EARL
ENTERPRISE APPLICATIONS OF THE R LANGUAGE

Pioneering R for Clinical Development at Amgen

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AMGEN

SOFTWARE TOOLS

CRAN

GitHub

AMGEN

BRIEF INTRO

CLINICAL DEVELOPMENT

Global Statistical Programming (GSP)

- Advance clinical development programs at Amgen
  - Early to late phase clinical trials
  - Regulatory submissions
  - Safety reporting
- High integration with SAS
- Metadata-based systems for clinical reporting

POSITIONING R IN GSP

Assessment

- More and more students learn R at university
- More and more statisticians use R at Amgen
- ggplot2 offers the super-efficient grammar of graphics
- plotly visualizations convey an extra layer of information

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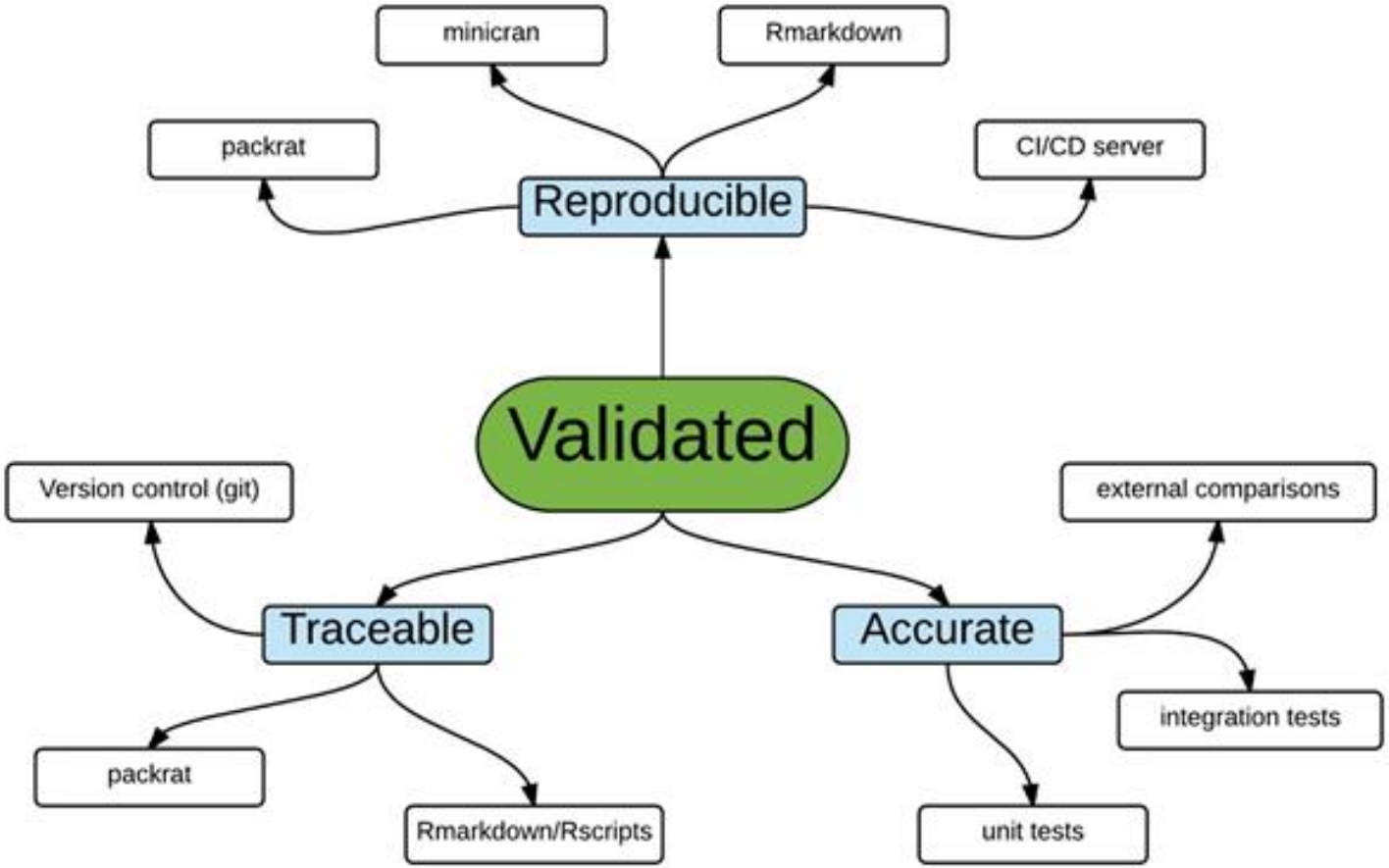
PROJECTS

- (plotly) Visualizations for department-level initiatives
- (Shiny) Apps for safety reporting
- (packrat) Package management for R projects
- (R Markdown) Manuals and sample R code for graphs
- (ggplot) Metadata-based system for standard graphs

REGULATORY REQUIREMENTS

- FDA does not require use of any specific software for statistical analyses, and statistical software is not explicitly discussed in Title 21 of the Code of Federal Regulations.
- However, the software package(s) used for statistical analyses should be fully documented in the submission, including version and build identification.
- The computer software used for data management and statistical analysis should be reliable, and documentation of appropriate software testing procedures should be available.

PROGRAMMING ENVIRONMENT



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REPRODUCIBILE

- Enable others to reproduce the results
  - packrat / minicran
  - Install packages in non-default location

- Challenges
  - One server (Microsoft R Server)
  - Maintain a validated programming environment

ACCURATE

- Produces correct results
  - Program in R / validate with SAS
- Challenges
  - R and SAS may produce different results
  - Some statistical terms are not well-defined (e.g., “quantile”)

KEY TAKEAWAYS

- Clinical systems have progressed to a higher-level programming paradigm
- R and SAS both offer compelling environments for clinical development
- FDA does not require use of any specific software
- Key elements of a validated environment
  - Reproducible
  - Traceable
  - Accurate