Academic and Clinical Central Office for Research and Development

RESEARCH TRANSPARENCY

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Research Transparency

- What is Research Transparency?
- Transparency Strategy
- Registering Research
- Reporting Results
- Informing Participants
- Best Practices

What is Research Transparency?

Transparency is about what research is happening, what the findings are, and making that information accessible to the public and to the research community.

This benefits

- Patients and the public
- Health professionals
- Funders
- Researchers
- Research participants

Science & Technology Select Committee Report


House of Commons
Science and Technology Committee

Research integrity: clinical trials transparency

Tenth Report of Session 2017–19

Report, together with formal minutes relating to the report

Ordered by the House of Commons to be printed 23 October 2018

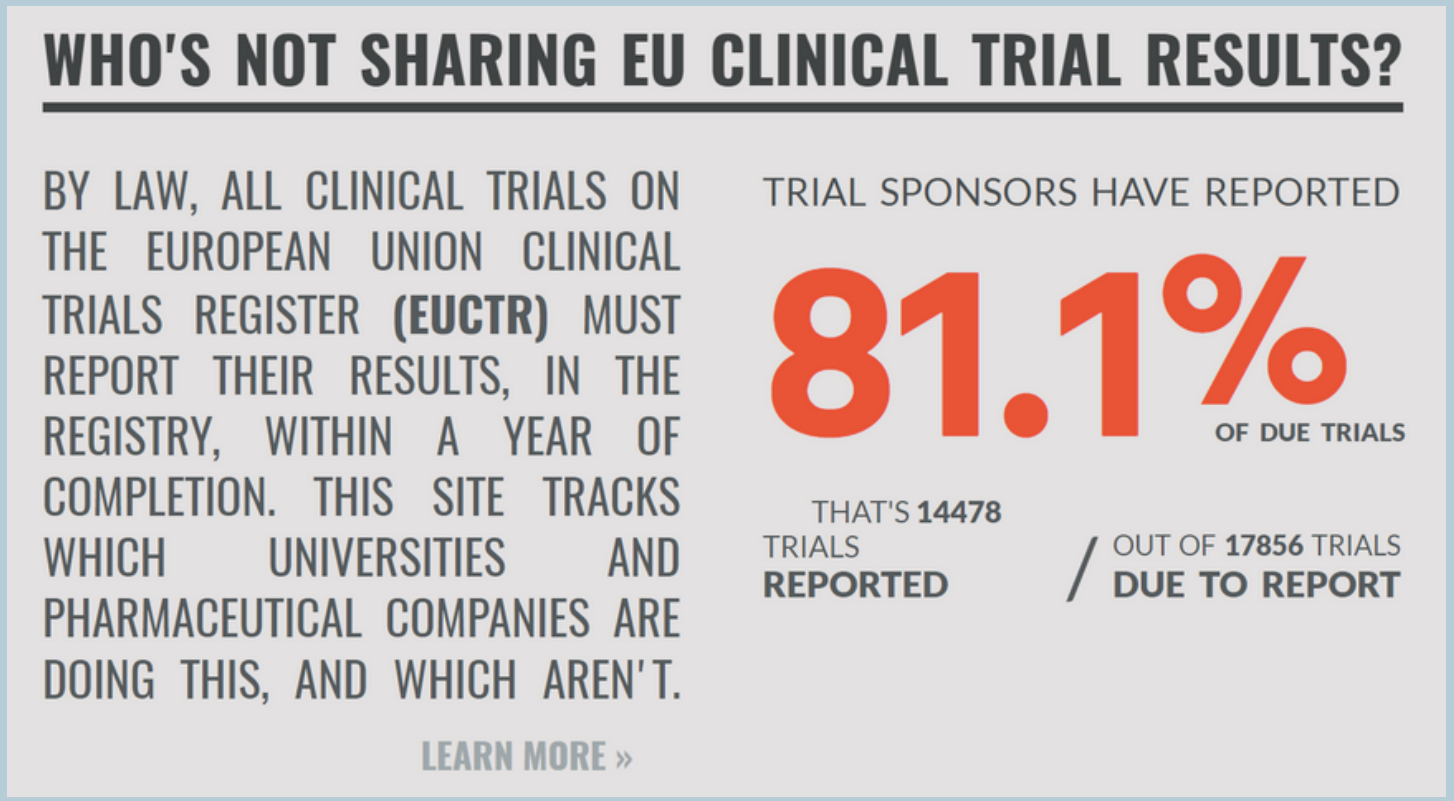
The Committee

- Called on universities and NHS organisations to improve their performance in registering and reporting results of clinical trials.
- Challenged the HRA to drive improvements in research transparency and outlined a set of recommendations.
- Norman Lamb MP wrote to over 40 UK universities to ensure they were complying with clinical trials transparency requirements.

Failing to publish results "presents risks to human health, contributes to research wastage and means that clinical decisions are made without access to all the available evidence"

