# Understanding SDTM: Demographics and Adverse Events Domain Analysis

# Introduction

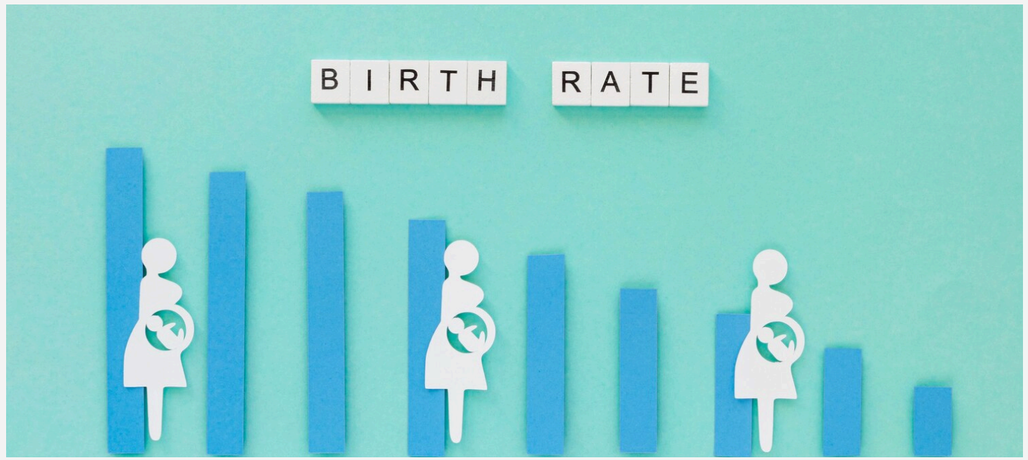
This presentation provides an in-depth analysis of **SDTM** in the context of *Demographics* and *Adverse Events* domains. It aims to enhance understanding and application of SDTM standards in clinical research.

# SDTM Overview

The **Study Data Tabulation Model** (**SDTM**) is a standard for organizing and formatting data to streamline regulatory submission. It ensures consistent data structure and facilitates data review and analysis.

# DEMOGRAPHICS DOMAIN

The *Demographics* domain in SDTM captures essential subject characteristics such as age, gender, and race. It provides a comprehensive overview of the study population.



# Adverse Events Domain

The *Adverse Events* domain in SDTM records details of adverse events experienced by subjects during the study. It includes information on the event, severity, and relationship to the study drug.

# DATA ANALYSIS CONSIDERATIONS

When analyzing **Demographics** and **Adverse Events** domains, it is crucial to ensure data quality, consistency, and compliance with SDTM standards. Proper mapping and validation are essential.


# Interpretation and Reporting

Interpreting and reporting data from the *Demographics* and *Adverse Events* domains requires attention to detail and adherence to SDTM guidelines. Accurate reporting is vital for regulatory submissions.

# Best Practices

Implementing best practices for SDTM data collection, transformation, and analysis ensures efficient regulatory submission and compliance. It involves thorough documentation and validation processes.

# CONCLUSION

This presentation has provided a comprehensive understanding of SDTM, particularly in the context of *Demographics* and *Adverse Events* domains. Adhering to SDTM standards is essential for successful clinical research.

# Thanks!

**ANY QUESTIONS?**

youremail@freepik.com
+91 620 421 838
yourwebsite.com