



From Roadblocks to Roadmaps: Overcoming Challenges in Registry Data Reporting

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Give me **six** hours to chop down a tree and I will spend the **first four** sharpening the axe.

- Abraham Lincoln

Registries

Real World Data



New gold standard for real world data



Observational studies

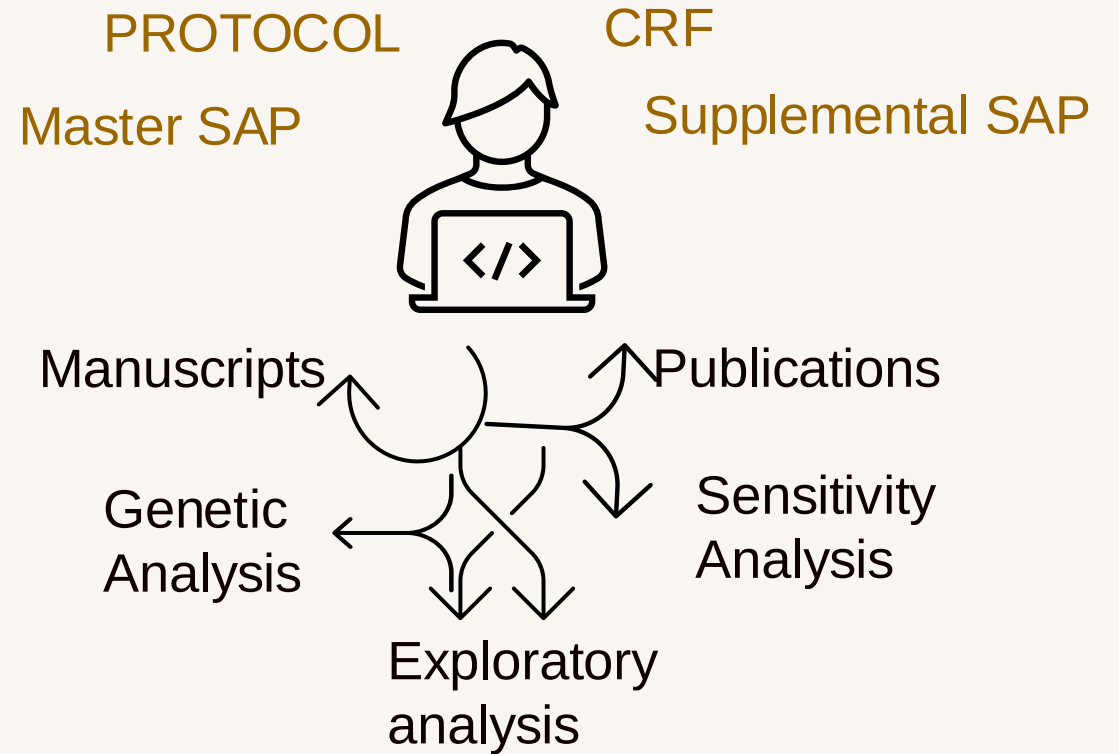


Used for broad range of purpose



Dearth of Guidance

RAW DATA



Optimizing Reporting with a Structured Folder Approach

Data Organization

RAW Data → Analysis Datasets → TLFs

Common
variables

RAW Data → **Global Datasets** → Analysis Datasets → TLFs

Macros

RAW Data → Global Datasets → Analysis Datasets → TLFs

Reusing variables
across analyses

Macros

RAW Data → **Structured RAW Data** → Global Datasets → Analysis Datasets → TLFs

Change in RAW Data - CRF updates/Protocol Amendments

Standards are the Wheel, Don't Reinvent!

