Health Research Authority

ICR GCP Forum
29 March 2022

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Change Manager

UK Vision

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7 areas for action

UK Clinical Research Recovery, Resilience & Growth

Reducing delays, improving consistency and speeding up the route to set up

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- **New and improved regulatory processes**
  HRA and MHRA combined review + Fast Track REC, IRAS and ILAP
- **National Contract Value Review Process** (Phase 1 roll out April 2022)
- **Site set up pilot for early phase cancer** (ECMC)
- **An expanded suite of model agreements**

UK Clinical Research Recovery, Resilience & Growth

New model agreements

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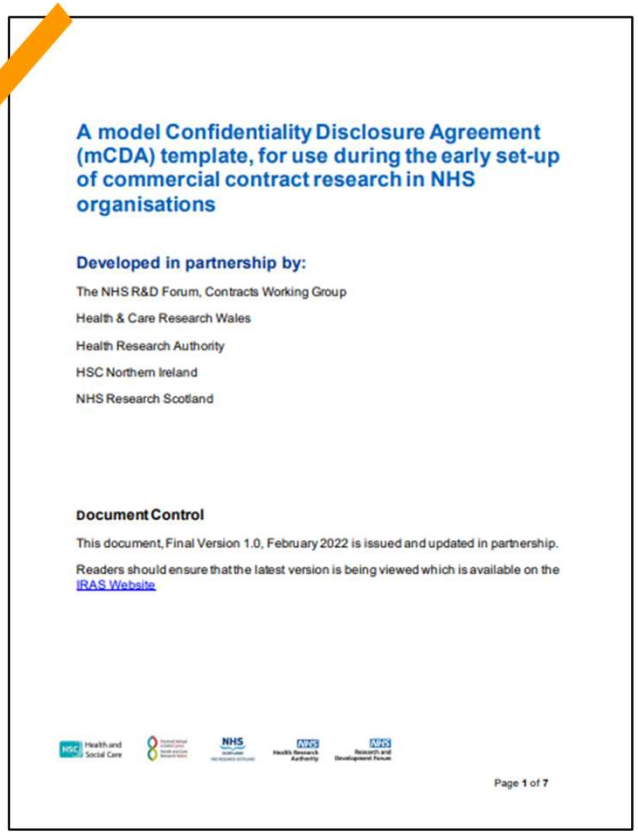
Saving admin burden and cost, improving speed

[Model Confidentiality Disclosure Agreement (mCDA)]

[Model Non-Interventional Study Agreement (mNISA & CRO mNISA)]



A model Confidentiality Disclosure Agreement (mCDA) template, for use during the early set-up of commercial contract research in NHS organisations

Developed in partnership by:

The NHS R&D Forum, Contracts Working Group

Health & Care Research Wales

Health Research Authority

HSC Northern Ireland

NHS Research Scotland

Document Control

This document, Final Version 1.0, February 2022 is issued and updated in partnership.

Readers should ensure that the latest version is being viewed which is available on the IRAS Website

Page 1 of 7

Coming soon

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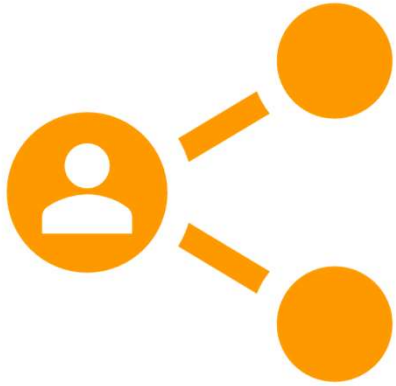
mCTA (redraft)

- allows to contracts to serve as head agreements
- incorporating feedback
- terminology alignment with interventional guidance

Hub and Spoke



Decentralised Trials

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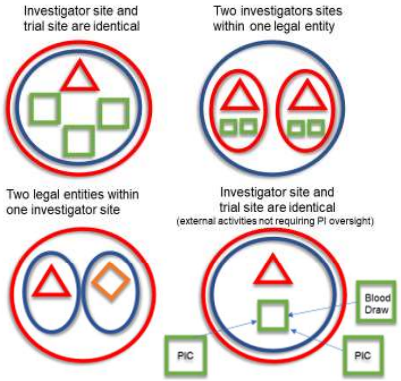
Guidance enabling research to be where people are

