Monitoring submission of clinical trial results in CTIS

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Reporting of summary of results

- Art 37(4) of the Regulation (EU) No 536/2014 (CTR) provides the legal basis for submission of summary of clinical trials results to CTIS
- Summary of results are submitted to CTIS in a PDF format and include a scientific summary and a text understandable to laypeople (lay person summary)
- Timelines for submission of results are 12 months after end of trial in the EU/EEA or 6 months for trials in paediatric population as per Regulation (EC) No 1901/2006
- Sponsors can inform authorities of delays in submission of results (*as per CTR, recital 39*)
- Summary of results submitted to CTIS are subject to publication rules:
  - phase II-IV trials results are published immediately after submission
  - phase I trial results are published 30 months after trial end

Guidance available for the preparation and submission of trial results

Annexes IV and V of the CTR define the mandatory structure and **content of the Summary of Results** and the **Lay Summary of Results,** respectively.

CTR Q&A (Questions 6.1, 6.2, 6.4 and 6.7) **provides additional guidance** on the preparation and submission of the Summary of Results and Lay Summary of Results.

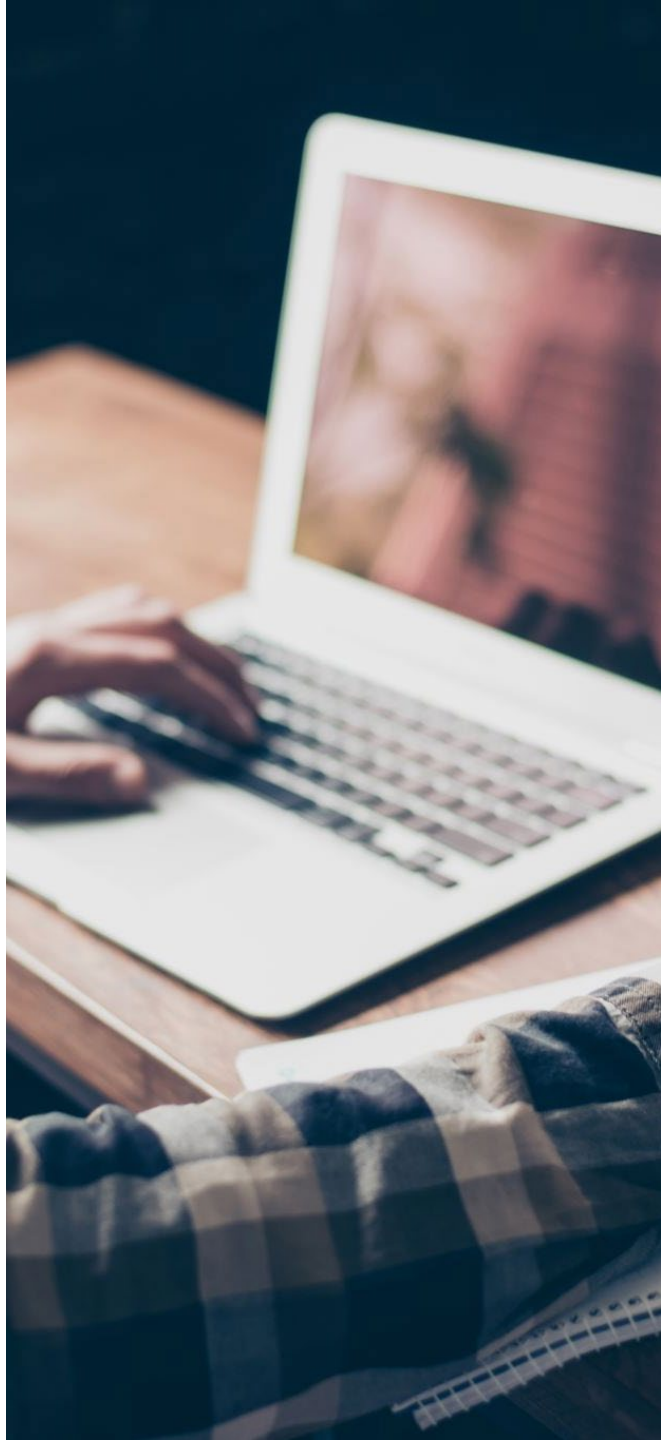
EudraLex Volume 10 contains **guidance** to support sponsors in drafting clear and understandable **Lay Summaries of Results.**

The **CTIS Sponsor Handbook** provides step-by-step instructions on how to submit the Summary of Results and Lay Summary of Results in CTIS.

Clinical Trial Results Submission

Shared responsibilities under the CTR:

- **EU/EEA Member States:** Clinical trial authorisation, assessment, supervision and CTR compliance.
- **European Commission:** Effective implementation of the CTR.
- **EMA:** Development, maintenance and operation of CTIS to support regulatory compliance.



Why submitting High-quality Summary and Lay Summary of results is important

Main reasons are:

- **Fulfil the legal obligation** under **Article 37 of the CTR**
- **Respect clinical trial participants** by sharing research outcomes and avoiding unnecessary duplication of research and avoidable risks.
- **Reduce research waste** by ensuring transparent reporting of clinical trial results.
- **Promote transparency and public trust** by making trial results accessible and understandable through lay summaries.
- **Strengthen the scientific evidence base** by supporting systematic reviews, meta-analyses and future research.

The submission of high-quality Summary of Results and Lay Summaries ensures transparency, reliable communication of trial findings, and the credibility of information published in CTIS.

Possible reasons for non-compliance

- Lack of compliance with reporting of summary of results can be multifactorial
- Reasons might be:
  - **lack of knowledge of regulatory requirements** and legal obligations as per Art 37(4) of CTR
  - **limited resources available** leading to activities to prioritise
  - **lack of engagement on trial related activities** after trial completion
  - **lack of template / clear instructions for results content** (only high-level information on document content is defined in the Annexes of CTR)

CTIS Notices and Alerts on the Submission of Summary and Lay summary of results

Alerts generated to sponsors :

- At 3 months, 1 month and 5 days before results submission due date
- In the due date if no results are submitted.
- 1 day, 3 months and 1 year after the due date for submission of results if no results have not been submitted;
- **every year** after the last alert and if still no results, it will send alert again the following year

Notices generated to Member-state users:

- When results are submitted
- When results are updated or withdrawn
- When Sponsor extends the due date to submit the results

Since 25 June 2026 sponsors can op-in to receive their notifications by email.

ACT-EU communication campaign being considered

Targeted mailing campaign non-compliant sponsors planned to start in September

Quarterly CTs KPI reports including the percentage of compliance as of Q4 2026.

Reminder on the importance of including high-quality data will be included on support materials and using dedicated communication tools

Video project to remind sponsors on this legal requirement highlighting the benefits derived from including high-quality data in CTIS. Planned for Q4.

Thank you

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