Update from HRA

NHS Health Research Authority

Janet Messer - Director Approvals Service

April 2019

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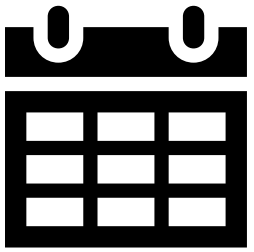
Strengthening the UK environment for clinical research - progress

UK-wide compatibility

- UK Local Information Pack site set-up
- Organisation Information Document template



5 June 2019

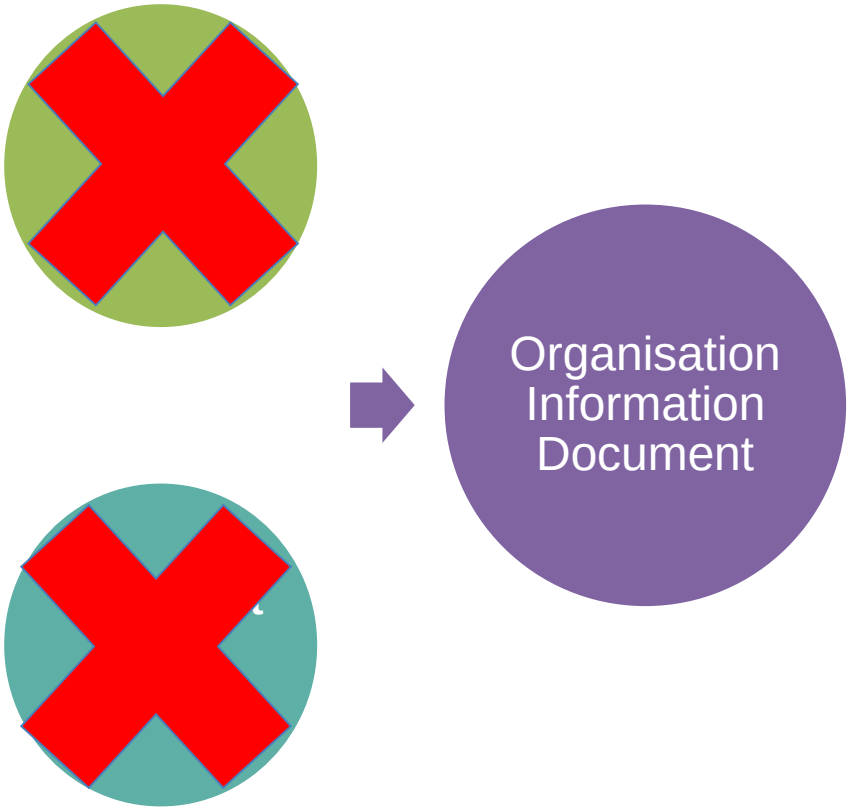
http://www.nhsresearchscotland.org.uk/services/uk-wide-working