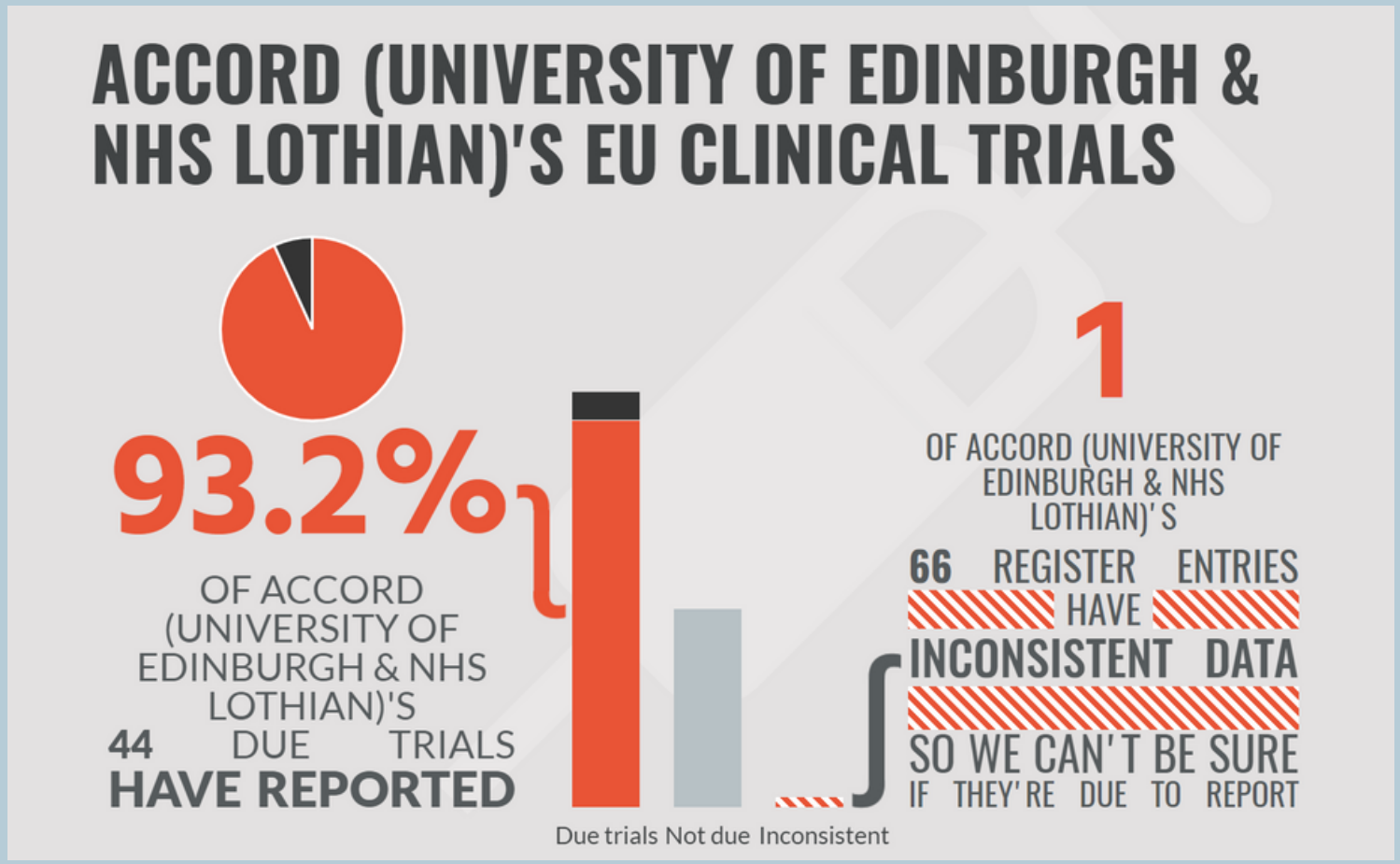
Transparency Campaigns

- All Trials Campaign tracked compliance with the EU Clinical Trials Regulations - legal requirement to post results to the EudraCT database within 12 months of completion.
- TranspariMED published reports on Clinical Trials Reporting by UK Universities (and reports of compliance across Europe and the US).



EU Trials Tracker

- In 2018, Edinburgh had a reporting rate of approximately 55%.
- We are now almost fully reported, with only 3 trials unreported.



HRA #MakeItPublic Strategy

Responding to recommendations made by the Science & Technology Committee, the HRA developed a strategy to make transparency easy and become the norm.

Shaped by the people and organisations it would affect:

- Research Transparency Strategy Group
- Public consultation across the UK

"During the public consultation, we heard from hundreds of researchers and sponsors, patients and participants, funders and registries from across the UK who, like us, feel passionately about transparency and openness in research. What really rang out were the voices of the people who had taken part in research studies but never heard about what the study had found. They were frustrated and felt that things really need to change."

About the #MakeItPublic Strategy

Three pillars of transparency are considered, with planned activities in each area to create better support and encouragement for researchers to be transparent:

Another area of focus in the future is sharing data and tissue to enable further research.

01

Registering Research

Registering Research

- Before Brexit, Clinical Trials of Investigational Medicinal Products (CTIMPs) were registered on EudraCT.
- From January 2022, **CTIMP**s and combined trials of an **IMP and device** are now automatically registered by the HRA on the ISRCTN registry.
