NHS
Health Research Authority

Health research Authority

Update

October 2014

Protecting and promoting patients interests in health research

‘Greater numbers of people can and do take part in health research, and continue to feel safe when they do’

Making the UK a great place to do health research

- Our values, our authority, our delivery
- Our credibility, our reputation

Inspiring leadership

Enabling people and teams to develop and deliver dynamic, innovative and transformative services and systems

Integrity

Being fair, ethical and honest in everything we do.

Trusted

Being respected for delivering to consistently high standards.

Transparent

Being accountable and open about all aspects of our work

Collaborative

Listening to and working with others to identify and make improvements to the health research environment

Empowering

Supporting independent thinking and decision-making

HRA – Non-Departmental Public Body Status

- Care Act clauses align to our business plan
- Places our functions on a statutory footing
- Greater authority and policy responsibility
- Gives duties to the HRA and to others
- Commitment is in this parliament, expected January 2015

Functions of HRA in Care Bill

- Co-ordination and standardisation of practice relating to the regulation of health and social care research:
  - Reduce duplication
  - Streamline
- Guidance – including replacement of RGF – NHS and local authorities must ‘have regard’
- Promote transparency in research

The Health Research Authority

- Research policy
- Research Ethics Committees
- Collaboration and Development projects
- HRA assessment and Approval programme
- Transparency
- Systems, including IRAS, TOPS and HARP
- Advice, guidance, training, quality assurance
- Communications and engagement
- Public Involvement
- Confidentiality Advisory Group and Team

HRA public involvement and engagement

- Public involvement strategy
- Commitment to engagement – all

‘Through a survey (Ipsos MORI) and a series of 11 workshops (7 HRA, 4 Ipsos MORI), part-funded by Sciencewise, we have worked to understand more about how people view health research.’