Non-commercial research

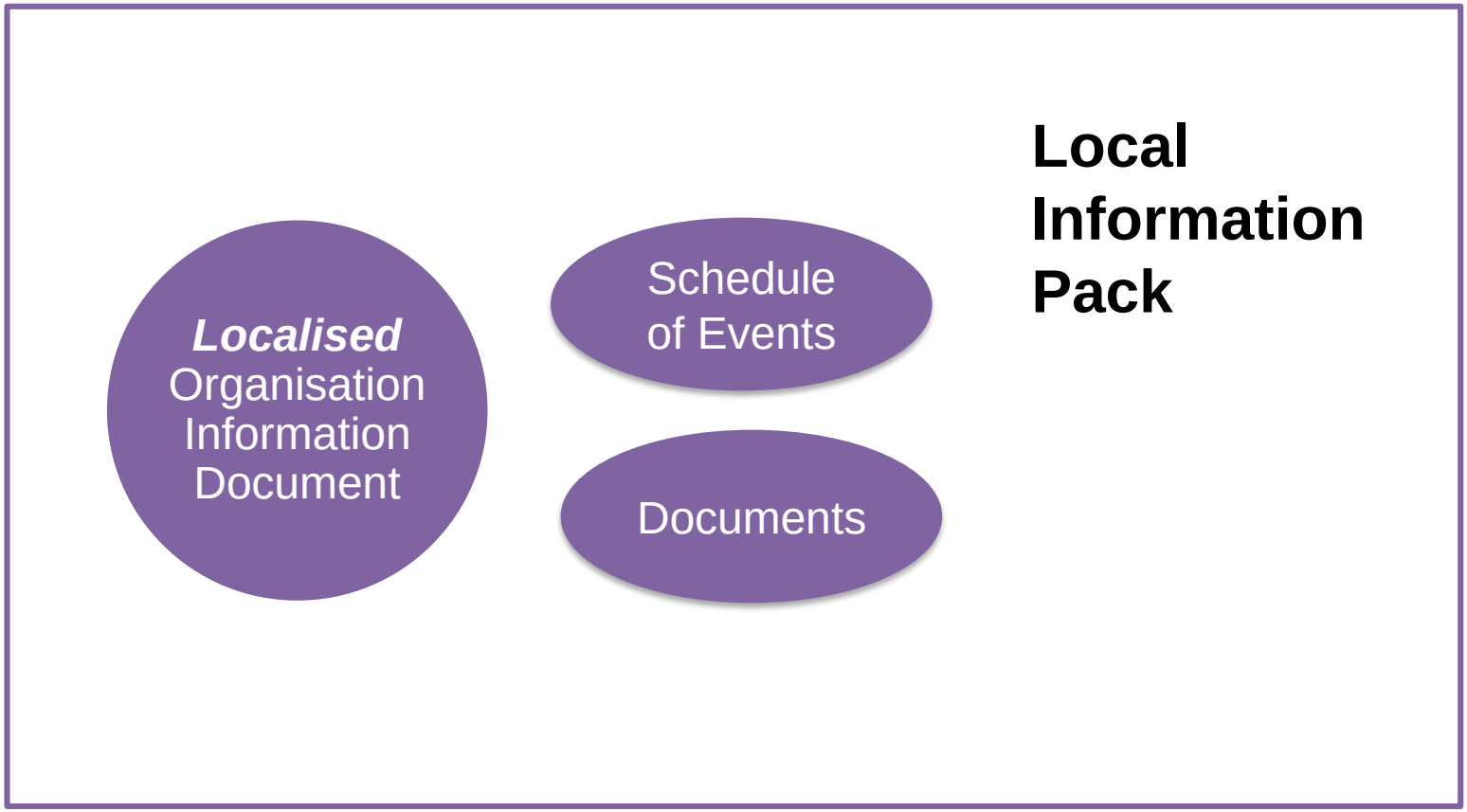
Scotland / NI

England / Wales

Non-commercial research



Non-commercial research

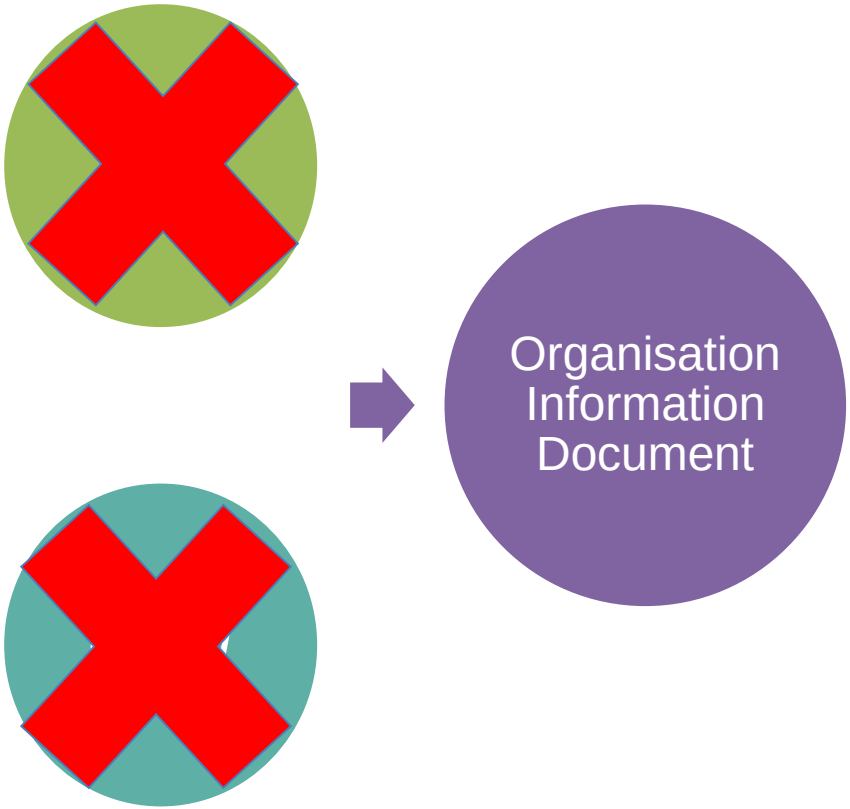


Commercial research

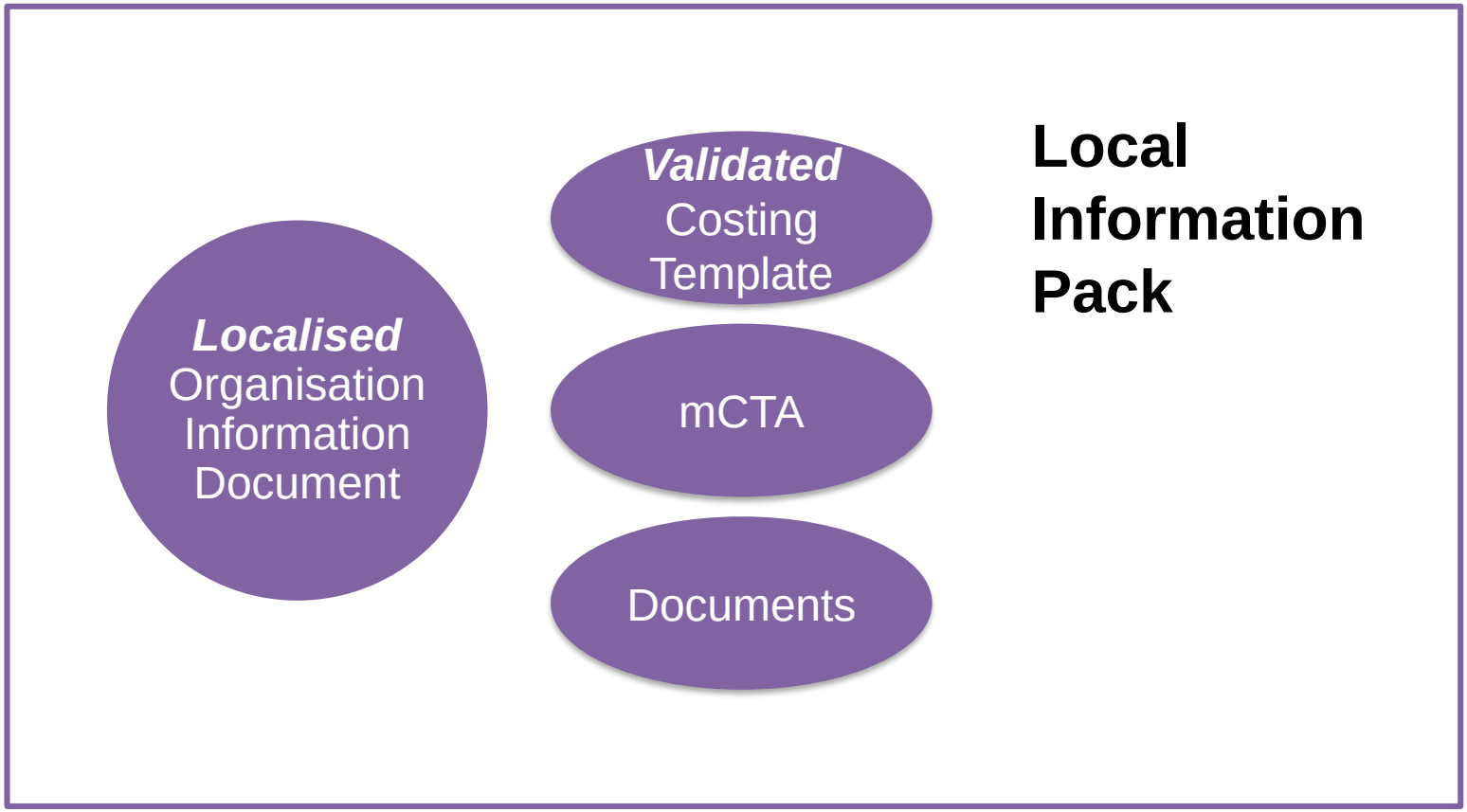
Scotland / NI

England / Wales

Commercial research

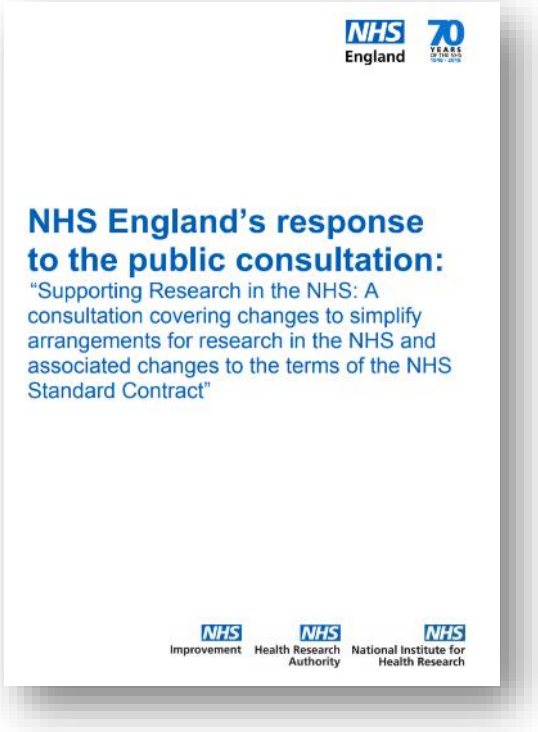


Commercial research



Strengthening the UK environment for clinical research: Progress

- Working towards single contract review for commercial research from April 2019
- Implementing new national model for excess treatment costs in non-commercial research



National Directive on Commercial Clinical Research Studies

