



# ***Leveraging Standard Analytics in Central Monitoring: The Good, The Bad, & The Ugly***

## **PRESENTERS:**

**Arianna Galli,**

Manager, Central Monitoring – PRA Health Sciences

**Angela Geiger,**

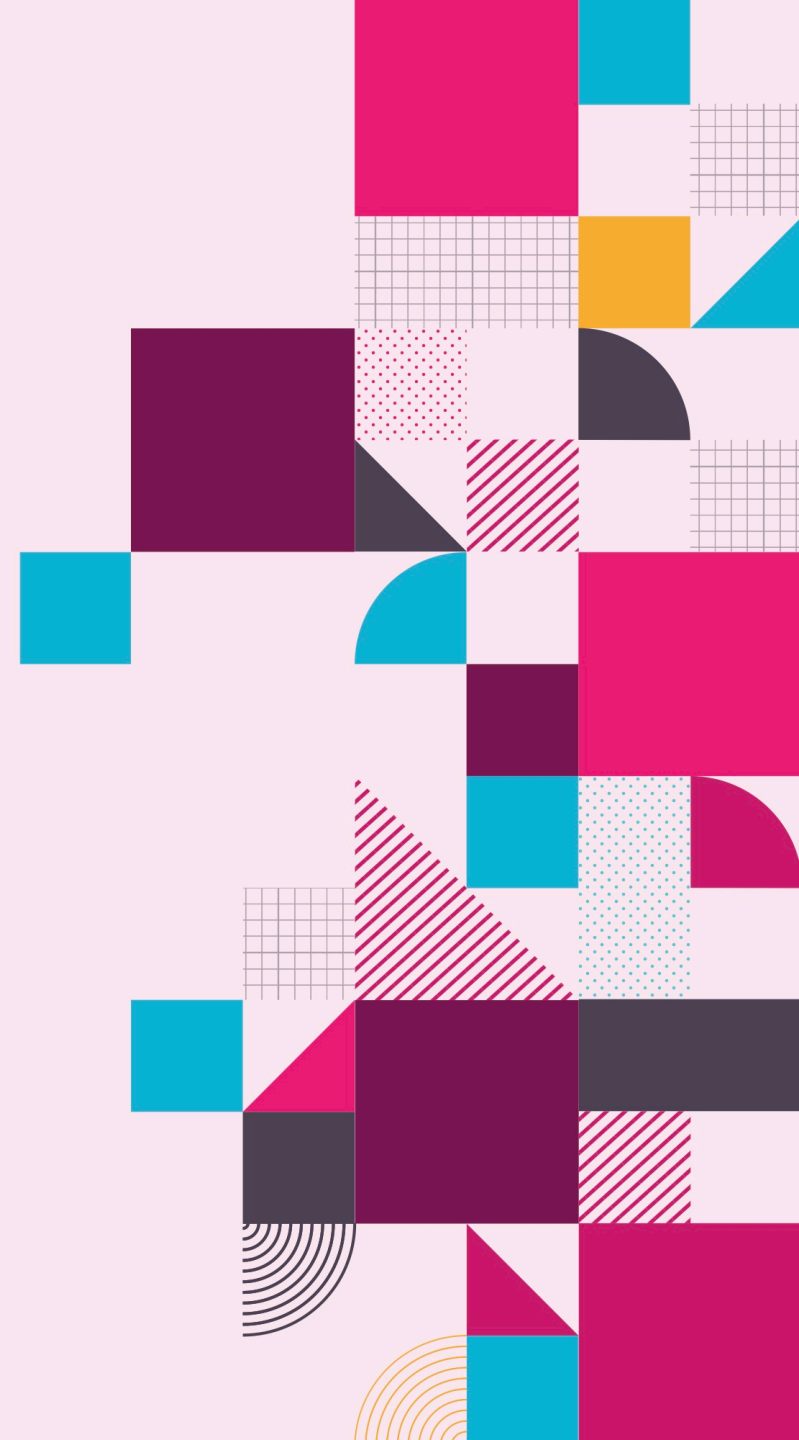
Sr Central Data Scientist, Central Monitoring – PRA Health Sciences



At PRA we define Centralized Monitoring as a remote evaluation of clinical data performed at a central non-site location, using clinical data from various systems (e.g., EDC, Lab database, ePRO, etc.).

Centralized Monitoring complements onsite monitoring activities and provides an aggregate, comprehensive review approach to identify data trends and issues that cannot be easily identified through traditional onsite monitoring activities.

