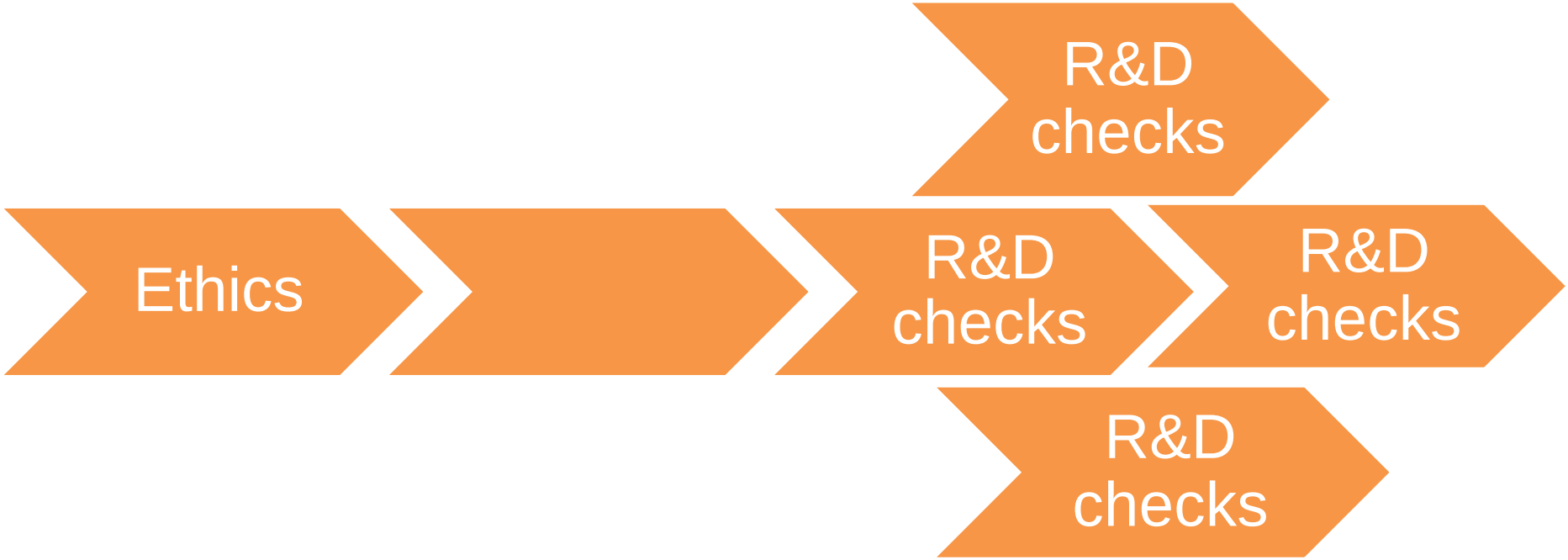
NHS
Health Research Authority

How do we create a conducive regulatory environment for experimental cancer medicine?
Update from the HRA

A complex and bureaucratic regulatory environment is stifling health research in the UK

A new pathway for the regulation and governance of health research – Academy of Medical Sciences report, January 2011

What was it like before HRA Approval?




COMPLEX REGULATORY SYSTEMS
NEW
APPROACH
NEEDED

NHS concerns

- Participan[t] [i]nformation – legal compliance and implications, accuracy post-study
- Allocation of rights, responsibilities, delegation
- Insurance/ indemnity
- Clarify finance, support costs, treatment costs, resource requirements
- Legal compliance – data protection, clinical trials, human tissue, mental capacity, radiation
- Other approvals and document versions

H

Ethics Committees – Is it ethical?

Confidentiality Advisory Group – can access to confidential patient information be justified without consent?

Medicines and Healthcare products Regulatory Agency

Is use of medicine/ device safe and compliant with regulation?

NHS
Can we provide the capacity and capability to deliver this study in accordance with the protocol?

Medicines and Healthcare products Regulatory Agency
Is use of medicine/ device safe and compliant with regulation?

HRA
Ethics Committees –
- Is it ethical?

Confidentiality Advisory Group –
- Can access to confidential patient information be justified without consent?

