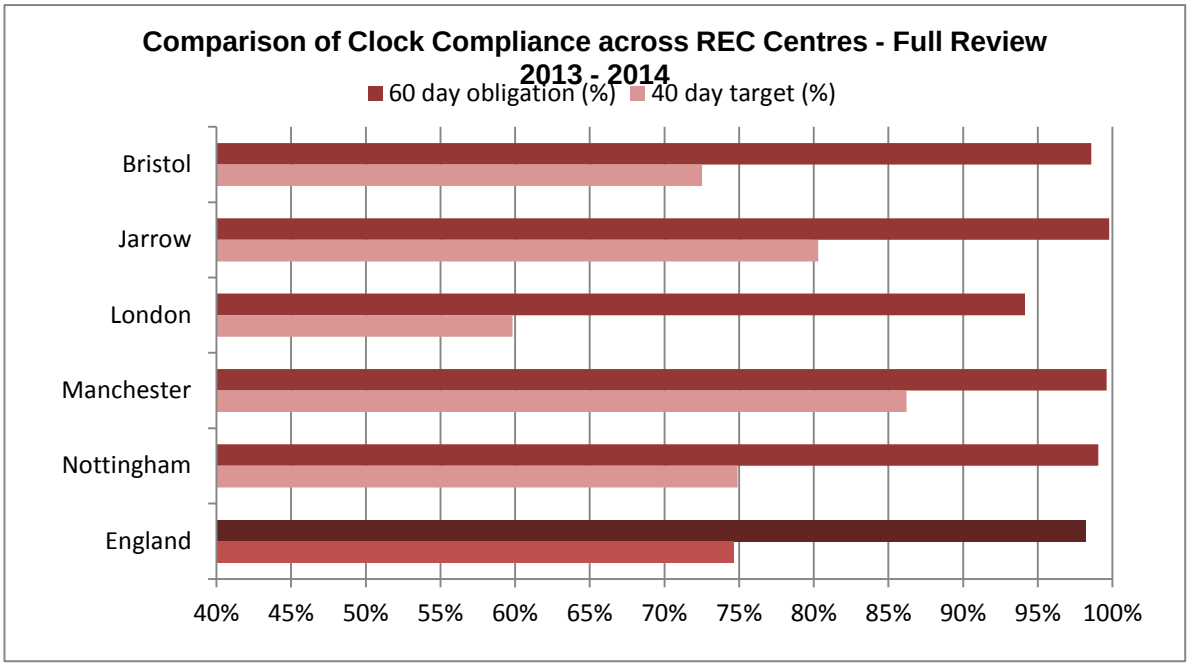
	All applications	CTIMPs	Other (full review)	Research Tissue Bank	Research Databases	Proportionate review	Full review (inc. CTIMPs)
Apr-13	433	58	283	3	1	88	345
May-13	431	62	252	3	4	110	321
Jun-13	378	56	251	5	2	64	314
Jul-13	449	83	261	5	5	95	354
Aug-13	352	55	207	3	0	87	265
Sep-13	364	66	206	4	4	84	280
Oct-13	452	99	257	3	1	92	360
Nov-13	380	80	221	5	3	71	309
Dec-13	398	75	240	4	4	75	323
Jan-14	415	69	240	2	2	102	313
Feb-14	358	55	210	3	2	88	270
Mar-14	422	62	244	4	5	107	315

CTIMP: Clinical Trial of Investigational Medicinal Product

Total applications reviewed in England April 2013 - March 2014 (year on year)



