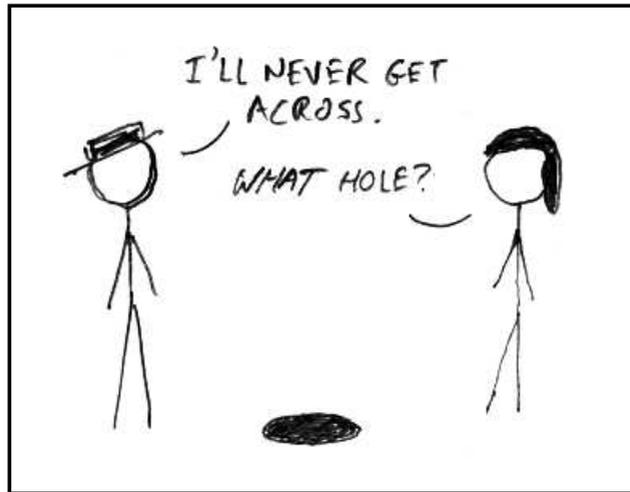


# **Qualifying R: the Open Source / Industry Disconnect**

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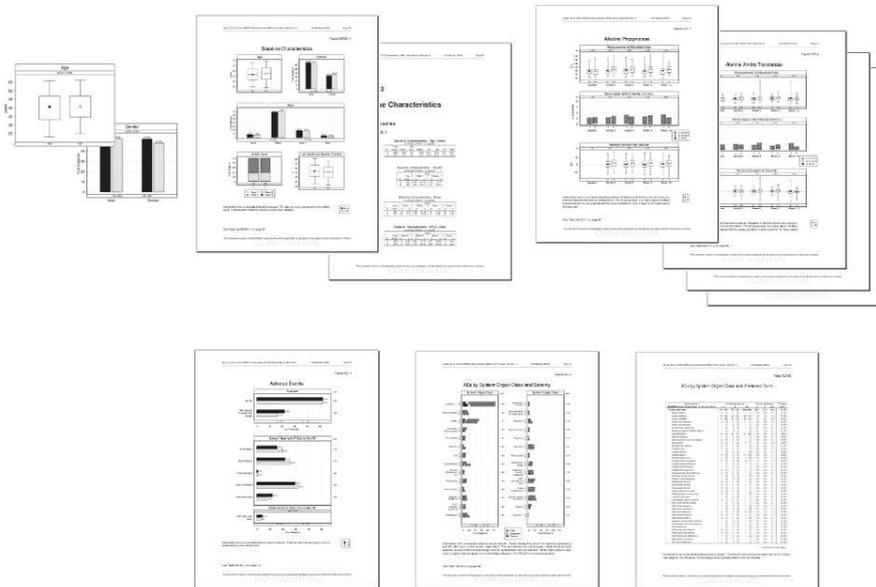
...with apologies to Randall Munroe (xkcd.com)

# **University of Wisconsin Statistical Data Analysis Center**

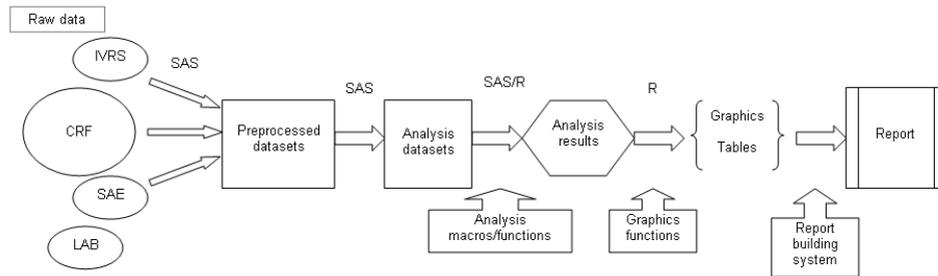
- UW SDAC is an independent statistical center supporting DMCs in monitoring industry-sponsored Phase 3 trials.
- 25 years experience, around 50 phase 3 trials/programs
- Our primary business is the preparation of interim reports on accumulating safety and efficacy data for DMC review.

# SDAC Approach to IDMC Reporting

Our reports place emphasis on graphical presentations, using simple graphical elements in a cohesive page-oriented layout with layered presentation integrated into a proper report.