Assessment –
- Participant information – legal compliance and implications, accuracy, post-study
- Allocation of rights, responsibilities, delegation
- Insurance/ indemnity
- Clarify finance, support costs, treatment costs, resource requirements
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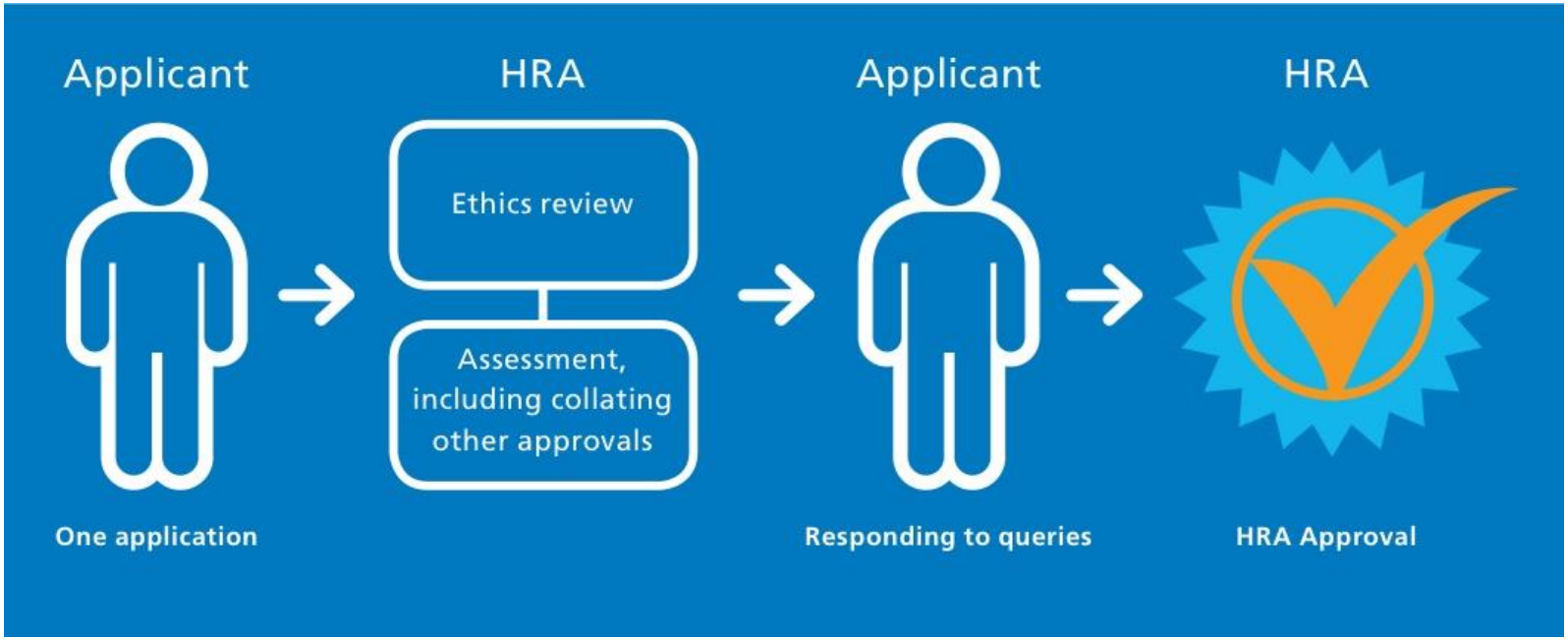
