

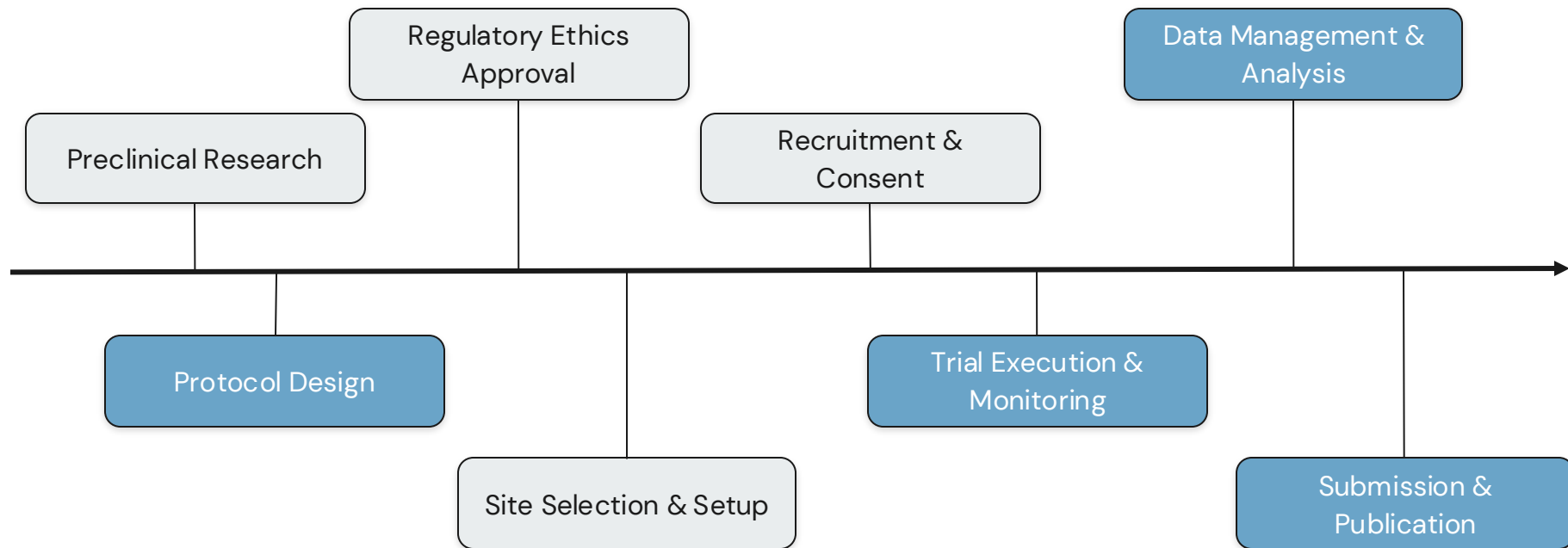
Data, Decisions, and Drug Development: A Statistical Programmer's Contribution

