CLINICAL TRIAL TRANSPARENCY POLICY

Trial Transparency Policy v 1.0

Effective Date: 18-Oct-21

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CONTENT

1 SCOPE

This policy applies to all clinical trials that receive full or partial funding from the ACF, where the collaboration agreement was signed by both parties from October 2021 onwards.

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2 BACKGROUND

Clinical trials are a key driver of medical innovation and progress. The medical community, the private sector and public bodies should have unrestricted access to reliable information on the benefits and harms of drugs, devices and treatments.

By 'clinical trial transparency' we refer to "the disclosure of clinical trial results and appropriate sharing of clinical trial data", *where 'data' refers to all information from a clinical trial, and is not limited to its raw data set.*

2 BACKGROUND

The 5 Pillars Of Clinical Trial Transparency

1. Prospective Trial Registration
2. Summary Of Results Posting
3. Final Study Reports sharing
4. Academic publication of results
5. Individual Participant/Patient Data Sharing (IPD)

The Benefits Of Clinical Trial Transparency

- Improvement of **allocation of public health resources**: Clinical trial results direct decision-making on Market Authorisation, pricing and reimbursement
- **Limiting waste** of research funds and unnecessary repetition of trials
- **Acceleration** of medical progress and the discovery of new treatments and cures
- Better **decision-making** by healthcare professionals and patients
- **Improvement of patient safety** by ensuring that all harms are reported

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3 PRINCIPLES OF TRIAL TRANSPARENCY FOR ACF-SUPPORTED TRIALS (I)

REGISTRATION

- Clinical Trials must be registered before the first participant receives an intervention
- Registries must be updated during the study
- Results & protocols must be made public within 12 months from Study Completion

RESULTS REPORTING

- Summary of Results
- Final Study Report

PUBLICATION

- In an open-access journal

RAW DATA/IPD SHARING

- Individual Patient Data

NOTE:

These principles are the basis for all clinical trial transparency clauses in the collaboration agreement signed between the ACF and the trial sponsor.

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3 PRINCIPLES OF TRIAL TRANSPARENCY FOR ACF-SUPPORTED TRIALS (II)

REGISTRATION

Clinical Trials within scope must be registered before the first participant receives an intervention

Compliant with regulations, ACF asks that the trial is registered on ClinicalTrials.gov before the first subject receives the first medical intervention in the trial. The sponsor is free to register the trial on one or more additional registries, according to country-specific requirements.

Registries must be updated during the study, and key outcomes and trial protocols are to be made publicly available within 12 months from Primary Study Completion

Clinical trial registry records must be updated as necessary to include final enrolment numbers achieved, and the date of primary study completion (defined as the last data collection timepoint for the last subject for the primary outcome measure).

In the case that the clinical trial is **terminated**, the status must be updated to note

- the date of termination,
- the reason(s) for termination and
- the number of participants enrolled up to termination.

Registry records must also be updated following **substantial changes to the trial protocol**, and following **any changes to the trial's status** (e.g. currently recruiting, suspended, completed etc).

The **trial protocol** (including amendments approved by ECs/ IRBs) must be made public within 12 months of the study completion date by linking it within the trial registry and in all publications.

3 PRINCIPLES OF TRIAL TRANSPARENCY FOR ACF-SUPPORTED TRIALS (III)

RESULTS REPORTING

Compliant with regulations, the results of every clinical trial must be made public on the trial registry/ies where it was initially registered **within 12 months of the study completion date**, without exceptions.

SUMMARY OF RESULTS

A Summary of Results must be posted on the registry/registries where the trial was originally registered **within 12 months of of the study completion date**.

FINAL STUDY REPORT

The Final Study Report should be made **publicly available within 6 months of having the Final Study Report ready.**

*Note: European regulations require the results of paediatric trials registered on the European trial registry EudraCT to be made public within **6** months of trial completion. In addition, European regulations require trials that were approved but never started to report their 'results' using a simplified procedure.*

Note: uploading tabular summary results onto a trial registry will not compromise the investigators' ability to later get the results published in a journal.

3 PRINCIPLES OF TRIAL TRANSPARENCY FOR ACF-SUPPORTED TRIALS (IV)

PUBLICATION IN AN OPEN-ACCESS JOURNAL

The results of every clinical trial must be submitted to a peer-reviewed, open access journal within **24 months of the study completion date** unless the trial was terminated early without participants.

The **trial registry identifier** (e.g. “NCT123456789”) must be included in the abstract of all publications, including in the published trial protocol and in all preprints, journal articles, conference abstracts, presentations etc.

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3 PRINCIPLES OF TRIAL TRANSPARENCY FOR ACF-SUPPORTED TRIALS (V)

RAW DATA/IPD SHARING

Raw data, or individual patient data (IPD) are an important output from Clinical Trials in terms of the **re-use of data.**

This is important because re-use of data increases the impact resulting from the initial financial, research infrastructure, and research participants' investments needed to collect data.

Appropriately anonymised datasets should be made available on an open data sharing platform.

On clinicaltrials.gov, the IPD sharing statement should be answered with 'yes'.

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4 COMPLIANCE MONITORING

ACF will monitor adherence to this data sharing policy.

The last payment milestone concerns final study report disclosure.

Sponsoring institutions are expected to have an approach in place to ensure compliance with this policy.

5 FINANCIAL COMPENSATION

The costs for complying with this policy are cost eligible items in the clinical trial budget.
This includes the time required for managing data on clinical trial registries, and open access journal fees.

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