



PHUSE EU Connect 2023

SA01: Drafting Your Plain Language Summaries: Hurdles to Overcome and How to Overcome Them

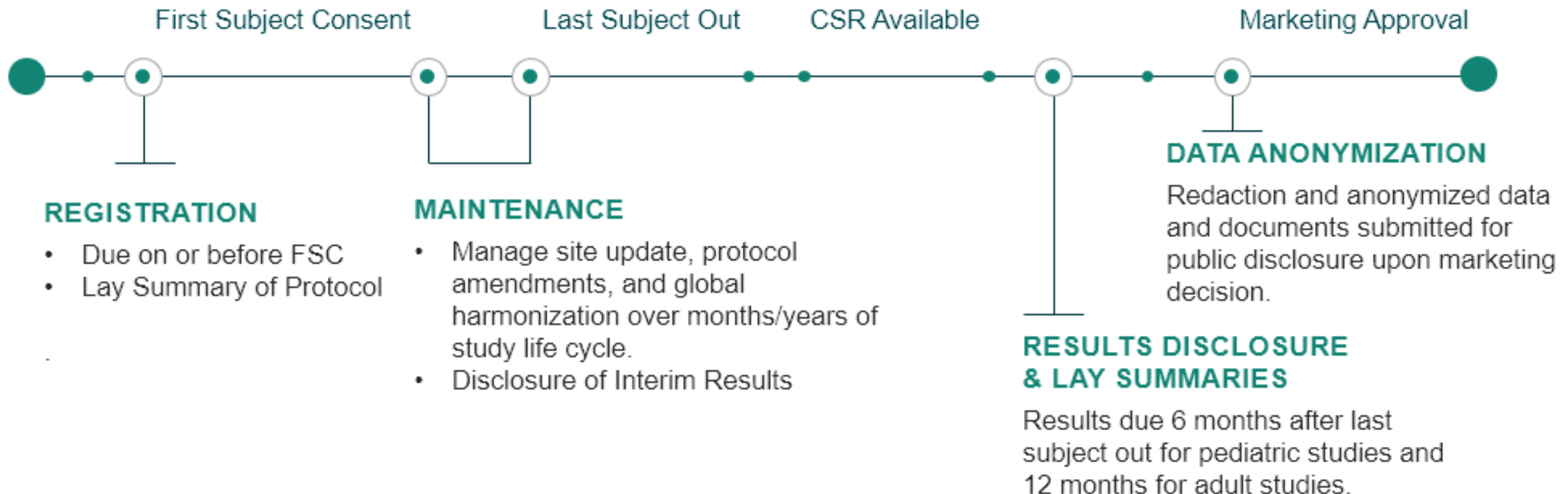
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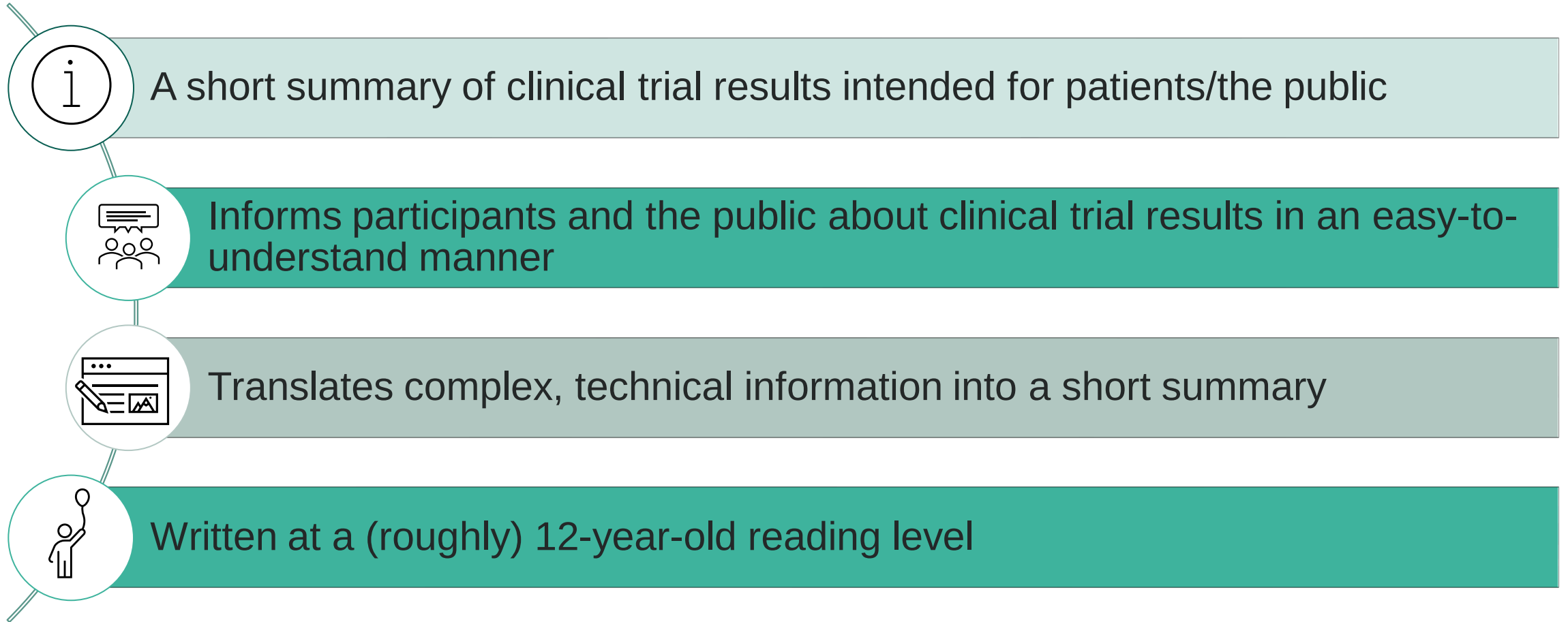
6 November 2023