[Study Set Up Interventional Studies (MHRA & HRA Guidance)]



E-consent

People Centred Clinical Research

Technical Assurance

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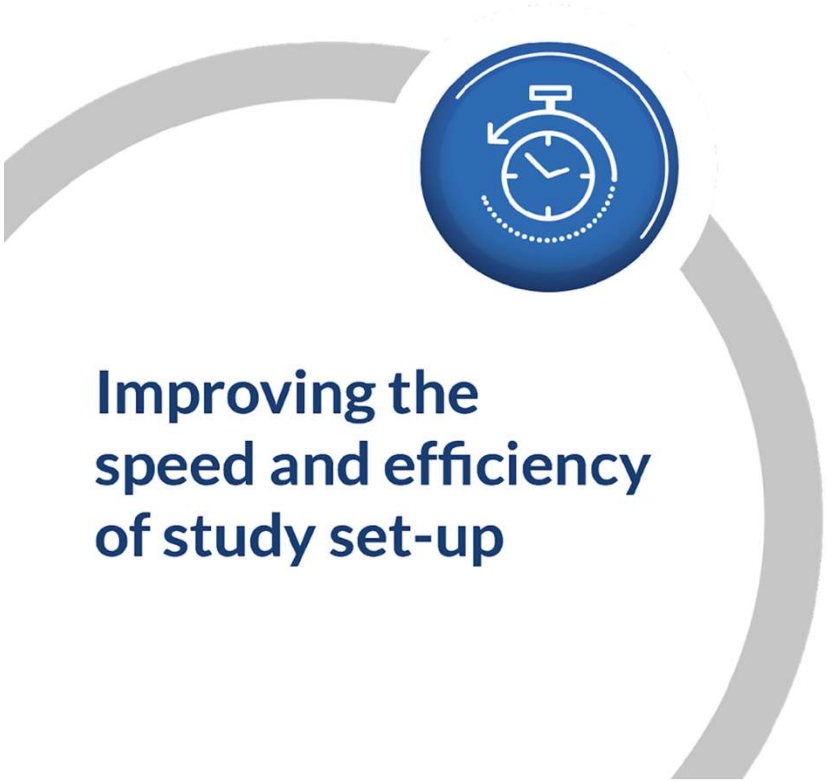
Improves speed
Use now without delay



Radiation Assurance

- All phase oncology, rheumatology, neurology and cardiology studies
- Studies involving general radiology

Pharmacy Assurance

- Phase I-III Clinical Trials of Investigational Medicinal Products (CTIMPS)

Studies must be in NHS/HSC secondary care

End-to-End Improvements

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What to do | When to do it | How to do it

- The right information at right time to the right place
- Integrating with other systems
- Signposting to advice and support

