IMS Health & Quintiles are now

IQVIA™

A Shiny Future

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Introduction

- The demand for dynamic outputs is growing
- Phrases like *“more for less”* have become mantras
- Although *“if it isn’t broke don’t fix it”* carries a lot of weight; so does *“evolve or die”*

Welcome to a Shiny Future!

What is Shiny?

- Shiny is an interactive way to present your data, using R
- The information is displayed in Webpages
- It can be shared over the web or on your local device

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Case Study

Case Study

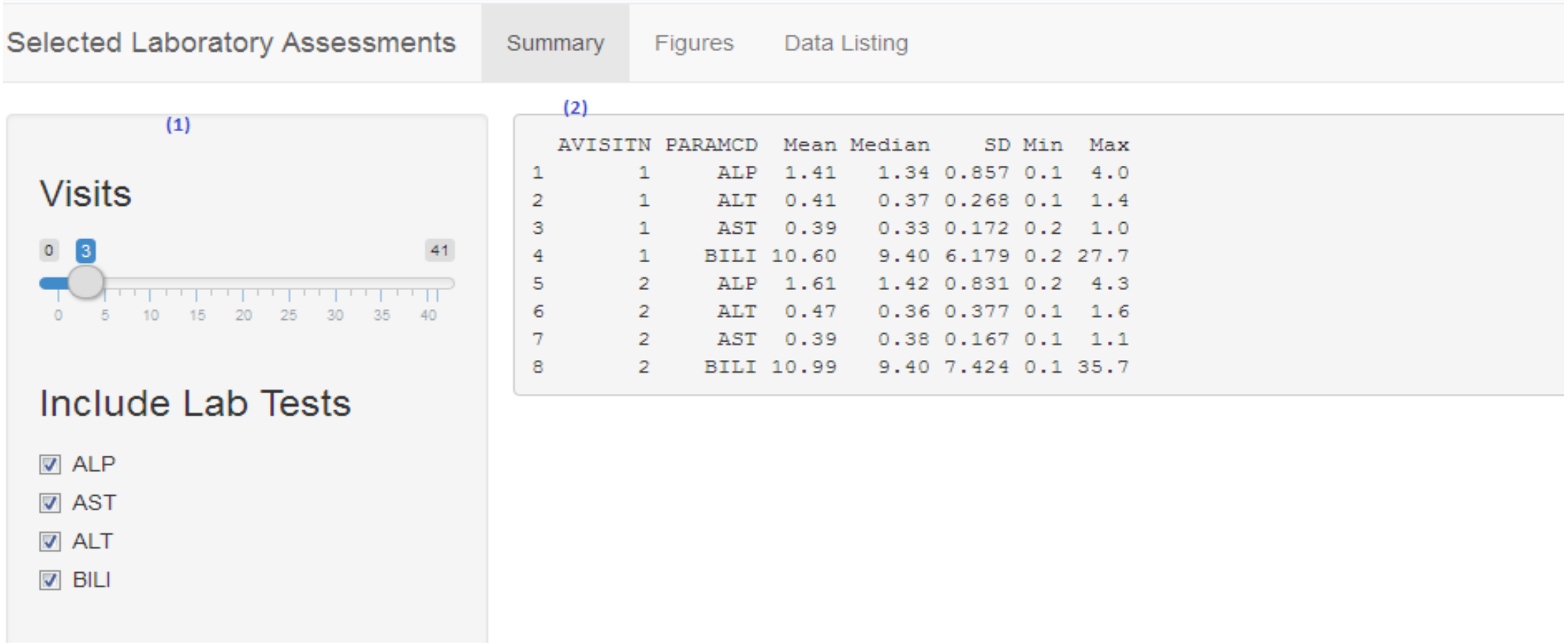
- We will be looking at four laboratory tests to replace our traditional Tables, Listings and Figures

- We need the following:
  - Create figures for the four laboratory tests combined
  - Create figures for the four laboratory tests, by Country, Sex, Visit
  - Create summary statistics for each laboratory test per Visit
  - Create a listing of the source data

- For the figures and tables, macros would be a good fit in our current setup, especially if we are to handle the: “What if scenarios?” for quicker turnaround time