Introduction: Clinical Trial Transparency

Clinical Trial Transparency is the disclosure of trial registration and results information to the public throughout the lifecycle of the trial. This can be via global registries (Clinicaltrials.gov/CTIS) or by production of patient facing material.



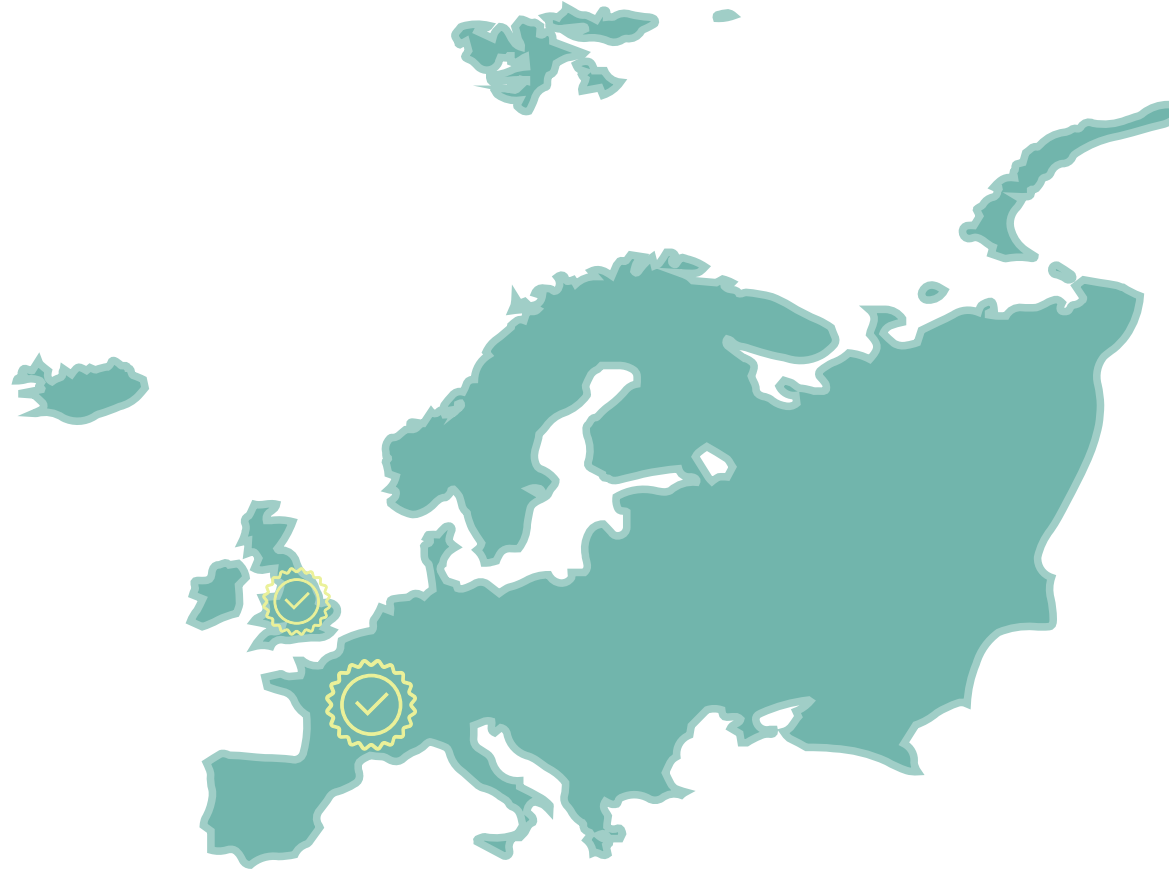
Introduction: What is a Plain Language Summary (PLS)?



