

Update from HRA

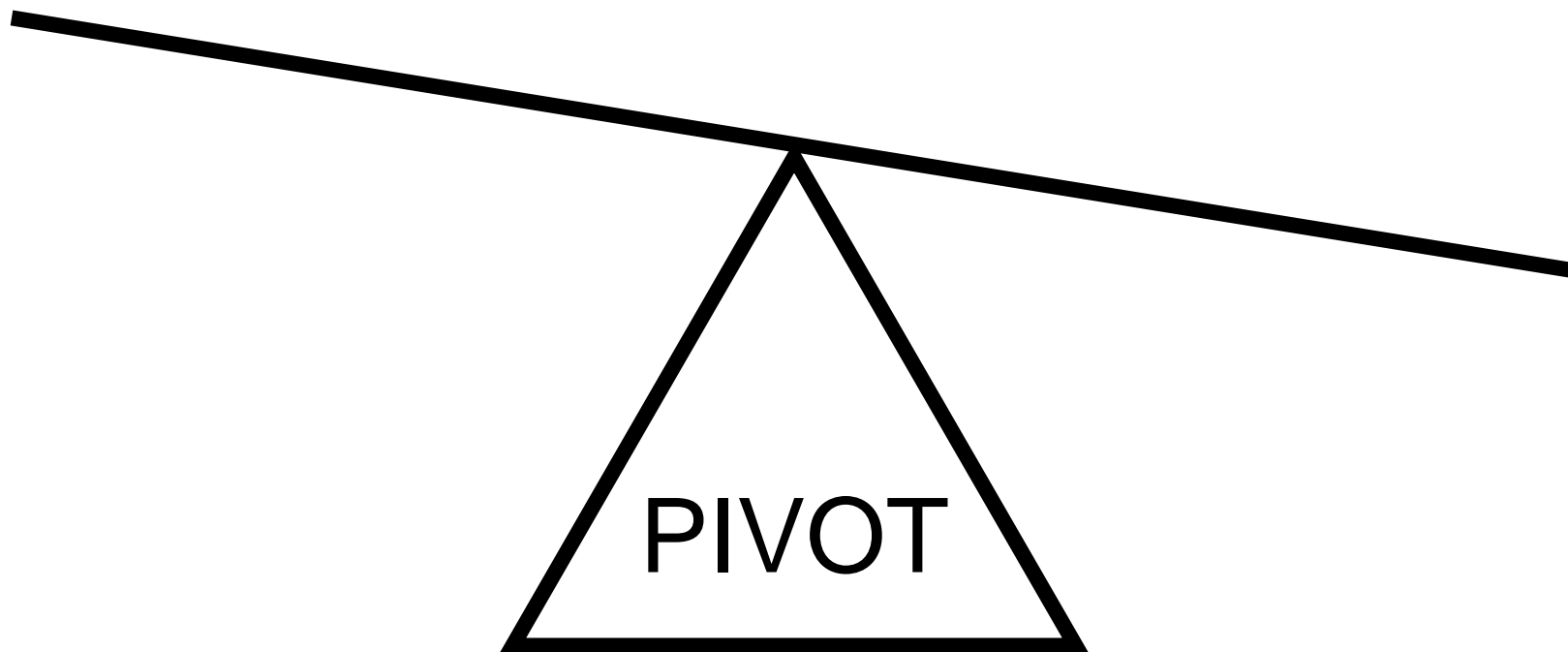


Dr. Janet Messer
Director HRA Approval, HRA
18 March 2021



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Recovery



Monitoring

- Physical monitoring
- Remote monitoring
- Remote SDV
- Cost implications?

For example....

- **Safeguard:**
 - Monitor should not print, save or otherwise record data;
- **System Requirement:**
 - Restricted user read-only role for monitoring
- **Short-term mitigation:**
 - Reliance upon mCTA obligations, sponsor training in IG, site training in system usage, site audit trail of system, etc.

