

## Clinical Research at Inserm: Quality and Transparency (June 2021)

In line with its commitment to the quality and transparency of clinical research on drug treatments, Inserm signed in 2017 of the [WHO Joint Statement on Public Disclosure of Results from Clinical Trials](#), which goes well [beyond](#) the regulatory obligations in France and Europe.

To comply with the Statement, the Clinical Research Unit established a set of precise procedures:

1. All trials promoted by Inserm – and not only drug trials – are registered prospectively (before the inclusion of the first participant) on public registration websites (clinical-trial.gov, ISRCTN registry, etc.).
2. An annual project review helps updating and completing the information provided to these registries.
3. Final report summaries or "study reports" of completed trials are submitted to the websites where these trials were registered, within 12 months at the latest after the study has ended (annual review of trials).
4. Along with the registration of trials, trial protocols themselves are registered on public registration websites (annual trial review).
5. All completed trials must be published in indexed scientific journals **and** the results of these trials must be filed:
  - a. the principal investigators (PI) of trials promoted by Inserm formally commit themselves to deposit the results on the registration website chosen for the study, to publish their results and to communicate such publications to the Clinical Research Unit;
  - b. the annual review of the promoted trials makes it possible to identify pending publications and to contact the PI in order to have them communicated;
  - c. The Clinical Research Unit helps researchers in the publication of their results.

A results publication policy has been developed for most trials and is intended to be applied to all trials.

6. The PI of a trial promoted by Inserm undertakes to include the identifier of the trial on the authorization registers in its publications of results; in the context of annual reviews of promoted trials and follow-up of publications, the Clinical Research Unit ensures that this is the case.
7. Inserm endorses the national open science strategy and supports the open access publication of research results. The PI of a trial promoted by Inserm undertakes to publish a version of its results in open access.

8. An Inserm naming charter is set up to harmonize the Inserm designation in trial registers and publications. The PI of a trial promoted by Inserm undertakes to respect this charter.
9. The Clinical Research Unit monitors all data from trials promoted by Inserm according to a monitoring plan adapted to the risk of the studies; this monitoring plan is designed on the internal management tool. It will submit monitoring reports to the registration websites from 2022 onwards.
10. The Clinical Research Unit has one to two external audits per year, according to a pre-established program, to control the quality of the trials it promotes.
11. In 2022, investigators will be offered an online training course on registration (declaration and summary) and research ethics, currently being developed. This 12-minute module will be followed by an online knowledge assessment questionnaire. Inserm will only promote research whose investigators received a training certificate.
12. An internal management tool tracks operations and keeps data useful for monitoring compliance with the Joint Statement on Public Disclosure for Results of Clinical Trials.
13. From 2022 onwards, PIs will also have to respect the Consort Statement, as well as an external audit in addition to the annual review of obligations.

All these actions are part of the Organization of ethical and responsible research program launched in 2021, through which Inserm aims, over five years, to improve its organization and research practices in order to develop and maintain them at the level of the most demanding ethical and deontological standards on an international scale.

While 100% of trials promoted by Inserm are already registered on the dedicated public websites, Inserm is committed to reaching by 2022 this same level of 100% for the submission of RIPH1 trial results in accordance with the regulations, and to do so for all trials promoted in the following years.