- **Other clinical trials** should register on a platform acceptable to the International Committee of Medical Journal Editors (ICMJE).

- ICJME define a **clinical trial** as '*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes*'.
- ICMJE only consider trials for publication if they have been registered in an appropriate registry e.g. www.clinicaltrials.gov and www.ISRCTN.org.
- **Other research** e.g. observational studies and questionnaires may use the Open Science Framework that supports transparency and enables collaboration.

01

Registering Research

Registering Research

What is New?

- **CTIMPs** and combined trials of an **IMP and device** are now automatically registered by the HRA on the ISRCTN registry (free of charge).
- Automatic registration is to be added for other types of clinical trials in time.

- Allows plain English summaries and public titles to be visible on the Be Part of Research website, where the public can search for clinical research relevant and local to them.

Contact ACCORD if you need advice, or a user account to access a registry.

"In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start."

02

Reporting Results

Reporting Results

- Publishing results in a peer-reviewed journal is important but not always achievable or accesible to the public.
- Results should be made available in a place they can be seen and in a way that they can be understood by the public.
- The HRA request a final report using their Final Report Form, which they publish on an accessible website.

- Also important to maintain the registration record, uploading results to the registry used to make the study public. **This applies to all types of clinical research.**
- As an Investigator, you are responsible for ensuring resource is available to upload results within 12 months of the end of the study. We recommend you do this in good time before the deadline, while staff are still funded.