Patient recruitment

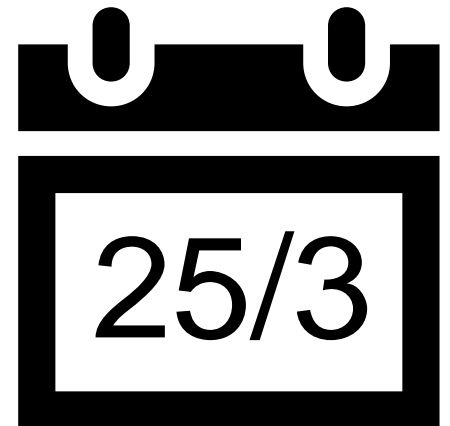
- Clinical pathways
- Patient identification
- Patient consent

Review sites

- Sites – share your price list
- Sponsors – identify site capacity
- Consider primary and community care
- Consider remote delivery

Amendment Tool updates

- Addition of new sites/PI for CTIMPs no longer Substantial Amendment
- Removal of requirement for Annex 2
- Clearer guidance for cross-border working with Adults Lacking Capacity



New studies

- Try Combined Ways of Working
- Integrated review – simpler navigation
- Rolling out during 2021



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Resilience

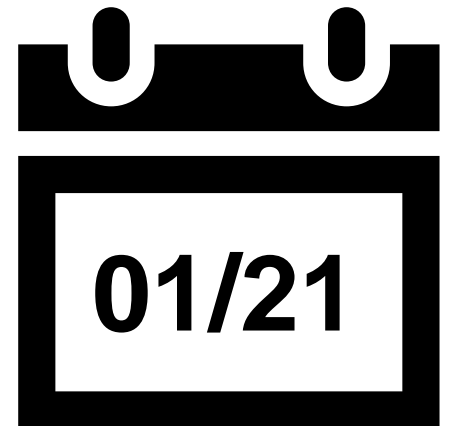
Virtual REC meetings

- Continue to September 2021
- Review underway
- Consider who can attend meeting



mCTA and CRO-mCTA

- Updates:
 - End of UK transition period
 - Stakeholder feedback
- Use latest version for new studies
- Swap to latest version for existing studies without amendment
- No waivers



New templates in development

- CDA
- Stand-alone DPA
- Non-interventional commercial agreement
- ATMP mCTA
- Third-party provider agreement
- Material Transfer Agreement
- Central Technical Review Agreement

Data Flow with EU and EAA

- Draft adequacy decision issued by European Commission
- UK has equivalent level of protection to GDPR
- To be ratified by Member States
- Bridging period - data can continue to freely flow



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Growth

Fast Track REC pilot

- Weekly meetings
- One Chair + UK panel of members
- Evaluation April 2021



50%

National Contract Value Review

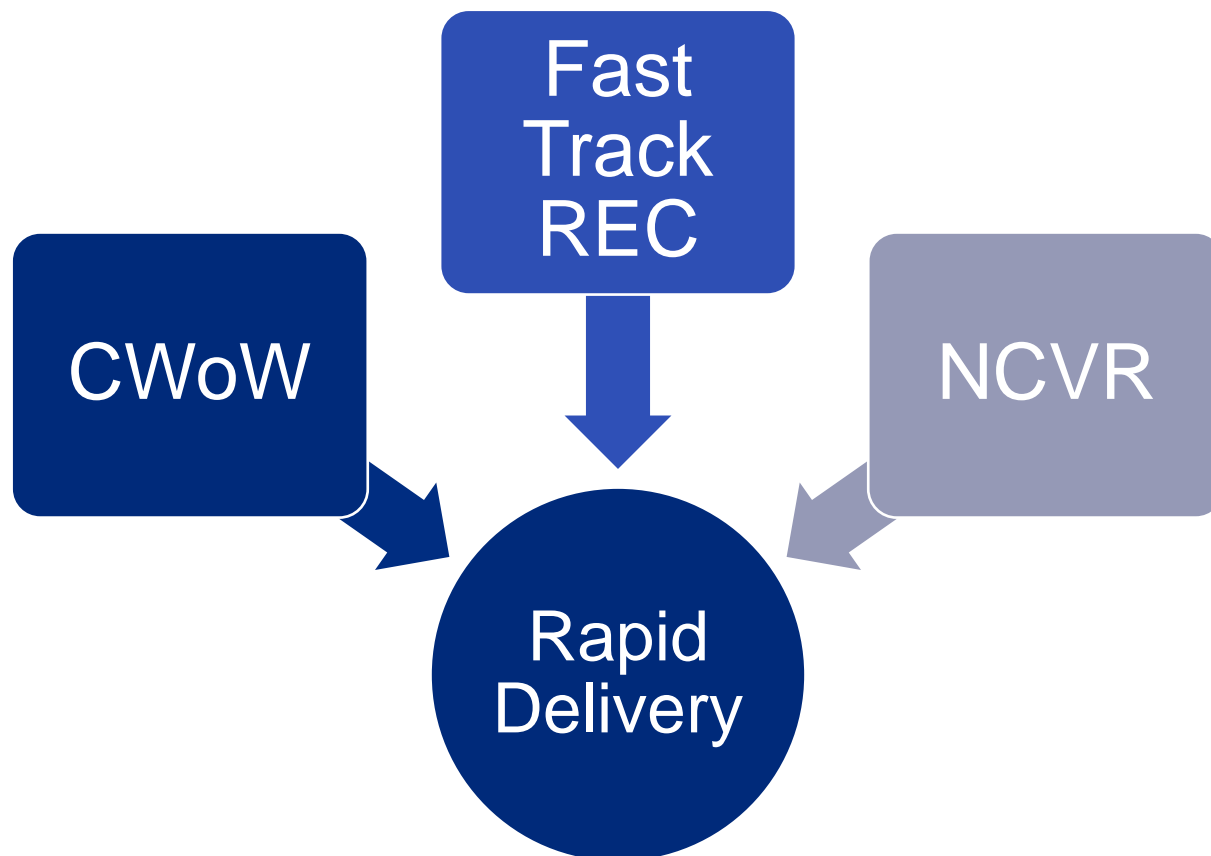
- National Co-ordinator
- Confirm all Sponsor and NHS requirements to deliver the study are captured
- NHS provider-specific adjustments
- Pilot paused 2019