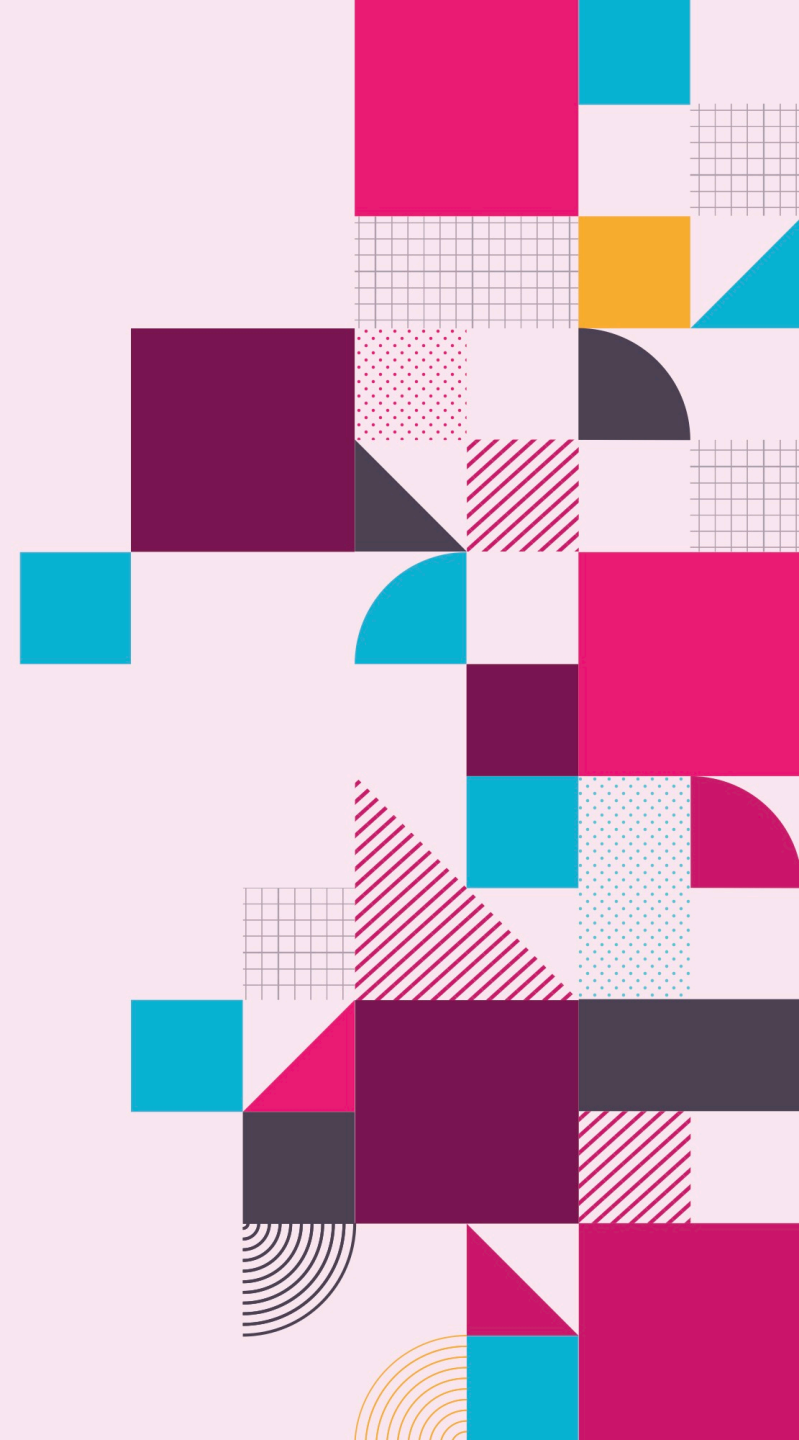
PRA has established a framework of standard central monitoring review activities and analytic outputs to streamline tasks and also provide consistency across projects.





The concept of the “standard” output is key since recreating outputs takes time, increases the risk of errors, and decreases consistency. Therefore, a process for having standard outputs available for all studies was developed.

A Library of Standard Outputs gains consistency and promotes efficiencies across studies and allows for a comprehensive data review as a minimum requirement to ensure central monitoring meets the RBQM concept





## Purpose of the Data Analytics Library

The Data Analytics Library is a structured model developed by PRA experts from various roles allowing harmonized reviews across the studies and creates an efficient end-to-end data review process.

### The objective:

- have outputs that are universal and consistent,
- limit the opportunity for error in their creation,
- keep the initial setup time to a minimum,
- avoid a complete rebuild of the outputs for each study.
- Simultaneously, the process also accounts for differences in studies and database design.

By taking this approach we allow the same output “templates” to be applied study-to-study with only minor changes, and in some cases, no changes at all.



## Definition of the Data Analytics Library

### Standard Outputs:

- Library Outputs that are expected to be applicable and relevant to all studies.
- Standard Outputs are currently created for use by 3 roles: Medical Affairs, Clinical Operations, and the Central Data Scientist.

### Standard Conditional Outputs:

- Library Outputs that are expected to be applied to a subset of studies, depending on therapeutic area, size of the study population, scope of functional area review, risks identified, etc.
- Standard Conditional Outputs are currently created for use by 2 roles: Medical Affairs and Central Data Scientist.



## Data Analytics Library : «The Good»

- PRA Role-Based Library consists of standard outputs that are expected to be applicable and relevant to all studies
- Role-specific outputs which are fit for purpose
- Consistency across studies of standard analytics applied
- Streamlined review efforts
  - Avoid use of multiple review tools (excel exports from various data sources)
  - Potential reduction in review time and increase in efficiency by getting used to standard data analytics
  - ability to validate, which reduces time spent ensuring that a modifiable review tool is accurate at each review.