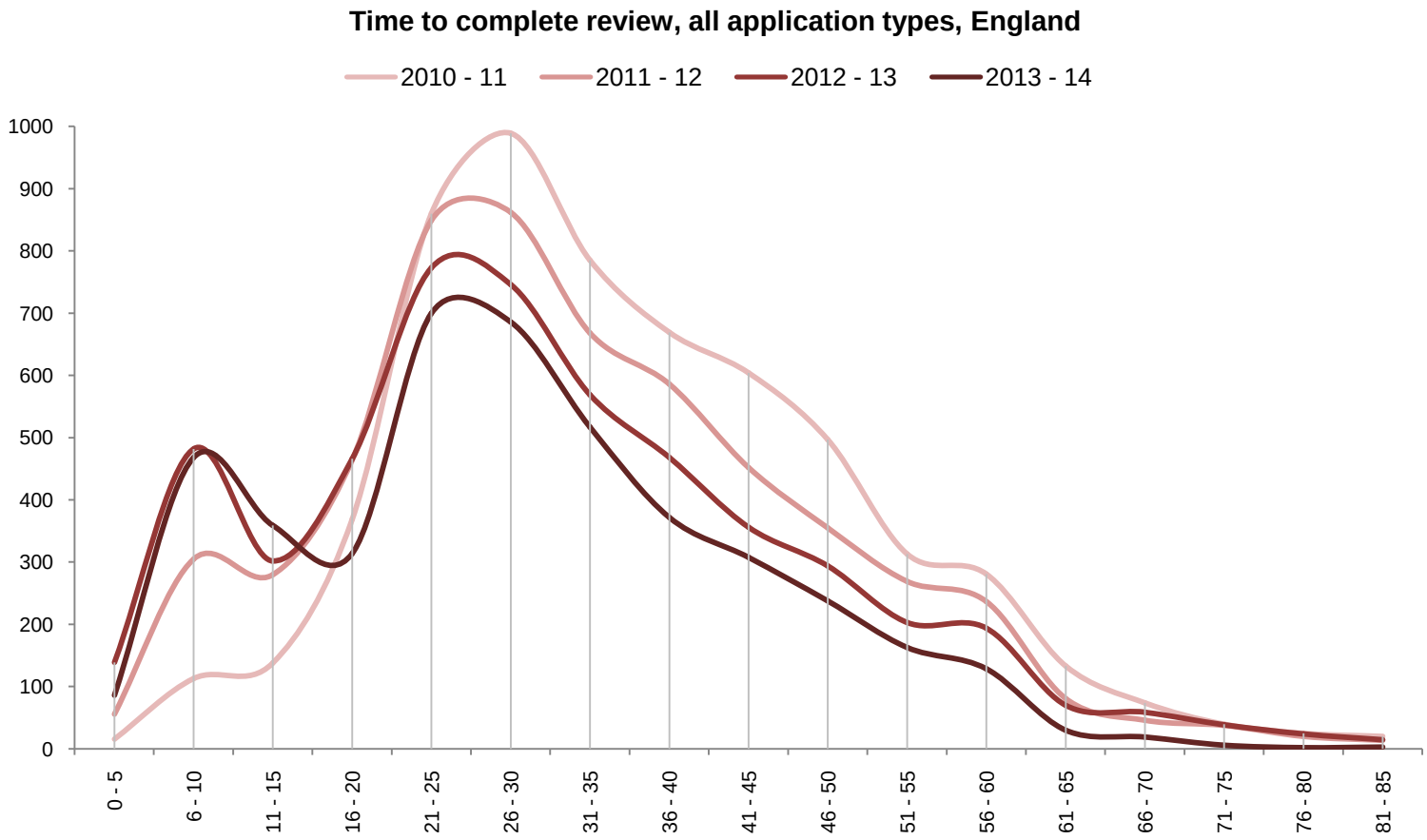
Views on health research

- Differences in views - public versus patients
- Differences in sources of confidence - expert versus patient
- Lack of understanding about clinical research and who could participate
- Trust in the NHS

Transparency

- Key issue with respect to public confidence
- HRA signed up to AllTrials
- HRA expectations and HRA requirements
- Transparency as a global issue
- Pragmatic and proportionate approach to support UK competitiveness

Delivering


Time to complete review, all application types, England
2010 - 11
2011 - 12
2012 - 13
2013 - 14
1000
900
800
700
600
500
400
300
200
100
0
0 - 5
6 - 10
11 - 15
16 - 20
21 - 25
26 - 30
31 - 35
36 - 40
41 - 45
46 - 50
51 - 55
56 - 60
61 - 65
66 - 70
71 - 75
76 - 80
81 - 85

The HRA Approval Programme

- A new operational framework – England
- Includes the REC opinion
- UK wide compatibility
- Scope is approval for the NHS
- Existing coordination with other regulators and approval bodies to build on

