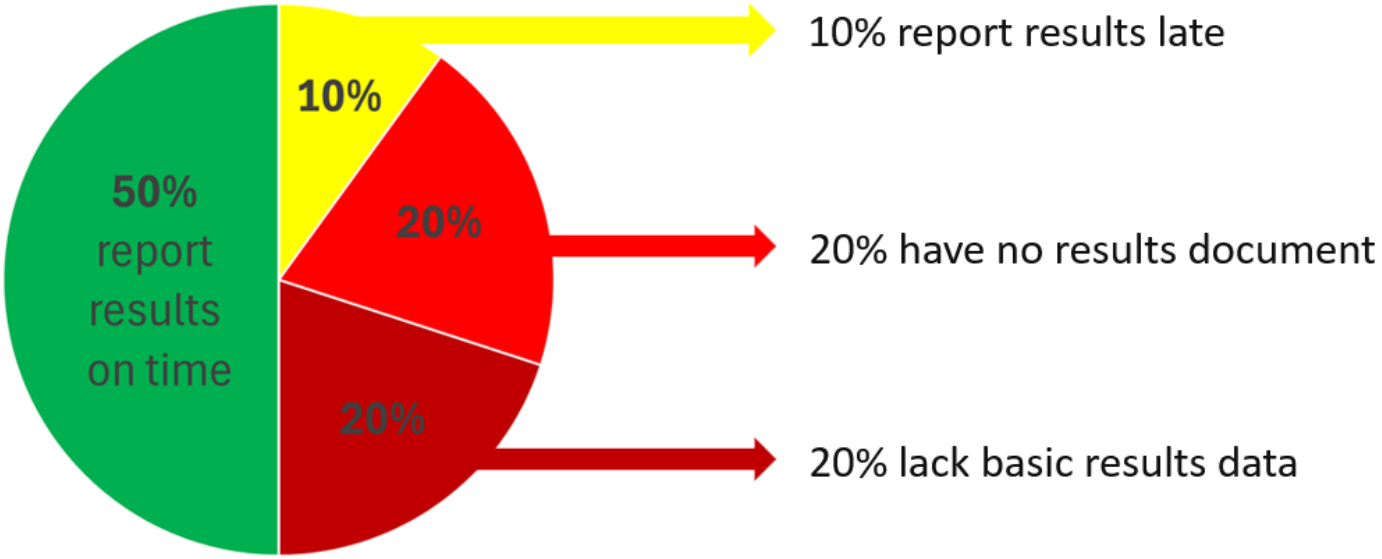
Policy Brief
Amsterdam, Paris, and Stockholm, 15 June 2026

Half of all clinical trials of drugs in Europe do not report results as required by law

Many pharma companies and universities are breaking a new law requiring the results of clinical trials of medicines to be rapidly made public. European regulators do not seem to be monitoring or enforcing compliance.

Only 49.6% of clinical trial results are available on the CTIS registry as required by law.



Breakdown of clinical trial results reporting on CTIS (numbers rounded)

Patients were promised that the new law and new registry would deliver "high levels of transparency never seen before for clinical trials." According to a recent study, just over half of the first 234 clinical trials subject to the new law did not make results public as required.[1]

The CTIS registry now contains more than 8,400 Phase II-IV clinical trials. Over the coming months and years, each of those trials will be legally required to make its results public.

Unless the European Medicines Agency and national regulators take corrective action, and do so fast, critical safety and effectiveness data for thousands of new medicines will remain hidden from scientists, doctors and patients across Europe.

[1] Bruckner, T., et al. 2026. "Assessing Compliance with Reporting Requirements in European Phase II–IV Clinical Trials: A Cross-Sectional Observational Study". medRxiv 2026.04.03.26350111; DOI: https://doi.org/10.64898/2026.04.03.26350111

What should the European Medicines Agency do?

- **Support compliance through CTIS**
    1. Actively remind sponsors before trials become due
    2. Publicly display due dates for all trials
    3. Clearly flag overdue trials
    4. Clearly flag trials that ended without recruiting patients
    5. Make all non-confidential data publicly accessible by default[2]

- **Support quality assurance on uploaded results**
    1. Provide a 24-item template to support PDF results reporting[3]
    2. Provide a 24-item checklist for Reporting Member States to review PDF results[4]
    3. Put into place a system for the future review of results in tabular format[5]
    4. Flag scientific results as "provisional" on CTIS until the Reporting Member State has reviewed them
    5. Flag trials as "results incomplete" if the initial review process identified gaps or errors, until all required results information has been uploaded and reviewed

- **Review the process for extending results reporting timelines for trials**
    - Ensure that sponsors only request extensions in exceptional circumstances[6]
    - Grant extensions only after review and approval by Reporting Member States

- **Publicly track progress in improving compliance**
    - Create a results reporting dashboard on CTIS[7]
    - Add a results reporting KPI to ACT-EU's quarterly CTIS monitoring reports

What should national competent authorities do?

- Issue a warning to sponsors the first day a trial result becomes overdue
- Verify that results posted onto CTIS contain all information required by law
    - Iterate with sponsors until all information has been reported
- Assess and approve/reject requests for reporting timeline extensions[8]
- Impose fines on sponsors that fail to rapidly achieve compliance



[2] For example, data on trials' reporting timeline extensions, their paediatric/adult legal status, and their Reporting Member States are currently not publicly accessible on CTIS. These could easily be included in CTIS downloadable datasets. Consider adding new data fields such as "reported on time", "reported late", "lay summary missing", and "timeline extension granted".

[3] A 24-item template mirroring the legally required 24 scientific results elements would help sponsors to improve reporting quality and make key data easier to identify and extract for both humans and LLMs. The SPIRIT/CONSORT checklists may be a useful model.

[4] A 24-item checklist would significantly reduce the time required for regulatory review. The SPIRIT/CONSORT checklists may be a useful model.

[5] The experience of ClinicalTrials.gov clearly shows that quality assurance will also be required in future, when sponsors will be required to upload results to CTIS in tabular format. See Bruckner et al 2026 (cited above) for more details.

[6] Based on data shared by EMA, it appears that many sponsors do not understand when and how to enter extensions related data.

[7] The dashboard should break down reporting performance by sponsor and by Reporting Member State. Sponsors would benefit from a dashboard that lists all of their trials together with the dates on which each trial's results will become due. The FDAAA Trials Tracker may be a useful model.

[8] Reporting Member States may welcome clarity on how to review and assess sponsor requests for reporting timeline extensions.