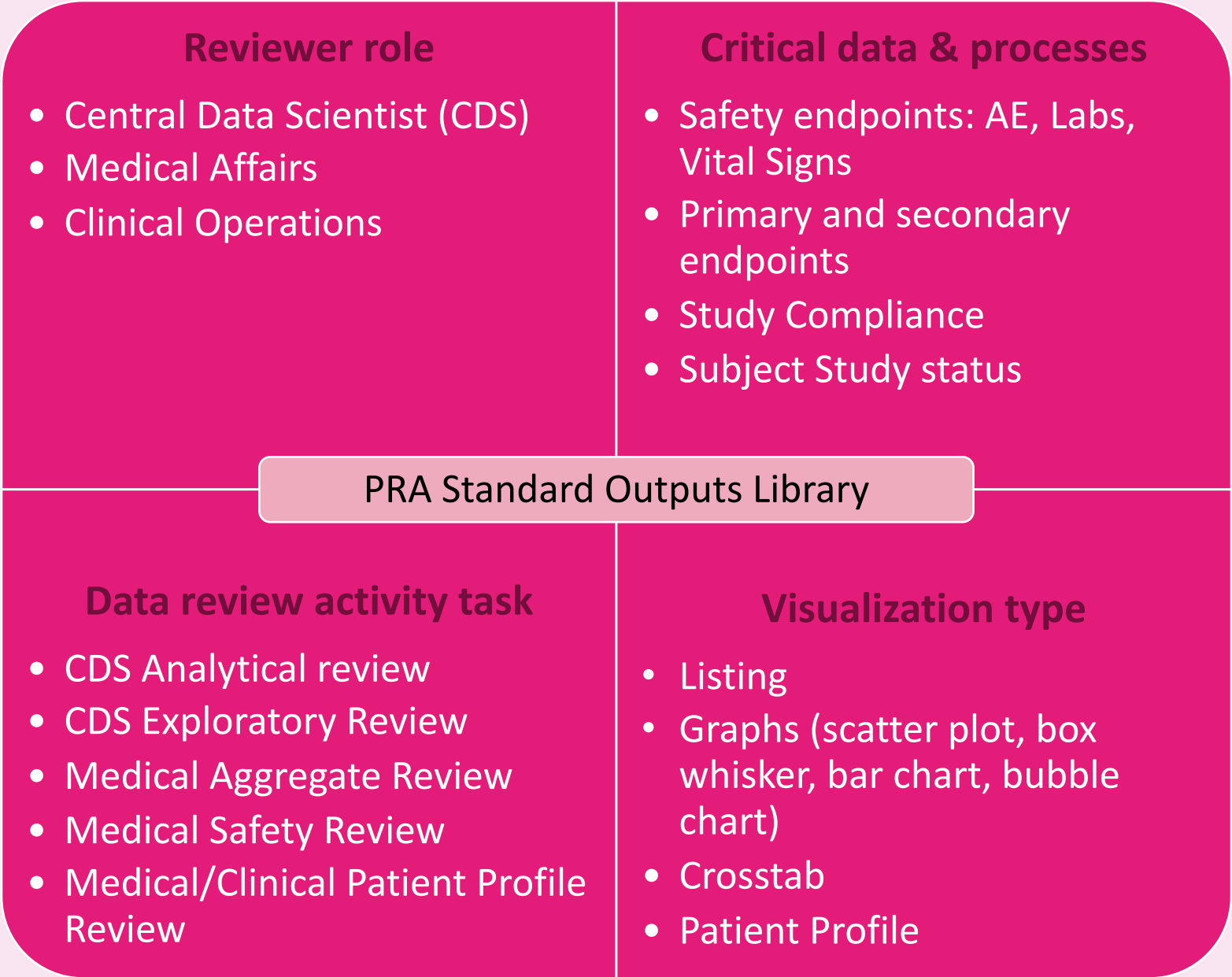
# The Library



PRA Role-Based Library consists of standard outputs that are expected to be applicable and relevant to all studies at a minimum

The Library outputs support data analytics review according to:

