

iCSR: A Wormhole to Interactive Data Exploration Universe

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Integrated Data Analytics and Statistical Programming



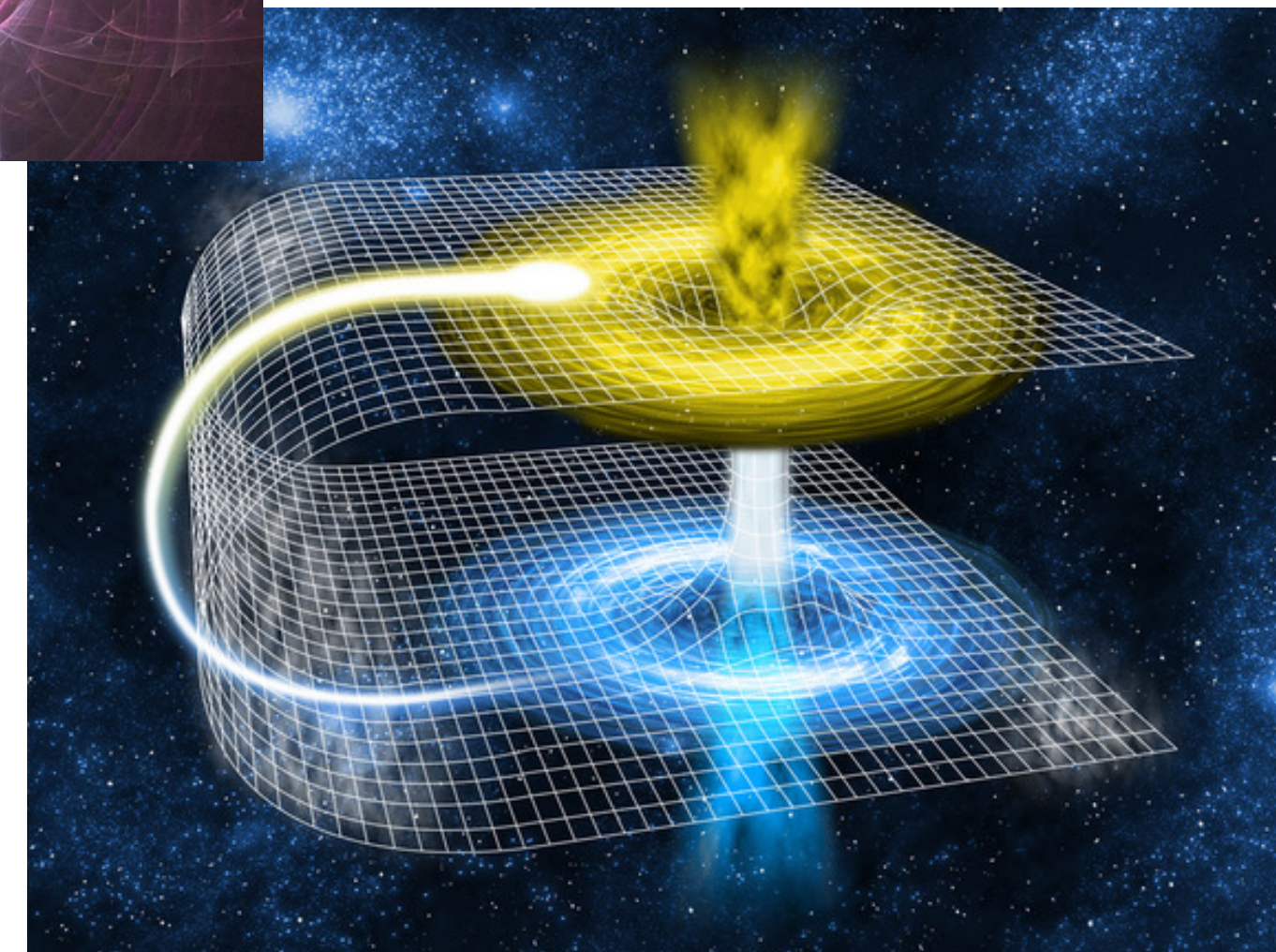
Agenda

- Introduction
- Current Challenge & Opportunity
- Approach and Workflow
- App Design
- Demo
- Lessons & Learned Future Potential



