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5-8 November
ICC Birmingham

EU 2023

The Clinical Data
Science Conference



Optimizing Clinical Trial Design
with Real-Time Sample Size
Calculation and Enrollment
Projection : A Shiny Dashboard
Solution



Vignesh V Gopal
Statistical Programmer I
vignesh.gopal@catalystcr.com

Sahalath K P
Biostatistician I
sahalath.kp@catalystcr.com

Akhil Vijayan
Manager - Statistical Programming
akhil.vijayan@catalystcr.com



Introduction

- ☐ Clinical trials are crucial for assessing and advancing medical treatments, medications, and interventions, ensuring their safety and effectiveness before they are made accessible to the public.
- ☐ Sample size determination is an essential statistical consideration that is decisive for every study.
- ☐ Accurate enrollment projection is another prominent aspect that helps to ensure the trial is conducted efficiently and within the planned timeline.
- ☐ Incorporating real-time data and adaptive approaches for estimating these parameters provides benefits such as improved resource allocation, budget management, and quicker decision-making.



Introduction

- ❑ Shiny is an R package that enables the creation of interactive web applications for data visualization and analysis by which we can explore the possibilities for optimization of clinical trials.
- ❑ In this paper, we present the idea of using a shiny dashboard that estimates the adjusted sample size and predicts the enrollment projection by taking real-time study inputs such as dropout rate, enrollment rate, etc.
- ❑ The dashboard will enable users to find reliable estimates of adjusted sample size, which is pivotal in optimizing the study design.



Introduction

- ❑ The enrollment projection measures such as enrollment duration, and enrollments in a selected timeframe, which will enhance the overall pace of the study.
- ❑ Advanced interactive visualization tools play a crucial role in harnessing data to make informed decisions and streamline the trial process, offering real-time insights into various aspects of the trial.
- ❑ This paper also depicts the scope for such an advanced visualization aspect in R shiny by taking inputs such as the primary outcome measures, effect size, and expected dropout rate into account.



Application Layout

Application contains two modules

- Sample Size Calculator - defines the adjusted sample size
- Enrollment Projection- predicts the enrollments

• • • • •

OptimizeR

Logout

Please log in

User Name

Password

Log in

Fig1. Landing page of the application



OptimizerR 

Sample Size Calculator

Enrollment Projection

COHORT LEVEL

Select number of cohorts

7

Select cohort size

9

Dropout Rate/Cohort

0.1

Cohorts	Adjusted Sample Size
A1	10
B1	10
C1	10
D1	10
E1	10
F1	10
G1	10
Total	70

Showing 1 to 8 of 8 entries

Fig2. Sample size calculator

❑ Fig1 represents the landing page of the application where the user can enter their credentials and log in to the Shiny dashboard application.

❑ Fig2, calculates the adjusted sample size for a given dropout rate for each cohort based on the user's input. The final cohort size along with the total count will be displayed in the data table.

Adjusted Sample Size Calculation is based on the following method.

$$N = n/(1-d)$$



OptimizeR

☰

Logout

Sample Size Calculator

Enrollment Projection

Enrollment duration

Select sample size

63

Enrollment Rate (patients/site/month)

0.3

Select total number of sites

49

Select number of site/month

5

Select number of initial sites

0

Dropout Rate (%)

0.1

70

Adjusted sample size

9.7 Months

Total duration to enroll 70 subjects

72

Subjects enrolled during site activation period(from Site 1 to site 49)