Case Study

Introduction to Shiny layout

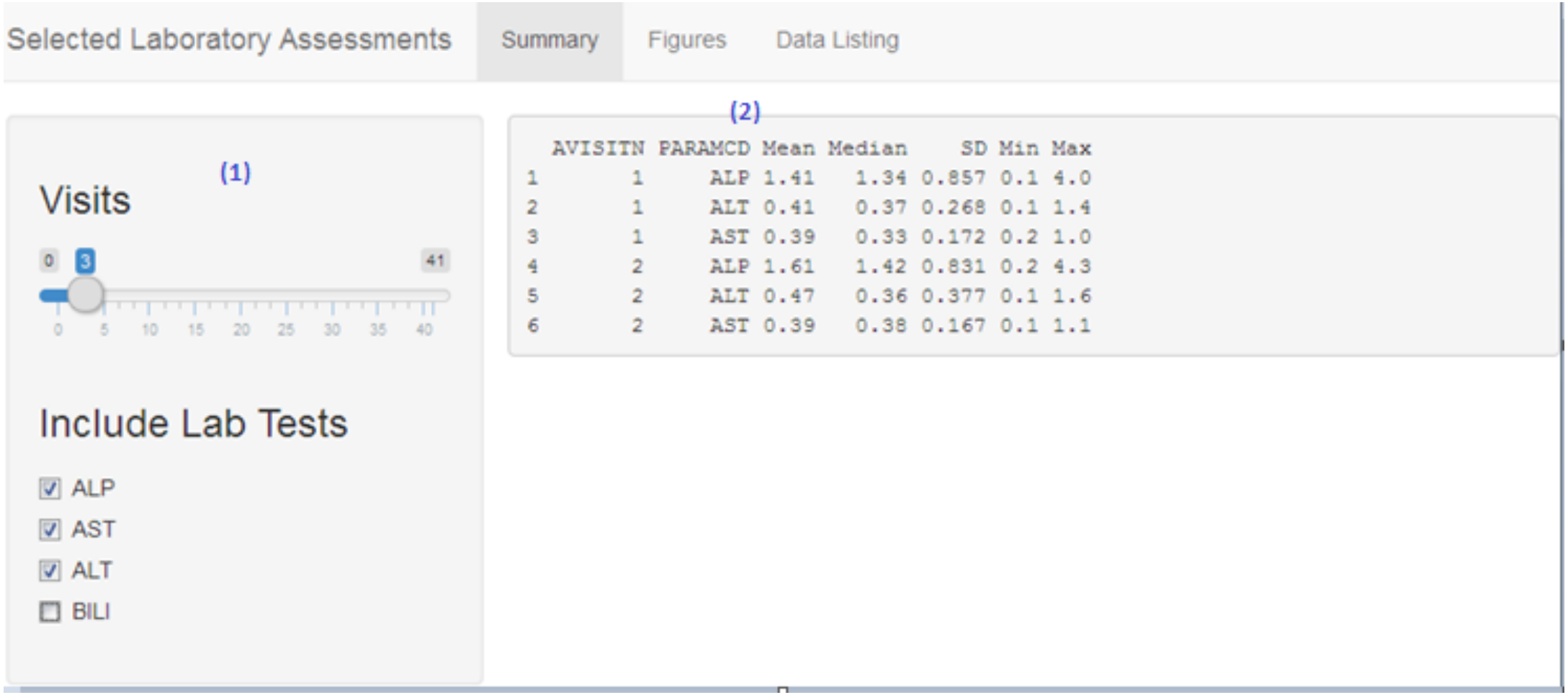


	AVISITN	PARAMCD	Mean	Median	SD	Min	Max
1	1	ALP	1.41	1.34	0.857	0.1	4.0
2	1	ALT	0.41	0.37	0.268	0.1	1.4
3	1	AST	0.39	0.33	0.172	0.2	1.0
4	1	BILI	10.60	9.40	6.179	0.2	27.7
5	2	ALP	1.61	1.42	0.831	0.2	4.3
6	2	ALT	0.47	0.36	0.377	0.1	1.6
7	2	AST	0.39	0.38	0.167	0.1	1.1
8	2	BILI	10.99	9.40	7.424	0.1	35.7