Introduction

- Why
- What
- How



Current Challenge & Opportunity

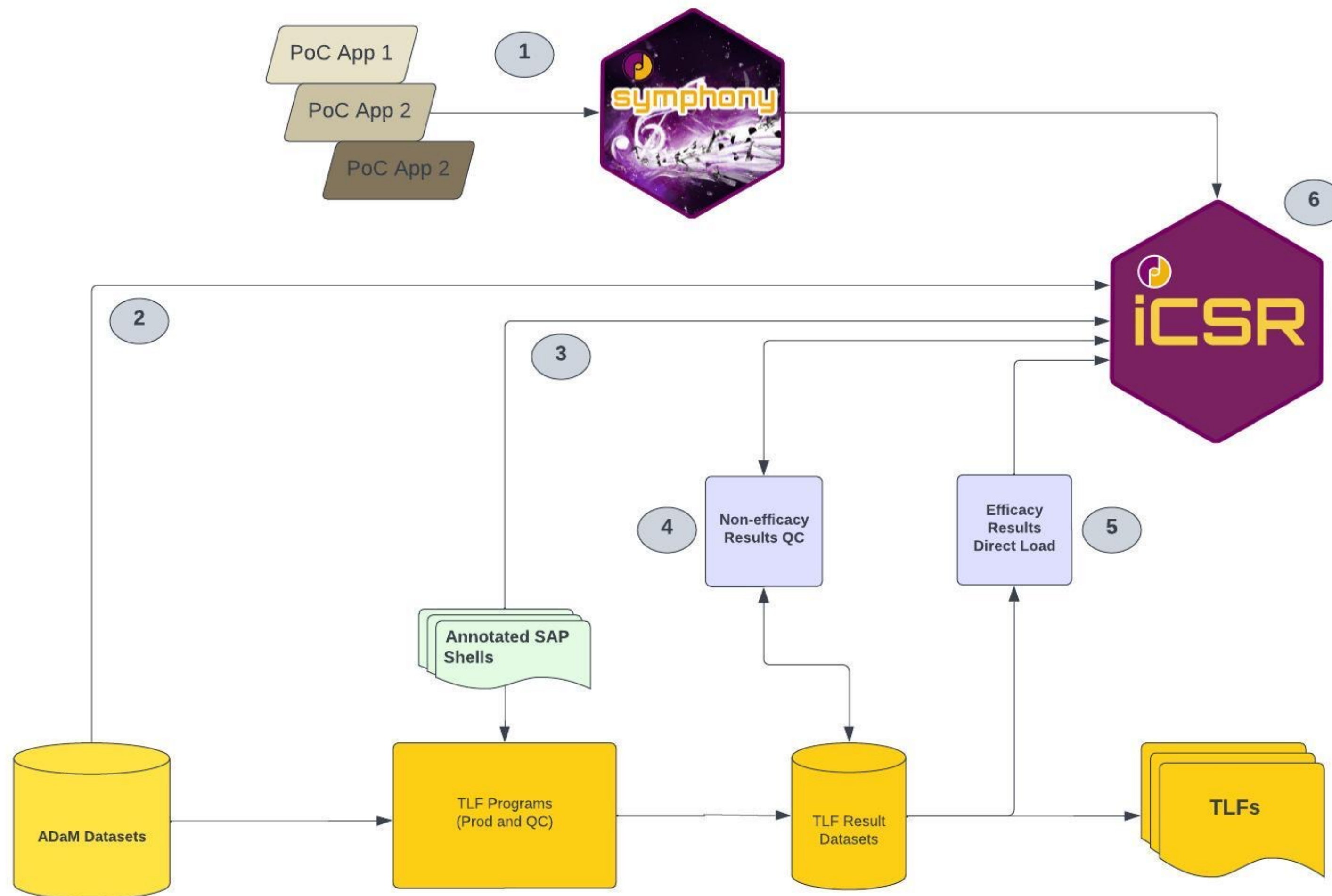
- Digital Transformation at expanding biopharma
- Current experience and need to improve data digestion
- Opportunity for interactive data presentation



