EMWA RPD SIG Meet & Share

Maintaining consistency across documents, including Plain Language Summaries

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General Discussion Topics

1. Public disclosure - consistency of trial results across different forums
2. Patient Information Sheets and Lay Language Summaries

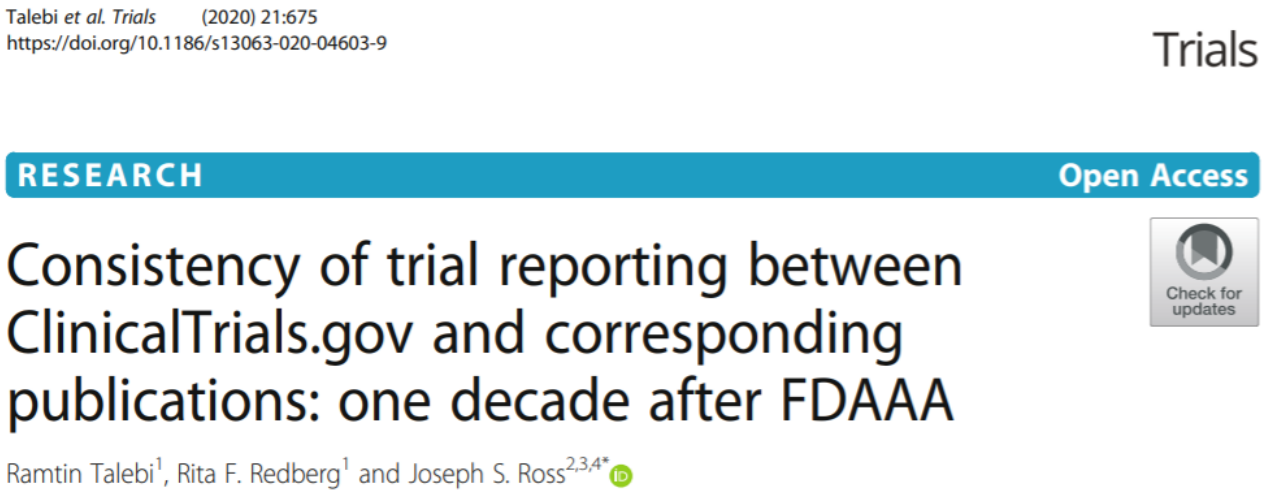
Please ask questions and contribute at any stage

1. Consistency of trial results across different forums

- Public disclosure of final CSR trial results
  - Final CSR
  - Summary Results from final CSR (summary results posted to registry databases) e.g. ClinicalTrials.gov, EudraCT
  - Lay Language Summary
  - Journal publication

Must ensure consistency of results presented across different forums

Consistency of Results Presented Across Different Public Forums



Talebi *et al. Trials* (2020) 21:675
https://doi.org/10.1186/s13063-020-04603-9

Trials

RESEARCH Open Access

Consistency of trial reporting between ClinicalTrials.gov and corresponding publications: one decade after FDAAA

Ramtin Talebi[1], Rita F. Redberg[1] and Joseph S. Ross[2,3,4*]

74% had at least 1 discrepancy between results reported in clinicaltrials.gov and corresponding publication
Authors recommend a checklist to provide systematic procedure to monitor accurate reporting
"….challenges of providing clear and consistent trial information and reported results across public sources of information still need to be addressed…."

Good Lay Summary Practice :Lay Summary QC

Quality control on the final LS should be carried out by person other than the LS author to ensure the accuracy of the content against the source data.

3.3.8 Skills for Quality Control (QC) and Accuracy Checks

Since the LS will be publicly disclosed, it is important that it is subject to an accuracy check before being released to the public. Quality Control (QC) of a LS entails checking of all numbers and all quantitative statements against the source documents. To ensure an objective unbiased QC process, the check should be performed by a professional who is not part of the immediate LS writing team, ideally a QC specialist. It is recommended to develop a checklist of all items that require QC review and to document any changes implemented.

At any review step, tailored checklists and review instructions will provide helpful guidance to reviewers.

2. Patient Information Sheets and Lay Language Summaries

Do they exist in parallel universes?

EU Lay summaries 10 specified elements

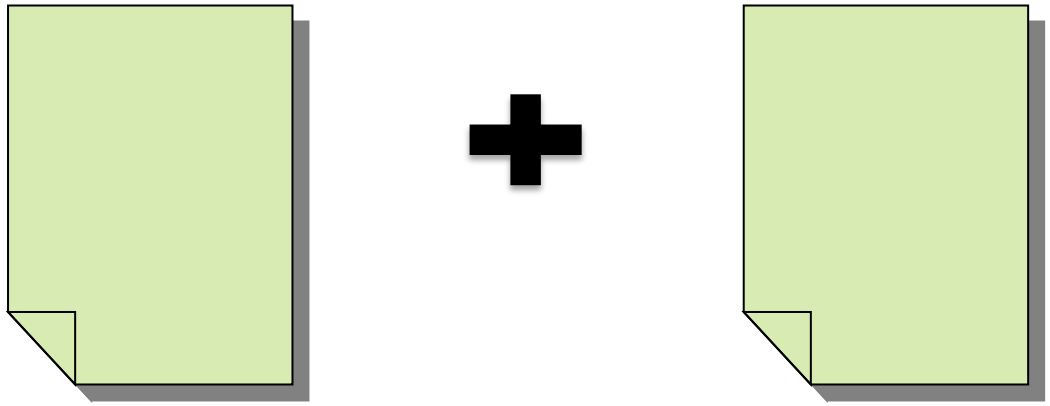
Original 10 Headings

1. Clinical Trial identification
2. Name & contact of the sponsor
3. General information about the trial
4. Population of subjects
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 trials are forseen
10. Indication where additional information could be found

Revised headings

1. Study name
2. Who sponsored this study?
3. General information about the clinical trial
4. What patients/people were included in this study?
5. What medicines or vaccines were studied?
6. What were the side effects?
7. What were the overall results of the study?
8. How has this study helped patients and researchers?
9. Are there plans for further studies?
10. Where can I find more information about this study?

Aligning the lay summary with the PIS



Patient
Information Sheet

Lay
summary

Consistency across both the PIS & the Lay Summary

PIS

1. Study name
2. Who is sponsoring this study?
3. General information about the clinical trial
4. What patients/people are invited to join this study?
5. What medicines or vaccines will be studied?
6. What are the likely side effects?

Lay Summary

1. Study name
2. Who sponsored this study?
3. General information about the clinical trial
4. What patients/people were included in this study?
5. What medicines or vaccines were studied?
6. What were the side effects?