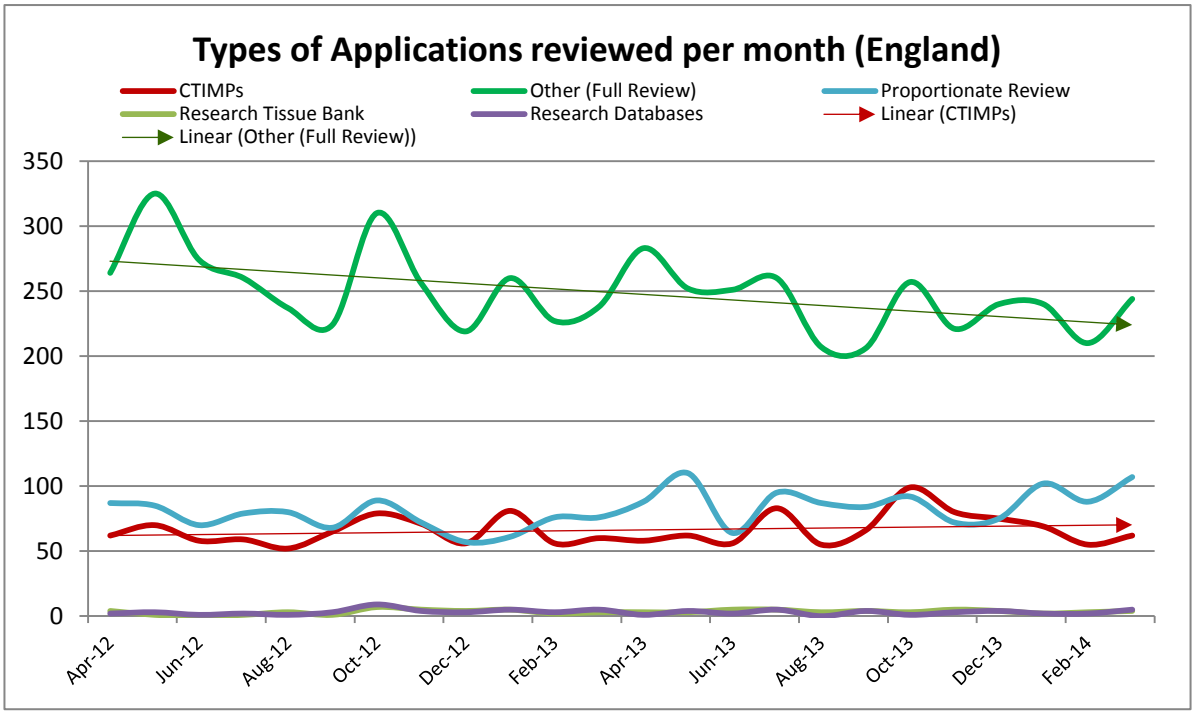
Review of full applications – comparison of Centres, England (year to date)



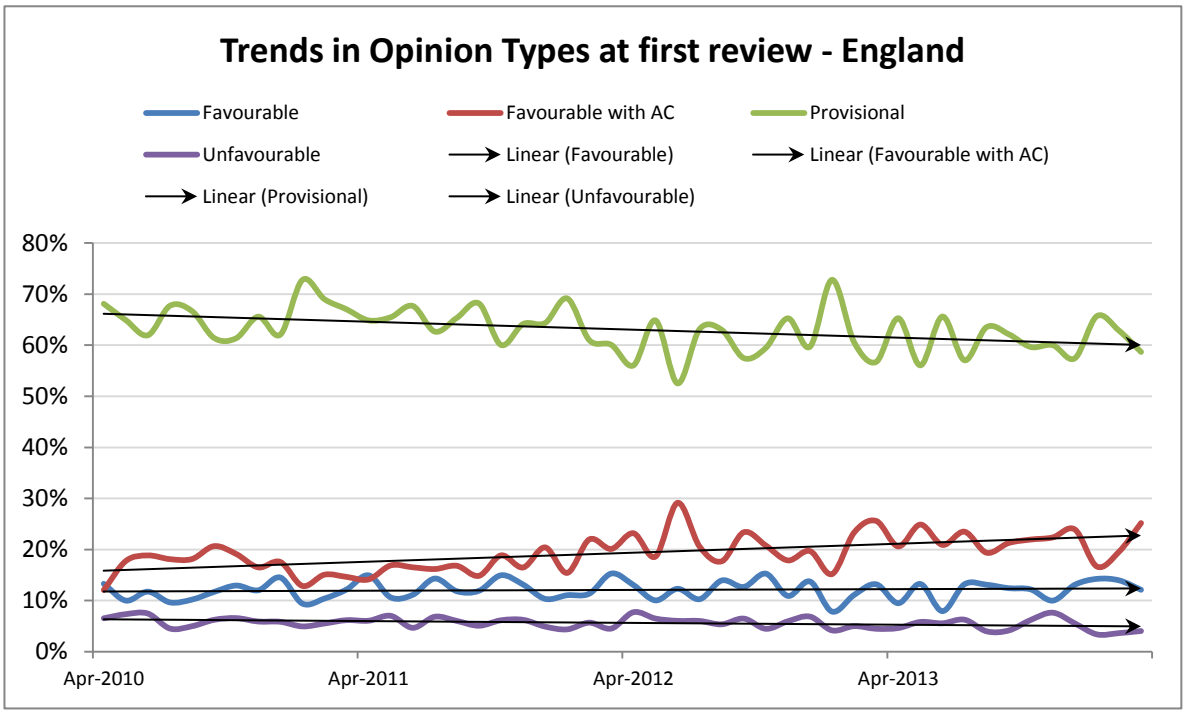
Statutory timeline is 60 calendar days – Business Plan KPI objective is 40 calendar days

