

CLINICAL TRIAL TRANSPARENCY POLICY

For ACF-funded research



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 February 2026 onwards.

Trial Transparency Policy v 2.0
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Introduction

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.

With '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, not limited to its raw data set.*

The Benefits Of Clinical Trial Transparency

- Improvement of **allocation of public health resources**: Clinical trial results are used to decide 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

The 6 Pillars Of Clinical Trial Transparency

- 1 Prospective trial registration
- 2 Summary of results posting
- 3 Final study report sharing
- 4 Academic publication of results
- 5 Sharing results with participants
- 6 Sharing individual patient data (IPD)

Clinical Trials must be registered **before** the 1st participant receives a study-related intervention

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.

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

The results of every clinical trial must be submitted to a **peer-reviewed, open access journal within 24 months** of the study completion date

Participants in clinical trials should **be pro-actively offered the results** of those trials irrespective of study outcome

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

NOTE:

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

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Prospective trial registration

Clinical Trials must be registered before the 1st participant receives a study-related intervention

Compliant with regulations, ACF asks that the trial is registered on **ClinicalTrials.gov** before the 1st participant receives the 1st medical intervention in the trial.

The sponsor is free to register the trial on one or more additional registries, according to country-specific requirements.

Trial protocol registration

Registry records must be updated

- following **substantial changes to the trial protocol**
- following **any changes to the trial's status** (e.g. 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.

Registries must be updated during the study, & key outcomes 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
- 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.

Key points

- Clinical Trials must be **registered** on ct.gov before the 1st participant receives an intervention
- Registries must be **updated** during the study
- **Results & protocols** must be made public within 12 months from Study Completion

2 Summary of results posting

Compliant with regulations, a Summary of Results must be posted on the registry/registries where the trial was originally registered **within 12 months of the study completion date** together with a summary understandable to **laymen**.

Where it is not possible to submit the summary of results within the defined timelines for scientific reasons, (e.g. when the trial is still ongoing in 3rd countries so data from that part of the trial aren't yet available, making statistical analysis not relevant), the sponsor should justify this in the protocol + specify when results will be submitted.

3 Final study report sharing

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** 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 a **summary of results** onto a trial registry will **not** compromise the investigators' ability to get the results published in a journal later .*

4 Academic publication of results

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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Sharing results with participants

Key reasons for sharing results

- **respect** for the participants' contributions
- increases the **transparency** of scientific research
- supports public understanding of research which can **improve participation** in clinical trials
- helps **building trust** in researchers and supports **informed health decisions**

Principles

- Participants in clinical trials should be **pro-actively offered** the results of those trials irrespective of study outcome. *Putting the results on a trial database or webpage and expecting participants to find them based on links given in the patient information sheet is not usually sufficient.*
- How results will be shared needs to be **part of the study plan** from the beginning.
- Results should be offered in a way that is **accessible** to participants, both in terms of the communication mechanism and the content.
- Participants **should be given the choice** of whether to receive research results. Ideally, this should be incorporated in the ICF.
- Results should be offered to participants in a **timely manner**.

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sharing individual patient data (IPD)

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

It increases the impact resulting from the initial financial, research infrastructures', and research participants' investments that were needed to collect data.

Key reasons for sharing IPD

- enables independent **validation** of results
- allows **further analyses** or addressing **new research questions**
- maximizes the value of **participants' contributions**
- accelerates **innovation and evidence-based decision-making**

Models of IPD sharing

- **Open access**: anonymised data are publicly available through an open data sharing platform
- **Controlled access**: researchers can apply for access to the data in a secure environment (via download or secure transfer).
- **Data enclaves/'safe havens'**: researchers can apply for access to the data without the data leaving the secure server

ACF encourages **appropriately anonymised datasets** to be made available on an open data sharing platform.



Annex 1: Reporting timelines

▪ Summary of key timelines

Requirement	Timeline
Trial End Notification	Within 15 days of last visit
Summary Results (Adults)	Within 12 months of trial end
Summary Results (Pediatrics)	Within 6 months of trial end
Lay Summary	Within 12 months of trial end
Annual Safety Report (ASR)	Annually
Public Access to Results	Shortly after CTIS submission

▪ Protocol-Related Reporting

Document/Change	Submission Timeline
Initial Trial Application	Before trial begins
Substantial Amendments	Prior to implementation
End of Trial Notification	Within 15 days of end of trial
Early Termination Notification	Within 15 days, with reasons
Annual Safety Report (ASR)	Annually, based on 1st participant's enrolment