



Statistical Programming Operational Review Dashboard

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Overview

Introduction

History of the Dashboard

Architecture and Software of the Metrics Generation

Major Components of the Operational Dashboard

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Introduction

Statistical Programming (SP) at MRL in the Biostatistics and Research Decision Sciences Department has developed a custom Statistical Programming Operational Review Dashboard (the Dashboard) as requested by the head of the organization.

The dashboard provides a vehicle for management to review and monitor Statistical Programming activities so that continuous efficiency improvements on the operations could be identified and achieved across the organization.

The Dashboard is the cornerstone for regular departmental operational review meetings across the Statistical Programming department. Statistical Programming is a worldwide organization with staff residing in Asia, Europe, and North America.

Statistical Programming Operational Review Dashboard (“the Dashboard”) displays metrics of completed deliverables which enable the targeting, discovery, development, manufacturing, and marketing of drugs and vaccines for the benefit of patients and global public health.

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History of the Dashboard

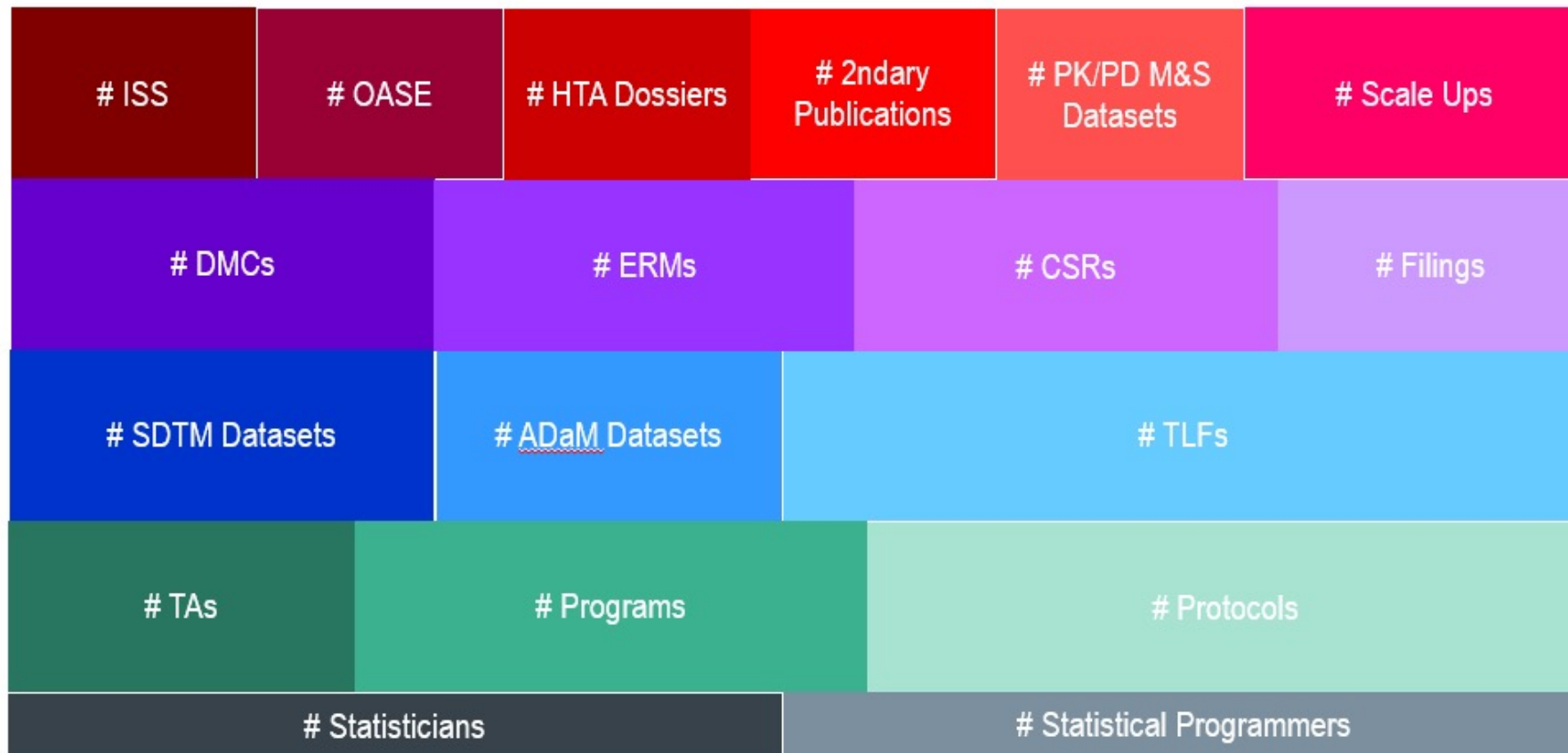
Architecture and Software of the Metrics Generation

