R consortium
R submission Pilot Updates

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Recap: R submission Pilots Scope and Plan

Our Mission

- Easier R-based clinical trial regulatory submissions today
  - by showing open examples of using current submission portals
- Easier R-based clinical trial regulatory submissions tomorrow
  - by collecting feedback and influencing future industry and agency decisions on system/process setup

Pilot principles

Provide open examples of submitting R-based clinical trial data/analysis packages to FDA.

- All pilots will be submitted from R consortium (non-profit identity) to FDA. Public available data will be used.
- All data, codes and documents will be fully available to public.
- FDA reviewers will be engaged to review submission package.
- Submitters and FDA Reviewers will provide feedback on current process/system.
- Contributions from multiple organizations are preferred in order to avoid bias towards organization specific tools.

3 planned pilots

- Pilot1: common analysis (Q4 2021)
- Pilot2: advanced analysis (Q2 2022)
- Pilot3: alternative formatting for package submission (TBD)

Recap: Pilot 1 Goal

Key evaluation aspects:

- For Submitter
  - Submission of proprietary R packages (in txt format)
  - Preparation of R-based submission materials
- For FDA Reviewer
  - Reproduce analysis results by reconstructing submitted proprietary packages / retrieving open source packages
  - Provide feedbacks and/or review comments

Data and analysis scope:

- 4 TLFs (3 tables, 1 figure)

Success Criteria:

- Submitter:
  - Successfully submit via eCTD portal
- FDA Reviewer:
  - Reproduce analysis results

Execution team updates

- Esub gateway setup (R consortium as sponsor)
- Rstudio cloud and Github setup
- Finalized pilot1 scope
- Ran P21 on cdisc pilot datasets
- Initiated code preparation and document preparation

Tentative timeline

- 9/30/2021: complete draft codes and documents, internal review within the execution team
- 10/1 - 10/15 2021: Review by WG
- Late Oct: actual submission after adjudication

Asks

- WG members: to provide feedback during WG review time frame (Oct)
  - Earlier feedback are also welcome (via GH issues)
- FDA members
  - Identify potential reviewers
  - Feedback on scope and timeline

Additional topic

Follow up on Paul Schuette's request that we suggest rewording to Section 4.1.2.10 of the Study Data Technical Performance Guide.

"Sponsors should submit software programs in ASCII text format. Executable file extensions should not be used."

We suggest adding -

Submission of programs with their native file extensions are acceptable, as long as binary file formats and pre-compiled code are not delivered.