1 Tab for Summary statistics
1 Tab for Figures
1 Tab for Data Listings

Case Study

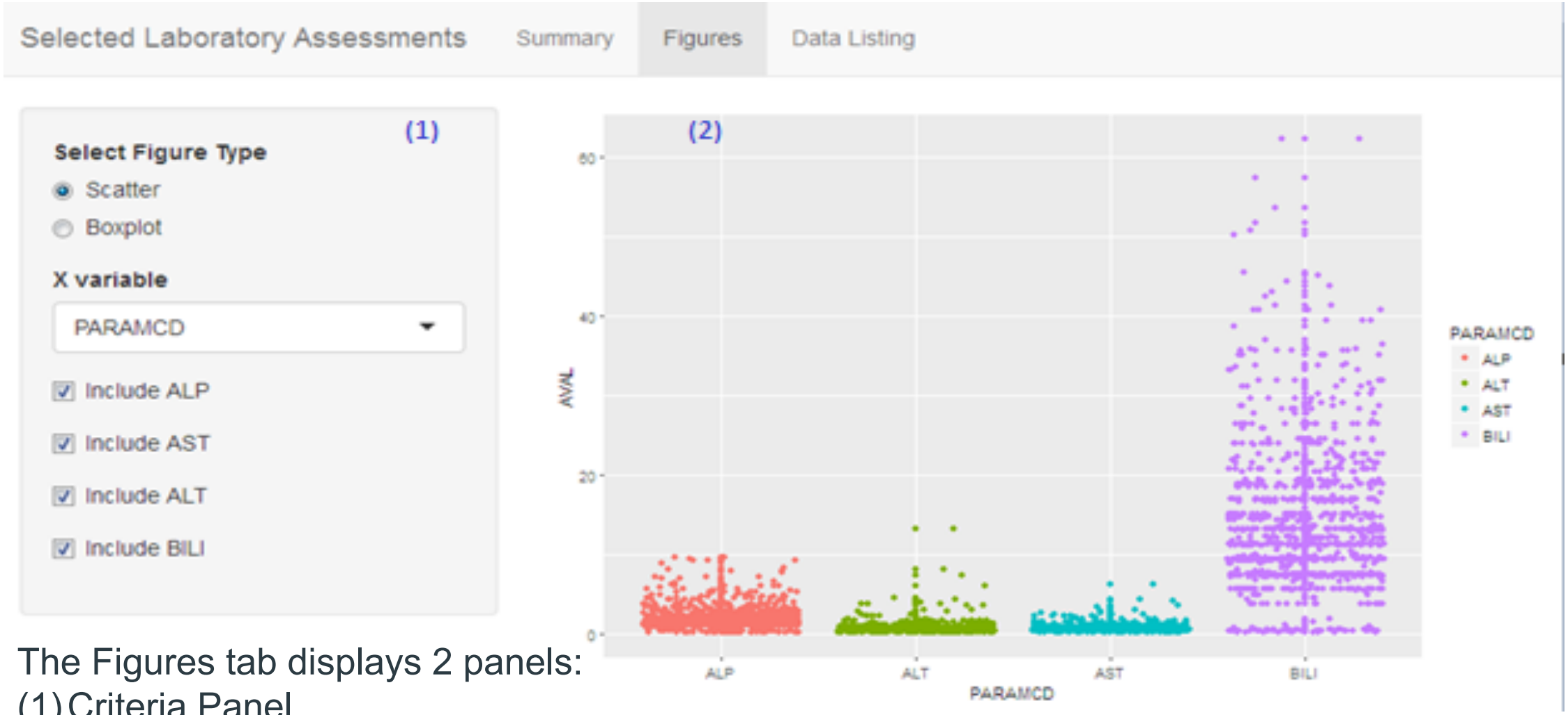
Tables



The summary tab displays 2 panels:
(1) Criteria Panel
(2) Output based on criteria set in (1)

Case Study

Figures



The Figures tab displays 2 panels:

(1) Criteria Panel

(2) The output based on criteria set in (1)

Case Study

Figures (cont.)