Major Components of the Operational Dashboard

Dashboard Demonstration

History of the Dashboard

The head of SP provided a “wall of metrics” graphic as the inspiration for the dashboard development team



History of the Dashboard

Next, we

- Looked at various technologies and vendor presentations
- Brainstormed what types of metrics would fall into each category

Conclusion

- To utilize in-house knowledge of SAS and R Shiny
- Categories of metrics include overall summary metrics for Tables, Listings, Figures and Dataset (SDTM, ADaM) deliverables, efficiency of programming, and timeliness to delivery for each of the four main research groups of statistical programming.
- The statistical programming dashboard presents metrics tailored to the organization and deliverable type such as Clinical Study Report, Interim Analysis, Health Technology Assessment Dossier, Real World Evidence Report, etc.

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Architecture and Software of the Metrics Generation

STEP 1: CPI Mainframe Platform Extraction

IT to “mine” CPI for the folder structure and file name by project.

- CPI is a Linux-based platform supporting BARDS reporting needs. It is the primary tool used in BARDS for the analysis and reporting of clinical data and regulatory submission deliverables.
- Each project in CPI is closely monitored and approved for access on a need-to-know basis.

Performed by IT support function

Output: a single SAS dataset containing every file name, date and time stamp

STEP 2: Metrics Generation

SAS is utilized to create the desired metrics based on the CPI folder structure and contents in Step 1

- We engaged contacts from each analysis and reporting team to review and finalize the requirements of the metrics.
- Over the past few years, the content and accuracy of the metrics have evolved to match the evolving organization and deliverable types.

Programmed in SAS by SP in-house staff

Output: excel file of metrics

STEP 3: Render in Dashboard

Metrics created in Step 2 are rendered using R Shiny on an internal server.

- The dashboard is a web-based interactive application that is built on R Shiny and R Markdown.
- Features include selecting period of interest, and downloading metrics reports and metrics data.

Programmed in R by SP in-house staff

Output: R Shiny application

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Major Components of the Operational Dashboard

- **Overview Page**
- **Functional Area Page**
- **Volume and Efficiency Metrics**
- **Export Function**

Dashboard Demonstration

Major

- Summary

- “T

by

- The

File

*Req

- Method

- Drill

- Each

pr

National Dashboard

All data presented on the dashboard is derived from the data warehouse.

Select Quarter(s)

☒ 2019Q4 ☒ 2020Q1

8
CSRMs

63
ITAs

4836
SDTM Datasets

4
Agency Requests

10
TAs

ADaM Datasets

5
EPI PDCS

987
Statistical Programmers

P21 Conformance

11
RWE

13
PK/PD M&S Datasets

3
ISS/ISE

10942
TLFs

23
Other

Output version: DummyData.xlsx .

HTA Dossiers

Show 10 entries

Search:

TA	Number of Requests
Cardiovascular	1
Oncology	12

Showing 1 to 2 of 2 entries

Previous 1 Next

Show 25 entries

Search:

