UNIVERSITY OF BIRMINGHAM

Trial portfolio registration & reporting - oversight & support for researchers

Birgit Whitman,
Head of Research Governance & Integrity

Plan for today

- Requirements
- Institutional Oversight & Support
- Dealing with EudraCT legacy issues
- Managing EudraCT registration & reporting prospectively & COVID 19 requirements
- Next steps

Requirements

- Sponsors of trials conducted in UK (+/- recruitment at international sites) that are registered on EudraCT are required to upload trial results within 12 months (6 months for paediatric trials) of declaring the end of trial
- Concordat to support Research Integrity 2012 (revised 2019)
- Science & Technology Select Committee inquiry 2018 and focus o reproducibility 2021
- Funder condition
- Health Research Authority (HRA) Make it public

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-transparency-make-it-public-transparency-and-openness-health-and-social-care-research/ /

Institutional Oversight

- Establish trial registry requirements & set up institutional account (verify list of trials)
- Resolve legacy issues
- Include trial registration & uploading of results in policies
- Direct researchers to appropriate registry & include in grant application / set-up process
- Monitor registries
- Ensure upskilled Research Ethics & Governance Teams with resource to offer support to researchers

Deal with EudraCT - legacy

- Ensure you have a central institutional account
- Verify EU Trial Tracker list
- Write to Regulator & EudraCT registry colleagues to request removal of those that are allocated incorrectly or where trial end dates need to be updated.
- Contact CIs to highlight reporting need for overdue trials and provide clear guidance for uploading results / uploading the publication
- Work closely with researchers and ensure appropriate support

Deal with EudraCT - legacy

- **Trials that completed pre 2013**

  Upload pdf for trials that closed pre-2013

- **Trials that ended prematurely**

  Post results in EudraCT as a pdf

- For trials approved but never started, sponsors are required to state the reasons for the premature interruption in the pdf document.

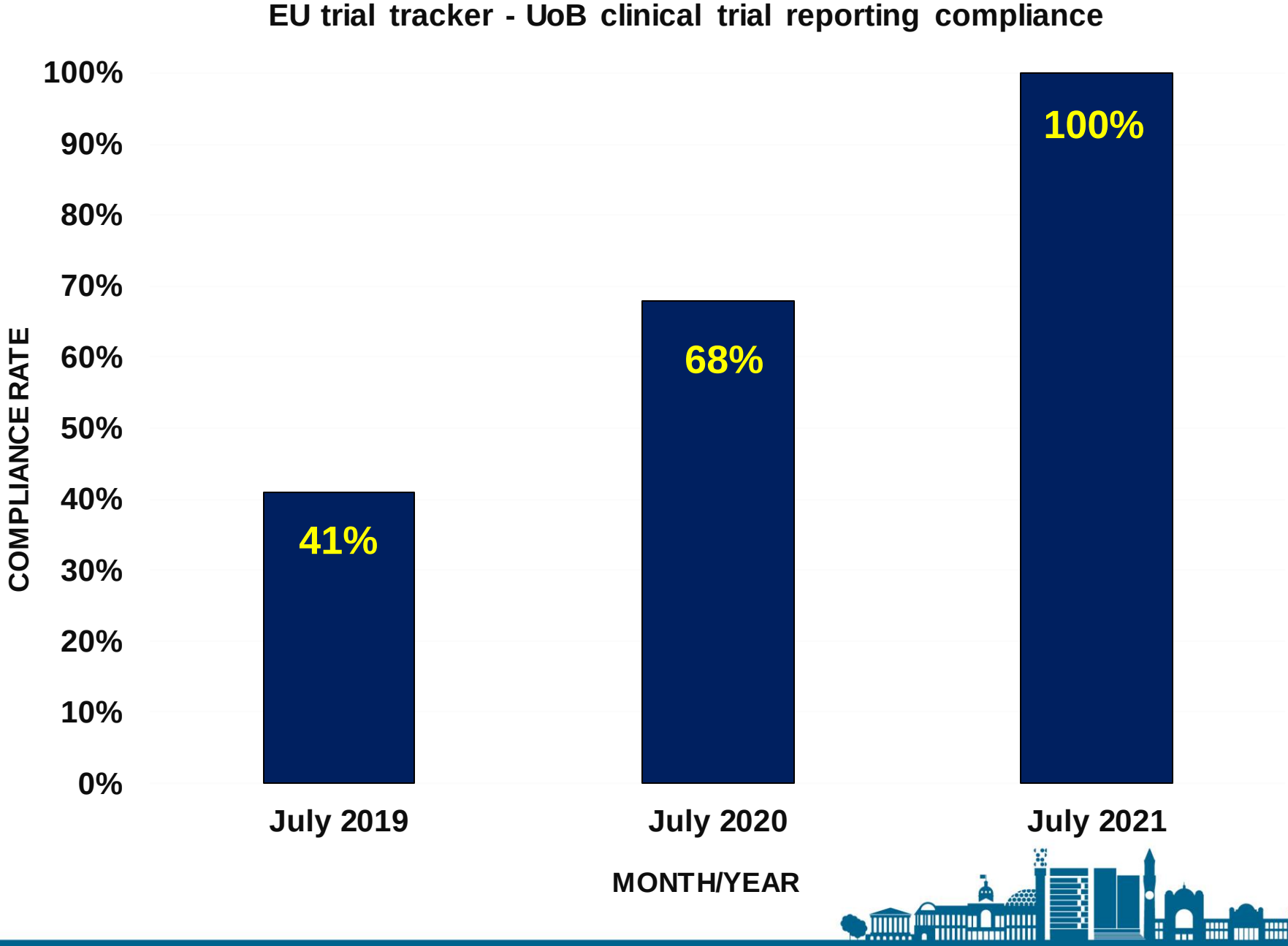
- For trials that started and terminated early, sponsors are required to state the reasons for the early interruption, together with any partial result, if available, in the pdf document.

EudraCT – prospectively

- Build trial registration and reporting needs into the grant application
- Ensure trials reporting needs are included in the statistical analysis plan at set-up
- Ensure appropriate tracking and reminders
- For those which have closed, provide the Eudra access letter which is needed for any staff member to upload trial results to EudraCT
- Ensure resource is available from appropriate team members and work with researchers to support the upload of results

EudraCT – for COVID-19 trial

- Sponsors of clinical trials on COVID-19 are requested to include the term "COVID-19" in the title of their trial
- Importance of timely reporting of SAEs (Serious Adverse Events) and of SUSARs (Suspected Unexpected Serious Adverse Reactions) to protect the safety of the participants.
- Post the relevant results as soon as it is feasible, even before the deadline.


EU trial tracker - UoB clinical trial reporting compliance
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
COMPLIANCE RATE
41%
68%
100%
July 2019
July 2020
July 2021
MONTH/YEAR

Next Steps – WHO definition

- For the purposes of registration, a clinical trial is 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.
- Clinical trials may also be referred to as interventional trials. This include drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care (Phase I to Phase IV trials)

Next Steps – Transparency

- Record numbers of people are taking part in health and social care research
- Ensure research findings are made public in a meaningful and timely way
- Transparency and openness are essential to ensure participants are likely to take part in future studies.

In summary

- Establish national requirements and engage with policy makers
- Amend policies & processes
- Assess team skills / interest
- Ensure protected resource
- Prepare list of trials
- Check / create registry institutional access
- Verify registry entries
- Contact research community and establish support needs
- Monitor