Selected Laboratory Assessments | Summary | Figures | Data Listing

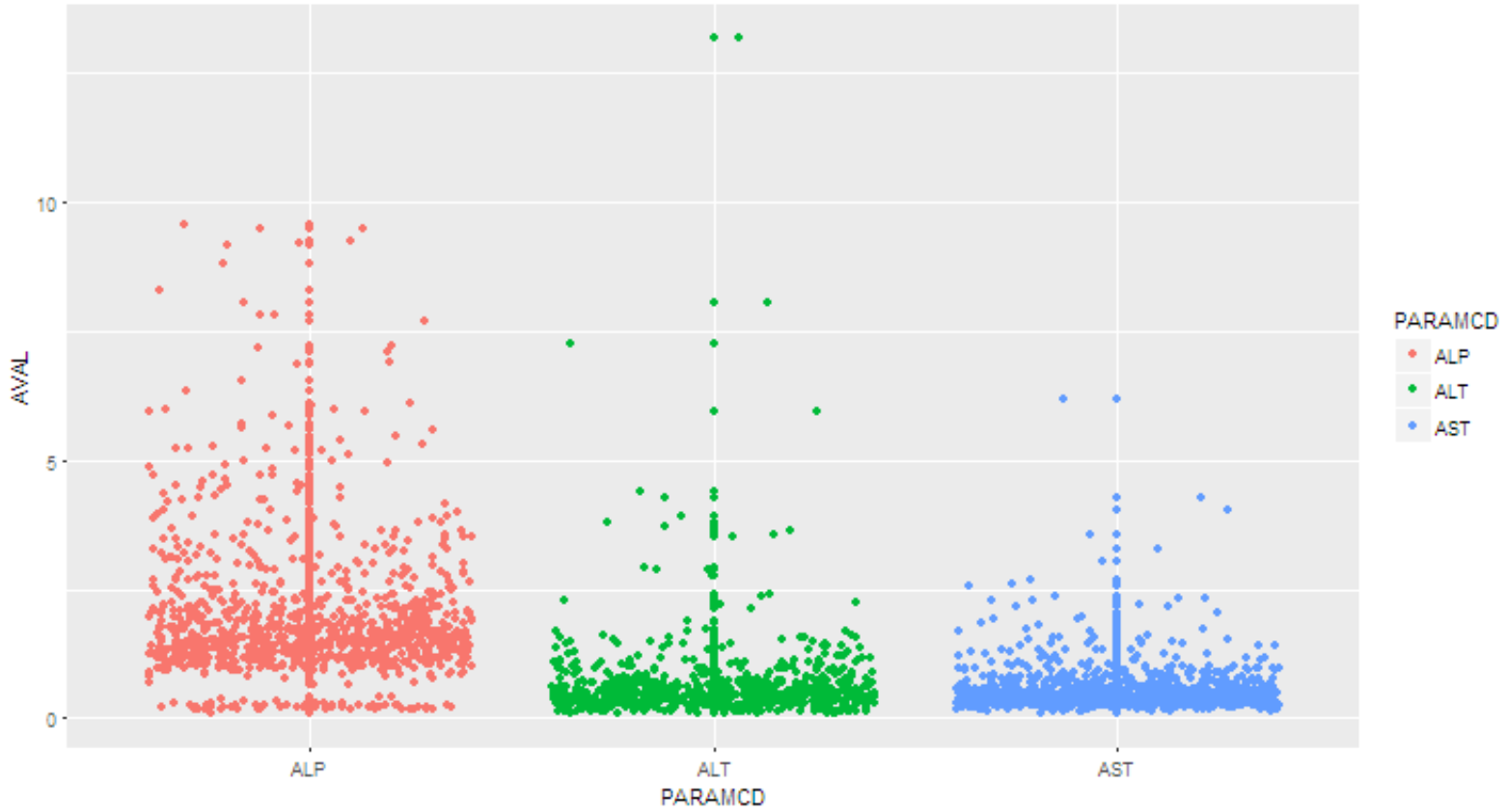
Select Figure Type

- (•) Scatter
- ( ) Boxplot

X variable

PARAMCD

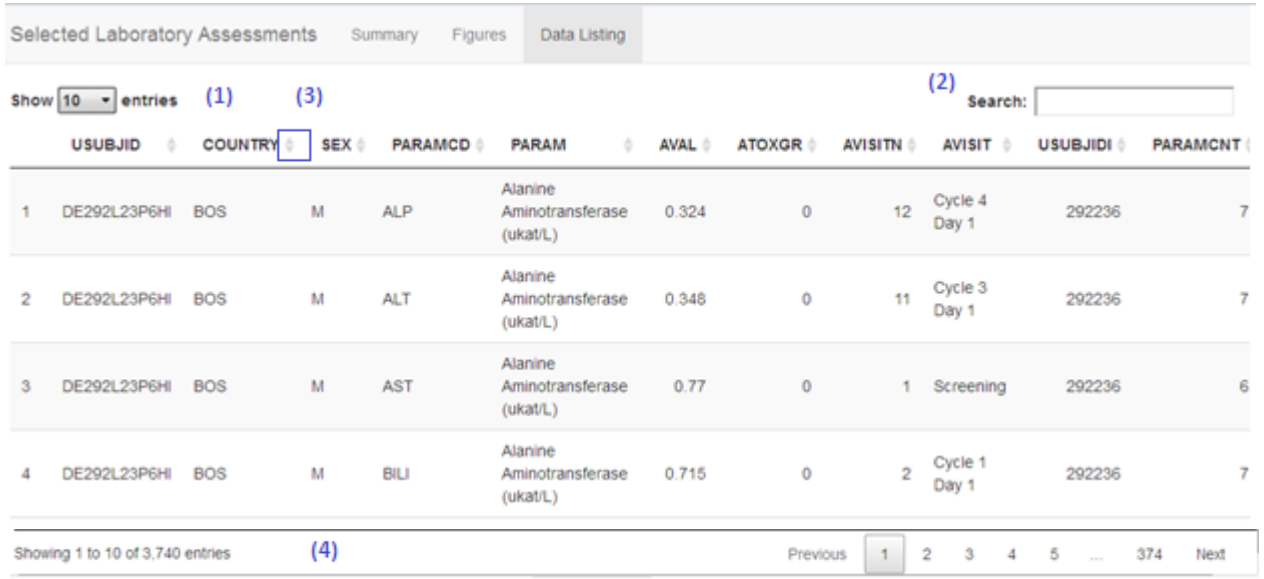
- [x] Include ALP
- [x] Include AST
- [x] Include ALT
- [ ] Include BILI



"BILI" makes the figure difficult to read and the reviewer wants to exclude BILI

Case Study

Data Listing



Although producing Data Listings appears straight forward, there are a few important points to note:

(1) You have the ability to control the number of observations per page

(2) Search functionality

(3) The up/down arrows provide the functionality to sort functionality

(4) Number of observations in the dataset

Case Study

Data Listing – Larger View

Selected Laboratory Assessments | Summary | Figures | Data Listing

Show 10 entries (1) (3) (2) Search:

	USUBJID	COUNTRY	SEX	PARAMCD	PARAM	AVAL	ATOXGR	AVISITN	AVISIT	USUBJIDI	PARAMCNT
1	DE292L23P6HI	BOS	M	ALP	Alanine Aminotransferase (ukat/L)	0.324	0	12	Cycle 4 Day 1	292236	7
2	DE292L23P6HI	BOS	M	ALT	Alanine Aminotransferase (ukat/L)	0.348	0	11	Cycle 3 Day 1	292236	7
3	DE292L23P6HI	BOS	M	AST	Alanine Aminotransferase (ukat/L)	0.77	0	1	Screening	292236	6
4	DE292L23P6HI	BOS	M	BILI	Alanine Aminotransferase (ukat/L)	0.715	0	2	Cycle 1 Day 1	292236	7

Showing 1 to 10 of 3,740 entries (4) Previous 1 2 3 4 5 ... 374 Next

Programming Impact

- Data preparation will not be impacted
- Interface programming will require a different skill set
- So, is it time to pack SAS away? The answer is resounding: **NO**
- This is an alternative to data presentation that is more with current trends and future developments

Quality impact

- This approach will require us to revolutionise our approach to quality and the role of the quality control
- For dynamic software or dynamic result generation:
  - We will need to take a page from software testing (up to clinical standards of course) to ensure the quality we deliver meets the demand of our clients including patients

The elephant in the room

- The following are taken from: http://blog.revolutionanalytics.com/downloads/FDA-Janice-Brodsky-UseR-2012.pdf
  - Key extracts:
    - › FDA does not endorse or require the use of any specific software for statistical analysis
    - › How should the FDA provide support to R users?
- R: Regulatory Compliance and Validation Issues A Guidance Document for the Use of R in Regulated Clinical Trial Environments (dated December 15, 2014)
  - Downloaded from: https://www.r-project.org/doc/R-FDA.pdf
  - Includes details about R's Validation credentials
- RShiny Validation credentials: https://www.rstudio.com/wp-content/uploads/2014/06/RStudio-Shiny-Server-Pro-Validation.pdf

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THANKS TO THE REVIEWERS FOR YOUR TIME

- Alex Brink
- Sharon Rossouw
- Armand Stone

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Questions