Phase	Protocol	Delivery Date
	hta/mk1234-hfref-prot987csr/pem	2020-02-04

Showing 1 to 1 of 1 entries

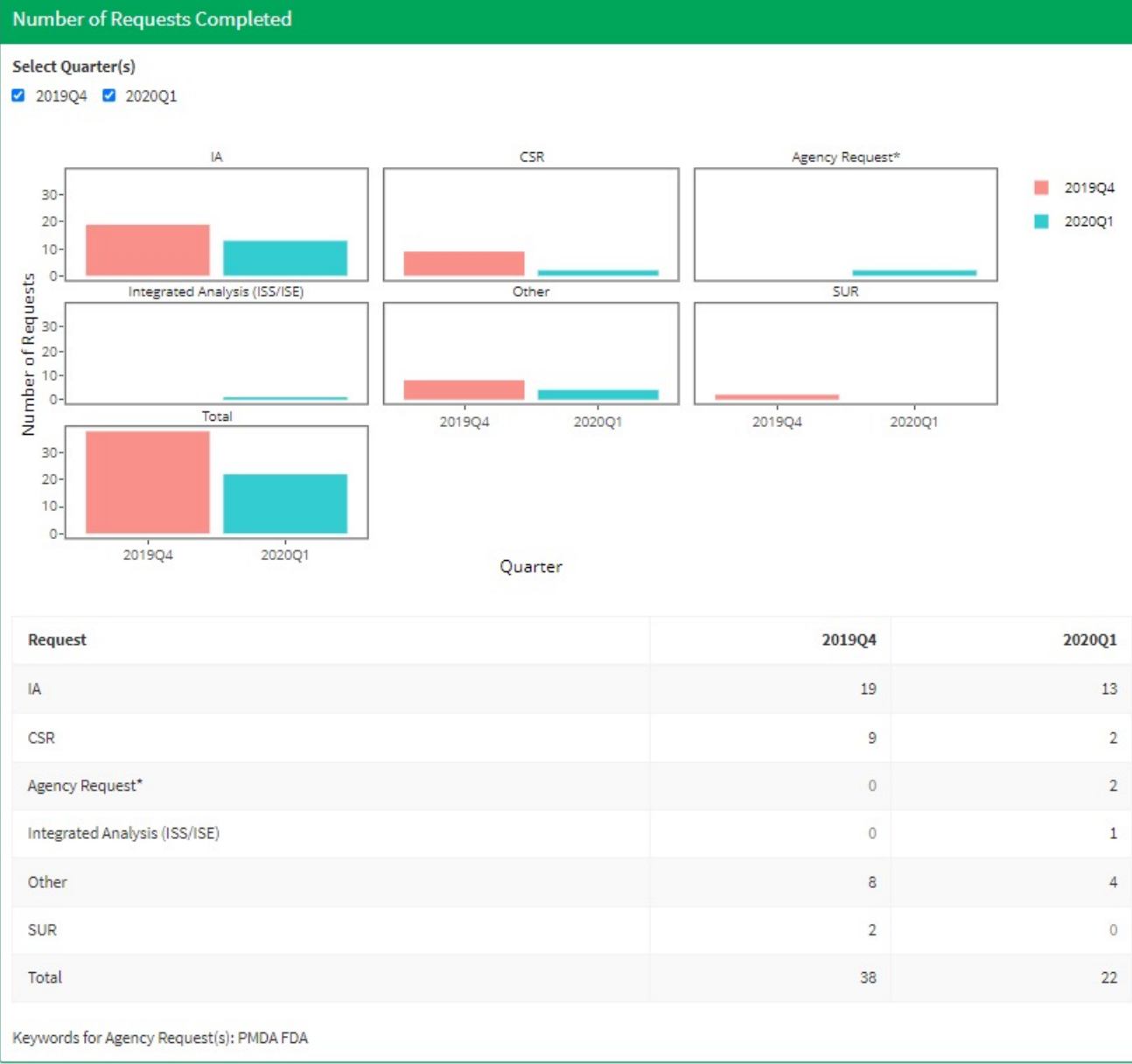
Previous 1 Next

Close

Major Component!

- *Summary Metrics* by functional area for the time-period as selected
- Package Type examples: Risk Management Report (PKPD), Real World Evidence Update Report (SUR) or

! All data presented on the dashboard are dummy.



Area Page

Functional Area

Select Functional Area

A&R Group 1 ▲

- A&R Group 1
- A&R Group 2
- A&R Group 3
- A&R Group 4

Major Components

- *Volume Metrics* are
 - Tables, Listings and and minimum pack
 - Dataset (SDTM and median, maximum
- *Efficiency Metrics* are
 - Tables, Listings and created with global TLFs created with p
 - Dataset (SDTM and relative days since

Efficiency

Average percent of TLFs created with global macros = 48.82 %
Average percent of TLFs created with TA macros = 1.54 %
Average percent of TLFs created with protocol specific macros = 49.64 %

SDTM

ADaM

Timeline

Show 10 entries

Search:

TA	Number of Requests
Antibacterial/Antifungal	2
Antiviral	2
Cardiovascular	4
Diabetes	4
Neuroscience	2
Vaccines	7

Showing 1 to 6 of 6 entries

Show 25 entries

Search:

Protocol	Earliest SDTM Creation From DBL/Final Specs	Latest SDTM Creation From DBL/Final Specs
mk1234-fungal/prot069-csr	0	2
mk1234-bli/prot014-csr/EudraCT_NIH	94	94

Showing 1 to 2 of 2 entries

Previous

1

Next

& Efficiency

an, maximum,
r average,
ent of TLFs
ge percent of
dataset creation

Major Components of the Operational Dashboard -Export Function

Dashboard metrics can be downloaded as a report in Word format, or the metrics can be downloaded in Excel format.

