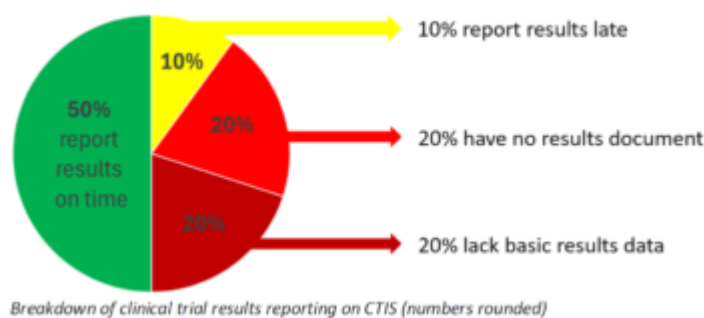


Half of all clinical trials in Europe do not report results as required by law

A [study](#) published this week found that half of clinical trials in Europe did not have results available 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 European Union's [Clinical Trials Information System](#) (CTIS) registry as required by law.



Patients were promised that the new law and new registry would deliver “high levels of transparency never seen before for clinical trials.” However, according to the [study](#), just over half of the first 234 clinical trials subject to the new law did not make results public as required.

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 (EMA) 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.

What Should the EMA Do?

1. Support compliance through CTIS.
2. Support quality assurance on uploaded results.
3. Review the process for extending results reporting timelines for trials.
4. Publicly track progress in improving compliance.

What should national competent authorities do?

1. Issue a warning to sponsors the first day a trial result becomes overdue.
2. Verify that results posted onto CTIS contain all information required by law.
3. Assess and approve/reject requests for reporting timeline extensions.
4. Impose fines on sponsors that fail to rapidly achieve compliance.

To find out more and to read the full set of recommendations, download the policy brief from [HAI](#), [TranspariMED](#) and [Prescrire](#) - **[Download PDF](#)**