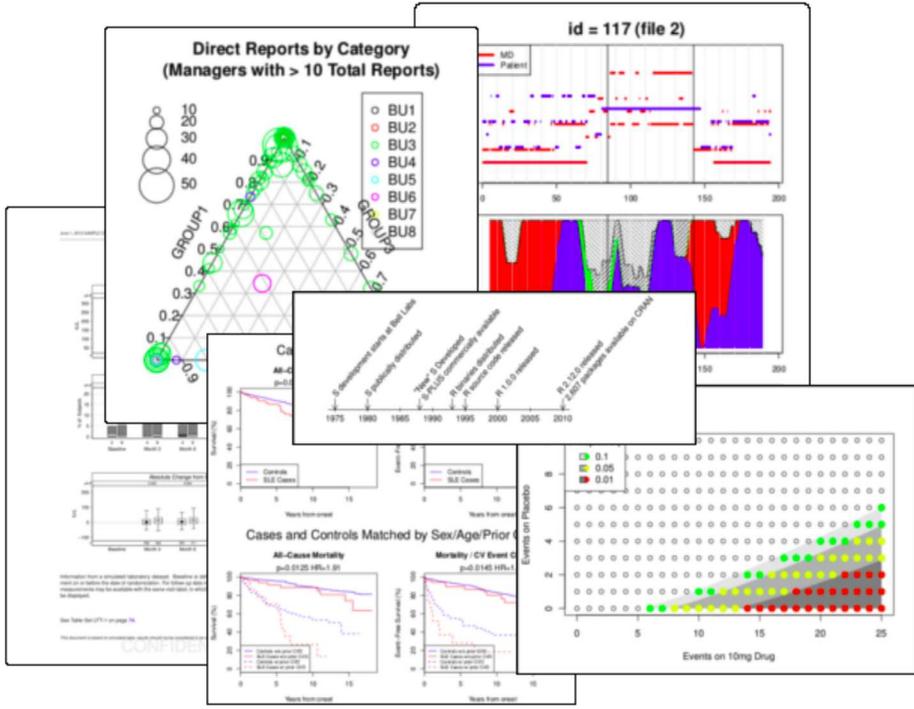


# SDAC's Pipeline



- Most of our analysts:
  - use SAS for data exploration, <sup>\*</sup> manipulation, and nuts-and-bolts analysis
  - use R for generating graphics and tables, and more complex analysis
- We've claimed we use SAS and R in ways that emphasize their relative strengths
- I've become somewhat skeptical

# OMG, Graphics!



## Business Case for R

- R's statistical and graphical capabilities
- productivity gains
- *quality and correctness*

# Qualification of Programmable Systems

- qualification of an off-the-shelf (OTS) programmable statistical / data analysis environment is different than qualification of other kinds of OTS software
- it's not necessarily more difficult
- but successful qualification has different implications

# Defects and Failures in Statistical Analysis

For a programmable, OTS statistical system:

- defects may exist:
  - in the OTS system itself (system defects)
  - in the programs produced by analysts (program defects)
- choice of system:
  - affects rate of failures due to system defects
  - but may also affect rate of failures due to *program* defects\*
- the largest organization risk comes from defects in programs\*

# Defects and Failures in Statistical Analysis

Therefore:

- Choosing a qualified system over an unqualified system does not necessarily reduce risk of failure.
- Resources directed at qualifying a system to address system defects may better be spent addressing program defects.

## SDAC Approach to Ensuring Quality

- SDAC isn't involved in regulatory submissions
- Because of our evaluation of relative risks due to system and program defects:
  - We don't qualify our OTS software
  - We rely on independent validation of results: another analyst attempts to reproduce analyses from raw datasets using independent code (and often independent facilities of a system or even independent systems)
- *cf.* attitude of others in R community

# Defects and Failures in Statistical Analysis

Therefore,

- choosing a qualified system over an unqualified system does not necessarily reduce risk of failure
- resources directed at qualifying a system to address system defects may better be spent addressing program defects
- *but this depends on the costs of qualification:*
  - program defects => big risk, hard to address
  - system defects => small risk, easy to address

# **The OSS/R Community / Industry Disconnect**

# R's Software Life Cycle

Development and release of R code is potentially hostile to qualification:

- R's development process is open: who? qualifications?
- R has a fast release cycle (2.x.0 releases twice a year)
- no formal release or testing policy
- anyone can build and distribute a version of R and call it R 2.15.0
- volunteers create "official" binary builds:
  - built with dependencies on shared libraries (e.g., BLAS)
  - unclear if build process includes successfully running compile-time test suite
  - compile-time test results not available
  - built without installing run-time test suite

# R's Package Ecosystem

R's package ecosystem (one of its greatest strengths) is potentially hostile to qualification:

- R has many packages available (3825 on CRAN) of varying quality
- How does end-user know that `library(survival)` is "approved" but `library(Hmisc)` isn't?
- `install.packages()`

# R's Test Suite

R has a large and publicly available test suite included with the source code (for R itself, base and recommended packages, and other packages).