PHUSE SDE, Denver (CO), US

May 9, 2025

Rafik Ghazaryan
CEO, BioBrain PRO

Clinical Trial



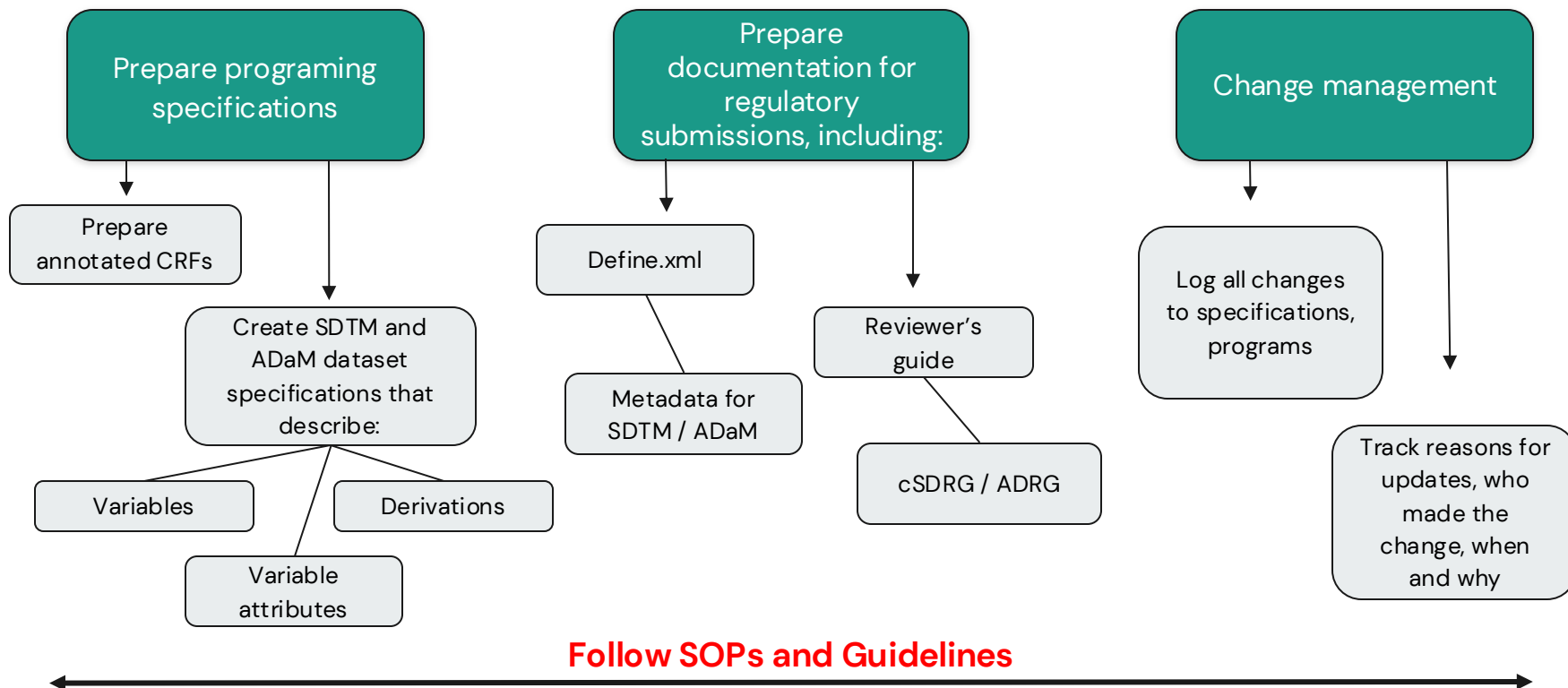
Programming

- **Create datasets according to the CDISC standards**
 - a. SDTM Dataset which include
 - i. Data collected on CRFs at Sites
 - ii. Vendor data
 - iii. Adjudicated Data
 - b. ADaM datasets
 - i. The source is SDTM datasets
 - ii. Includes additional Derived Data
- **Implement statistical methodologies defined in the SAP**
 - a. Create Tables, Listings and Figures
 - b. Ad-hoc analysis
 - c. Other graphical and tabular displays
 - i. Patient profiles
 - ii. Safety reports
 - iii. Data listings

Validation



Documentation



Automation



1. Streamline repetitive tasks (e.g., auto-generation of outputs)
2. Build tools for automated data quality checks, report generation
3. Reduce manual errors
4. Implement end-to-end pipelines from data to reporting