If the Provider chooses to participate in any Commercial Contract Research Study which is submitted to the HRA for approval on or after 1 October 2018, the Provider must ensure that that participation will be in accordance with the National Directive on Commercial Contract Research Studies, at a price determined by NIHR for each Provider in accordance with the methodology prescribed in the Directive and under such other contractual terms and conditions as are set out in the Directive.

Before

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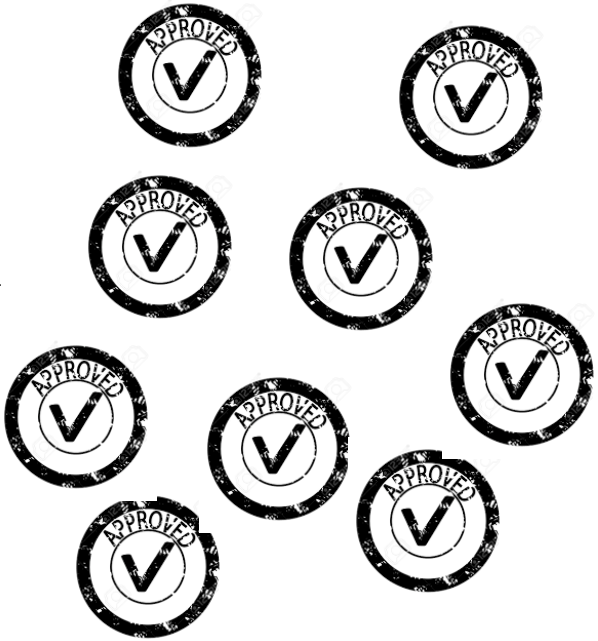
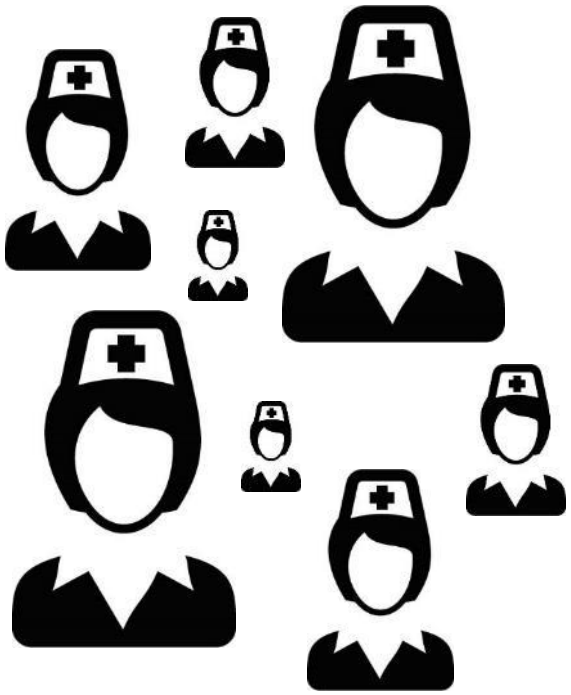
Negotiate resource requirements at multiple sites



