

Data Visualization for Medical Review

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Agenda

- Overview of Medical Review Function
 - Scope
 - Data Visualization(DV) steps
- Case Scenario for Medical Review
- Interactive Visualization Environment (IVE)
- Live demo of Medical Review in IVE
- Summary

Scope of Medical Review Function

Ensures patient safety and validity of collected data

Study Setup

- Support Protocol and eCRF design
- Medical Review plan

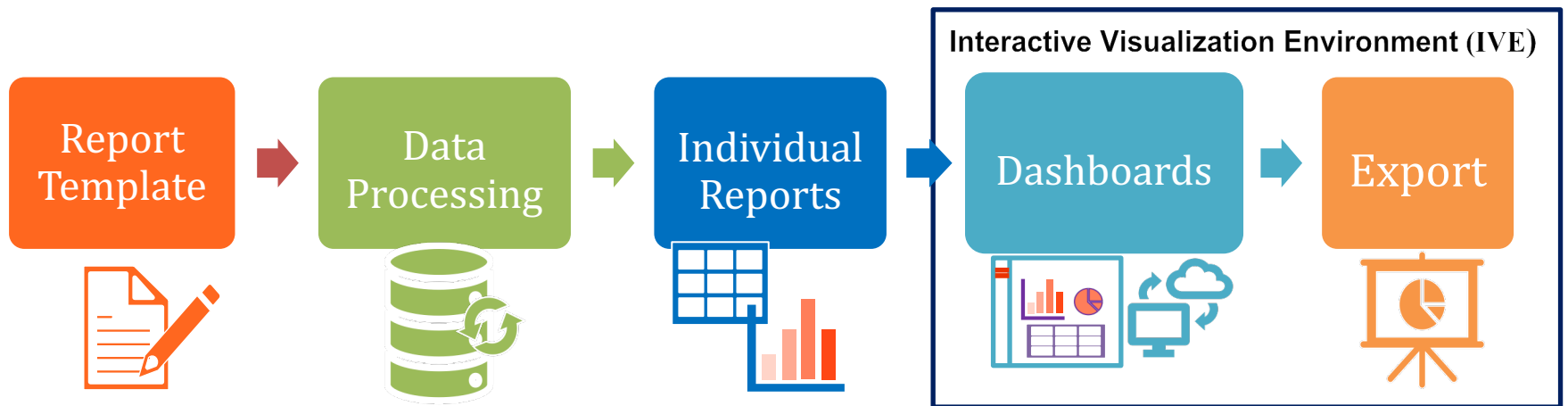
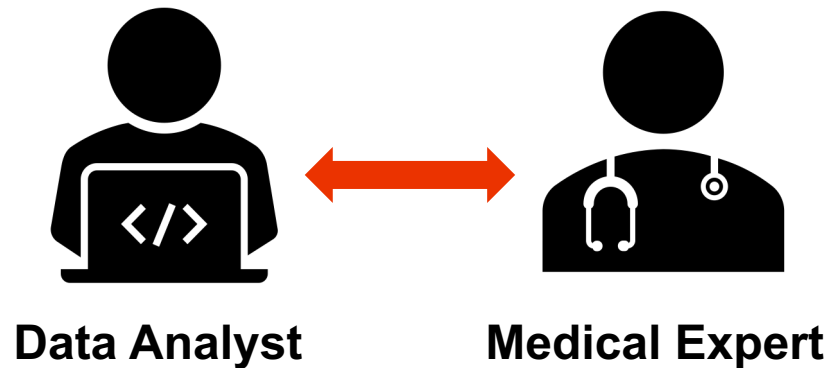
Study Conduct

- Review Medical Reports on regular basis-Daily/weekly
- Prepare Medical Review Summary Report-Monthly/quarterly
- Attend DMC ,Steering Committee and other external committee data review meetings