Proposed Process

Principles:

- All NHS organisations up-front on any deviation from national tariff
- No Surprises once single negotiation commenced

Timing, detail, etc. in development





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IRAS Development

What we have done so far

On-line Booking

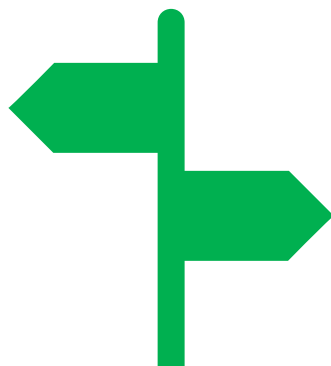
- May 2020

Online submission of amendments

- June 2020

CWoW Module

- March 2020 private beta
- Dec 2020 question set
- Feb 2021 sponsor roles
- Feb 2021 final reporting



Ideal Path

What to do

When to do it

How to do it

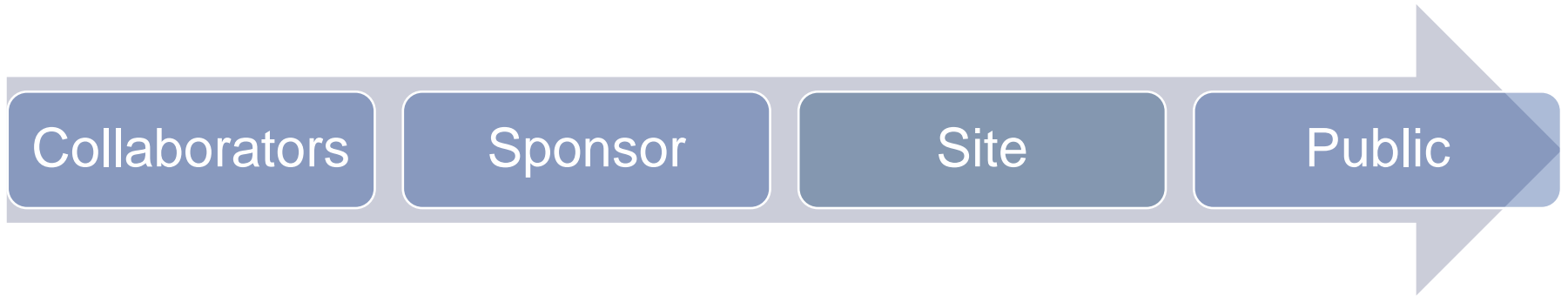
Right information at right time to right place