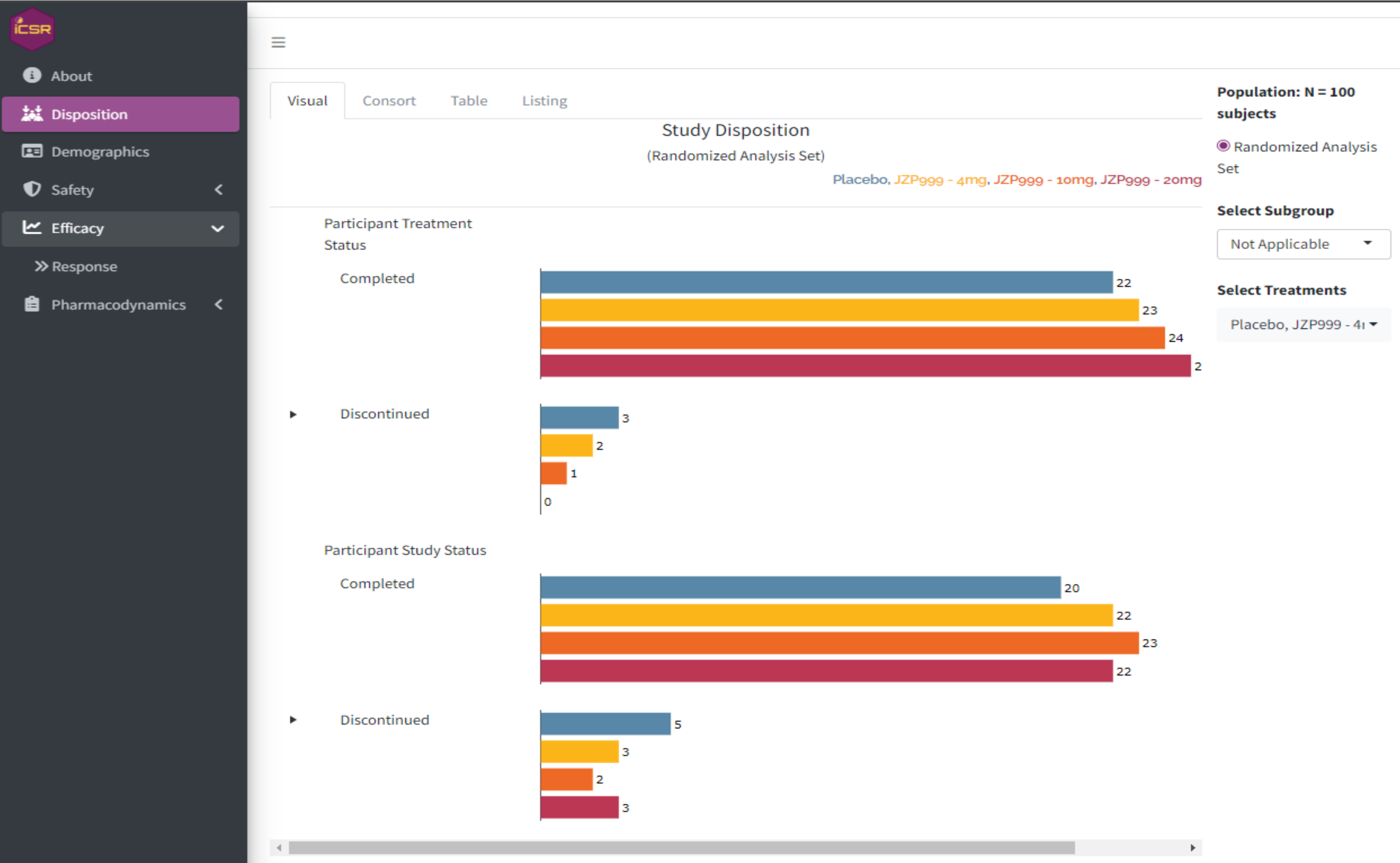
Approach

- Identify pilot studies
- On paper design for Shiny App
- Identify input and output of App
- Central template