REC Centre	Total no. applications (year to date)	Mean average time to process	Complete within 40 days (%)	Complete within 60 days (%)
Bristol	1,055	34.51	73%	99%
Jarrow	477	31.18	80%	100%
London	682	37.96	60%	94%
Manchester	769	29.11	86%	100%
Nottingham	741	33.64	75%	99%

Types of applications reviewed per month, England (rolling 2 years with trend)



Trends in REC opinion types at first review, England (rolling 3 years)

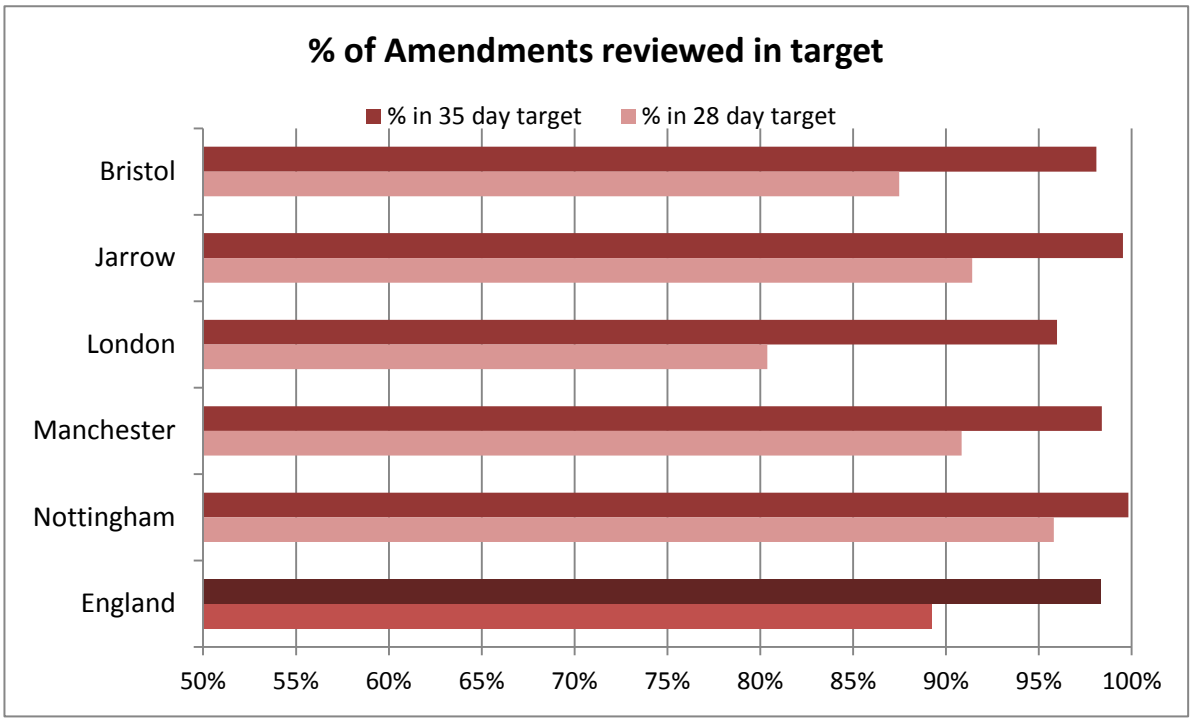


The 2012 HRA Business Plan determined that the use of Provisional opinions at first review should be reduced in favour of Favourable with Additional Conditions (AC). The downward trend in Provisional opinions and the upward trend in Favourable AC reflect progress in this. Other opinion types remain stable