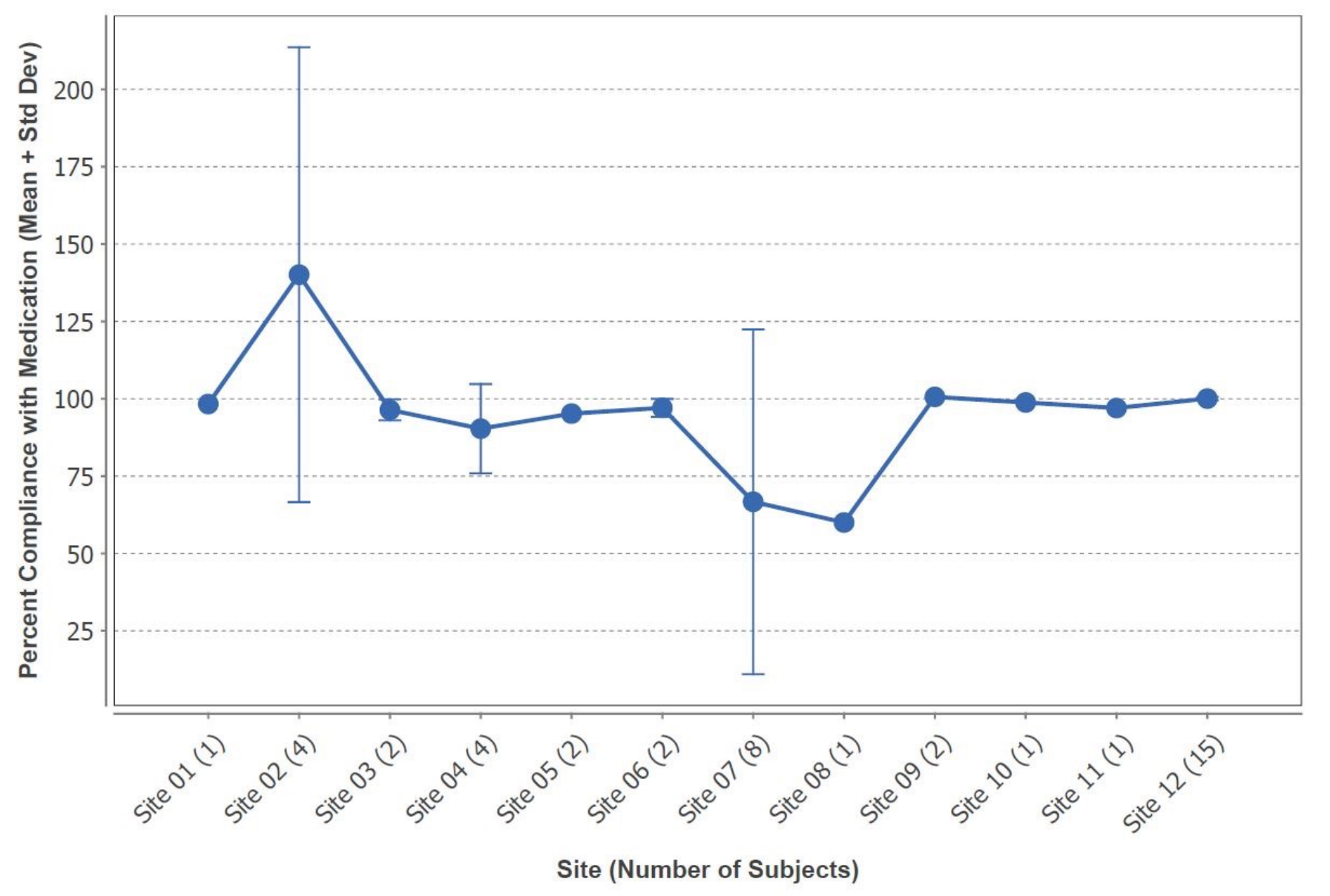
- Which role conducts the review
- Identified critical data and processes
- Most suitable visualization type to fit the expected data review activity tasks

