Pharma Working Groups Overview and Updates

Ning Leng
(on behalf of R consortium board and pharma oversight committee and the R submission working group)
Adrian Waddell
(on behalf of the Regulatory Reporting Table working group)
Kate Ostbye
(on behalf of the R certificate working group)
Andy Nicholls
(on behalf of the R adoption series)

R Consortium Overview

- A non-profit organization to
  - Support the R Foundation and R Community
  - Collaborate with industry to promote, develop and extend the reach of R software
  - Help ensure the future of R through infrastructure, education, collaboration and financial support

Members

R Consortium Pharma Oversight Committee and Pharma Working Groups

R Consortium Pharma Oversight Committee

- One voting member from each pharma member companies, oversees
  - Initiation of new pharma working groups
  - Funding allocation to working groups
- Established Mar 2021

R Consortium Working Groups

- Proposals from the community
- Anyone can participate in any working group
- Operates openly
  - All meeting notes, materials are publicly available at https://github.com/RConsortium

Overview of Selected R Consortium Pharma Working Groups

- R-based submission pilots to FDA: provide example R-submission materials to the public, identify potential gaps in R based submissions
  - Presenter: Ning Leng (Roche)
- R table for regulatory reporting: develop packages and white papers for generating tables to fulfill regulatory requirements
  - Presenter: Adrian Waddell (Roche)
- R certification: R trainings and certification for the SAS->R transition
  - Presenter: Kate Ostbye (SCHARP)
- R adoption series: A series of webinars focusing on adoption of R
  - Presenter: Andy Nicholls (GSK)
- R validation hub (jointly with PSI): develop software risk assessment tools and whitepapers
  - Presenter: Andy Nicholls (GSK)

R Consortium R Submission Working Group

- **Our Mission**
  - *Easier R-based clinical trial regulatory submissions today*
    - by showing open examples of using current submission portals
  - *Easier R-based clinical trial regulatory submissions tomorrow*
    - by collecting feedback and influencing future industry and agency decisions on system/process setup
- **Upcoming Activities**
  - R-based eCTD submission pilot 1 - targeted Dec 2021
    - Goal: Provide R-based submission material examples (scripts, proprietary R package, ADRG, etc.), identify area for improvement
      - Examples covering 4 TLFs
      - Simulated data from CDISC Pilot
- **WG Link:** https://rconsortium.github.io/submissions-wg/
- **Key Participate Organizations**
  - FDA, Roche, Merck, Atorus, GSK, Eli Lilly, Biogen, Rstudio, Phastar, EMD Serono, Bayer, Jassen, J&J, Procogia, EQRx
  - Contact: Ning Leng (leng.ning@gene.com), Yilong Zhang (yilong.zhang@merck.com), Joseph Rickert (joseph.rickert@rstudio.com)

R Consortium Regulatory Reporting Table Working Group

- **WG Mission**
  - Creating standards to guide the development of R tools for creating tables that meet the requirements of the FDA and other regulatory agencies
  - Work on a number of papers on the tables in R topic
    - cell values derivation
    - rendering
    - tables in production
    - listings
- **How to Help**
  - Send us examples of difficult tables
  - Join us! Contact joseph.rickert@rstudio.com
- **WG link**
  - https://github.com/RConsortium/rtrs-wg/