One application, one assessment and one approval for the NHS

HRA assessment and Approval

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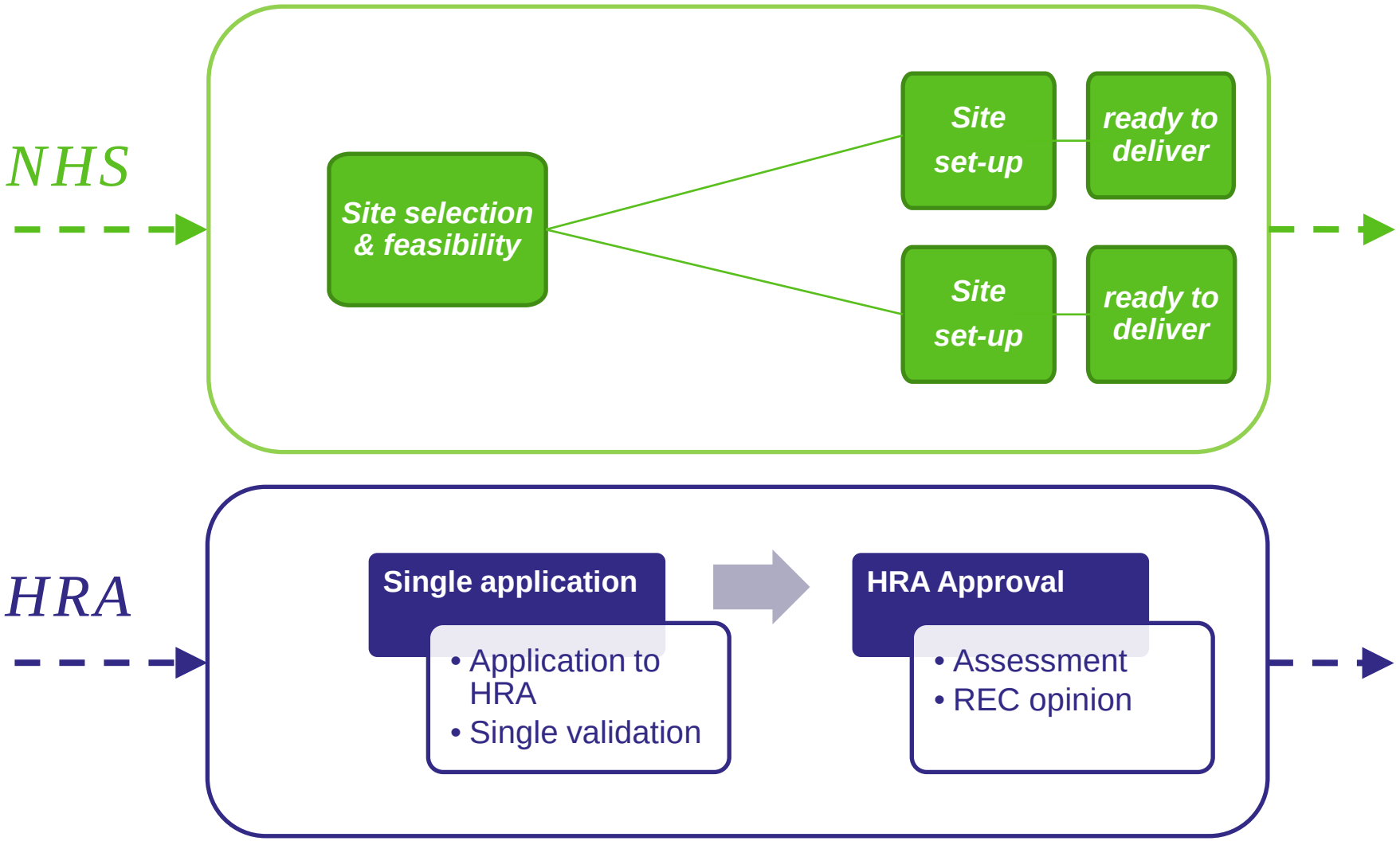

Key messages / agreed positions

- One application, one assessment and one Approval for research in the NHS – England
- UK wide compatibility
- Single application form provided by IRAS
- IRAS and current HRA ethics database (HARP) to be updated to provide required system platform UK wide

Key messages / agreed positions – cont.

- HRA assessment comprises a set of components:
  - Contract assurance
  - Technical assurance
  - Compliance and delivery
  - Participant interests
  - Research passport assurance
- HRA Approval is this assessment and the REC opinion

Key messages / agreed positions – cont. (2)

- HRA Approval Programme is a set a projects and programmes that will come together as HRA Approval
- Individual components will deliver early improvement
- HRA Approval will be rolled out by study type; ambition is by end of 2015

Key messages / agreed positions – cont. (3)

- Expertise for technical assurances will be coordinated by the HRA and provided by NHS
- Assessors will be a dedicated HRA staff resource
- Funders with direct influence across the NHS will be used to support implementation
- Application managers (slides later)

HRA Approval status – October 2014

- Single pharmacy assurance – roll out active in partnership with Cancer Research UK
- Single radiation assurance – close to go live
- Information Governance project – started
- Communication with NHS – Research support functions document – issued and change leads appointed
- Single validation – tested
- Compliance and delivery package – agreed UK wide

HRA Approval status – October 2014 cont.