Validate locally per site

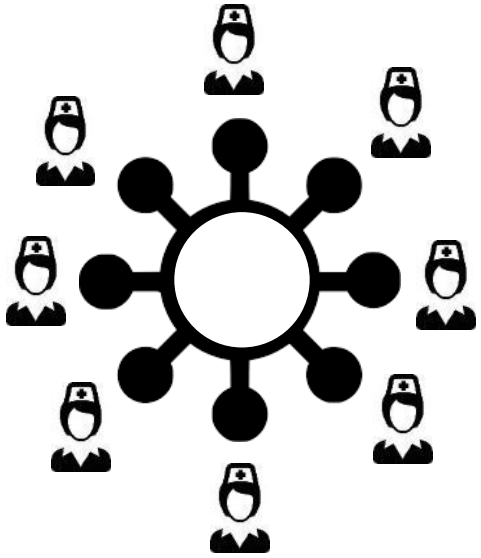


Variation in resource at different sites

After

Define resource requirements at lead site

Validate by Clinical Research Network

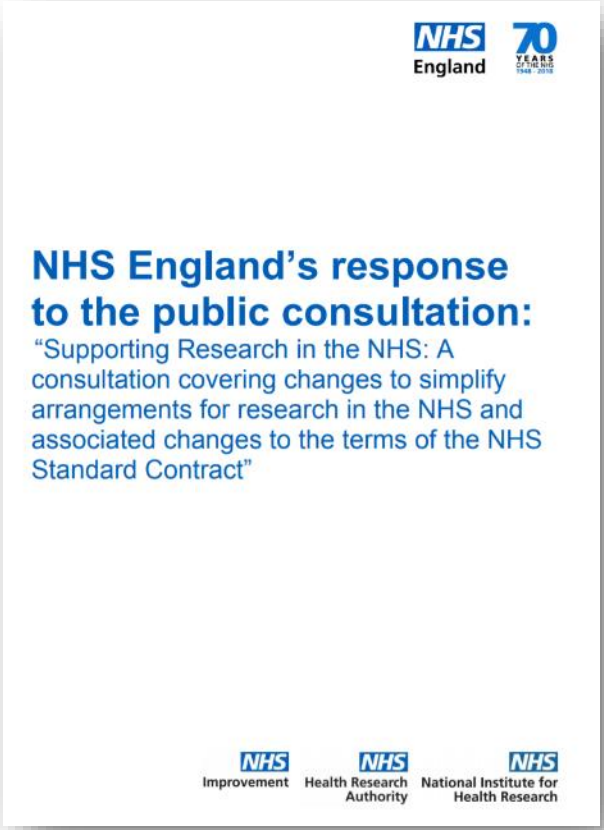


Apply at other sites

Benefits

- National standards for defining resource requirements
- Consistent approach to site costing
- Enable earlier ‘site open’ dates by minimising the time negotiating costs and contracts at individual sites

www.supportmystudy.nihr.ac.uk



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Strengthening the UK environment for research - next steps

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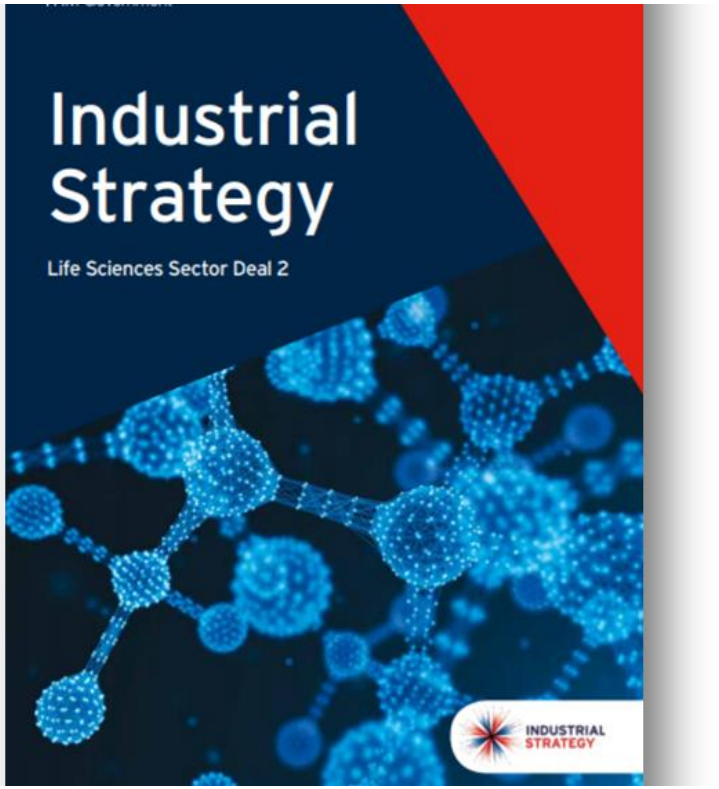
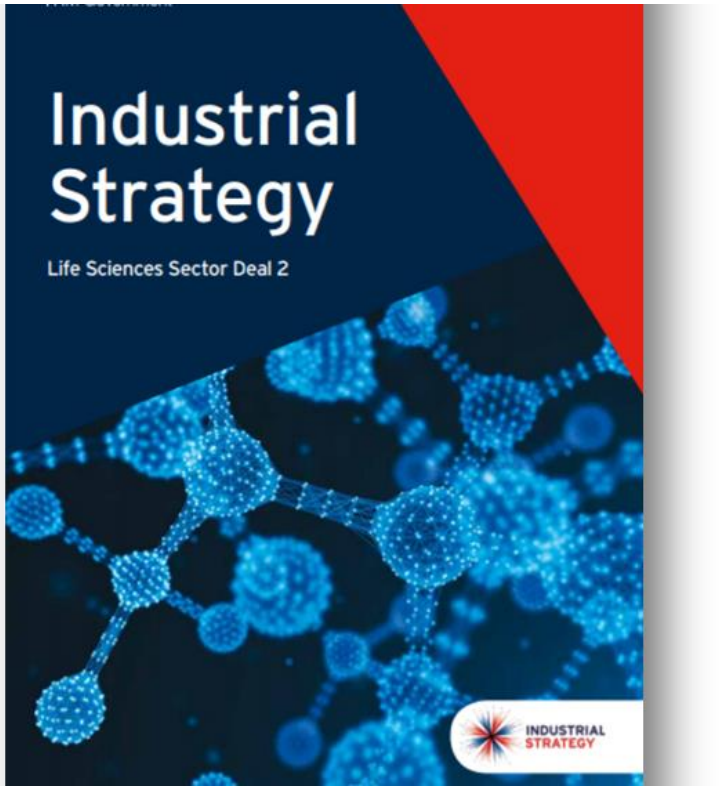
Strengthening the UK environment for clinical research: next steps