9.8 Months

Average time required for 49 sites to be active and enrolling

Fig3. Enrollment duration

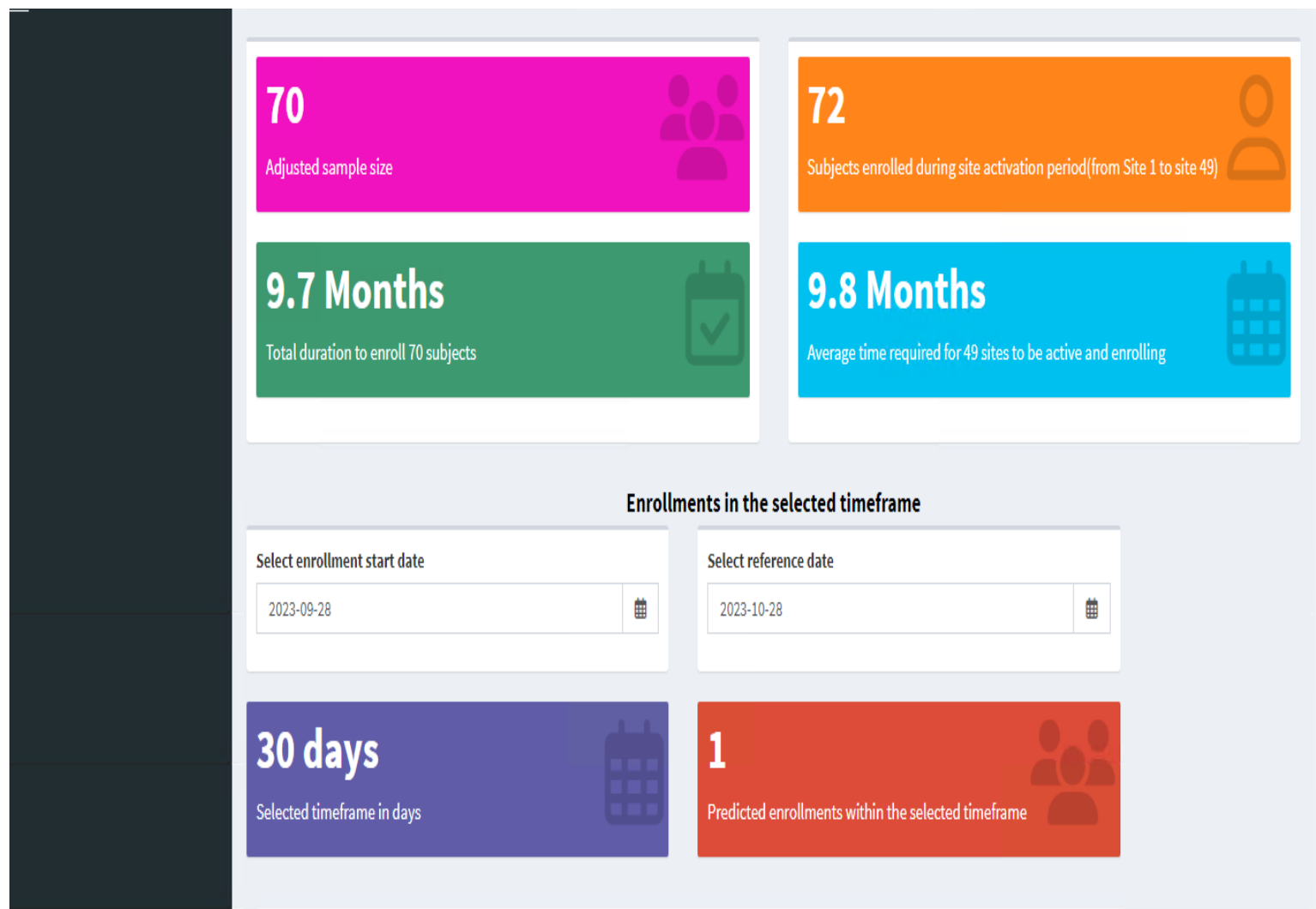


Fig4. Enrollment in selected timeframe

- ❑ Fig3 is the enrollment projection tab. The enrollment projection tab computes the adjusted sample size, total duration to enroll the subjects, the average time required for all sites to be active and enrolling, and the number of subjects that can be enrolled during the site activation period based on the enrollment rate (patient/sites/month).
- ❑ The tab also includes two calendar date inputs to provide the enrollment start date and reference date as shown in Fig4. Here the predicted enrollments indicate the number of subjects that can be enrolled during the specified time frame, and the timeframe is the number of days between the enrolment start date and the reference date.



Scope of Advancement

- ❑ Clinical trials generate vast amounts of data that are crucial for assessing treatment efficacy, safety, and overall trial progress.
- ❑ Advanced interactive visualization tools play a pivotal role in harnessing this data to make informed decisions and streamline the trial process.
- ❑ Such tools can offer a dynamic and user-friendly interface for stakeholders involved in clinical trials.
- ❑ This paper explores the use of the shiny application for advanced interactive visualization, providing real-time insights into trial inputs like primary outcome measure, effect size, and expected dropout rate.



Scope of Advancement

□ For instance,

- Recruitment progress dashboard, For Identifying Enrollment Rates and Challenges, Establish Enrollment Goals and Monitor Progress.
- Patient dropout analysis dashboard, a dynamic dashboard for observing dropout rates and provides real-time insights into patient retention trends.
- Treatment response tracking dashboard, provides a comprehensive view for tracking treatment responses which enables researchers to monitor trends in real time.
- Real-time safety data visualization dashboard, which can help to assess the severity and frequency of adverse events and compare them across treatment arms.



Scope of Advancement

- ❑ As an advanced application of the dashboard discussed, it is feasible to update the same by incorporating primary outcome measures that can calculate sample size requirements specific to the trial's primary endpoint.
- ❑ Also, the interactive visualization can allow users to input various effect sizes to assess their impact on sample size requirements. This flexibility enables trial designers to explore different scenarios and their consequences.
- ❑ Users can also conduct scenario analysis by adjusting the input parameters which allows for a comprehensive analysis of how these factors influence sample size and enrollment projections.



Conclusion

- ❑ OptimizeR enables statisticians or clinicians to make informed decisions about study design, resource allocation, and project timelines by utilizing the capabilities of the Shiny framework.
- ❑ The application simplifies the process of computing the sample size for each cohort and estimates how long it will take to enroll the subjects.
- ❑ The scope of evolving these applications is not limited.

THANK YOU

Any Questions?

Behind the scenes:



Vignesh V Gopal
Statistical Programmer I



Sahalath K P
Biostatistician I

LISTEN, DEVISE, **BREAKTHROUGH**