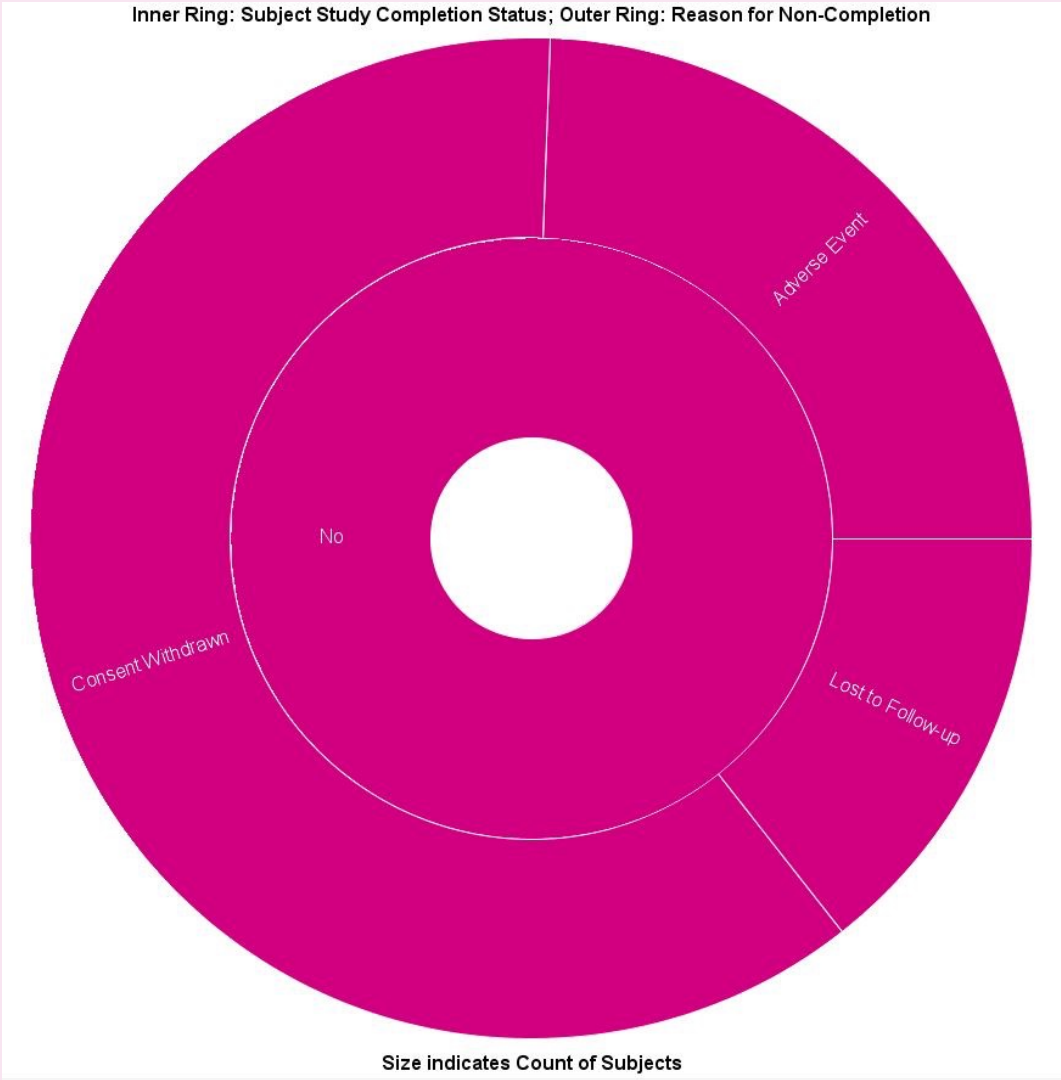
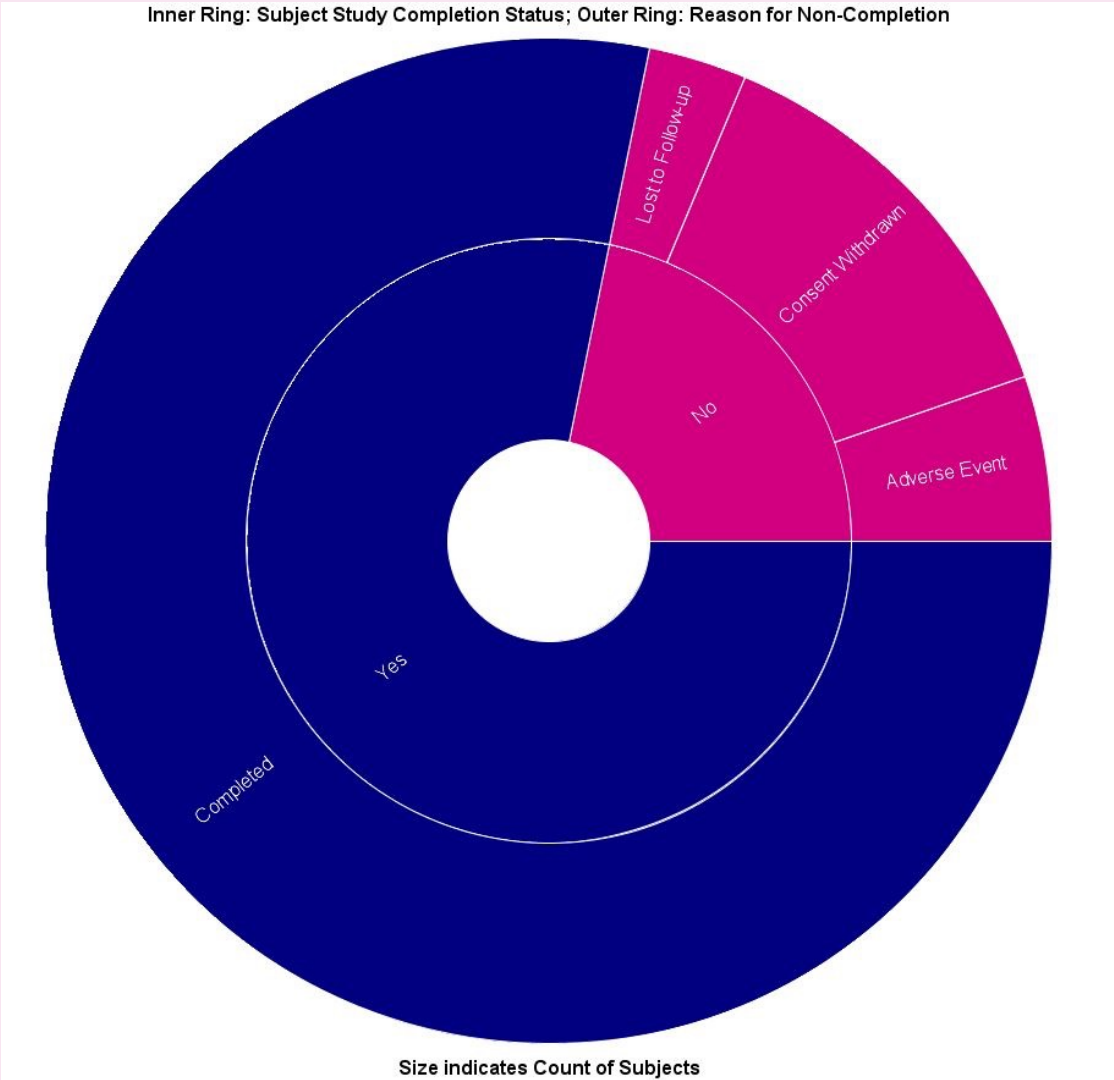