- Model contracts under review, currently supported by HRA and will transfer to the HRA in the New Year
- Research passports – NHS England
- Q and A – published
- Call for named contacts to support communications – issued

Effective management of amendments

- Amendments are a significant barrier to research in the UK
- The HRA, Devolved Administrations and NIHR have agreed a new streamlined process
- Achieved through a system of categorisation and presumed implementation model

Application Managers, within the HRA

- In recognition that traditionally more effort has been provided to improve quality of applications
- Some studies are particularly disadvantaged by current processes e.g. rare diseases
- The full potential of some good initiatives e.g. Participant Information Centres have not been fully realised
- There are areas where new thinking about application of policy will give tangible improvement and prepare the NHS for culture change of HRA Approval

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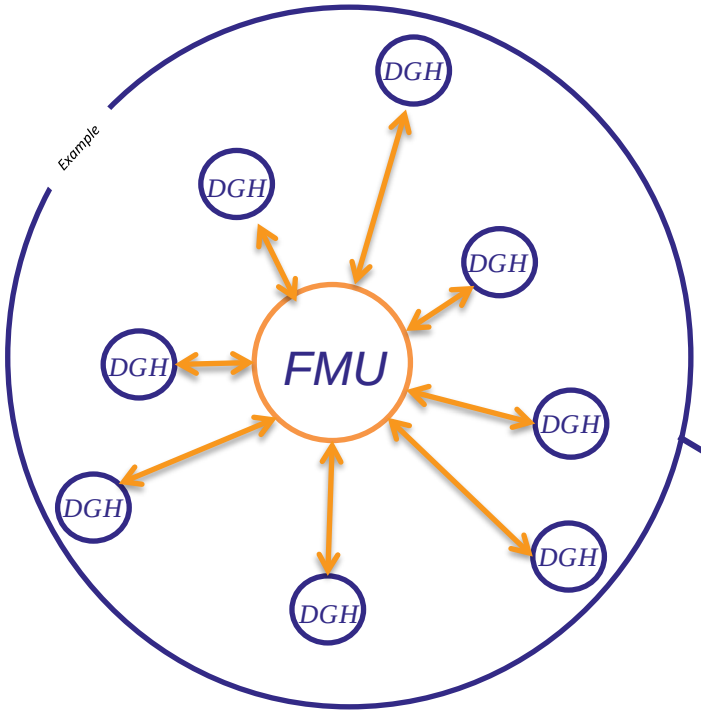
Complex Rare Disease Case Study

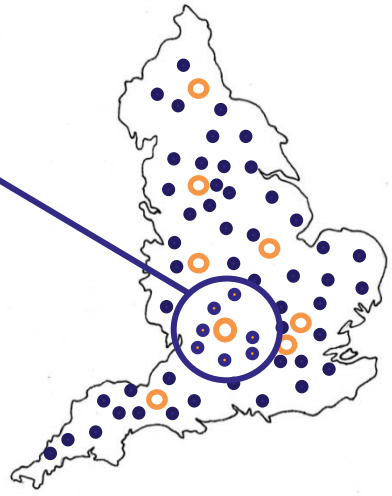
AMIPROM II- A widespread feasibility study and pilot of serial trans-abdominal amnioinfusion (AI) versus standard management in very early preterm premature rupture of membranes (vPPROM) between 16 and 24 weeks of pregnancy.

"HRA recent initiatives are unblocking barriers to trials and the excellent advice and support provided by the team during this period of change has been invaluable to this study"

Helen Hill
Senior Trials Manager
University of Liverpool



Potential for 150 separate R&D approvals reduced to 15 .



Fetal Medicine Unit: *Hub- R&D Approval*
Activity*: Consent, Randomisation, Intervention Arm*

District General Hospital: *Spoke-*
Activity*: Identify Participant, routine care, Control Arm*