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Clinical Trials in Drug Development – From a Statistical Programmer's Point of View

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Agenda

- **What is a clinical trial?**
- **How does the data flow through a clinical trial?**
- **Roles and responsibilities of a statistical programmer.**

What Is a Clinical Trial

- **Research study to answer specific questions about a new therapy or new way of using known treatment**
 - **Determine if a drug is safe and effective in humans**
 - **Determine at what doses the drug works best**

Clinical Trial Phases

- Phase I
- Phase II
- Phase III
- Phase IV
- Phase 0

Clinical Trial Phases (Phase I)

- Test a new drug or a treatment in a small group (20-80) for the first time.
- Evaluate Safety
- Dose escalation
- Healthy volunteers for most studies
- Several months in duration

Clinical Trial Phases (Phase II)

- Includes controlled clinical studies
- Evaluate effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and
- Determines the common short-term side effects and risks associated with the drug
- In a relatively small number of patients (no more than several hundred)

Clinical Trial Phases (Phase III)

- Expanded controlled and uncontrolled studies
- Intend to gather additional information about effectiveness and safety after preliminary evidence of effectiveness
- Usually include from several hundred to several thousand patients

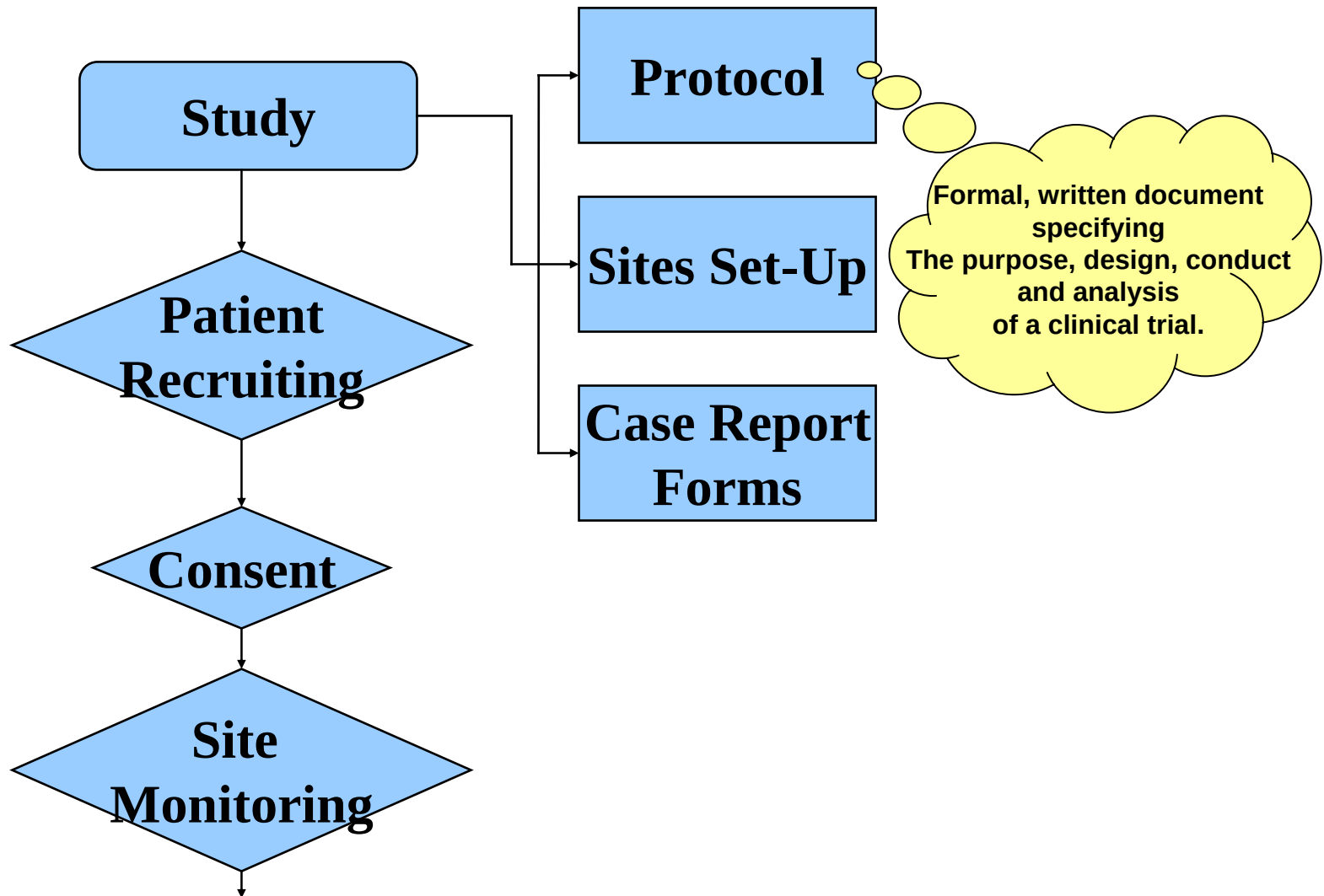
Clinical Trial Phases (Phase IV)