Review of amendments per REC Centre, England (year to date)

REC Centre	Number of amendments	Mean average time to process	Complete within 28 days (%)	Complete within 35 days (%)
Bristol	2,060	16.76	87%	98%
Jarrow	850	18.24	91%	100%
London	1,244	18.91	80%	96%
Manchester	1,365	16.40	91%	98%
Nottingham	1,620	15.62	96%	100%
England	**7,141**	**16.98**	**89%**	**98%**

Review of amendments in target per REC Centre, England (year to date)



Statutory timeline is 35 calendar days – Business Plan KPI objective is 28 calendar days

Action Plans from accreditation of RECs, England

Month	No of action plans received	% in target
April 2013	2	100%
May 2013	2	100%
June 2013	1	100%
July 2013	0	N/A
August 2013	0	N/A
September 2013	1	100%
October 2013	1	100%
November 2013	1	100%
December 2013	0	N/A
January 2014	1	100%
February 2014	1	100%
March 2014	1	100%

Section 6: Confidentiality Advisory Group (CAG) metrics

CAG METRICS

- CAG was established in April 2013 when the function transferred to the HRA. During this reporting period CAG meetings were bi-monthly. From April 2014 CAG will meet monthly, which will improve timelines.
- Additional resource secured in December 2013 has assisted in reducing timelines. Since January 2014 there has been a reduction in processing times as follows:
  - new applications: 10% decrease
  - precedent set review: 40% decrease (please see comment below)
  - amendments: 23% decrease
- Unlike applications submitted to NHS Research Ethics Committees, whether an application submitted to CAG is suitable for Precedent Set review is determined by whether precedent advice has been set in relation to the key issues engaged by the application, rather than by the application itself raising no material issues. As with review of new applications submitted to the full Confidentiality Advisory Group, applications for consideration through Precedent Set review are subject to an office assessment stage, as well as review by a sub-group of members, and precedent advice will be reviewed and applied where relevant

Summary of applications reviewed by CAG (year to date)

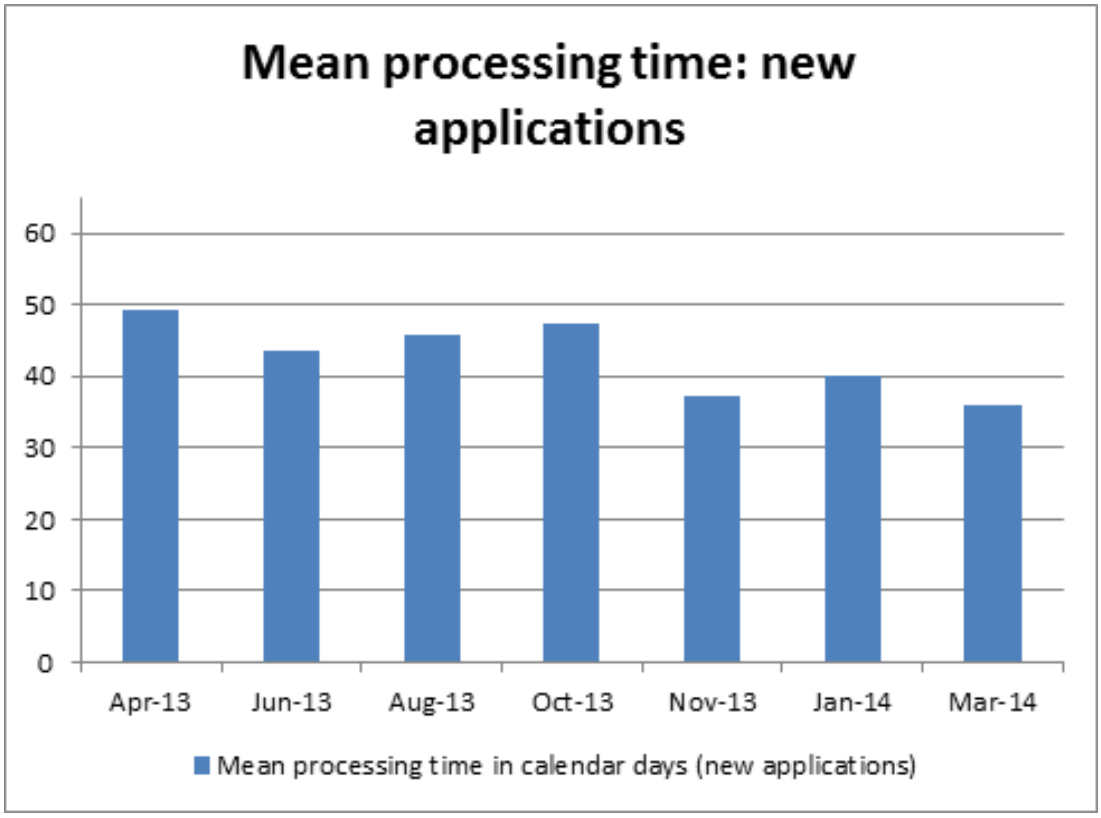
Application type	Apr-13	Jun-13	Aug-13	Oct-13	Nov-13	Jan-14	Mar-14	Total
New full CAG applications reported	8	6	10	14	4	7	5	**54**
Precedent Set reviews reported	7	5	6	5	11	7	4	**45**
Amendments reported	7	2	3	4	9	4	13	**42**