- Establish five purpose-designed centres dedicated to late-phase commercial research
- Address challenges in NHS workforce resourcing to deliver commercial research
- Exploring opportunities to incentivise NHS Trusts and GP practices to act as participant identification centres (PICs)



Strengthening the UK environment for clinical research: next steps

- Promote expertise in designing innovative trials
- Develop expertise in delivering innovative studies in the NHS



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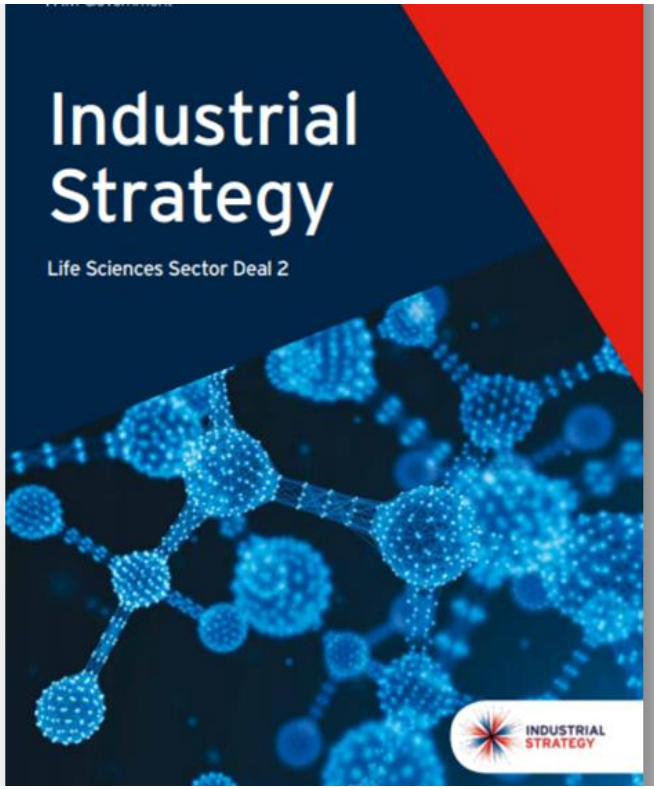
Strengthening the UK environment for clinical research: next steps

- Investment in the infrastructure needed to support the expansion of digitally-enabled clinical research
- Creation and linkage of national data systems to support rapid, efficient trials



