

R Got This!

Delivering a Complete
Statistical Package Using R



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We did it!



What did we do?



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**Complete statistical package delivered
using R for all data transformations**

Study Characteristics

Open label
Phase III-b
Priority study
Interim milestone

500+ Patients
30+ ADaMs
120+ Tables
15+ Figures
50+ Listings
5-10 Developers

**Primary Milestone
targeted for
regulatory
submission**

Can we use R for production?



R for Production

the underlying business process



Skilled Staff

a robust support infrastructure for programmers

Field of play

a GxP compliant analytical platform

The Right Tools

a recommended and trusted toolkit

To-do Checklist

- ☐ Bootcamp on R, RStudio, GitHub
- ☐ Production flow with current tools
- ☐ Satisfy GxP compliance
- ☐ Bespoke tool development
- ☐ Creating and submitting the package
- ☐ Gaining leadership support

Why can't we?



What's are the risks of doing this?



Risk Assessment

Identify the risks of
using **R** for **production** with
our current **people**, **platforms**, and **tools**

Mitigate

Accept

Avoid

Transfer

Risks and Mitigations



What questions did we ask?

GxP Compliance

How do we demonstrate
code control?

How do we demonstrate
data integrity?

How do we ensure *accuracy* of
our results?

How do we ensure
reproducibility of our results?

How do we ensure
traceability of our results?

Risk to Submission

Can packages be attached to
an eCTD backbone?

Leadership Buy-in

Are those responsible for the
asset willing to accept
unmitigated risk?

Risks and Mitigations



What questions did we ask?

Team Skills

Will the S&P study team be able to upskill in R?

Will the S&P study team be able to upskill in GitHub?

Tools

How do we ensure business continuity when we introduce an additional SCE?

Can we create figures easily from analysis results data without standard reporting macro?

Flow

Do we have the operational agility required to work between RStudio and the traditional SCE?

How do we transfer data between SAS and R and vice versa?

What we didn't do...



- Didn't 'validate' packages → accuracy ensured by SAS double programming
- Didn't develop e2e R-based rendering tools → leveraged existing platform for rendering, define.XML, publishing, etc.
- Didn't deploy experienced R programmers → bootcamp, SMEs, graphics
- Didn't require audit trailed R platform → qualified RStudio installation – created pseudo audit trail

We...



What did we get?



Gains

- ✓ Completed analysis package
- ✓ More R programmers in department
- ✓ Base of sample code / reference code
- ✓ Opportunity to improve our toolkit
- ✓ Opportunity to engage regulatory agency



“in this specific application”

- **On this study**
- **With this data**
- **For these analyses**



Notable Points

- Not the long-term solution for R
- Did what we could with the current set of tools/platforms
- Other groups working to reinforce the tech and not require this bespoke process and tools



What's Next?

- Test bespoke QA tools for process compliance
- Prepare for 12mo Primary
- Trusted solution for MMRM* in R
**not necessarily ddfm=KR*

Thank you!



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