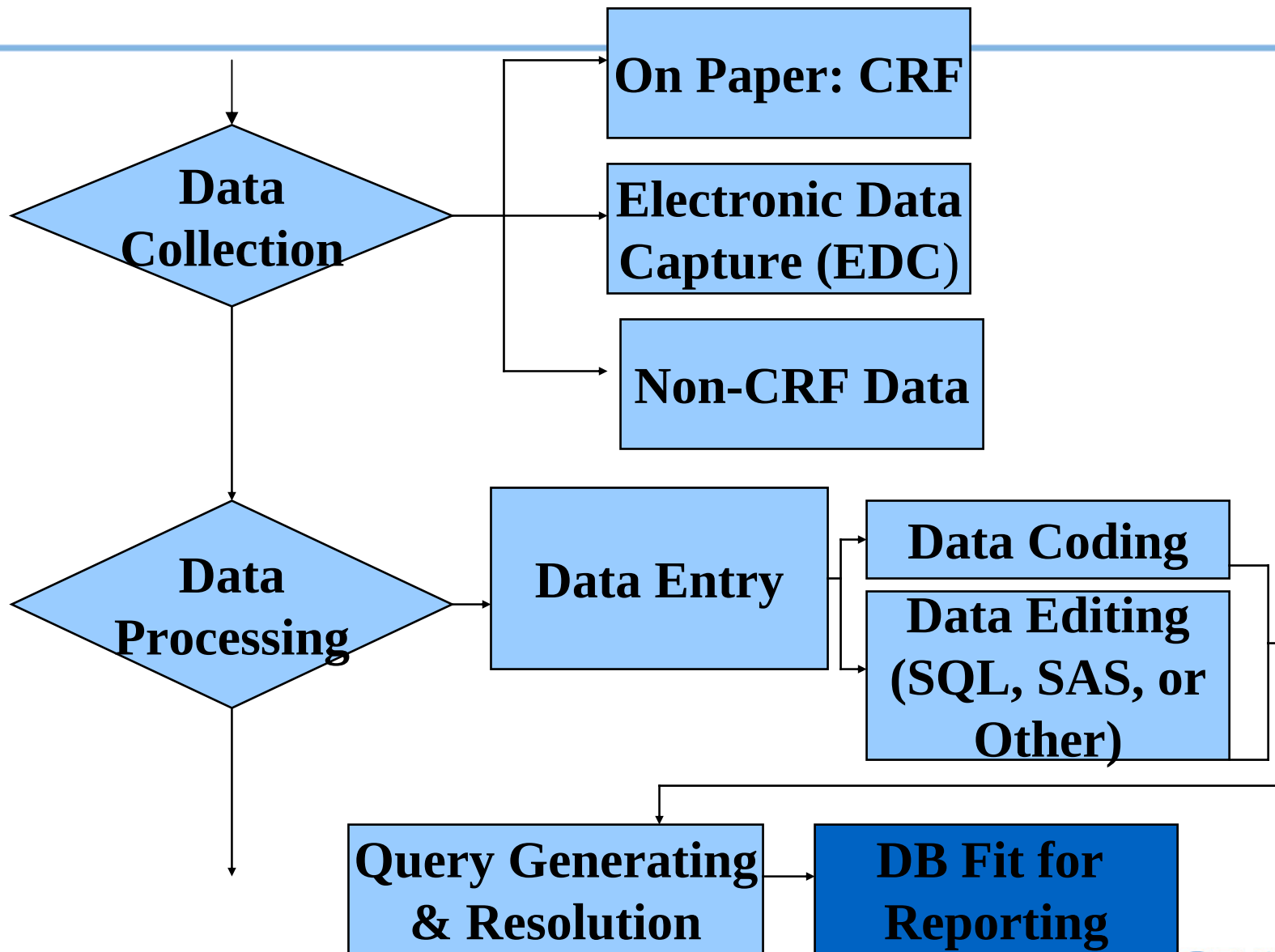
- After New drug Application (NDA) is submitted to FDA
- After drug or treatment has been marketed
- Continue collecting efficacy information and long term safety information.
- Also called post-marketing studies