Improving the speed and efficiency of study set-up

Creating the ideal path UK-Wide

The Future of UK Clinical Research Delivery

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Combined review update

Combined Review process

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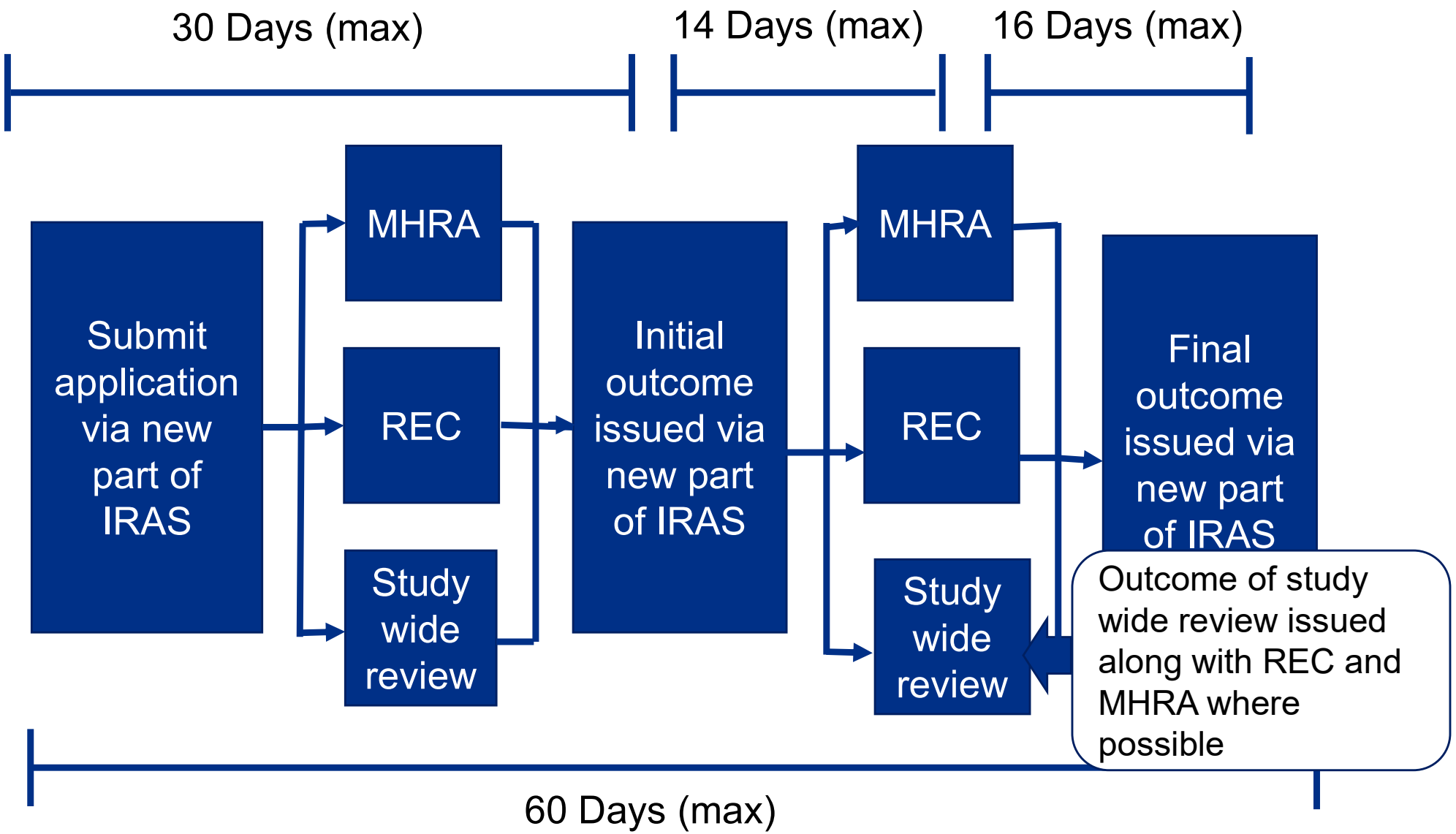

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28 Feb 2022

- Any existing partially submitted CTIMPs or CTIMP + device studies in standard IRAS must be submitted.

11 March 2022

- Changes to EudraCT requirements, Collaborator role & “Dear Investigator Letter” sent to REC as well as MHRA

30 March 2022

- Change to banners, download options, PDFs and destinations for amendments

Why are we making the changes?

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In response to user feedback

Regulatory or technical requirements

All with the goal of facilitating a streamlined research application process

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11 March 2022

What were the changes made earlier in March 2022?

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- EudraCT number no longer mandatory
- Changes to the role of Collaborators
- Document type “Dear Investigator Letter” sent to REC as well as MHRA

EudraCT Number no longer mandatory

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This means you can leave this field blank. IRAS ID will be the number used to identify each study instead (e.g. in submission of DSURs).

Previously, studies had to create a EudraCT number for combined review applications to be accepted.

Projects submitted to EU countries using CTIS after 31 January 2022 can record a European Union Clinical Trial number (EU CT number) under other reference number in IRAS when making an application in the UK.