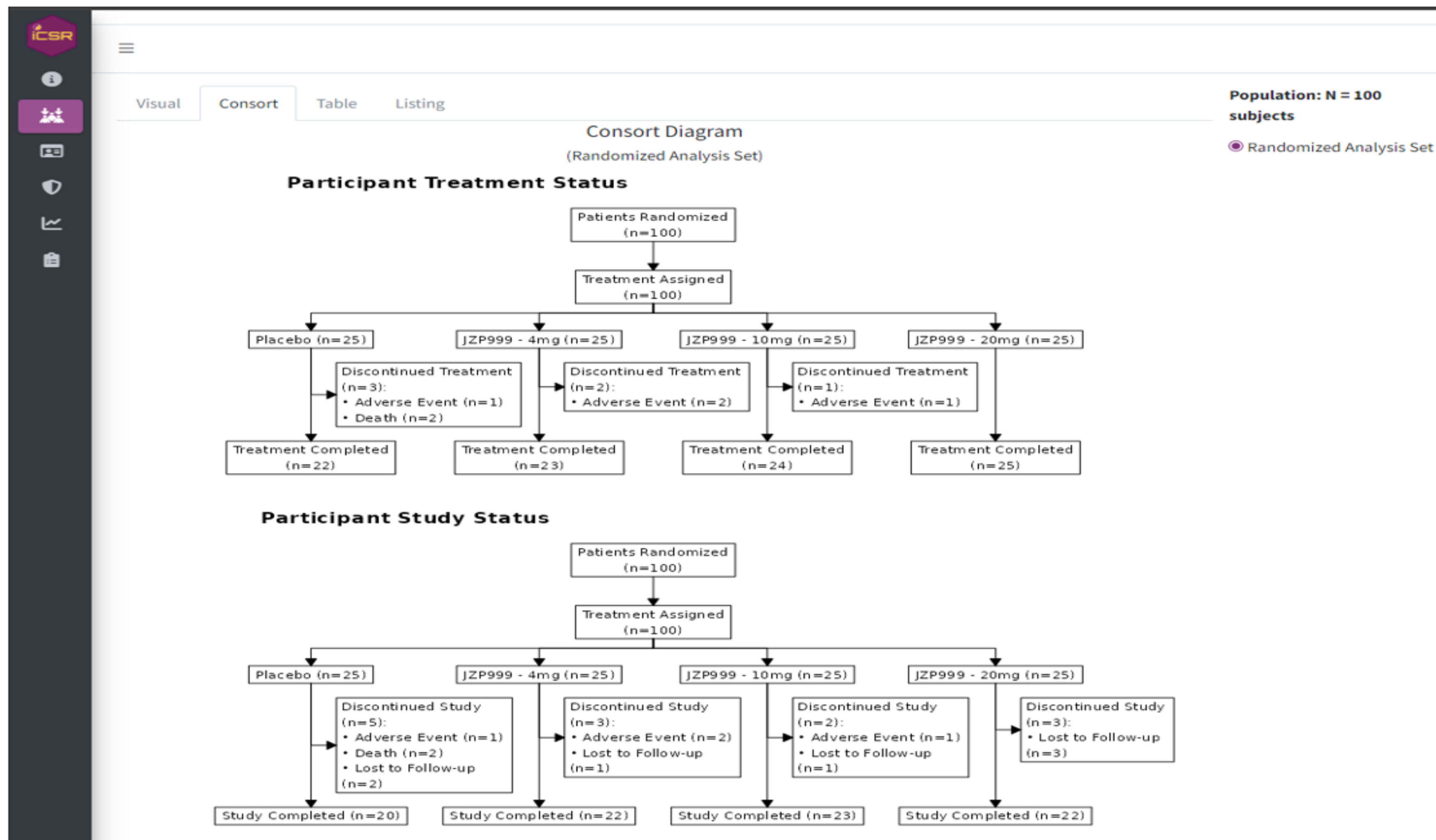
Workflow



App Design - Visual



App Design - Specifics



App Design - Table



- About
- Disposition**
- Demographics
- Safety
- Efficacy
- Response
- Pharmacodynamics

