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SCIENCE MEDICINES HEALTH

Submission of trial results and layperson summary

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

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Trial Reporting

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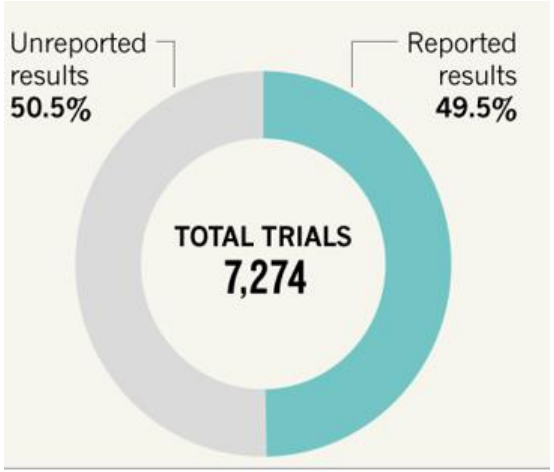
NEWS · 13 SEPTEMBER 2018

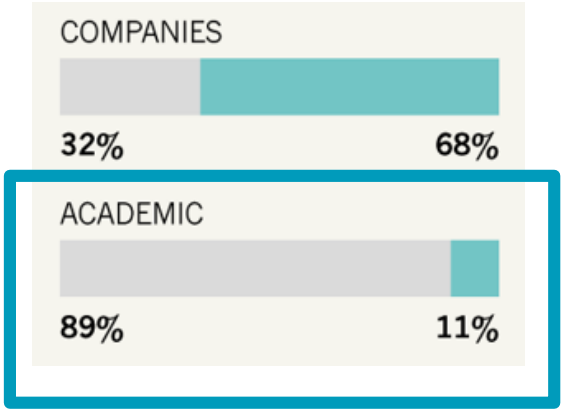
Europe's academics fail to report results for 90% of clinical trials

But nearly 70% of industry-sponsored trials report their results within a year of ending

FAILING TO COMPLY

Around half of all clinical trials in the European Union do not report results within a year of ending. Company-sponsored trials are more likely to report within the EU-stipulated one-year deadline than are academic institutions.





1 Submission of trial results and layperson summary

Trial reporting now….

- Academia in Europe is struggeling with reporting obligations
- Reporting on **national and european** level
- Lack of awareness on reporting obligations
- Reporting in different portals
- **Full data** set needed

Trial reporting under the new EU Regulation 536/2014

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- **one single portal**
- Upload of report according to the **specifications in Annex IV**
- **Layperson** summary according to the **specifications in Annex V**
- **Intermediate or final results**

Article 37

End of a clinical trial, temporary halt and early termination of a clinical trial and submission of the results

4. Irrespective of the outcome of a clinical trial, within one year from the end of a clinical trial in all Member States concerned, the sponsor shall submit to the EU database a summary of the results of the clinical trial. The content of that summary is set out in Annex IV.

It shall be accompanied by a summary written in a manner that is understandable to laypersons. The content of that summary is set out in Annex V.

Submission of trial results and layperson summary

Layperson Summary

27.5.2014 EN Official Journal of the European Union L 158/71

NEW!

NEW!

ANNEX V

CONTENT OF THE SUMMARY OF THE RESULTS OF THE CLINICAL TRIAL FOR LAYPERSONS

The summary of the results of the clinical trial for laypersons shall contain information on the following elements:

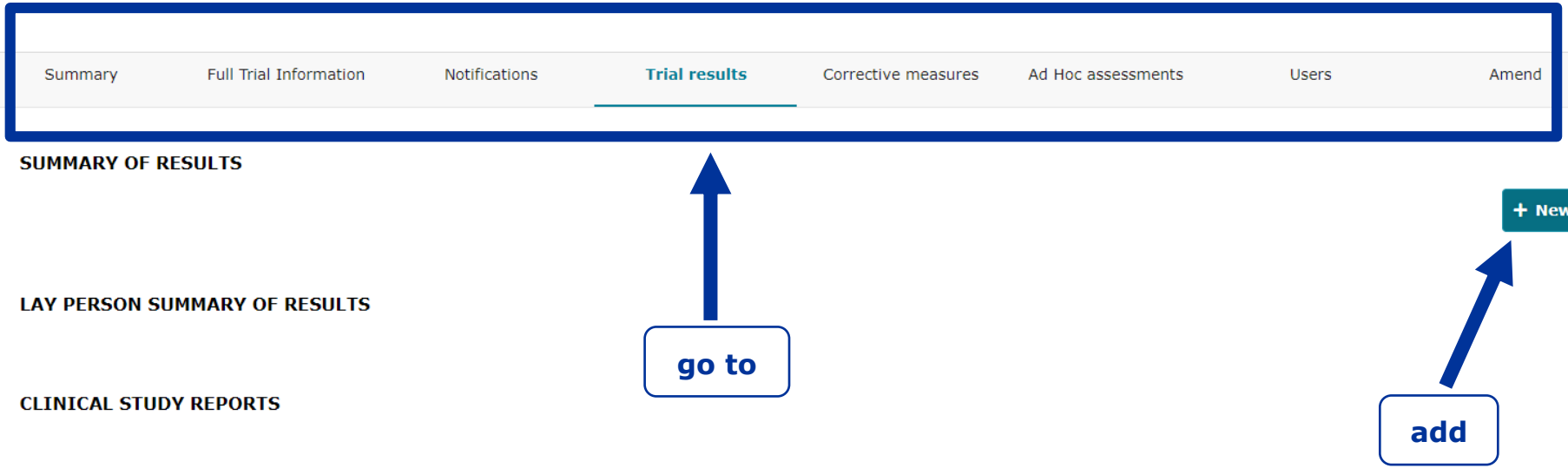
1. Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers);
2. Name and contact details of the sponsor;
3. General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it);
4. Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria);
5. Investigational medicinal products used;
6. Description of adverse reactions and their frequency;
7. Overall results of the clinical trial;
8. Comments on the outcome of the clinical trial;
9. Indication if follow up clinical trials are foreseen;
10. Indication where additional information could be found

Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

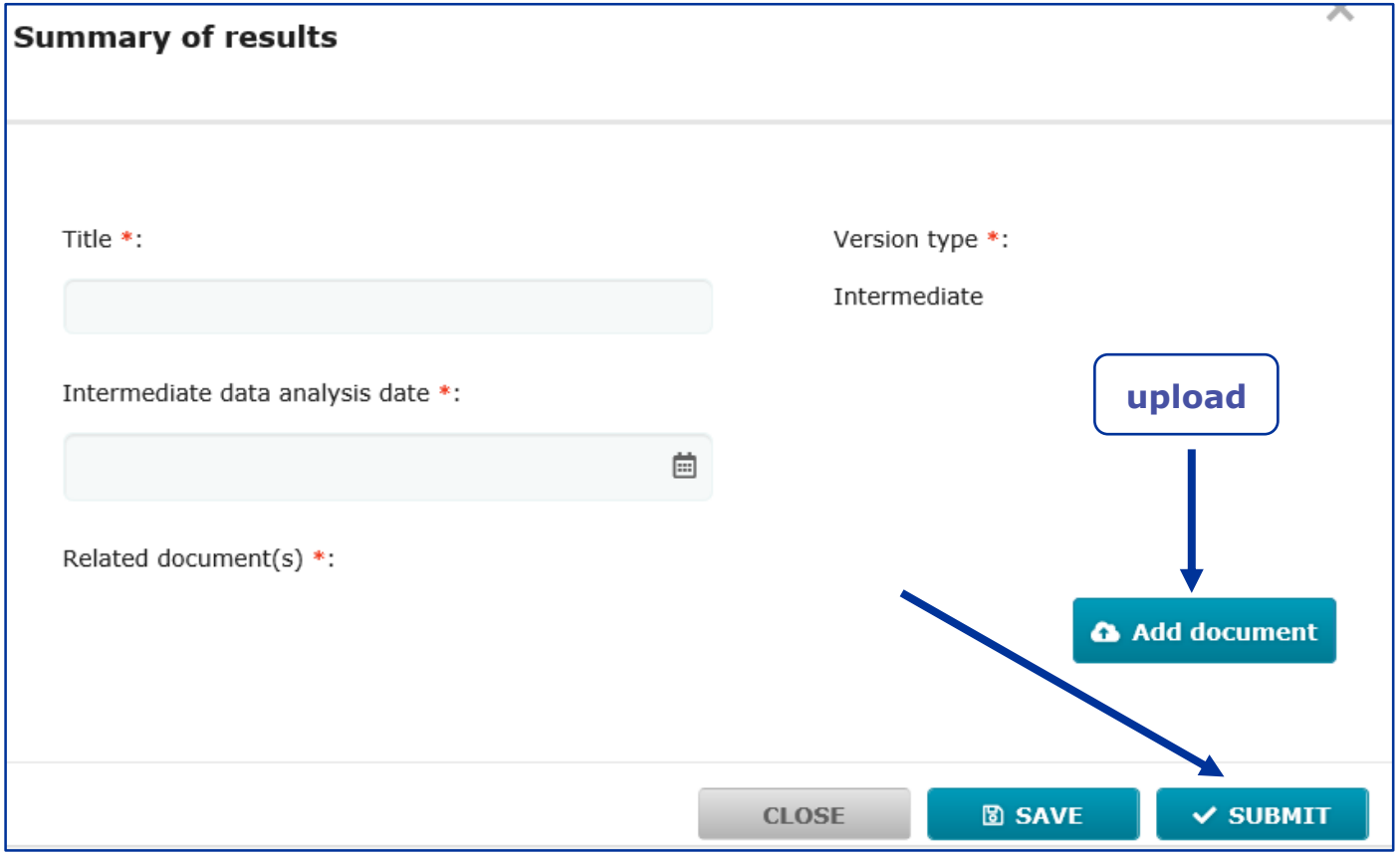
Purpose of the layperson summary

- **Inform** research participants about the trial they participated in
- Patient Engagement-Patient **as partners** in research
- help to **identify clinical trials** easily and evaluate relevance for patient treatment
- Public interest/**Transparency** on trial results
- **Compliance** with the new EU CTR 536/2014

Reporting results in CTIS



Uploading results in CTIS



Any questions?

Further information

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