DIA Biostatistics Industry and Regulator Forum

April 6-8 | Virtual

#BioStats22

Yes, You Can use R in Regulatory Submissions

Coline Zeballos | R Strategy Lead | Roche

Panel discussion with:
Ning Leng | People and Product Lead, Data Science Product Development | Genentech

A look at the past

2019

"Embrace R in Pharma"

2020

Creation of the
Submission Working Group

2021

Roche submission example - the early days

Project Sautoir Tecentriq (2019)

First submission with majority of analyses done in R, first time R packages were submitted to FDA.

What did we learn?

- All program files need to be in txt format (*proven wrong in later submissions*);
- No underscore is allowed in file name;
- No folder structure is allowed – all program files need to be in a flat folder structure.

Since 2019, we've learned…

Other submissions in R

Submission Working Group R consortium

Successful eCTD FDA submission package including a proprietary R package, R scripts for analysis, R-based analysis data reviewer guide (ADRG), and other required eCTD components.

What did we learn?

- FDA accepts R codes in its natural file extension (.r)
- Proprietary R packages can be submitted by converting to a .txt file using pkglite
- FDA staff was able to reproduce analysis results based on open source packages

Next steps

- R submission pilot 2 to experiment with Shiny app code submission through the eCTD gateway.
- R based pilot submissions to other health authority agencies globally.

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Take action!

➔ Create your own validation process

GitHub Action Validation Report:
github.com/insightsengineering/thevalidatoR

covtracer:
github.com/genentech/covtracer

https://www.pharmar.org/

➔ Check out the set of open source R packages to enable clinical reporting (from CRF to eSubmission)

https://pharmaverse.org/

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