Integration with other systems

Signposting to guidance and support



Visibility



Visibility for collaborators for input

Visibility for sponsors of status

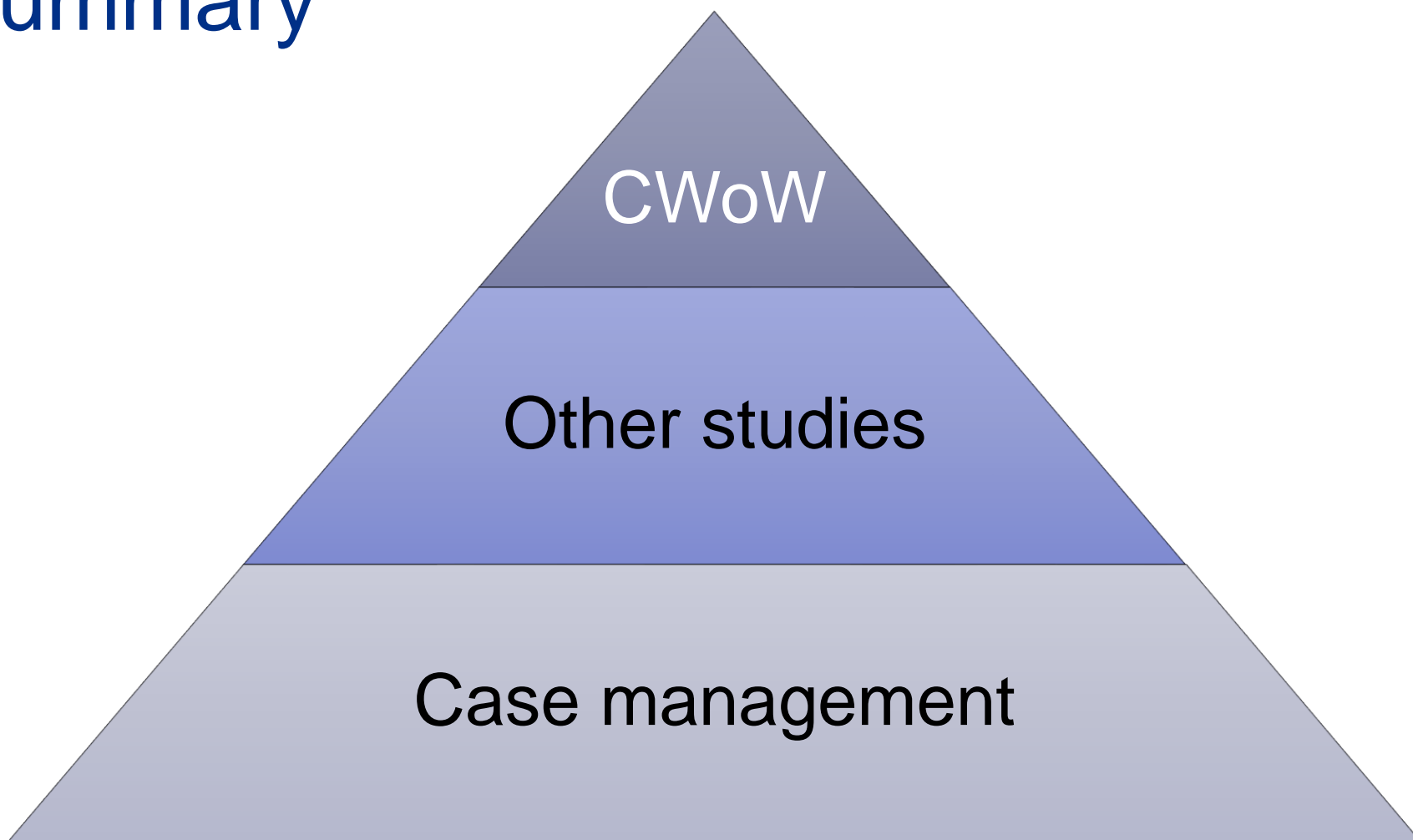
Visibility for sites of documents

Visibility for public of study information

Already released

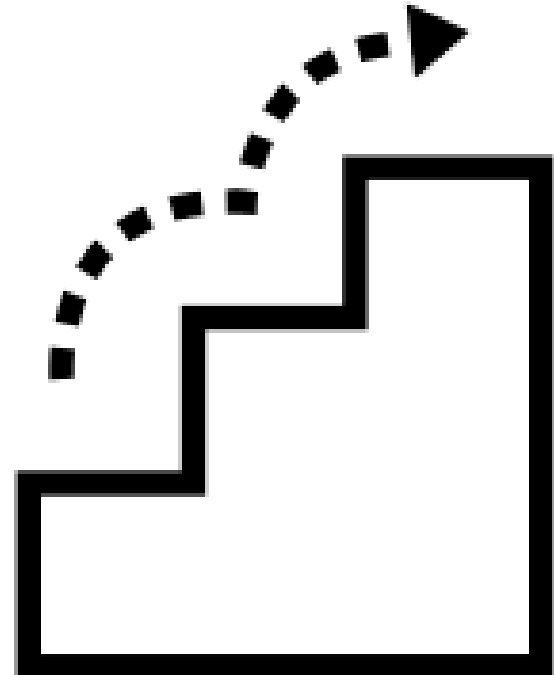
- Shared identify authentication with NIHR
- Project Deputy
- Collaborator
- Sponsor/ CRO oversight
- Amendments
- End of study reporting

Summary



Get ready...

- Change in work practices for everyone
- Iterative releases
- Indicative sequence to come



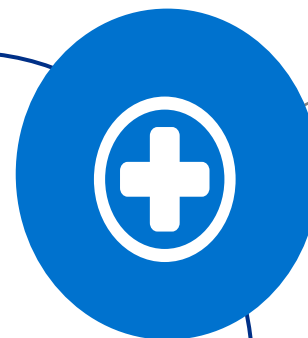
Supporting more patient-centred trials and investigations

Where participation is as easy as possible, with patients recruited 'where they are' - ensuring study populations are diverse and patients are actively involved and in control of their data



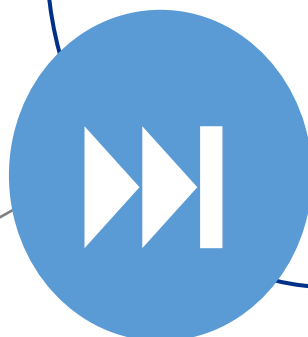