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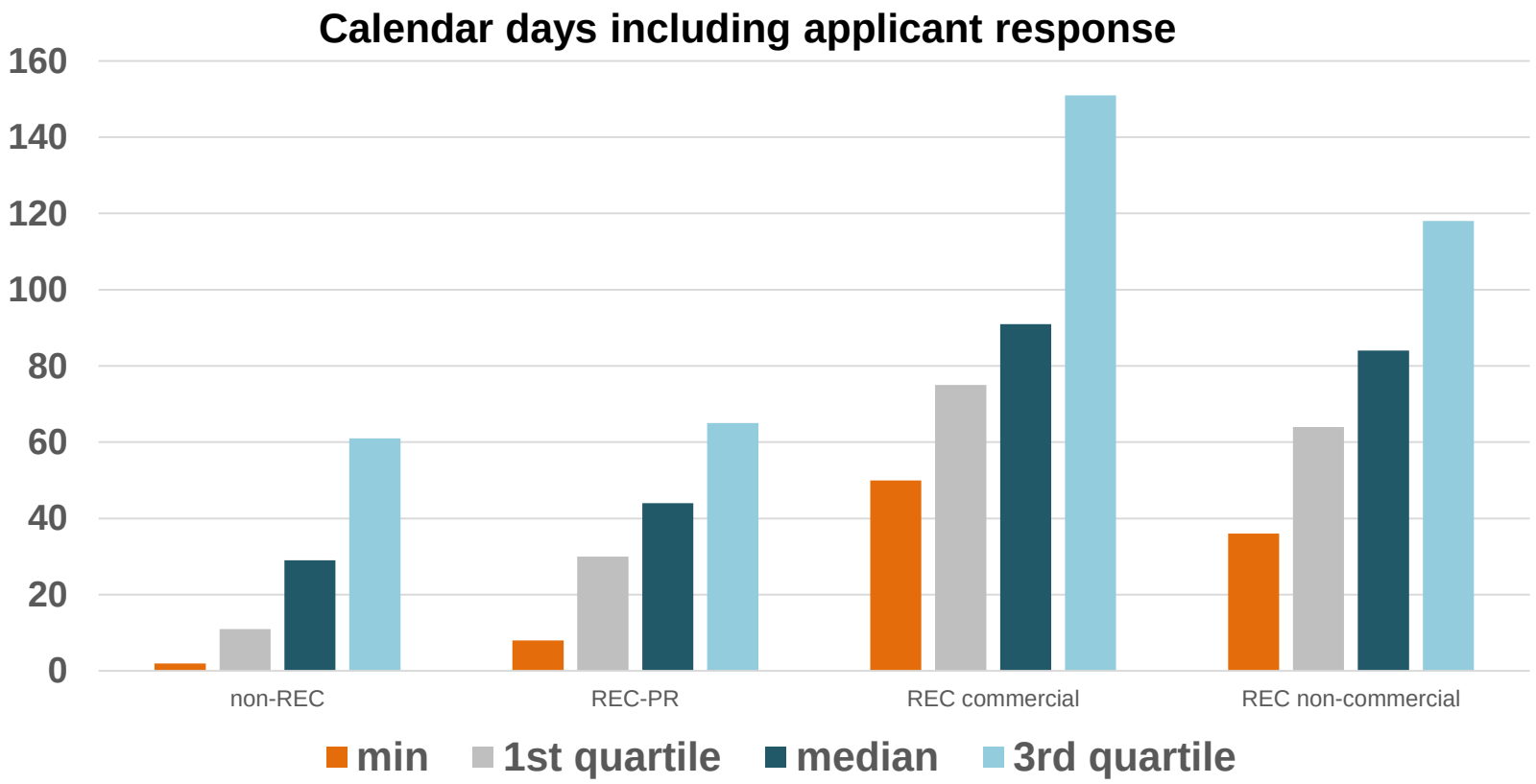
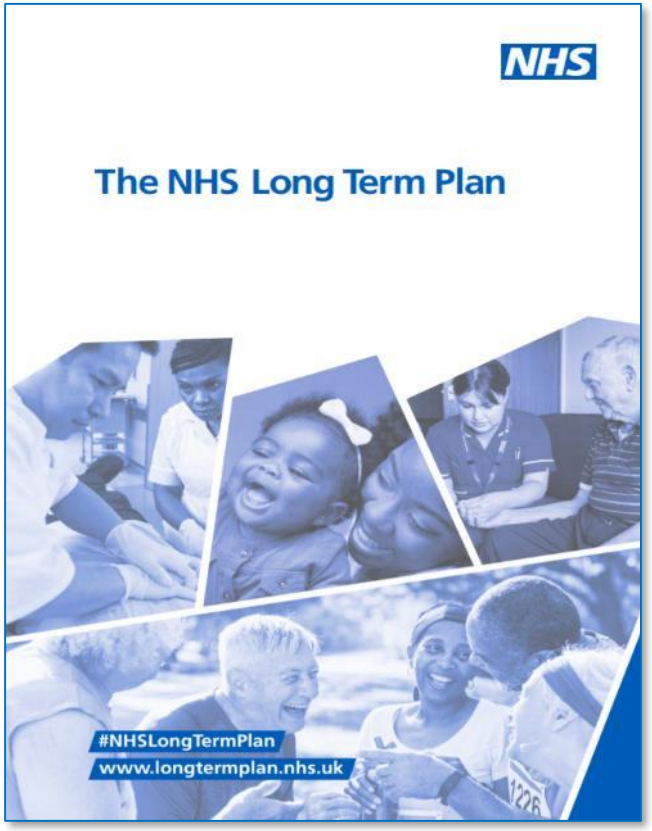
Strengthening the UK environment for research - how are we doing?

HRA Approval Performance



NHS Long Term Plan

- Recognises the critical importance of research and innovation to drive future medical advance



