

Unraveling the term “Validation”



Community Meeting
12:00 EST
20th Feb, 2024



There are multiple ways to approach validation, with no right or wrong answers:

It depends on:

- Perspective: user, admin, package developer, regulatory agency...
- Type of work/needs: exploratory, submission related, etc
- Company culture
- Many other things



~~How do I validate R?~~

ICH Topic E 9 Statistical Principles for Clinical Trials

covariates. When exploratory, these analyses should be interpreted cautiously; any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses are unlikely to be accepted.

5.8 Integrity of Data and Computer Software Validity

The credibility of the numerical results of the analysis depends on the **quality and validity of the methods and software** (both internally and externally written) used both for data management (data entry, storage, verification, correction and retrieval) and also for processing the data statistically. Data management activities should therefore be based on thorough and effective standard operating procedures. **The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.**

Is my software reliable?



How to Identify Reliable Software?

- *“I know the actual answer”*
- *“It’s in the ballpark of what I might expect to see”*
- *“I’ve used the software before and it did what I expected”*
- *“Many others use the software and it does what they expect”*
- *“When I learnt statistics, I was taught using the software”*
- *“The software is used/cited in statistical literature”*
- *“I trust that the software owner develops it using best practice”*
- *“The software owner provides tests that I can use to verify that it is working”*

Intuition

Community Exposure

Developer SDLC





Let's discuss! When is an R package “validated”?

- If many others use it regularly?
- Bugs tracked?
- Consistent behavior across version updates?
- Active community?
- Reproducibility of results using different systems?



Planned structure of today's meeting

- Chats in breakout rooms with 6-8 people (depending the number of participants today)
- Someone from R validation hub in each room to help out
- Approx. 10 minutes
- We discuss together at the end



Thank you for joining!