02

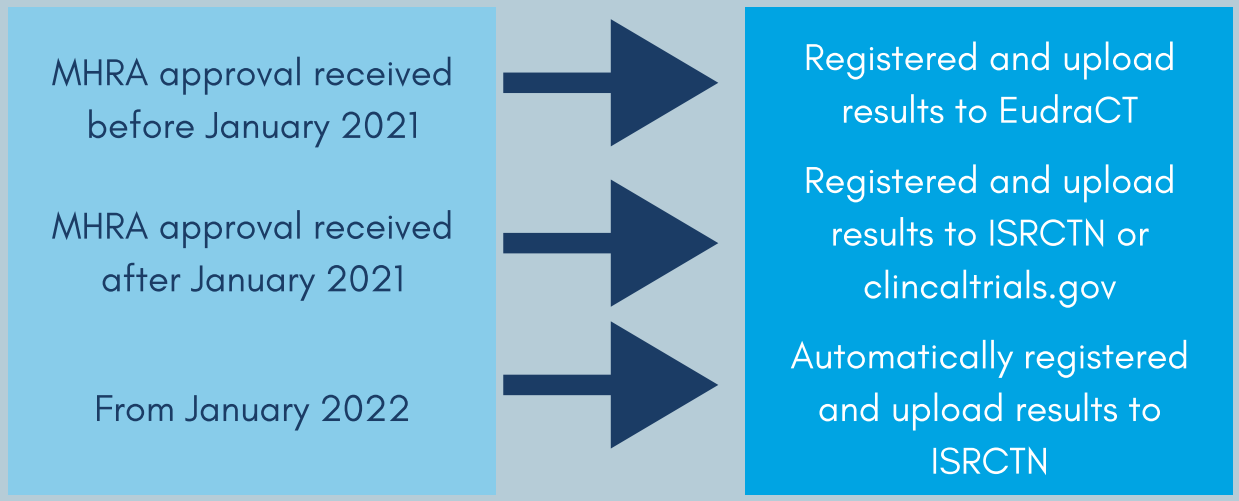
Reporting Results

Reporting Results

What is New?

- Anyone who has experience of EudraCT (!) will be pleased to hear that the upload of CTIMP results to ISRCTN is more straightforward.
- The HRA will now measure transparency performance based on receipt of final reports. They plan to publish institutions' compliance and consider an applicant's past transparency performance when reviewing new studies.

CTIMP Reporting



"Other than research for educational purposes and early phase trials, the findings, whether positive or negative, should be made accessible in a timely manner after the research is finished."

03

Informing Participants

Informing Participants

- Providing research findings to the participants is an important part of good public engagement, respecting the participants and acknowledging their contribution.

What is New?

- A dissemination plan must be submitted with HRA applications for approvals to describe how participants will be informed.

- The HRA is drafting guidance around informing participants, particularly in research where this may be more of a challenge e.g. adults with incapacity, emergency research, research where participants may die from an existing illness.
- The final report form required by the HRA also includes a lay summary of study results that they will publish on an accessible website. They have developed an e-learning module explaining how to write a plain language summary of research findings.

"Information about the findings of the research should be available in a suitable format and timely manner, to those who took part in it, unless otherwise justified."

Best Practice

- Across Edinburgh, clinical research is also conducted that doesn't fall under the remit of the HRA, but should make the same considerations when it comes to research transparency.

Help

- ACCORD will advise at Sponsor Review on registration.
- Follow up at end of CTIMPs to check results upload is on track.
- The HRA is introducing additional monitoring to check that researchers are registering and reporting results, and to collect information about study findings.
- The HRA will celebrate good practice and highlight poor performance, by publishing transparency information about individual sponsors.
- HRA guidance, support, and tools are available / being developed.

Examples of Transparency

The **RESTART trial** is an excellent example of transparency.

- Registered on ISRCTN
- Webpage providing:
  - trial summary for patients and carers and a version for professionals
  - plain English summary of the results
  - clear and informative video abstracts
  - links to slides and presentations
  - link to access a fully anonymised dataset

Covid-19 Research

The pandemic is another great example of the importance of transparency:

- we needed to know what research was going on to avoid duplication
- we needed to get access to the results of those research projects quickly to change clinical practice and improve care
- we needed to honour the contribution of the research participants by letting them know what the study had found

Transparency should become the norm for all research.

Useful Information

- EU Trials Tracker
- HRA Research Transparency Strategy
- Make It Public video
- HRA Implementation Plan

- **PPI Activity in Edinburgh**
  - PPI Summer School 21-24th June 2022
  - 3 half day sessions online and meet with a PPI Lead to finalise your PPI plans
  - PPI Bursaries launching May 2022
    - Apply for a reasonable sum of money to cover PPI costs. Keen to strengthen PPI with underserved populations.
    - Contact carol.porteous@ed.ac.uk
  - PPI Seminar Series launching June 2022

- Any questions?