UK in a Global Setting

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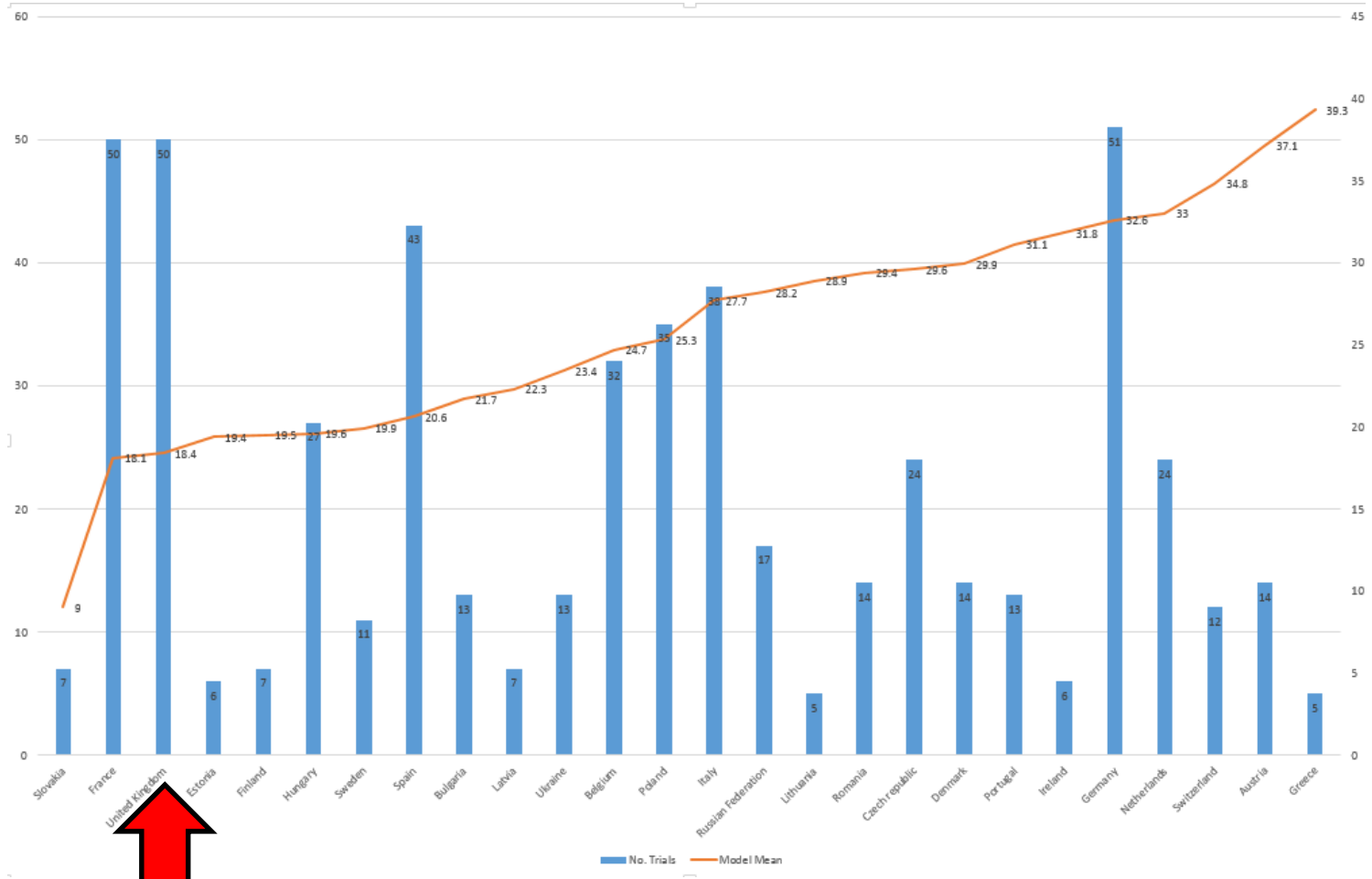
Data source: Global CRO



Already implemented

- HRA/ HCRW Approval – England and Wales
- UK-wide IRAS Form
- E-submission to MHRA for medical devices
- Technical Assurances

Radiation Assurance

- Open to cardiology, oncology, neurology and rheumatology studies
- Coordinates lead Clinical Radiation Expert (CRE) and lead Medical Physics Expert (MPE) reviews in IRAS

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/radiation-assurance/

Pharmacy Assurance

- Open to oncology phase I to III
- Clear information for sites
- Reduces queries from sites to sponsor
- Reduces duplication at sites – to reduce delays

Pharmacy manual is not mandatory!

https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/pharmacy-assurance/

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What can you do?

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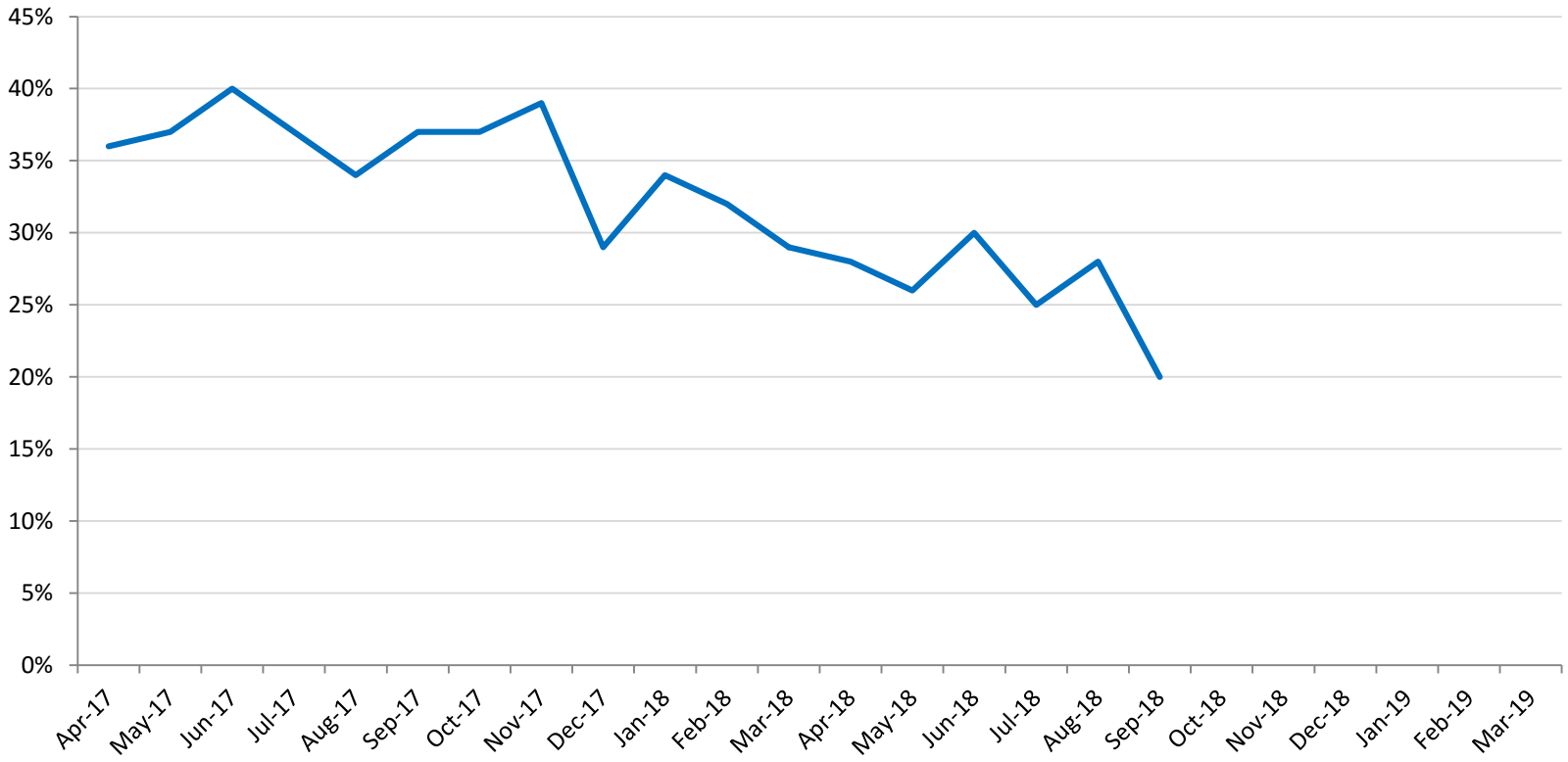
Applications with missing documents