Embedding clinical research within the NHS

so all health and care staff view research and trials as key element of effective patient care and prioritise it accordingly



Delivering faster, more efficient and more innovative trials

to ensure the UK remains internationally competitive and UK patients are some of the first in the world to get access to new treatments



Developing the underlying data and digital infrastructure

to leverage our globally leading research expertise and support our thriving life sciences sector to by facilitating faster set up, recruitment and delivery of research across the NHS



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#ResearchVsCovid



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Thank you for listening

Contact information:

- **Janet Messer**
- Janet.Messer@hra.nhs.uk

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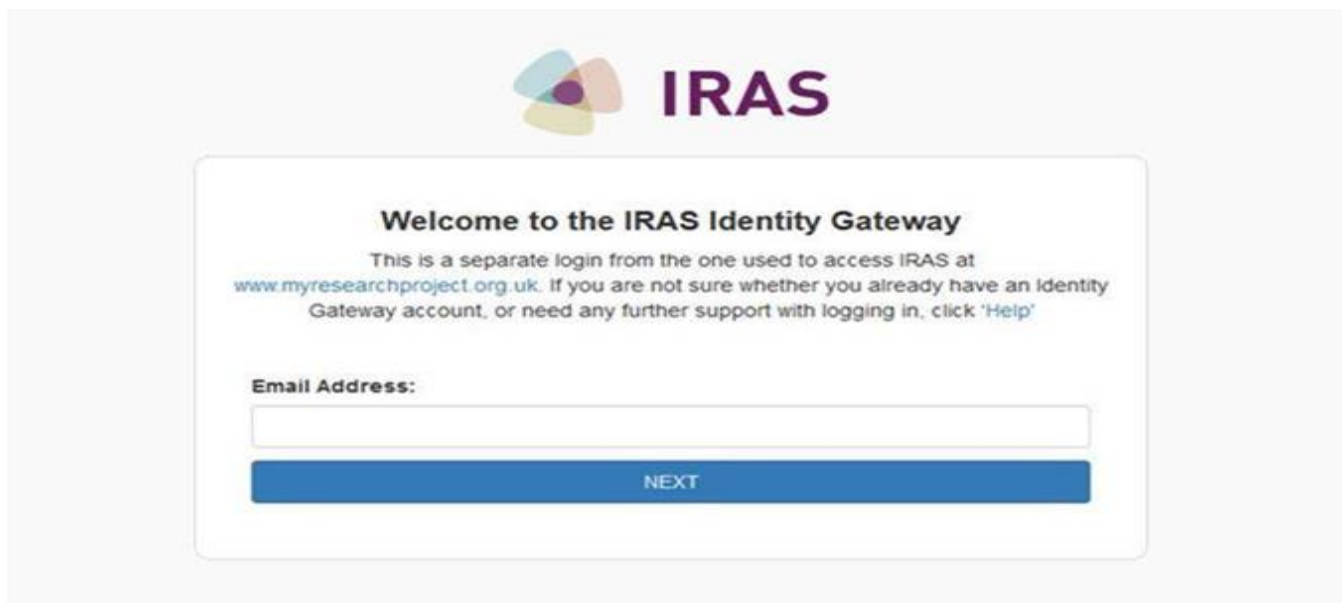