Introduction: Are There Requirements to Produce PLSs?



Under EU Clinical Trial Regulation 536/2014 all EU trials require a PLS



In the UK “sharing trial findings with participants in a timely manner and suitable format will be required by law”

Medicines and Healthcare products Regulatory Agency (MHRA)

Introduction: Why are PLSs Important?

Improve public trust in
clinical research



Recognise and value
the participants'
contributions to
clinical research



Enhance participant
recruitment and
retention

What Information Does a PLS Include?

Summary of Study Results



Study Purpose: A study to learn about how well drug X works compared to drug Y and how safe it is in participants with condition Z



Who sponsored this study?



Why was the research needed?



What Information Does a PLS Include?

Summary of Study Results



Study Purpose: A study to learn about how well drug X works compared to drug Y and how safe it is in participants with condition Z



Who took part in the study and what treatments did they take?



What were the overall results of the study?



What Information Does a PLS Include?

Summary of Study Results



Study Purpose: A study to learn about how well drug X works compared to drug Y and how safe it is in participants with condition Z



What medical problems did the participants report?



Where can I learn more information about this study?





Drafting Your Plain Language Summaries: Hurdles to Overcome and How to Overcome Them



Hurdle #1:

PLS Drafting Needing to be Done in Parallel with CSR Drafting

Plan ahead

Confirm and
document data
sources

Utilise other

source documents
e.g., protocol, SAP
and ICF

Effective

communication
Communicate
timelines
effectively



Hurdle #2: Drafting a Paediatric PLS under Expedited Timelines



Draft ahead

Create a “shell” draft of the PLS and finalise data entry once the CSR/TFLs become available

Effective communication
Communicate timelines effectively



Hurdle #3: Making PK Data Understandable to Lay Audiences

Keep it simple

Present high-level
text overviews of
complex PK results

Use graphics

Use call out boxes
to highlight key
information

Keep the reader in mind

Simplify
presentation and
avoid complex
jargon



Hurdle #3: Making PK Data Understandable to Lay Audiences

Summary of Study Results

ICON

Study Purpose: A study to learn about how well drug X works compared to drug Y and how safe it is in participants with condition Z



How did drug X act in the blood compared to drug Y?

Overall, the researchers found that the average highest levels of drugs X and Y in the blood were similar.

C_{max}

AUC

Overall, the researchers found that the average total level of drug X in the blood was higher than the average total level of drug Y.

Hurdle #4: Making Statistical Analyses Accessible in a PLS

Simplicity is key
Present high-level
text overviews of
complex statistical
analyses

**Only discuss if
necessary**
e.g., if key to
understanding the
results

Make it relevant
Provide context
and comparisons



Hurdle #4: Making Statistical Analyses Accessible in a PLS

Summary of Study Results



Study Purpose: A study to learn about how well drug X works compared to drug Y and how safe it is in participants with condition Z



Did the participants feel less pain after taking drug X compared to drug Y?

Endpoint results not statistically significant



Overall, the researchers found that the difference between treatments was too small to know if drug X reduced pain more than drug Y. The difference in results could have been due to chance.



Questions?

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