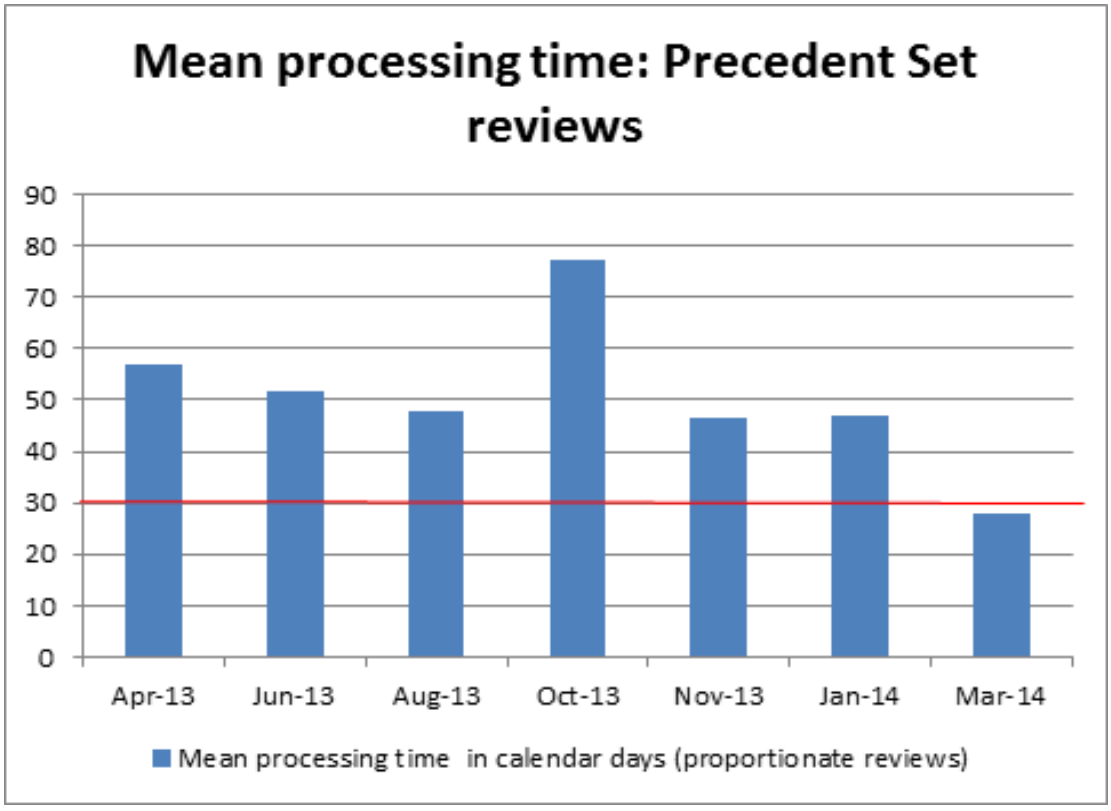
Mean processing time in calendar days	Apr-13	Jun-13	Aug-13	Oct-13	Nov-13	Jan-14	Mar-14	Target
New applications	49	44	46	45	31	40	36	**60**
Precedent Set reviews	57	52	48	49	58	47	28	**30**
Amendments	72	52	34	88	52	35	27	**30**