Changes to the role of Collaborators

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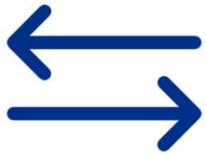
Based on user feedback, the optional role of collaborator will be changed to align their access to Project Deputy.

Collaborators will retain read/ write access after initial submission – will be able to submit projects to Sponsors for their confirmation and work on amendments.



All Collaborators will have edit access.

Collaborators will be able to submit DSURs after initial submission via IRAS.

Document Type “Dear Investigator Letter”

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Documents classified as Dear Investigator Letter have in the past only been shared by the system with the MHRA.

Now, this document type will be shared with REC and MHRA.

You do not have to do anything in response to this change, please continue to categorise documents correctly to ensure they are routed to the appropriate regulators.

What do I need to do?

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- ✓ Ensure **study identifiers** (EudraCT/ EU CT number/ IRAS number) are recorded as required.
- ✓ Submission of **DSURs** – if at least one of the trials covered by the DSUR has gone through Combined Review, the report should be submitted via IRAS and include the IRAS IDs of the studies to prevent rejection. This can be done by a collaborator.
- ✓ Consider who in your organisation will need to be assigned as a **collaborator** & ensure they understand the responsibility.
- ✓ Add in **collaborators** again as they may have been deleted
- ✓ Consider if any of your **working processes or practices** need to be updated as a result of these upcoming changes.

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30 March 2022

What are the changes coming on 30 March 2022?

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- Banner, feedback and downtime notifications
- Update to automatic registration question
- Document download options including draft PDFs
- User will select destination (to regulators) for amendments

Banner, Feedback & Downtime Notifications

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You may notice a “Beta Banner” in the new part of IRAS.

This banner will include the ability to give feedback on the system directly within IRAS.

Downtime notifications (e.g. when the system is offline for upgrades) may appear at the top of your task list.

Update to automatic registration question

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Registration deferral question will be updated.

Will allow applicants to select an option that they have or will register with clinicaltrials.gov, and thus don’t need to register with ISRCTN.

Ensure you add the necessary information to ensure your request is processed appropriately and not as a deferral.

Document Download options

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DSURs, USMs and associated RFIs won't be able to be downloaded once uploaded to protect the information they contain.

You will be able to download partially filled PDFs of the question sets *before* submission to the Sponsor.

These PDFs will present the information you enter into the system into a format that can be shared outside the system.

Destinations for amendments

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Users will continue to use the amendment tool to work out the type of amendment.

You will select where your amendments should be sent based on this information.

Based on completed amendment tool, you control where the amendment goes, it is no longer automated.

What do I need to do?

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- ✓ Give **Feedback** directly via IRAS on what is working or not for you.
- ✓ Submission of **DSURs** – if at least one of the trials covered by the DSUR has gone through Combined Review, the report should be submitted via IRAS and include the IRAS IDs of the studies to prevent rejection. This can be done by a collaborator, but the documents can't be downloaded.
- ✓ Consider if you need to **download a draft PDF** (perhaps to share with people who previously had read-only collaborator access) for your processes.
- ✓ Be prepared to select **Amendment destination** based on the Amendment Tool.
- ✓ Consider if any of your **working processes or practices** need to be updated as a result of these upcoming changes.

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Strategic Review

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Radiation Assurance

Pathway

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Self managed pathway

- HRA conducts consistency review
- Applicant allocates reviewers (must be certified by HRA)
- CRE & MPE complete reviews & authorisations in IRAS

HRA managed pathway

- HRA conducts consistency review
- HRA assigns requested reviewers or first available
- CRE & MPE complete reviews & authorisations in IRAS

Benefits

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Streamlined	Single Point of Entry	Quality	Standards
• Standardised information to REC, ARSAC & sites	• Process is applicable UK wide for all submissions, regardless of lead nation	• Inconsistencies identified early, reducing queries & saving time	• Reviewers in a variety of specialisms, following nationally agreed standards

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Questions and answers

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Thank you for listening

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