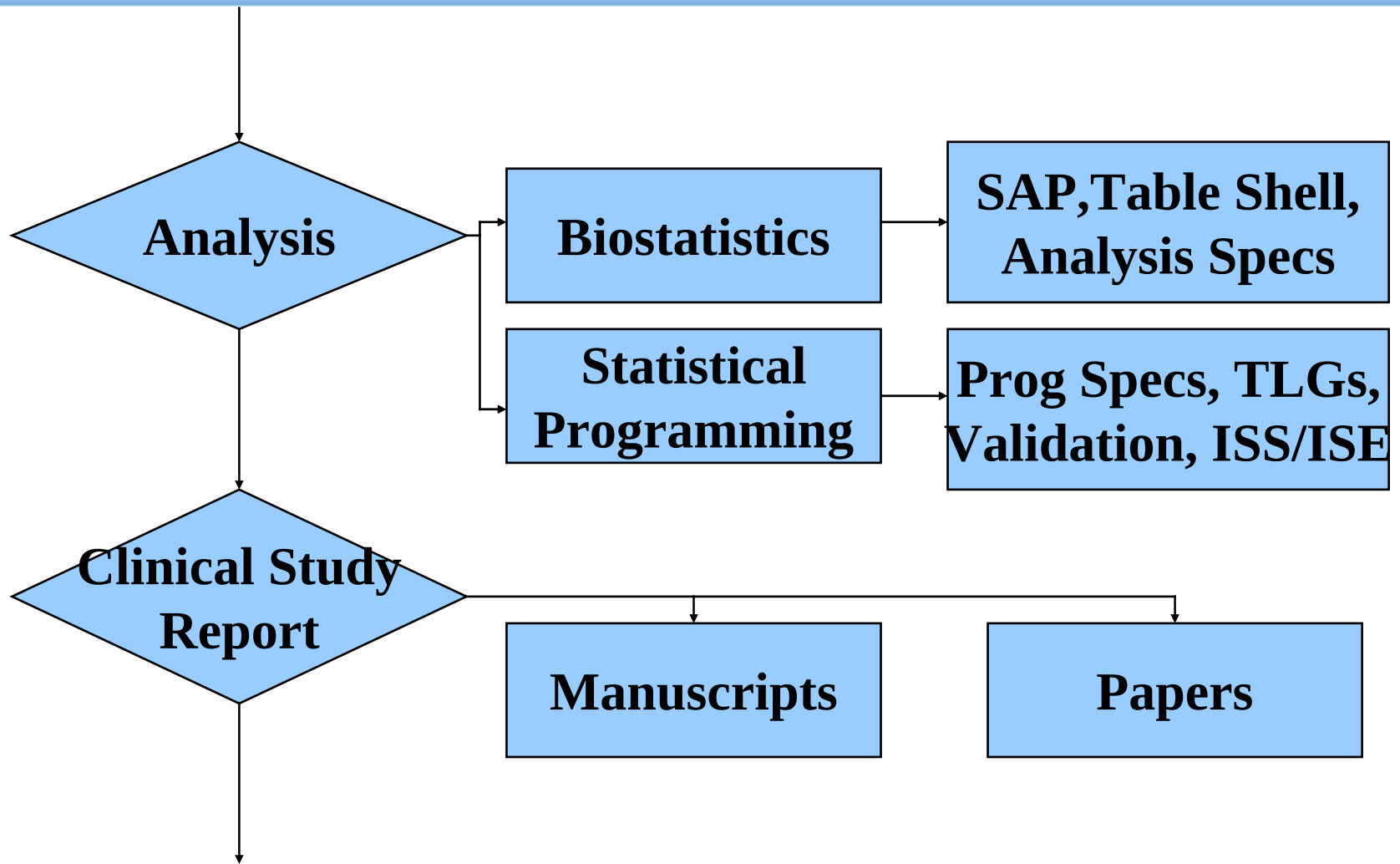
Clinical Trial Phases (Phase 0)