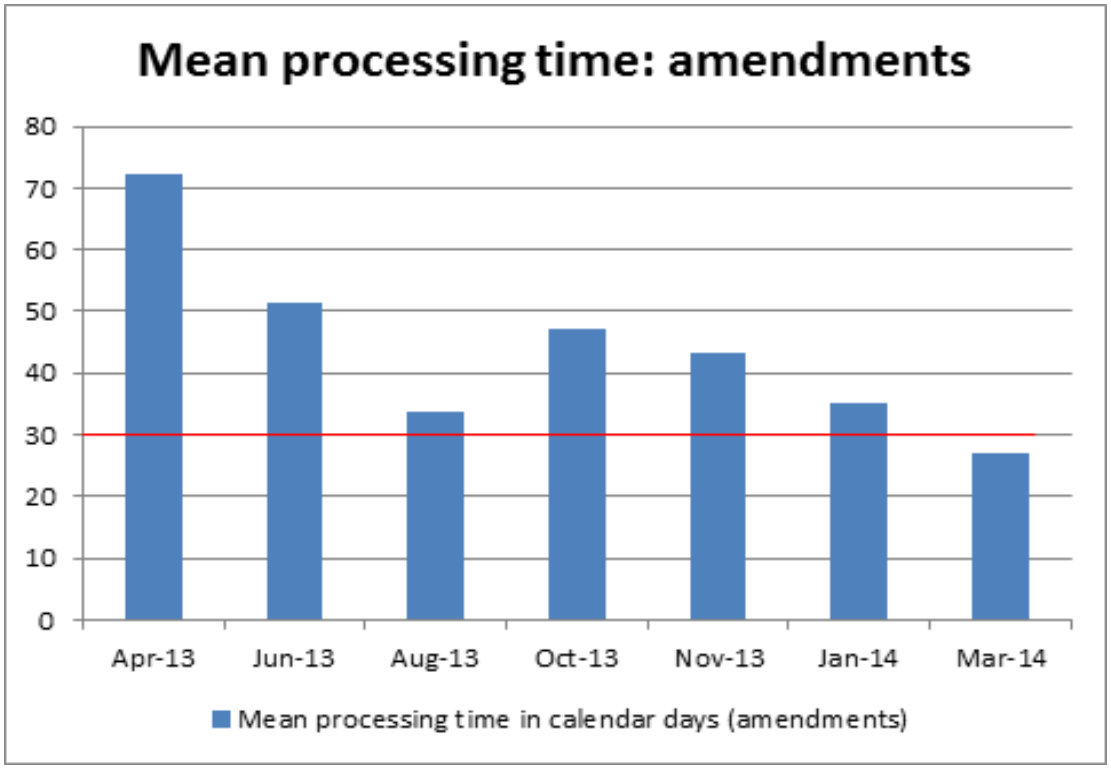
No. of applications meeting target processing time	Apr-13	Jun-13	Aug-13	Oct-13	Nov-13	Jan-14	Mar-14	Target
New applications	7	6	8	13	4	7	5	**60**
Precedent Set reviews	0	0	0	1	0	0	2	**30**
Amendments	2	0	2	0	2	1	11	**30**

Proportion of applications meeting target processing time	Apr-13	Jun-13	Aug-13	Oct-13	Nov-13	Jan-14	Mar-14	Target
New applications	88%	100%	80%	93%	100%	100%	100%	**100%**
Precedent Set reviews	0%	0%	0%	20%	0%	0%	50%	**100%**
Amendments	29%	0%	67%	0%	22%	85%	85%	**100%**

Review of applications by CAG (year to date)