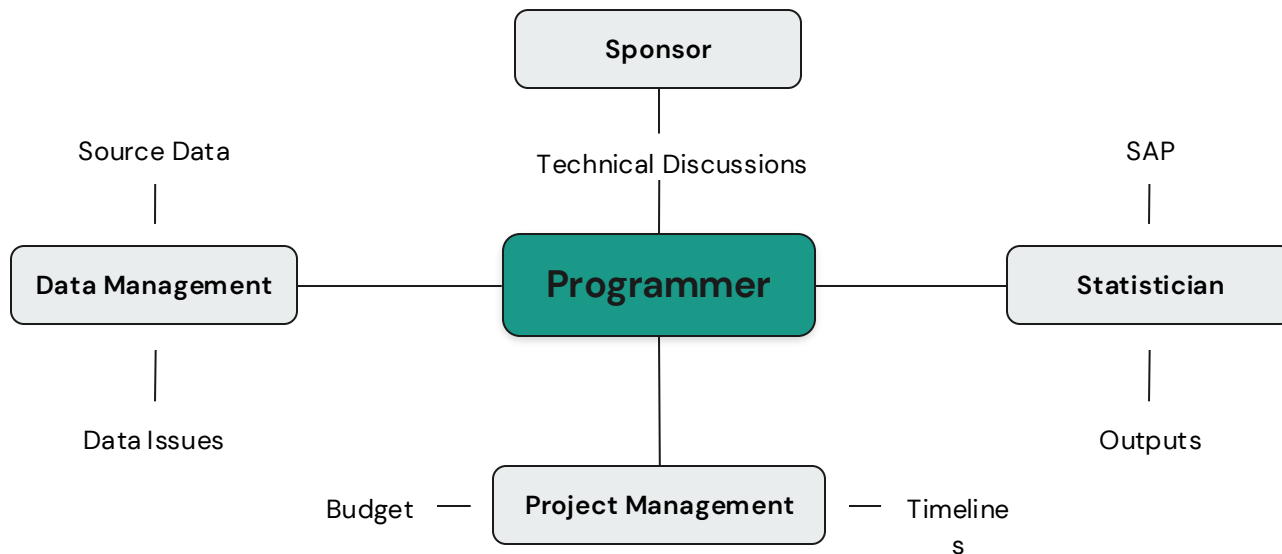
Innovation



1. Explore emerging technologies (e.g., R shiny, Python dashboards, AI integration)
 - a. R Shiny
 - b. Python dashboards
 - c. AI integration
2. Build Custom Tools
 - a. Internal aps or macro libraries
 - b. Develop automated QC checkers
 - c. Traceability visualizers
3. Broaden Technical Stack
 - a. Pinnacle 21 API
 - b. OpenCDISC scripts
4. Engage with the Community
 - a. Join Phuse, CDISC, LinkedIn forums, or GitHub open-source projects
 - b. Present at events or write blog posts to share ideas

Communication

- Support responses to regulatory queries with technical clarity
- Present programming approaches and results to cross-functional teams
- Translate statistical requirements into actionable code



Tools



Statistical Systems

Commercial Software for advanced analysis
Data lives in SAS Datasets
Graphical Interface and programming language

Data steps for data manipulation
Procedures for analysis
Macros for reusable code
Built in SAS functions



Programming Languages

Open-source language
Data lives in Objects
Programming Interface

Function-based expressions for data transformation
Function calls with customizable parameters
User defined functions and packages
R functions from base R and packages



Career Growth

1. Entry-Level Programmer

- a. SAS, CDISC standards
- b. Works under supervision
- c. Takes well defined tasks

2. Statistical Programmer

- a. Participating in study team meetings
- b. Understanding statistical analysis plans

3. Senior Statistical Programmer

- a. Leads programming efforts
- b. Review deliverables,
- c. Mentor juniors
- d. Ensure compliance with regulatory requirements
- e. Timeline management and client interactions

4. Managerial roles

Career Growth



Growth enables

Certifications & Training: CDISC certifications, SAS Advanced Programmer, GCP training.

Conferences & Communities: PHUSE, PharmaSUG, CDISC Interchange—platforms to learn, present, and network.

Mentorship: Learning from senior programmers or mentoring juniors enhances leadership and technical skills.

Soft Skills: Communication, problem-solving, and adaptability are crucial for stepping into leadership roles.

As the industry shifts toward AI/ML, real-world evidence, and automation, programmers who embrace cross-functional skills and innovation are well-positioned for exciting opportunities in data science, regulatory strategy, or even hybrid programmer–statistician roles.

And in the end...



During the
Day / Night



Thank you!