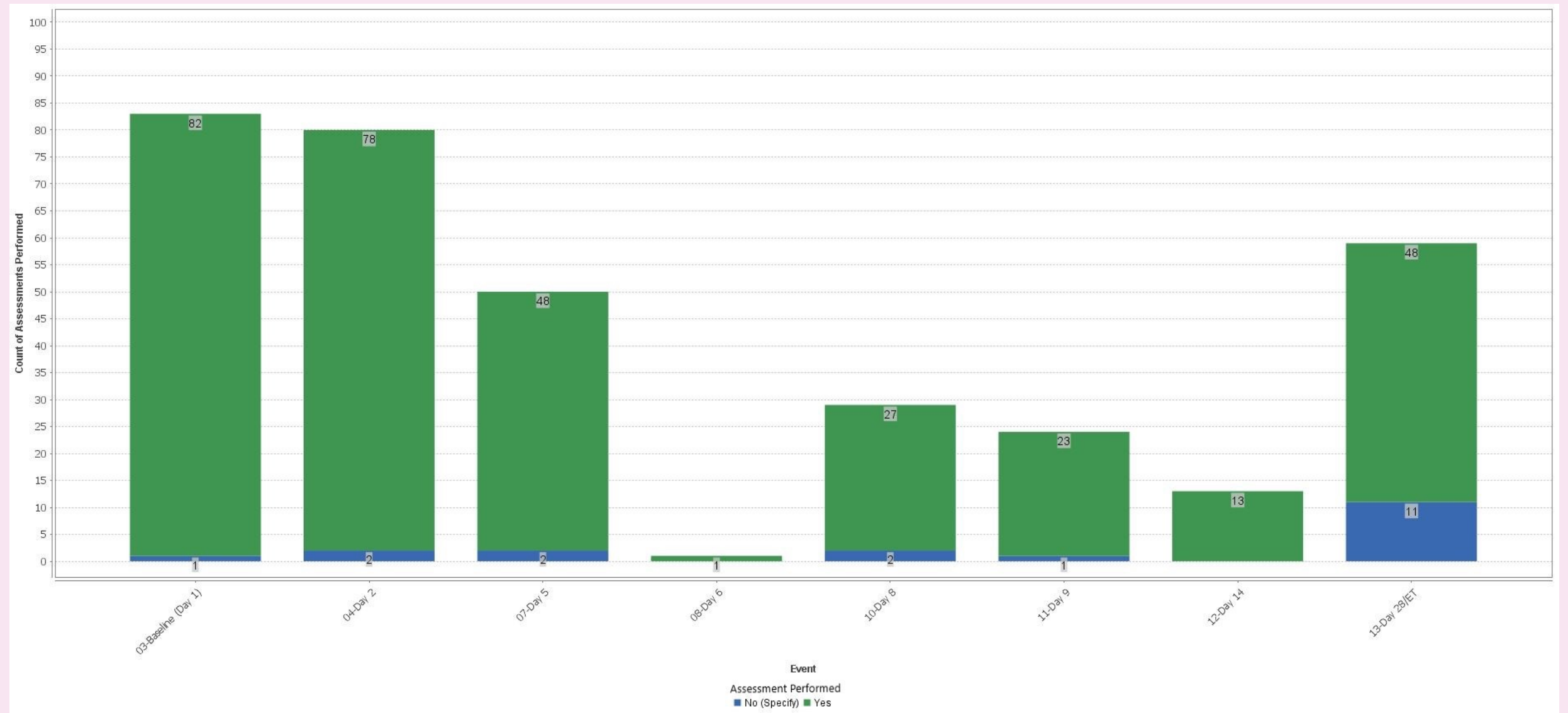


## Central Data Scientist outputs macro-areas:

- Assessment compliance at site and study level
  - external data
  - endpoint data
- Lost to Follow-Up / Discontinuation and End of Study Reason
- IP compliance
- Adverse Event of Special Interest rate









## Medical Affairs outputs macro-areas:

- Safety data review

- Adverse Events
- Medical History
- Concomitant Medications
- Laboratory Tests
- Physical Examination and/or Imaging
- ECG test results
- Vital Signs



- Listing developed as Standard to conduct Medical Affairs review
- Efficiency gained by
  - highlighting out of ranges values
  - specific listings showing abnormal lab values
- Combination of Physical Examination and Adverse Events data into a single listing to allow for easier cross-checking to ensure the Clinically Significant abnormal PEs are logged as Adverse Events