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Additional IRAS info if needed

Key concept – Logging in

- Sharing identity authentication with NIHR



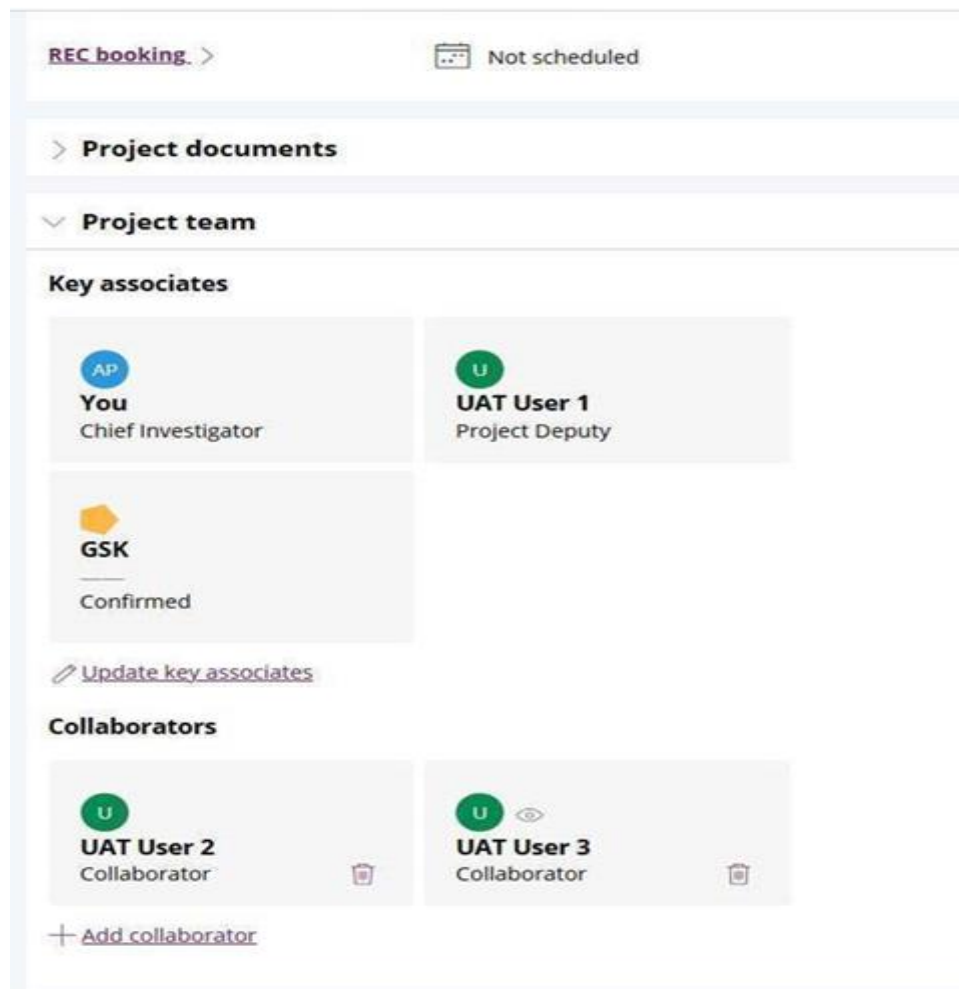
The screenshot shows the IRAS Identity Gateway login page. At the top center is the IRAS logo, which consists of three overlapping circles in blue, orange, and green, followed by the text "IRAS" in a purple font. Below the logo is a white rectangular box with a thin border. Inside this box, the text reads: "Welcome to the IRAS Identity Gateway". Underneath, it says: "This is a separate login from the one used to access IRAS at www.myresearchproject.org.uk. If you are not sure whether you already have an Identity Gateway account, or need any further support with logging in, click 'Help'". Below this text is a label "Email Address:" followed by a white input field. At the bottom of the box is a blue button with the text "NEXT" in white capital letters.