However,

- comprehensiveness/coverage of tests is not documented
- tests are not clearly identified and organized
- by design, some random number tests fail with small, positive probability
- on a successful run, test suite doesn't give clean output
- on any run, no summary of test results
- many CRAN packages don't include test suites (an arbitrary sample of five packages showed none with a tests subdirectory)

## What, Me Qualify?

Is it any wonder there are those in industry who are skeptical R can be qualified?

The disconnect:

- By and large, industry sees these problems as insurmountable
- By and large, the R community fails to see these as problems



# **Some Apparent Weaknesses may be Strengths**

# R's Software Life Cycle

R's development process is open:

- complete source tree (with revision control) is publicly available  
svn checkout <https://svn.r-project.org/R/trunk/> *path*
- complete change history is publicly available
- bug database is publicly available  
<https://bugs.r-project.org>

# R's Software Life Cycle

R has a fast release cycle:

- new features can be widely tested
- bugs are quickly found and fixed

Anyone can build and distribute a version of R:

- "anyone" includes the end-user or site
- "anyone" includes a third-party vendor

# R's Software Life Cycle

This leads to the following observations:

- fine-grained customization and control of release process is possible at site level
- no pressure to use the latest version or even any "official" version
- let other R users be your beta testers
- need critical fix but otherwise happy with current version: no problem!
- need a build of R that meets your qualification requirements: no limit on customization

To take advantage of these benefits, you must be willing to build it yourself or buy it from a third-party.

# R's Package Ecosystem

R has many packages available:

- Some are of high quality, many with a test suite that runs automatically
- Consider these alternatives:
  - qualifying and using an existing CRAN package
  - writing and qualifying your own package
  - having users code one-off analyses from scratch
  - having users copy random code off a webpage

A rich package ecosystem:

- comes with some inherent risk
- probably reduces use of even riskier alternatives

# R's Test Suite

- The test suite is large and publicly available
- The test suite covers R itself, base R, and recommended packages
- Some other packages come with test suites
- The test suite is extensible
- Infrastructure exists for package testing

## Addressing Other Weaknesses

Again, if you are willing to build it yourself or buy it from a third-party, you can take an active role in the release cycle, including:

- implement release and testing policies
- control dependencies on shared libraries
- run and ensure success of a compile-time test suite
- install and use a run-time test suite
- apply the same scrutiny to packages
- implement package (and external code) use policies
- identify the result as a site's qualified R w/ build-time (design), installation, and run-time (operation) qualification

# Criticism versus Contribution

Typical OSS community reaction to criticism versus contribution:

- "Your software doesn't do X, Y, and Z."  
"No right-thinking person would want to do X, Y, and Z, and here are one million reasons why!"
- "I've patched your software to do X, Y, and Z."  
"Wow, thanks! I've checked it into the source."
- "I want to pay someone money to do X, Y, and Z."  
"Funny you should mention that..."

# R Community / Industry Collaboration

The R community and industry should collaborate on:

- cleaning up and expanding the test suite
  - document (and improve) coverage
  - organize and document tests
  - make tests run cleanly
  - provide simple summary ("certificate") of test suite results

# R Community / Industry Collaboration

The R community and industry should collaborate on:

- adding build and run-time infrastructure for qualified builds:
  - make monolithic build (with all critical dependencies) easy
  - enforce success of compile-time testing
  - install compile-time test certificate and run-time tests
  - support installation qualification
  - add "qualification-only" mechanism for restricting packages

# The Way Forward

- industry case studies (of all types: take, build, or buy)<sup>\*</sup>
- identification of industry qualification needs
- implementation of general mechanisms to aid qualification
- *contributing success back to community*
- public, documented procedures for qualifying R
- public, written guidance to developers (core and packages) to help them address these needs on an ongoing basis
- *collaboration*, especially with package developers, to help them address these needs on an ongoing basis

## Conclusions

- if you care about correctness, using R can be a net win
- the R community underestimates the seriousness of the barriers to using R in industry
- industry overestimates the difficulty in overcoming those barriers
- more dialog between R community and industry representatives can lead to shared solutions, that like R, can be made freely available