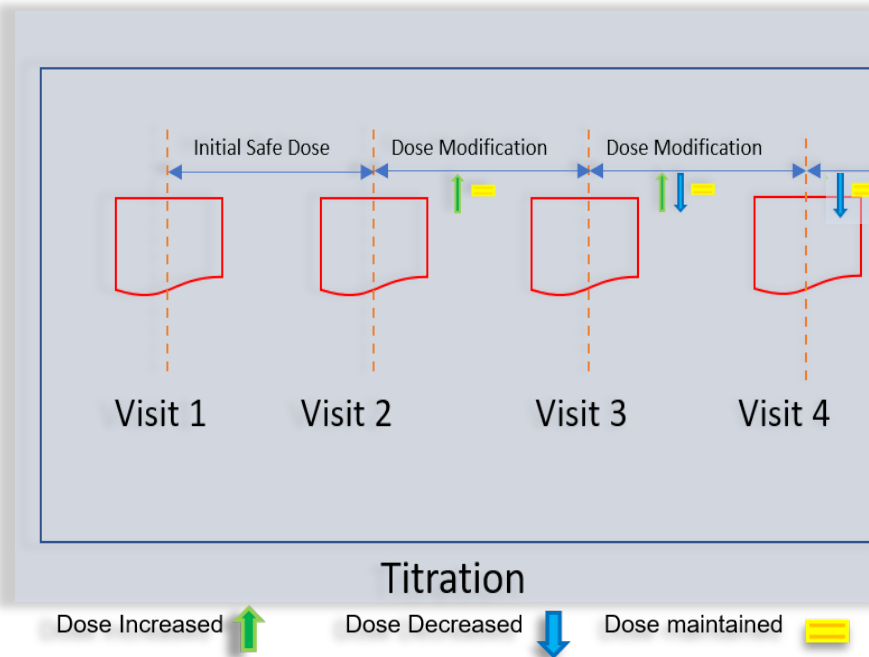
Study Closeout

- Blinded Data Review meeting before Database Lock
- Patient Narratives for Clinical Study Report

Data Visualization (DV) Steps for Medical Review



Case Scenario



Subject	Visit	Dose Modification	Reason for Dose Modification	Dose Step
All	All	All	All	All
ORL202006	visit 1	maintained		Step-1
ORL202006	visit 2	increased		Step-2
ORL202006	visit 3	increased		Step-3
ORL202006	visit 4	increased		Step-4
ORL202006	visit 5	maintained		Step-4
ORL202016	visit 1	maintained		Step-1
ORL202016	visit 2	increased		Step-2
ORL202016	visit 3	decreased		Step-1
ORL202016	visit 4	maintained	Adverse Event	Step-1
ORL202016	visit 5	maintained		Step-1

Review below data with Interactive Visualization Environment

- Titration Overview
- Reasons for Dose Modification

DV Steps for Case Scenario



- Data Filters
- Bar Graph of dose steps at each visit
- Bar graph of dose modification by Visit
- Exposure and Adverse Event subject listing

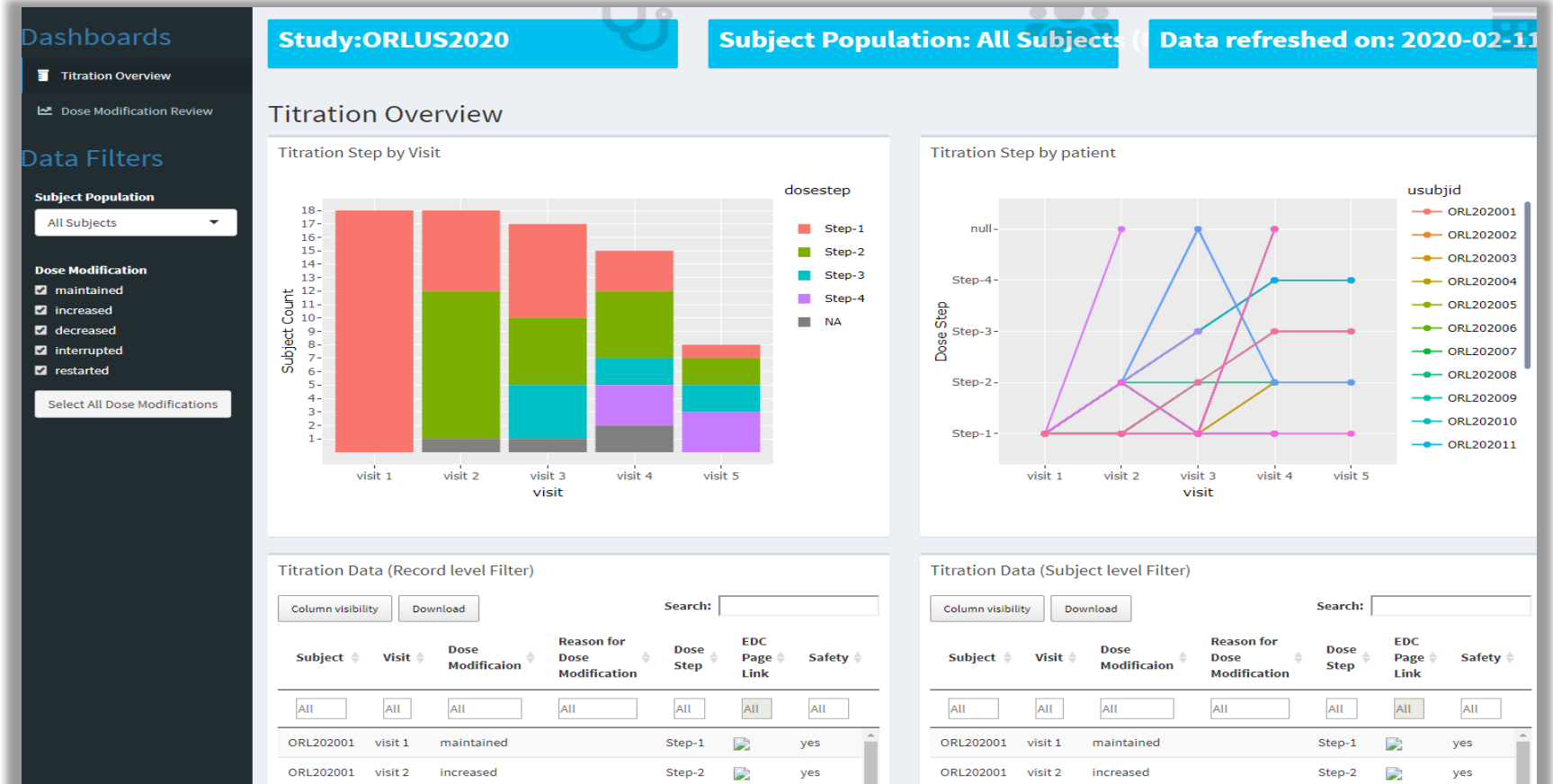
- Demographics
- Exposure
- Adverse Events

