Clinical trial registration & reporting of results – reflection on the experience of a non-commercial organisation.

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A case study

- FOI requests about institutional policies and result upload for trials received
- 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.
- Actively engage with colleagues from trial registry
- Review trial registration to ensure accurate allocation to the institution
- Remove those that are inaccurately allocated
- Work closely with research community
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.

What has been your experience?
EudraCT - legacy

- Ensure you have / create a central institutional account
- Verify EU Trial Tracker
- Ensure resource is available from appropriate team members
- Work closely with researchers to support the upload of results
EudraCT - legacy

- Upload of a pdf has been possible for trials that were completed pre 2014
- Recently there have been some positive developments that will make the upload of results for studies that terminated early easier

https://www.transparimed.org/single-post/reporting-prematurely-ended-trials-on-eudract

- King’s Health Partners Case Study

file://adf/corp/RCS/Users/WhitmanB/Desktop/To%20do/Trial%20Reporting%20Jan%202019/Kings%20case%20study.pdf
EudraCT – prospectively

- Build trial registration and reporting needs into institutional policies and procedures
- At pre-award ensure the resource requirement for result upload is included in grant applications
- Build reporting needs into the statistical analysis plan and quality assurance processes
- 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?
Future challenge: Register all trials - 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. 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.

- Have you achieved this yet?
Thank you

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