Visual
Consort
Table
Listing

Population: N = 100 subjects

Randomized Analysis Set

Select Subgroup

Not Applicable

Table 9.1.1.1

Study Disposition

(Randomized Analysis Set)

Total Number, n (%)	Placebo (N=25)	JZP999 - 4mg (N=25)	JZP999 - 10mg (N=25)	JZP999 - 20mg (N=25)	Overall (N=100)
Participant Treatment Status					
Completed	22 (88.0)	23 (92.0)	24 (96.0)	25 (100)	94 (94.0)
Discontinued	3 (12.0)	2 (8.0)	1 (4.0)	0	6 (6.0)
Adverse Event	1 (4.0)	2 (8.0)	1 (4.0)	0	4 (4.0)
Death	2 (8.0)	0	0	0	2 (2.0)
Participant Study Status					
Completed	20 (80)	22 (88.0)	23 (92.0)	22 (88.0)	87 (87.0)
Discontinued	5 (20)	3 (12.0)	2 (8.0)	3 (12.0)	13 (13.0)
Adverse Event	1 (4.0)	2 (8.0)	1 (4.0)	0	4 (4.0)
Death	2 (8.0)	0	0	0	2 (2.0)
Lost to Follow-up	2 (8.0)	1 (4.0)	1 (4.0)	3 (12.0)	7 (7.0)

Note: The Randomized Set will include all participants in the enrolled analysis set that have been assigned a randomization number.

Note: The percentages are based on the total number of randomized participants reported in each column.

Source: Listing 10.4.1

App Design - Listing

ICSR

About

Disposition

Demographics

Safety

Efficacy

Response

Pharmacodynamics

Visual

Consort

Table

Listing

Population: N = 100 subjects

Randomized Analysis Set

Listing 10.4.1

Listing of Subject Disposition

(Randomized Analysis Set)

Show 10 entries

Search:

Participant ID	Age/Sex/Race	ENR/RND/SAF/PD	Date of Informed Consent	Treatment	Date of Randomization	Completed Treatment (Y/N)	First Dose Datetime	Completion or Discontinuation Date (Study Day)	Primary Reason for Discontinuation
All	All	All	All	All	All	All	All	All	All
1	25/M/B	Y/Y/Y/Y	2023-06-15	JZP999 - 10mg	2023-07-12	Y	2023-07-12 09:07:13	2023-08-18 (38)	Completed
2	41/M/B	Y/Y/Y/Y	2023-03-28	JZP999 - 20mg	2023-04-24	Y	2023-04-24 09:07:13	2023-05-31 (38)	Completed
3	34/F/N	Y/Y/Y/Y	2023-02-06	Placebo	2023-03-05	Y	2023-03-05 09:07:13	2023-04-11 (38)	Completed
4	45/M/A	Y/Y/Y/Y	2023-02-09	Placebo	2023-03-08	Y	2023-03-08 09:07:13	2023-04-14 (38)	Completed
5	54/M/B	Y/Y/Y/Y	2023-06-17	JZP999 - 4mg	2023-07-14	Y	2023-07-14 09:07:13	2023-08-20 (38)	Completed
6	47/M/B	Y/Y/Y/Y	2023-03-23	Placebo	2023-04-19	Y	2023-04-19 09:07:13	2023-05-26 (38)	Completed
7	43/F/W	Y/Y/Y/Y	2023-04-20	JZP999 - 20mg	2023-05-17	Y	2023-05-17 09:07:13	2023-06-23 (38)	Completed





Demo

Lessons Learned

- Software development approach
- Technology and internal skillsets
- Challenge to break the status quo



Future Potential

- Pilot to Production
- iCSR as standard
- iCSR to QC static outputs
- Expand current module library
- Automate app code generation, testing and deployment
- Working with wider functional group



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Thank You – Questions?