Create reports as per template using Statistical Analysis tool or DV tool

Build dashboards with data filters, linked reports and provide options to share and download reports using DV tool

Interactive Visualization Environment (IVE)

Screenshot of IVE with Data filters and Titration Overview Dashboard



For Interactive application go to <https://bharath-sunkavalli.shinyapps.io/TitrationDB/>

IVE features

Data Filters

Dashboards

Titration Overview

Dose Modification Review

Data Filters

Subject Population

All Subjects

Dose Modification

☐ maintained

☐ increased

☐ decreased

☐ interrupted

☒ restarted

Select All Dose Modifications

Titration Data (Record level Filter)

Column visibility Download

Search:

Subject	Visit	Dose Modification	Reason for Dose Modification	Dose Step	Safety	ITT	PP	Diabetis	Region	NYH/FC
All	All	All	All	All	All	All	All	All	All	All
ORL202013	visit 5	restarted	Pateint recovered from AE	Step-2	yes	yes	yes	yes	APAC	Class I

Titration Data (Subject level Filter)

Column visibility Download

Search:

Subject	Visit	Dose Modification	Reason for Dose Modification	Dose Step	Safety	ITT	PP	Diabetis	Region
All	All	All	All	All	All	All	All	All	All
ORL202013	visit 2	maintained		Step-1	yes	yes	yes	yes	APAC
ORL202013	visit 3	increased		Step-2	yes	yes	yes	yes	APAC
ORL202013	visit 4	interrupted	Adverse Event		yes	yes	yes	yes	APAC
ORL202013	visit 5	restarted	Pateint recovered from AE	Step-2	yes	yes	yes	yes	APAC
ORL202013	visit 6	maintained		Step-2	yes	yes	yes	yes	APAC

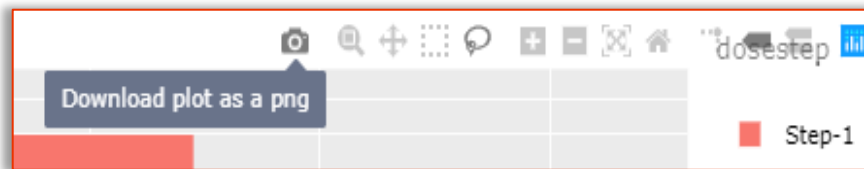
Dynamic Headers

Study:ORLUS2020

Subject Population: All Subjects (N)= 18

Data refreshed on: 2020-02-10

Interactive Graphics and Export reports



Titration Data (Record level Filter)