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What are we seeing?

- Missing contracts and costings
- Copy/paste answers in IRAS not reflecting the study
- Contradiction between documents
- No IRAS ID on PIS
- Unclear on information governance
- Unclear on tissue handling
- Unclear on contracts and modifications
- Costing template not validated by CRN

Queries raised in REC meeting

- Detail on recruitment strategy – including approach
- Which tests are standard and which additional
- Justification on inclusion of adults lacking consent
- Is access to medical records necessary
- What support for participants in distress or anxious

Requests raised in REC letter

- Clarity on study procedures – expectations
- Will (and how) findings be fed back to participants
- How is the research different from standard care
- General risks and burdens to the participant should be made explicit
- Travel/expense reimbursement provided
- Complaints procedure
- Written in lay language

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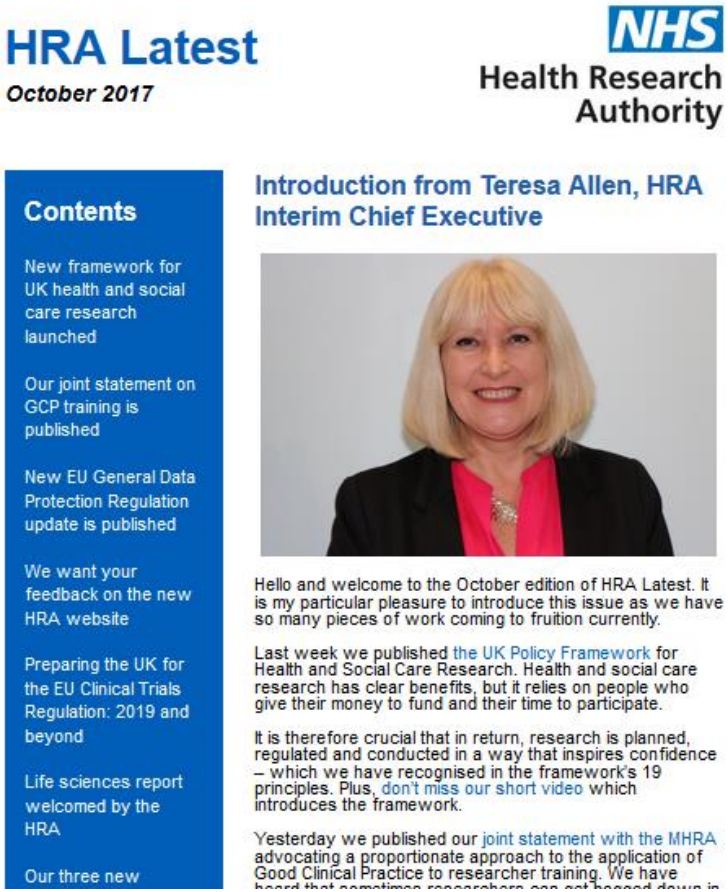
Issues with industry PIS

- Handling of clinically significant findings
- No distress policy
- Not clear how the substance has previously been used
- Side-effects frequency is not clear
- Summary information sheets have not been produced
- No information on alternatives
- No information about *relative* risk and benefit. How does the risk profile of the research option compare with that of the alternative available treatment (or no treatment) options?

Sign up to HRA Latest –

Follow the link at
www.hra.nhs.uk



HRA Latest

October 2017

NHS Health Research Authority

Contents

New framework for UK health and social care research launched

Our joint statement on GCP training is published

New EU General Data Protection Regulation update is published

We want your feedback on the new HRA website

Preparing the UK for the EU Clinical Trials Regulation: 2019 and beyond

Life sciences report welcomed by the HRA

Our three new

Introduction from Teresa Allen, HRA Interim Chief Executive

Hello and welcome to the October edition of HRA Latest. It is my particular pleasure to introduce this issue as we have so many pieces of work coming to fruition currently.

Last week we published the UK Policy Framework for Health and Social Care Research. Health and social care research has clear benefits, but it relies on people who give their money to fund and their time to participate.

It is therefore crucial that in return, research is planned, regulated and conducted in a way that inspires confidence – which we have recognised in the framework's 19 principles. Plus, don't miss our short video which introduces the framework.

Yesterday we published our joint statement with the MHRA advocating a proportionate approach to the application of Good Clinical Practice to researcher training. We have

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Thank you!