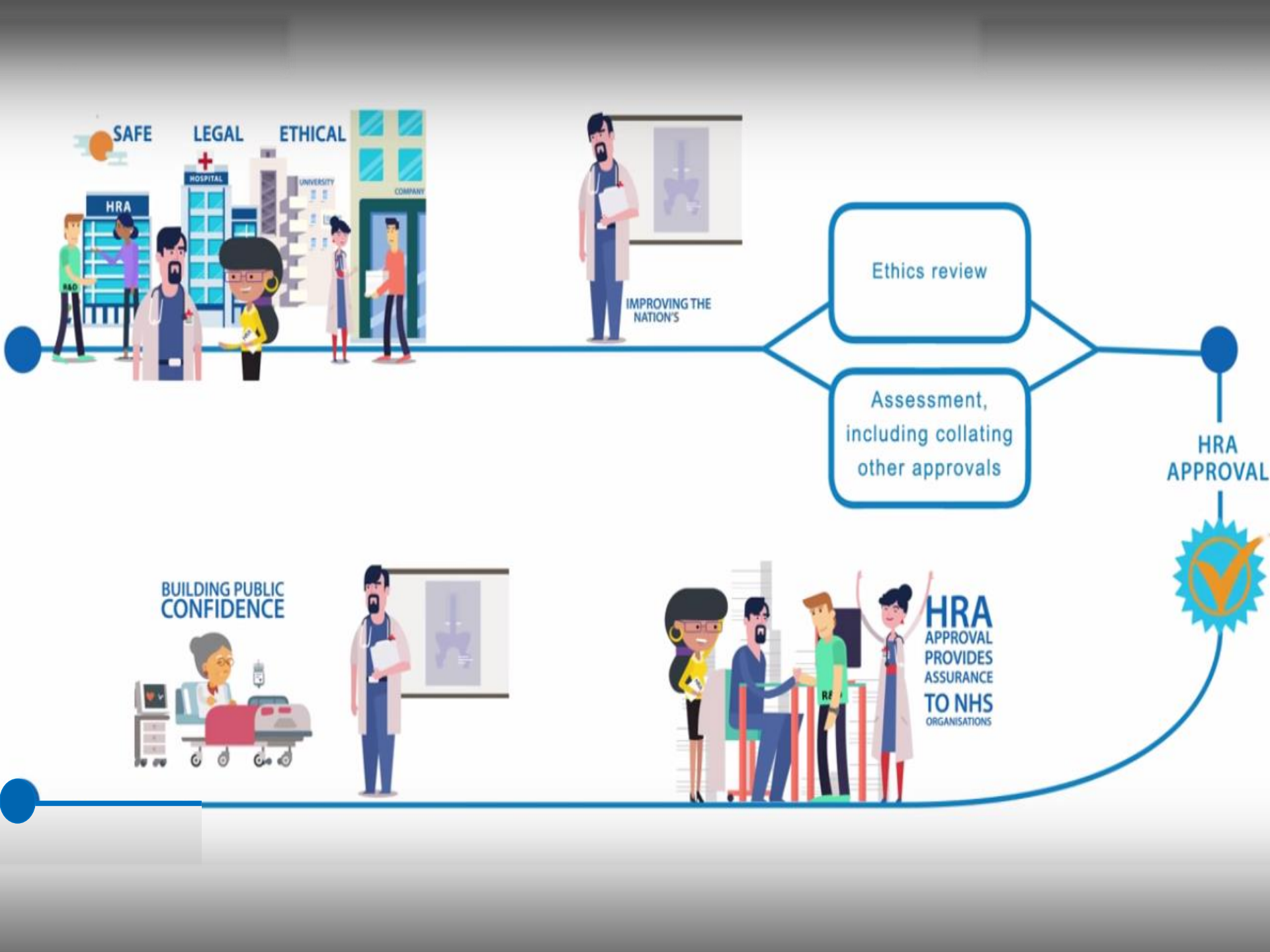
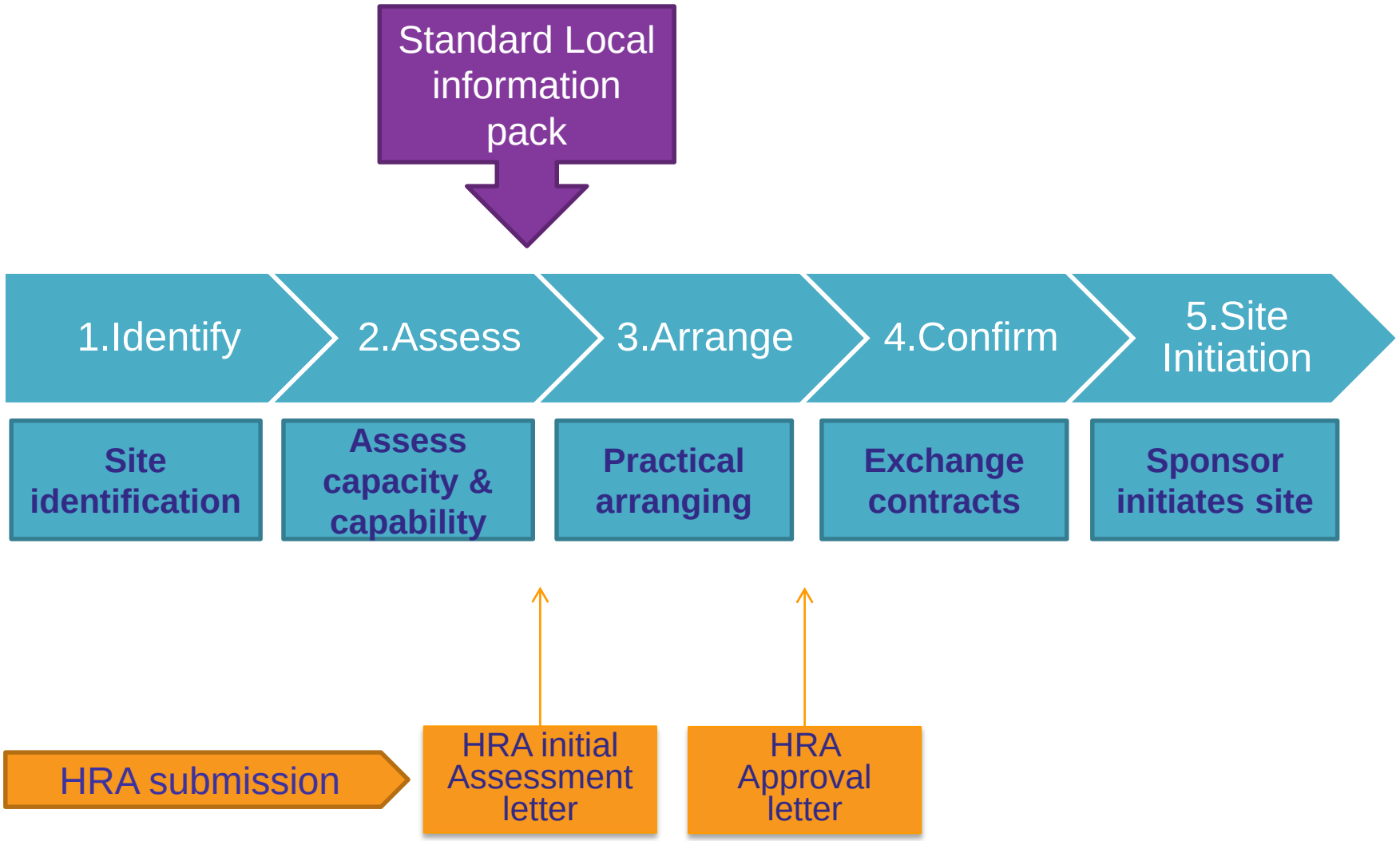
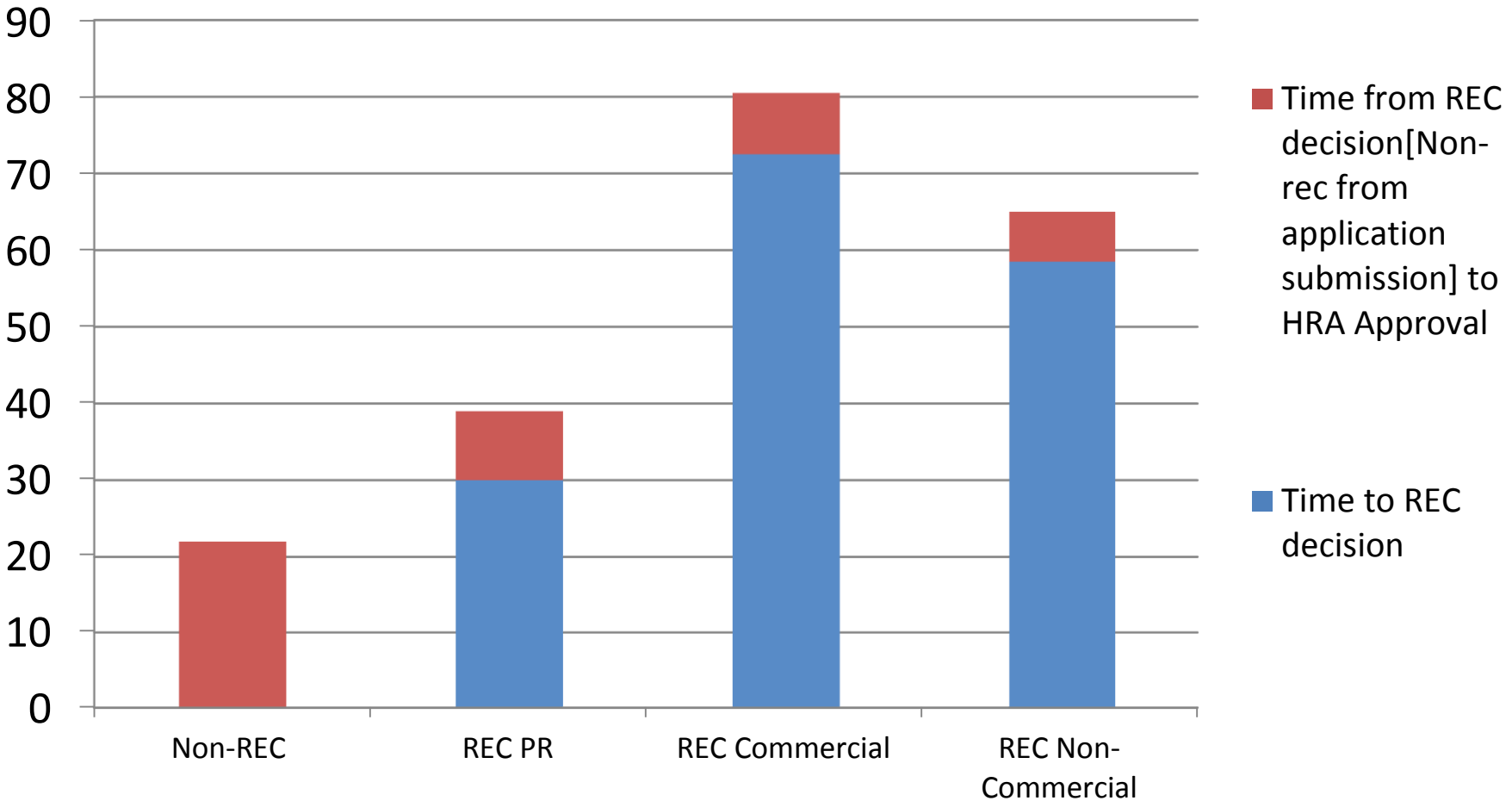
From multiple approval systems to one pathway