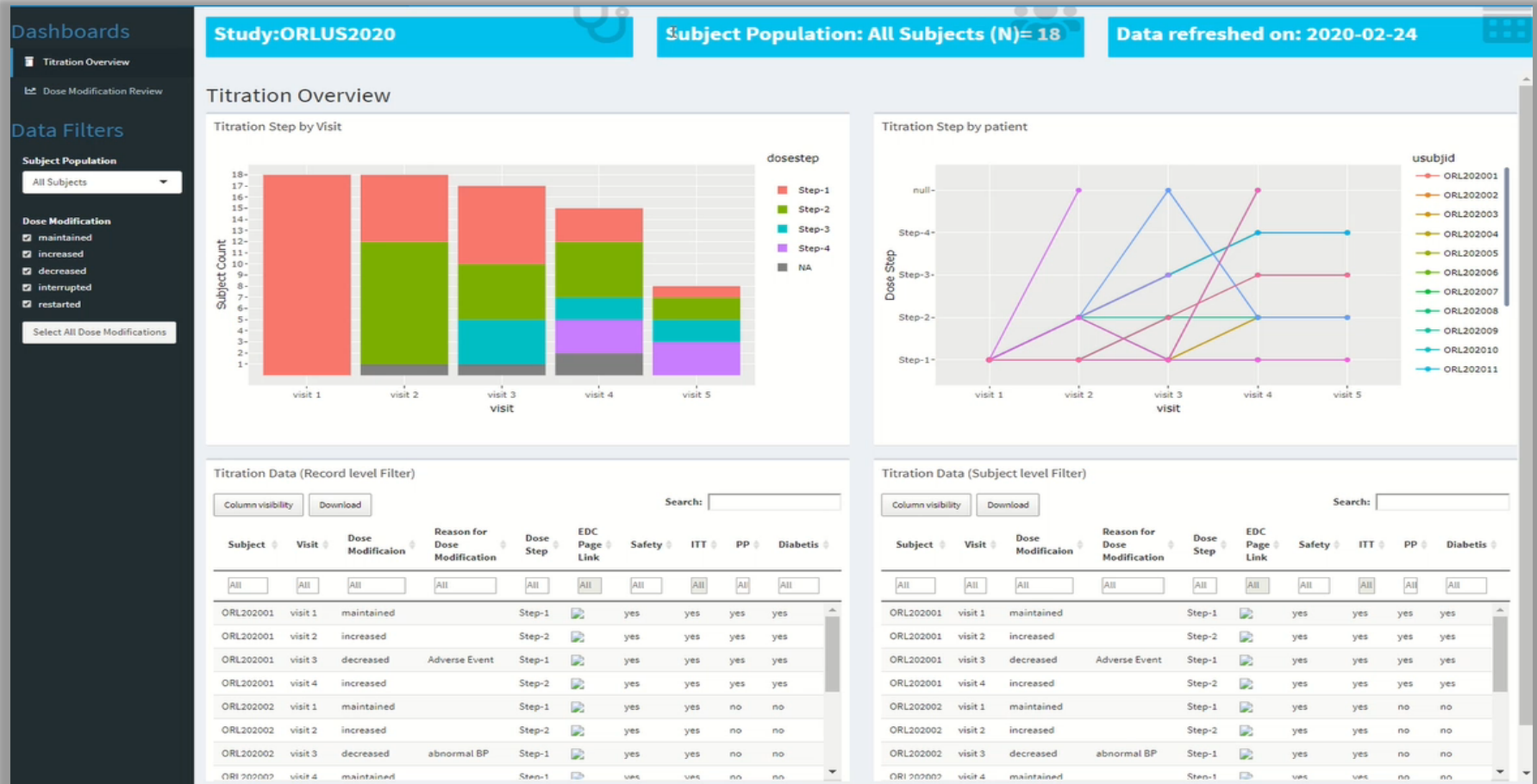
Column visibility Download

Excel

Subject	Visit	Dose Modification	Reason for Dose Modification	Dose Step	EDC Page Link	Safety	ITT
All	All	All	All	All	All	All	All