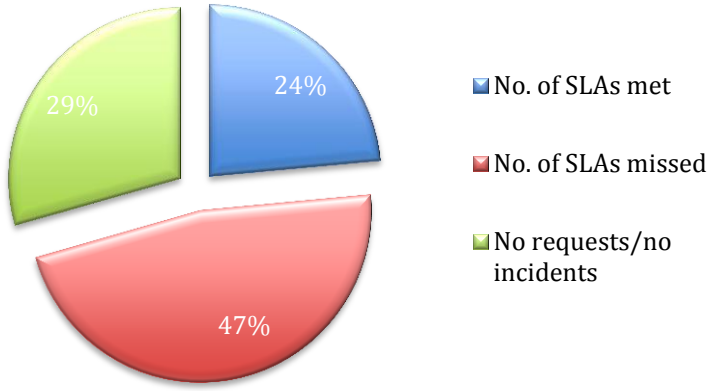

Mean processing time: amendments
80
70
60
50
40
30
20
10
0
Apr-13
Jun-13
Aug-13
Oct-13
Nov-13
Jan-14
Mar-14
Mean processing time in calendar days (amendments)

Open Service dashboard

SLA/KPIs*	*Jan-14*	*Feb-14*	*Mar-14*
No. of SLAs met	4	5	**5**
No. of SLAs missed	8	7	**7**
No requests/no incidents	5	6	**6**
Total	17	18	**18**

**more SLA/KPIs will be added to future Service Review reports*

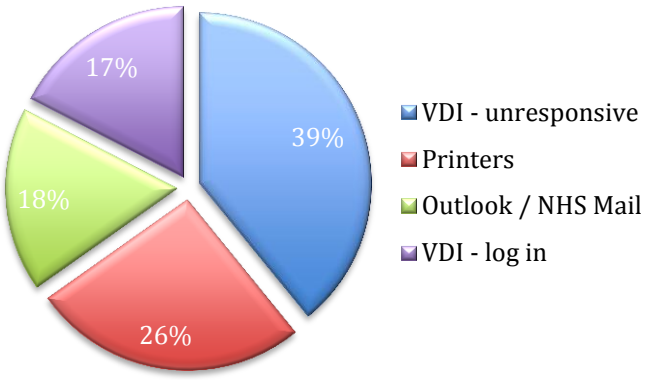
No. of SLAs met/missed



INCIDENTS	*Jan-14*	*Feb-14*	*Mar-14*
No. of Major Incidents	3	3	**2**
No. of new calls	76	82	**62**
No. of open calls as 31/03	7	9	**6**
No. of days of oldest call*	66	47	**75**

**the oldest call refers to the wider NHS mail / Outlook issues which has now been closed. These issues have been recognised as a high priority and there is an ongoing project in place to improve performance.*

Top Issues



Top Issues	Details	Result	No.
VDI - unresponsive	VDI sessions become unresponsive	Sessions reset by 1st Line support enabling users to log back in	9
Printers	Users unable to print or print quality issue	Printers fixed by Ricoh engineers	6
Outlook / NHSmail	Users unable to access Outlook or Outlook becomes unresponsive	Resolved by Atos and NHSmail support	4
VDI - log in	Users unable to log in to Thin Client	Access restored within SLA	4

Top Requests	Details	Result	No.
Shared Drive	Request for shared drive access	Access given within agreed SLAs	8
Passwords	Requests to have any of the passwords reset	Passwords reset by 1st or 2nd line support	4
New Accounts	Requests for new user IT accounts	Accounts created within SLA	3
Software	Request for additional software	Software installed within agreed SLA	3

D. HRA procurement pipeline 2014/15

Procurement pipeline FINAL Vers 1.2.xlsx

E. Estates Footprint

Office Location	Approximate Size (m2)	Staff Numbers	Lease Cost (p.a.)	Cost per Head p.a.
HRA HQ & London REC Centres Ground Floor (Old Library) Skipton House, 80 London Road, London. SE1 6LH	476m2	47	£279,900	£5,955
Nottingham Centre. The Old Chapel, Royal Standard Place, Nottingham. NG1 6FS	207m2	16	£39,800	£2,488
Manchester Centre. 3rd Floor, Barlow House, 4 Minshull Street, Manchester. M1 3DZ	522m2	20	£114,695	£5,735
Jarrow Centre. Room 002 - TEDCO Business Centre, Viking Industrial Park, Rolling Mill Road, Jarrow, Tyne & Wear. NE32 3DT	116 m2	14	£28,350	£2,125
Bristol Centre. Level 3, Block B, Whitefriars, Lewins Mead, Bristol . BS1 2NT	287m2	24	£75,575	£3,149