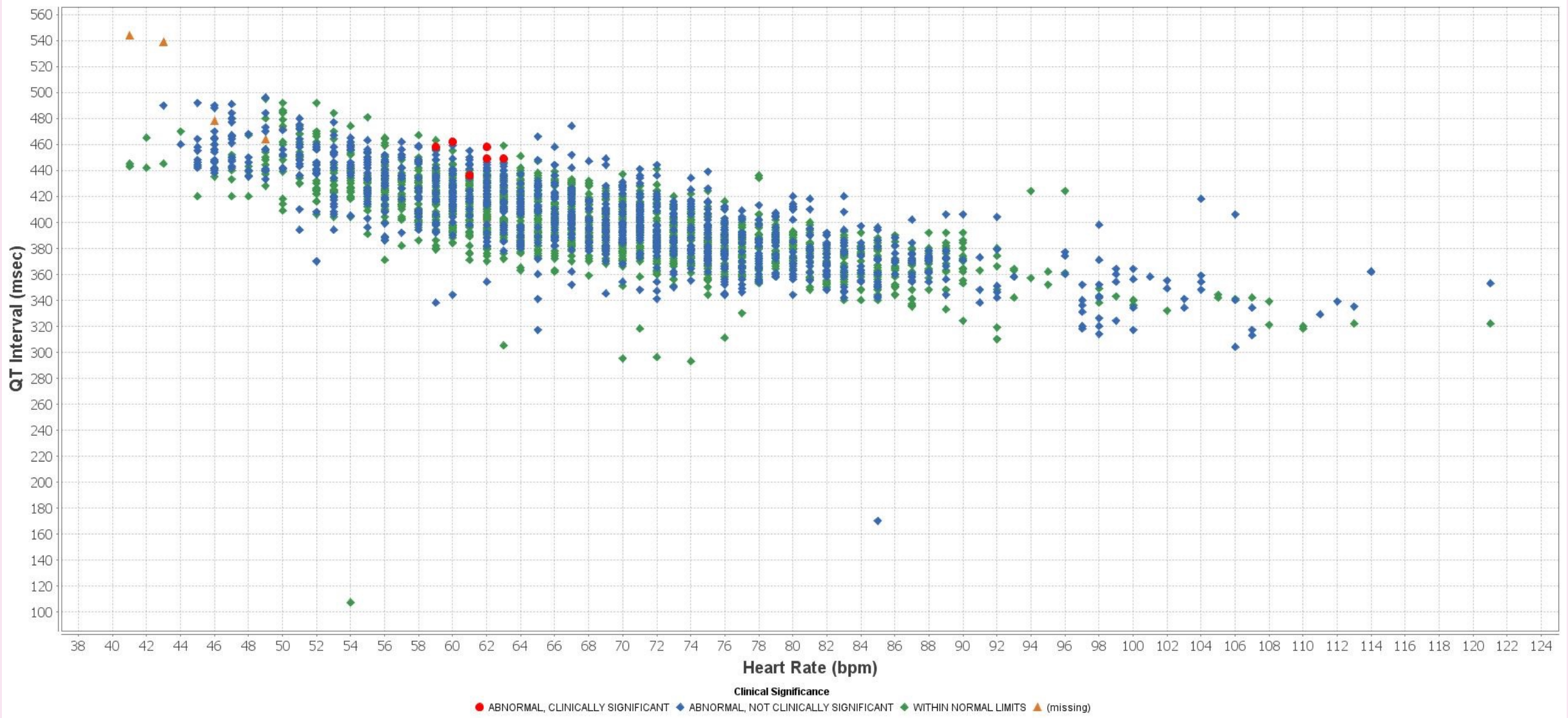


## Medical Affairs outputs macro-areas (cont):

- Aggregate Data Review
  - Adverse Events
  - Laboratory Test
  - ECG Results
  - Vital Signs
  - Subject Status and Termination
- Patient Profile Review



Medical Affairs outputs macro-areas : Scatter Plot & its efficiency





| Adverse Event Preferred Term             | No Reasonable Possibility | Reasonable Possibility | Row Sum                     |
|------------------------------------------|---------------------------|------------------------|-----------------------------|
| Urinary tract infection                  | 8 (3.6%)                  | 0 (0.0%)               | 8 (3.6%)                    |
| Fatigue                                  | 2 (0.9%)                  | 3 (1.3%)               | 5 (2.2%)                    |
| Nausea                                   | 2 (0.9%)                  | 3 (1.3%)               | 5 (2.2%)                    |
| Headache                                 | 4 (1.8%)                  | 1 (0.4%)               | 5 (2.2%)                    |
| Nasopharyngitis                          | 4 (1.8%)                  | 0 (0.0%)               | 4 (1.8%)                    |
| Blood creatinine phosphokinase increased | 4 (1.8%)                  | 0 (0.0%)               | 4 (1.8%)                    |
| Back pain                                | 2 (0.9%)                  | 1 (0.4%)               | 3 (1.3%)                    |
| Upper respiratory tract infection        | 3 (1.3%)                  | 0 (0.0%)               | 3 (1.3%)                    |
| Breast tenderness                        | 0 (0.0%)                  | 2 (0.9%)               | 2 (0.9%)                    |
| Abdominal pain upper                     | 0 (0.0%)                  | 2 (0.9%)               | 2 (0.9%)                    |
| Column Sum                               | 29 (12.9%)                | 12 (5.4%)              | Total Subjects 224 (100.0%) |



## Clinical Operations outputs macro-areas:

- Patient Profile Review
  - To ensure data integrity and patient safety by performing targeted review of the patient data
    - e.g. enrollment details,
    - for protocol compliance,
    - IP management including dose modifications,
    - adverse events,
    - concomitant medications,
    - study procedures, etc.