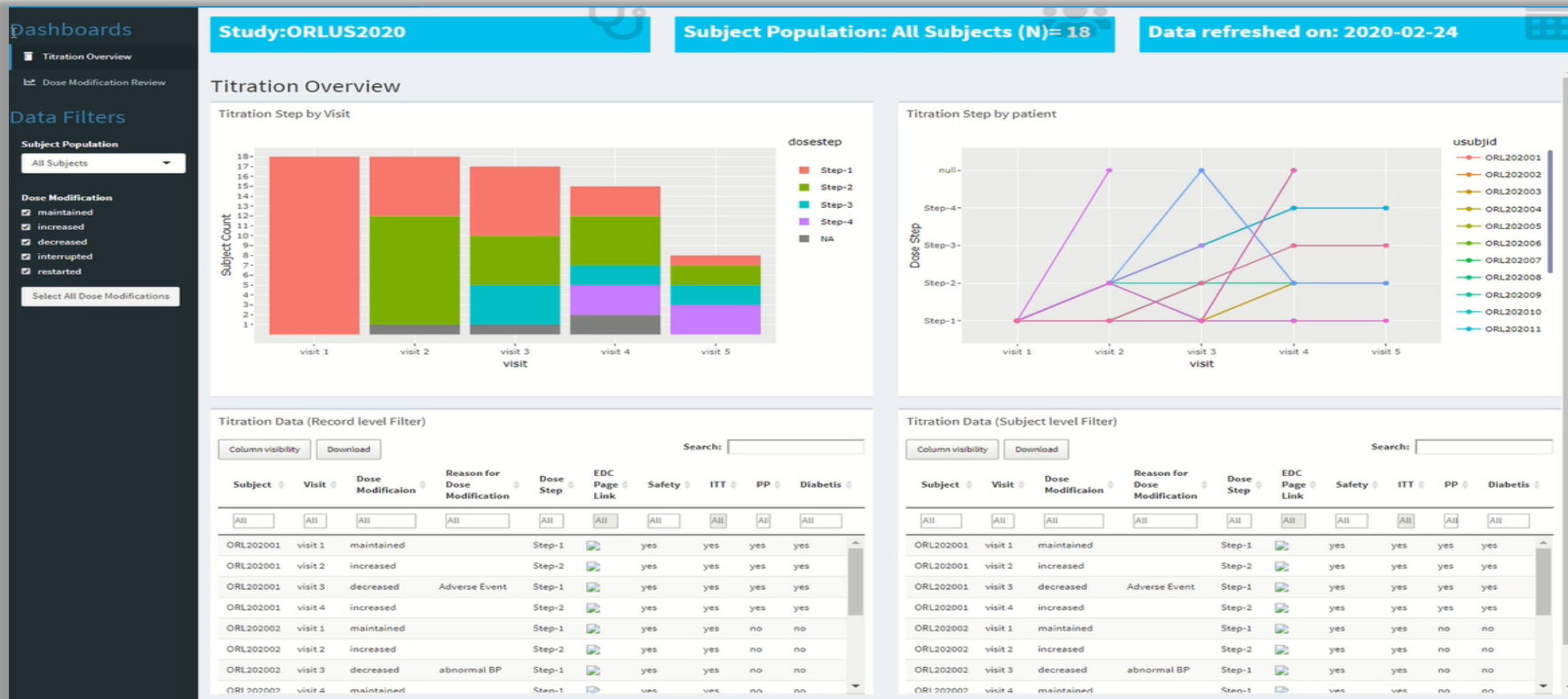
IVE features –Titration Overview

Play below Screen recording for demo of drill down to Safety population subjects in Step-1 at Visit 4 and export the titration data



IVE features –Reasons for Dose modification

Play below Screen recording to identify reasons for dose interruption in PP population



A query will be raised to investigator by medical expert in below scenarios:

- Reason for dose modification is not entered except when dose increased
- Adverse Event (AE) that caused dose interruption is not entered in AE page or AE action taken is not Drug Withdrawn

Summary

- IVE provides a focused and productive data review with dashboards and user controlled reports
- IVE can be shared with multiple end users and can be used for review at the same time, individual reports can be shared and exported for presentations
- IVE can benefit several functional areas in clinical research where data is reviewed, analyzed and reported

Q&A



Presentation prepared with
reference to phuse US
connect 2020 Paper#DV11



phuse US connect
2020- Paper-DV11

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For Interactive application go to <https://bharath-sunkavalli.shinyapps.io/TitrationDB/>

References

- Interactive visualizations used for demonstration are developed with RStudio® and Shiny® and are deployed on <https://www.shinyapps.io/>
 - Winston Chang, Joe Cheng, JJ Allaire, Yihui Xie and Jonathan McPherson (2019). *shiny: Web Application Framework for R*. R package version 1.4.0. <http://shiny.rstudio.com>
- Graphs are creating using ggplot2 and plotly
 - H. Wickham. *ggplot2: Elegant Graphics for Data Analysis*. Springer-Verlag New York, 2016.
 - Carson Sievert (2018) *plotly for R*. <https://plotly-r.com>
- Tables are created using R package DataTables
 - Yihui Xie, Joe Cheng and Xianying Tan (2019). *DT: A Wrapper of the JavaScript Library 'DataTables'*. R package version 0.11. <https://github.com/rstudio/DT>
- **RECOMMENDED READING**
 - <https://shiny.rstudio.com/tutorial/>
 - https://rstudio.github.io/shinydashboard/get_started.html

Shortening the Distance From Lab to Life®.