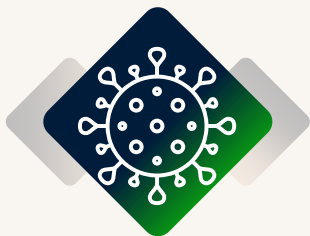
CDISC Guidelines



Structured Raw
Datasets
mapped as per
SDTMIG



Global Datasets
and Analysis
Datasets to be
designed as per
ADaMIG



Disease specific
data to be mapped
as per TAUG



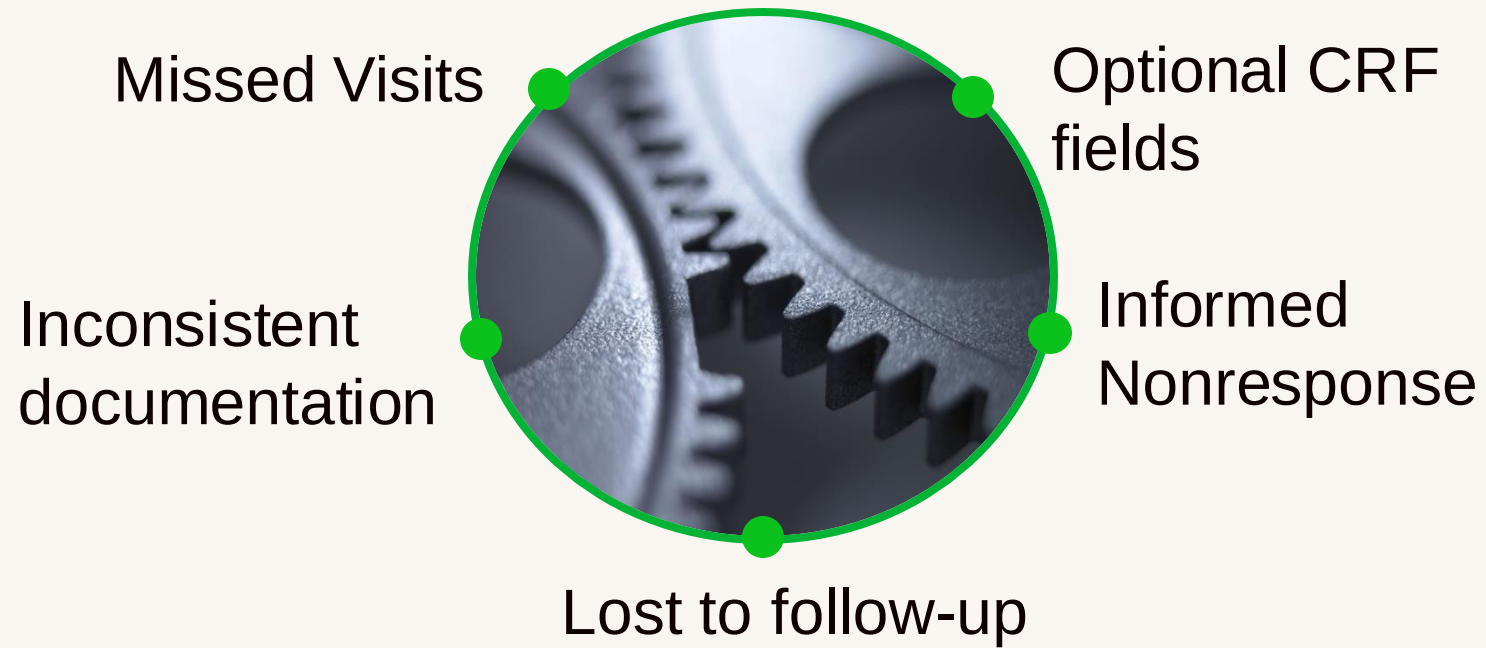
Genetic
testing data
based on
SDTMIG-PGx



Custom
Domains
using the
standard
variable
naming
conventions

The SAGA of Missing Data

Observational = Not Mandatory



The SAGA of Missing Data

Identify Critical Core variables

Minimum set of data expected for a patient to be included in the registry and eligible for analysis

Variables important for analyses of safety and effectiveness

Should be actionable and measurable

Critical Core Variables are prioritized for data entry, cleaning and reporting



The SAGA of Missing Data

Data Completeness

- A tool to evaluate the completeness of data from Registry CRFs
- The report shows CRF completeness of Critical Core Variables by providing metrics (percentages) of data completeness globally, by country, and by site
- Considers all data fields marked as Unknown, Not Done and Not Available and uses CRF-based time periods
- Findings shared with sites thereby improving data quality

- The patient has result available at time point of interest
- The patient does not have result, and site has indicated that response is “No” “Unknown” or “Not Done”
- **The patient does not have result, and site has not indicated that result is “No” “Unknown” or “Not Done”**

Data Completeness may identify issues with a particular site, such as high rates of missing data or loss to follow-up for certain sites

Adding consistency checks. e.g., a “yes” answer to a question at one point and “no” to the same question at another.

Checks for out-of-range data were also added (e.g., a 150-year-old patient and a pediatric patient with future date of birth)

The SAGA of Missing Data

Data Availability

- Availability of data from Registry CRFs that can be used in the analyses
- It is based on standard analysis datasets, accounts only for analyzable results, and uses defined analysis periods.
- It shows data available for analyses, aggregated by treatment, age groups or other subgroups of interest.
- This report excludes data marked as 'Not Done', 'Unknown', 'Not Available', as well as outlier results, and it uses date-based period definitions and analysis time windows.



Reviewers get a preview of data aiding in decision making on the appropriate time and content of the analyses



Reduction in change requests thereby decreasing the reporting time and unnecessary delays from the programming team

The Final Piece

UNDERSTANDING YOUR CONTRIBUTION

No single end goal in sight

Multiple analyses of varied nature

Plethora of ad-hoc requests



Communicate the overall goals and milestones of registry projects to the programmers

Share links to published materials and encourage team members to seek out published results related to their work.

Programmers should connect their efforts to the big picture.

Seeking the end result of analyses provides them with a sense of purpose and satisfaction as they see the impact of their contributions in published journals and other sources.

Conclusion



"It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change."

- Charles Darwin

THANK YOU!

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