[illegible]



## Data Analytics Library:

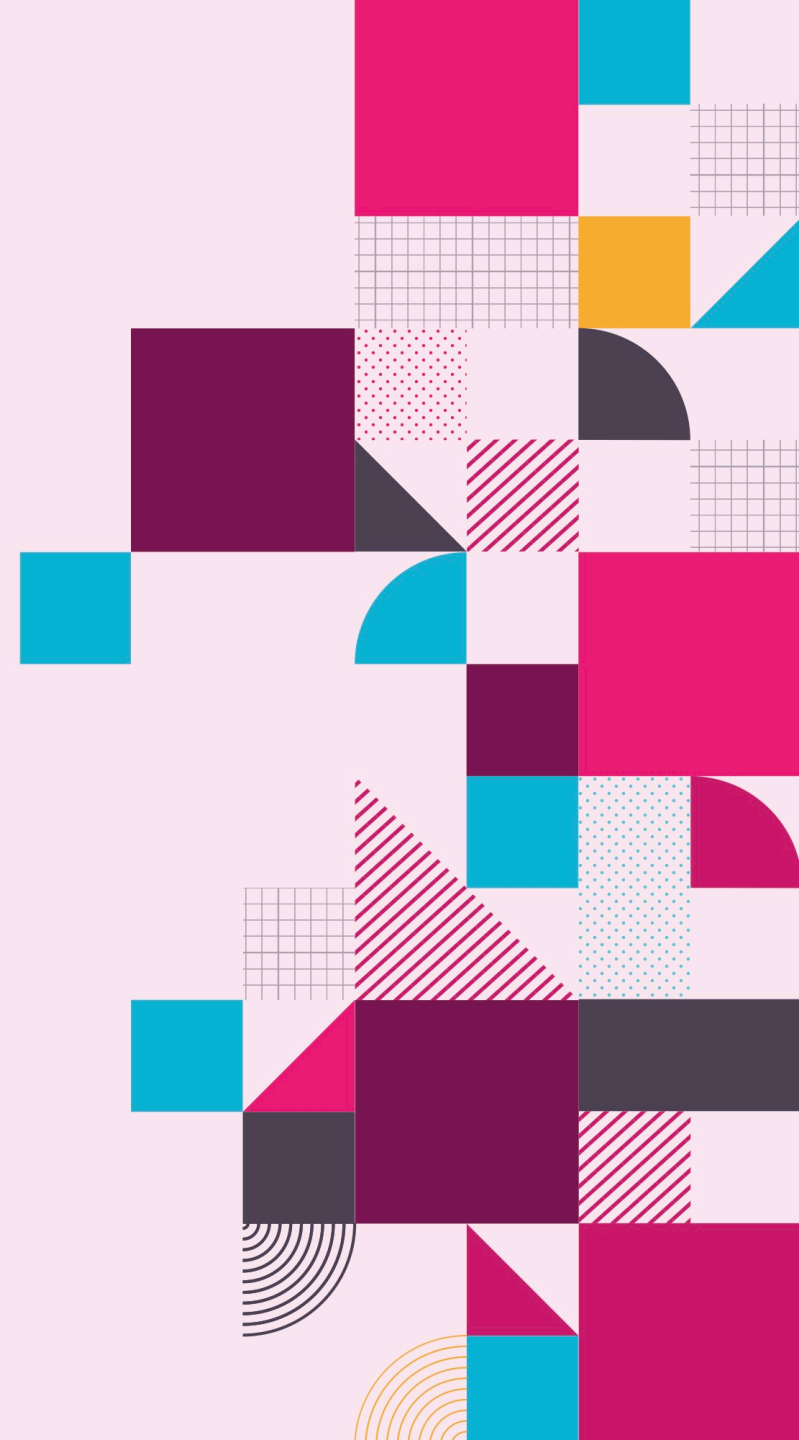
### The «Bad» and the «Ugly»

- Specialized role for designing the Library templates and dedicated role to develop the output which should have a combination of clinical experience and logic/programming skill
- Even if data can be standardized, some standard outputs need to be modified to meet non-standard studies:
  - for example, AE reporting period is often ICF through EOT +30 days and that can define the standard, but some studies may consider AE reporting period from Enrollment to EOS
- Need of custom outputs according to the study requirement and risk assessments
- Need to define feedback process and maintenance process to ensure that outputs continue to meet user needs resulting in a need of ongoing investment for full value
- Training efforts to ensure end user alignment in the streamlined data review activity



# The Goal is to transform data into information, and information into insight

- Carly Fiorina -





Arianna Galli,  
*[galliarrianna@prahs.com](mailto:galliarrianna@prahs.com)*

Angela Geiger,  
*[geigerangela@prahs.com](mailto:geigerangela@prahs.com)*