UNIVERSITY OF BIRMINGHAM

Clinical trial registration and reporting of results – challenges for non-commercial organisations

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A case study – still on the journey…

- FOI requests about institutional policies received in 2017
- Contact with ALLTrials Campaign and TranspariMED & Transparify
- Steps to ensure trial transparency for the institution across three main registries

Clinicaltrials.gov - legacy

- Create a central institutional account
- Ensure resource is available from appropriate team members.
- Work closely with research community
- Actively engage with colleagues from trial registry
- Review trial registration to ensure accurate allocation to the institution
- Remove those that are inaccurately allocated

Clinicaltrials.gov – prospectively

- Build trial registration and reporting needs into the grant application
- Allocate access to the registry for researchers if appropriate for the trial
- Avoid as far as possible duplicate registration
- Ensure resource is available from appropriate team members.
- Work closely with research community
- What has been your experience?

EudraCT - legacy

- Ensure you have / create a central institutional account
- Verify EU Trial Tracker list
- Ensure resource is available from appropriate team members
- Actively engage with colleagues from trial registry
- Work closely with researchers to allow them access to the uploading of results

EudraCT – prospectively

- Build trial registration and reporting needs into the grant application
- Allocate access to the registry for researchers if appropriate for the trial
- Avoid as far as possible duplicate registration
- Ensure resource is available from appropriate team members.
- Work closely with research community
- What has been your experience?

Consider other registry entries

- Action plan for your organisation
- Assess resource needs
- Retrospectively posting the summary results of older trials poses significant challenges
- How are you monitoring this prospectively?

Register all trials - WHO definition

- Have you achieved this yet?
- 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. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

Thank you

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