SAFE
LEGAL
ETHICAL
HOSPITAL
HRA
UNIVERSITY
COMPANY
IMPROVING THE NATION'S
Ethics review
Assessment, including collating other approvals
HRA APPROVAL
BUILDING PUBLIC CONFIDENCE
HRA APPROVAL PROVIDES ASSURANCE TO NHS ORGANISATIONS


Standard Local information pack
1.Identify
2.Assess
3.Arrange
4.Confirm
5.Site Initiation
Site identification
Assess capacity & capability
Practical arranging
Exchange contracts
Sponsor initiates site
HRA submission
HRA initial Assessment letter
HRA Approval letter


90
80
70
60
50
40
30
20
10
0
Non-REC
REC PR
REC Commercial
REC Non-Commercial
Time from REC decision[Non-rec from application submission] to HRA Approval
Time to REC decision

Other set-up improvements

- UK-wide compatibility programme
- UK-wide Pharmacy Technical Assurance
- UK-wide Radiation Technical Assurance
- Reviewing model contracts (commercial and non-commercial)
- UK-wide amendments process (REC and R&D)

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Work in progress

- EU Clinical Trial Regulation
- EU General Data Protection Regulation
- EU Basic Safety Standards Directive (relevant to ARSAC)

What can you do?

- Follow guidance and submit all relevant information
- Plan ahead – minimise amendments
- Understand and clarify roles and responsibilities
- Make sure research patients get the right investigations (esp radiation)

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