Enter report filename	Enter data filename
ORM Dashboard_report	ORM Dashboard_data
Report content	Download data
☒ A&R Group 1	☒ A&R Group 1
☒ A&R Group 2	☒ A&R Group 2
☒ A&R Group 3	☒ A&R Group 3
☒ A&R Group 4	☒ A&R Group 4
Download	Download
Download report for Overview page	
Download data for Overview page	

Overview

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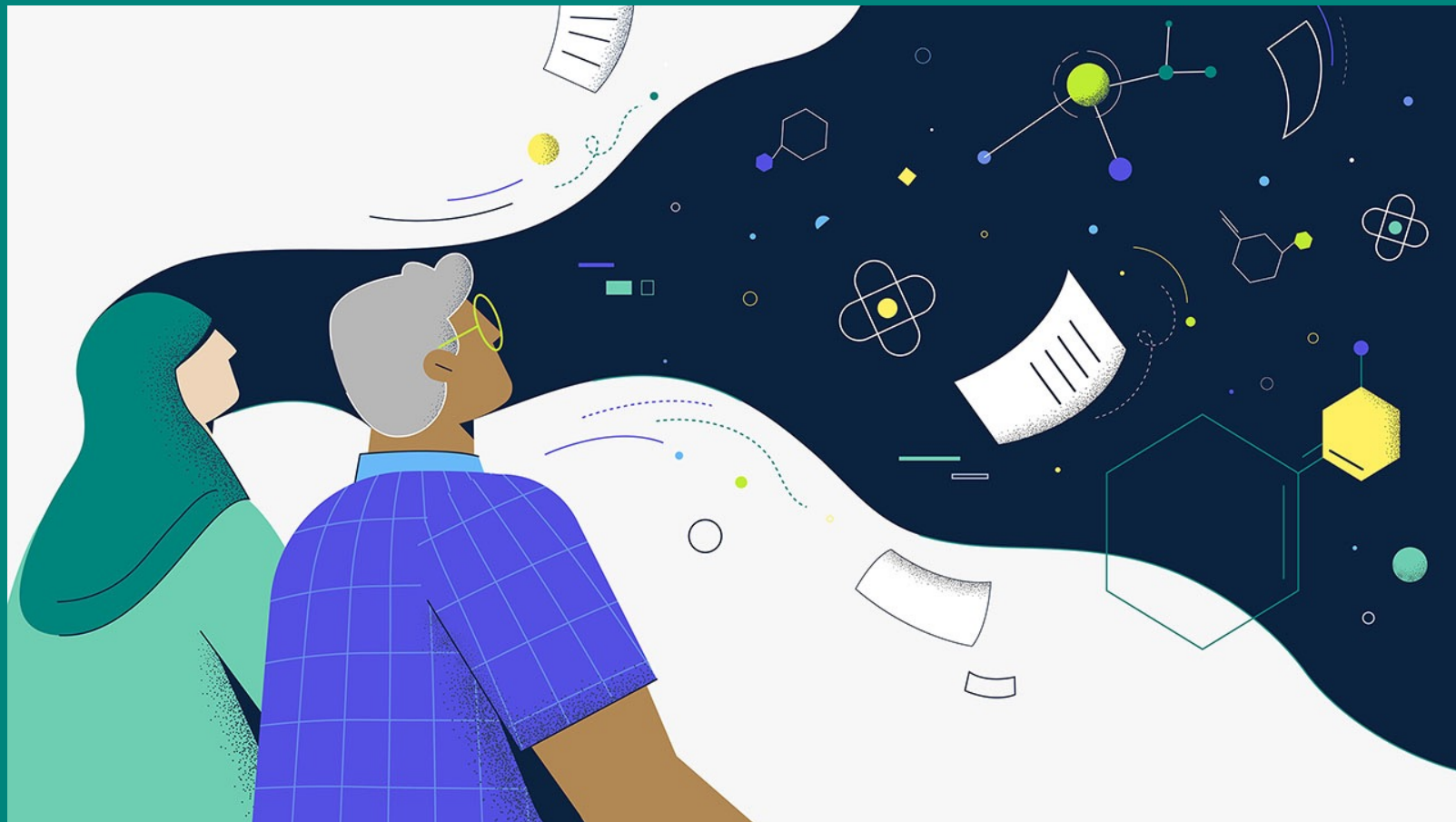
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Thank you



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