Key concept – Project Deputy

- Always have more than one person nominated to work on the project
- CI can assign tasks to a deputy
- Project Deputy can hand over the role to someone else

Key concept - Collaborator

- Can work on the project but cannot submit or respond to queries once submitted
- Can be used by sponsor teams

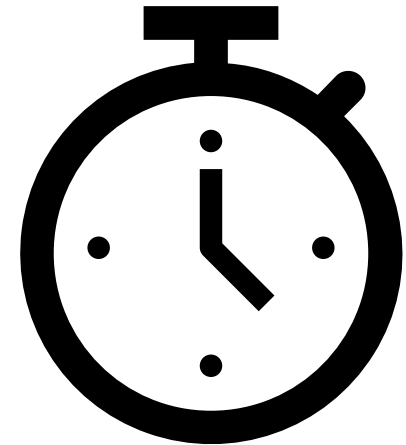


The screenshot displays a project management interface with the following elements:

- REC booking >** (top left) and **Not scheduled** (top right)
- > Project documents** (middle section)
- Project team** (expanded section)
- Key associates** (sub-section):
 - You** (Chief Investigator) with a blue 'AP' icon
 - UAT User 1** (Project Deputy) with a green 'U' icon
 - GSK** (Confirmed) with a yellow hexagon icon
- [Update key associates](#) (link)
- Collaborators** (sub-section):
 - UAT User 2** (Collaborator) with a green 'U' icon and a trash icon
 - UAT User 3** (Collaborator) with a green 'U' icon, an eye icon, and a trash icon
- [+ Add collaborator](#) (link)

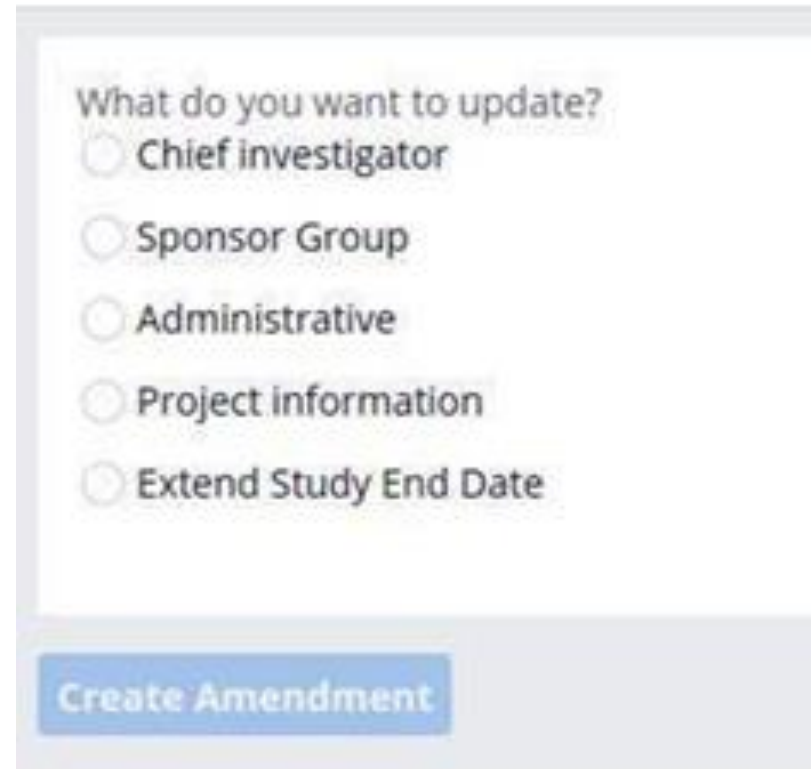
Key concept – Sponsor oversight

- All sponsors will be named in IRAS
- Sponsor roles:
 - Accept study at creation
 - Review study as collaborator
 - Maintain visibility of all studies
 - Authorise application after booked to REC



Key concept - Amendments

- Different types of amendments
- Sponsors authorise
- Amendment Tool built in



What do you want to update?

- Chief investigator
- Sponsor Group
- Administrative
- Project information
- Extend Study End Date

Create Amendment

Key concept – end of study



Reminders to confirm end date or extend



Reminders for final reports after end of study



Sponsors will be able to see compliance