F. Workforce Statistics

Projected Headcount position as at 31 March 2014 (based on position at 31/12/13)

Description	Headcount	WTE
Payroll HRA	130	118.71
Non-payroll HRA temporary members of staff	14	9.68
Secondees	15	5.55
Non-payroll recharged permanent staff	0	0
TOTAL	**159**	**133.94**

Projected headcount position by quarter 2014/15

	Q1 (Apr – Jun) projected		Q2 (Jul – Sep) projected		Q3 (Oct – Dec) projected		Q4 (Jan – Mar) projected	
Description	Headcount	WTE	Headcount	WTE	Headcount	WTE	Headcount	WTE
Payroll HRA	130	118.71	212*	208.55	212	208.55	212	208.55
Non-payroll HRA temporary members of staff	14	9.68	12	10	10	8	8	6
Secondees	15	5.55	15	5.55	15	5.55	15	5.5
Non-payroll recharged staff	0	0	0	0	0	0	0	0
TOTAL	**159**	**133.94**	**239**	**224.1**	**237**	**222.1**	**235**	**220.1**

reflects recruitment of staff to support delivery of HRA Assessment and Approval

Further staff analysis (as at 31/12/13)

2012/13 (as at 31/12/12)	Headcount	M	F	WTE	M	F	Ethnicity	Disability
On payroll	130	34	96	118.71	32.23	86.48	30% (Non-White British)	>1% declared

Sickness absence

	2013/14 (period Apr 13 - Dec 2013)
Short - term sickness absence	0.89% *(1.42% 2012/13)*
Long- term absence	0.84% (*3.73%)*
Overall	1.73% *(5.15%)*

National comparator 's = 2.66% for SpHA'S and 4.18% for NHS overall (as at Oct 2013)

Comparators requested by ALB Team

Description	Measure 2013/14	2012/13
Ratio of VSM or SCS to WTE (on payroll) staff complement;	1:39	1:36
Number of staff earning more than £142,500 now and any projected change during the planning period	0 (no projected changes)	0
HR staff to WTE employee ratio	1:198	1:196
Cash ratio - (has been based on a staff salary cost of c4m p.a.)	£121/member staff	£121/member staff

Document Control

Change Record

Version Status	Date of Change	Reason for Change
V 0.1	N/A	First draft presented to Senior Management Group (SMG) Jan 2014
V 0.2	22.01.2014	Changes made after input from SMG
V 0.3	11.02.2014	Input / amends from DH / JW / SMG. For EMT review.
V 0.4	14.02.2014	Amends after EMT & submit to DH
V 0.5	19.04.2014	Amends after submission & comment from DH
V 0.6	06.03.2014	Amends from Board and prior to final submission
V 0.7	12.03.2014	Inclusion of new KPI section prior to final submission
V 0.8	14.03.2014	Amends requested by Sponsors
V 0.9	31.03.2014	Minor Board amends
V 1.0	02/05/2014	Final – addition of completed KPIs for 2013 / 14
V 1.1	06/05/2014	Final – minor proofing amendments & change to organisation structure
V 1.2	07/05/2014	Final – further minor proofing amendments
V 1.3	08/05/2014	Revision to table p.61

Reviewers

Name	Position	Version Reviewed
EMT		V 1.0

Distribution of Approved Version

Name of person or group	Position	Version Released
S. Robinson	Corporate Secretary	V 1.0 Final for Widespread Release
G. Habicht	Head of Corporate Business	V 1.1 Final (with minor amendments) for widespread release
G. Habicht	Head of Corporate Business	V 1.2 Final (with minor amendments) for widespread release and publication
G. Habicht	Head of Corporate Business	V 1.3 Final (correction to figures in table) for widespread release and publication