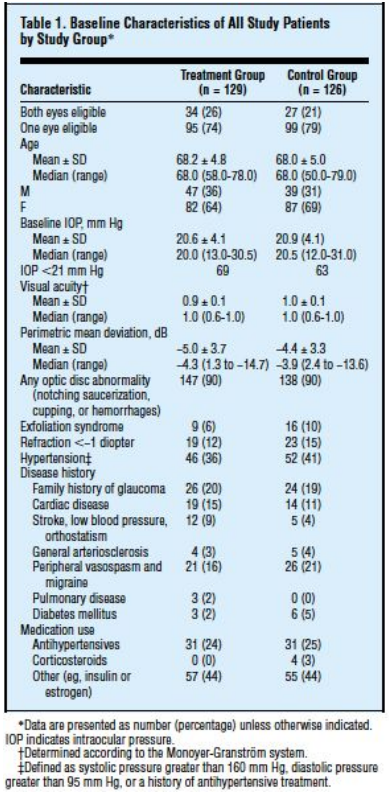

Table 1. Baseline Characteristics of All Study Patients by Study Group*

Characteristic	Treatment Group (n = 129)	Control Group (n = 126)
Both eyes eligible	34 (26)	27 (21)
One eye eligible	95 (74)	99 (79)
Age		
Mean ± SD	68.2 ± 4.8	68.0 ± 5.0
Median (range)	68.0 (58.0-78.0)	68.0 (50.0-79.0)
M	47 (36)	39 (31)
F	82 (64)	87 (69)
Baseline IOP, mm Hg		
Mean ± SD	20.6 ± 4.1	20.9 (4.1)
Median (range)	20.0 (13.0-30.5)	20.5 (12.0-31.0)
IOP <21 mm Hg	69	63
Visual acuity†		
Mean ± SD	0.9 ± 0.1	1.0 ± 0.1
Median (range)	1.0 (0.6-1.0)	1.0 (0.6-1.0)
Perimetric mean deviation, dB		
Mean ± SD	−5.0 ± 3.7	−4.4 ± 3.3
Median (range)	−4.3 (1.3 to −14.7)	−3.9 (2.4 to −13.6)
Any optic disc abnormality (notching saucerization, cupping, or hemorrhages)	147 (90)	138 (90)
Exfoliation syndrome	9 (6)	16 (10)
Refraction <−1 diopter	19 (12)	23 (15)
Hypertension‡	46 (36)	52 (41)
Disease history		
Family history of glaucoma	26 (20)	24 (19)
Cardiac disease	19 (15)	14 (11)
Stroke, low blood pressure, orthostatism	12 (9)	5 (4)
General arteriosclerosis	4 (3)	5 (4)
Peripheral vasospasm and migraine	21 (16)	26 (21)
Pulmonary disease	3 (2)	0 (0)
Diabetes mellitus	3 (2)	6 (5)
Medication use		
Antihypertensives	31 (24)	31 (25)
Corticosteroids	0 (0)	4 (3)
Other (eg, insulin or estrogen)	57 (44)	55 (44)

*Data are presented as number (percentage) unless otherwise indicated.
IOP indicates intraocular pressure.
†Determined according to the Monoyer-Granström system.
‡Defined as systolic pressure greater than 160 mm Hg, diastolic pressure greater than 95 mm Hg, or a history of antihypertensive treatment.

Tables can make a submission

R Consortium R Certification Working Group

Our mission is to develop the content for a process to certify that statistical programmers have the basic skills to function effectively in a mixed SAS and R clinical trial programming environment.

Recent/upcoming activities
We are establishing the curriculum and developing technical content

Current scope includes the following:

- Clinical Trials overview
- SAS background knowledge & overview
- R foundational skills
- Modelling expectations/examples
- Best Practices (verification, documentation and workflows)

Key participants

Mike Garcia, ProCogia
Joseph Korszun, ProCogia
Rafael Kuttner, SCHARP at Fred Hutch
Kieran Martin, Roche
Katherine Ostbye, SCHARP at Fred Hutch
Mehar Pratap Singh, ProCogia
Joseph Rickert, R Consortium

Join us!

Scope review
Content creation
Content review and editing

Contact:

kostbye@fredhutch.org
joseph.rickert@rstudio.com

https://github.com/RConsortium/R-Certification-WG

R Consortium R Adoption Seminar Series

- To share and discuss topics relating to the adoption of R
- Focus on *how2*, not *why*
- Typically 1.5 hours combining presentation with panel / breakout
- Videos available
  - R Training Strategies at Janssen
  - Scaling R at GSK
- https://www.r-consortium.org/webinars

R Consortium R Validation Hub

- A collaboration to support the adoption of R within a biopharmaceutical regulatory setting
- Key deliverables:
  - White paper
  - The riskmetric R package
  - The Risk Assessment app
- Currently looking for case studies
- See mailing list and blog for latest updates
- https://www.pharmar.org/

- Executive committee:
  - Andy Nicholls (Chair)
  - Lyn Taylor (Secretary)
  - Joe Rickert (R Consortium)
  - Juliane Manitz
  - Doug Kelkhoff
  - Yilong Zhang
  - Keaven Anderson
  - Marly Cormar
  - Paulo Bargo

Thank you!