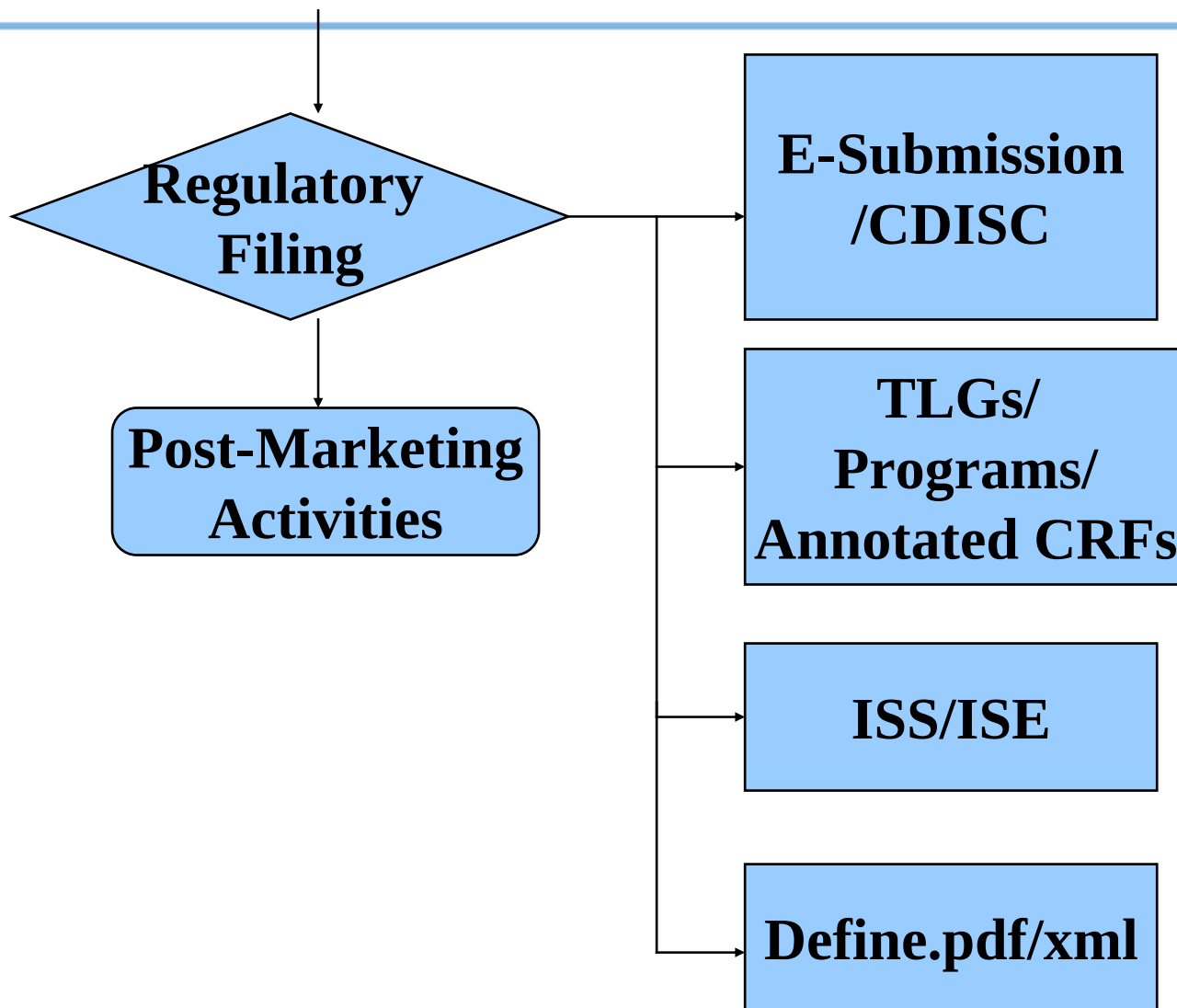
- Does not involve any study drugs
- May involve known treatment already on the market
- Understand disease and patient behavior, social-economic outcome of patient population

How does data flow through a clinical trial



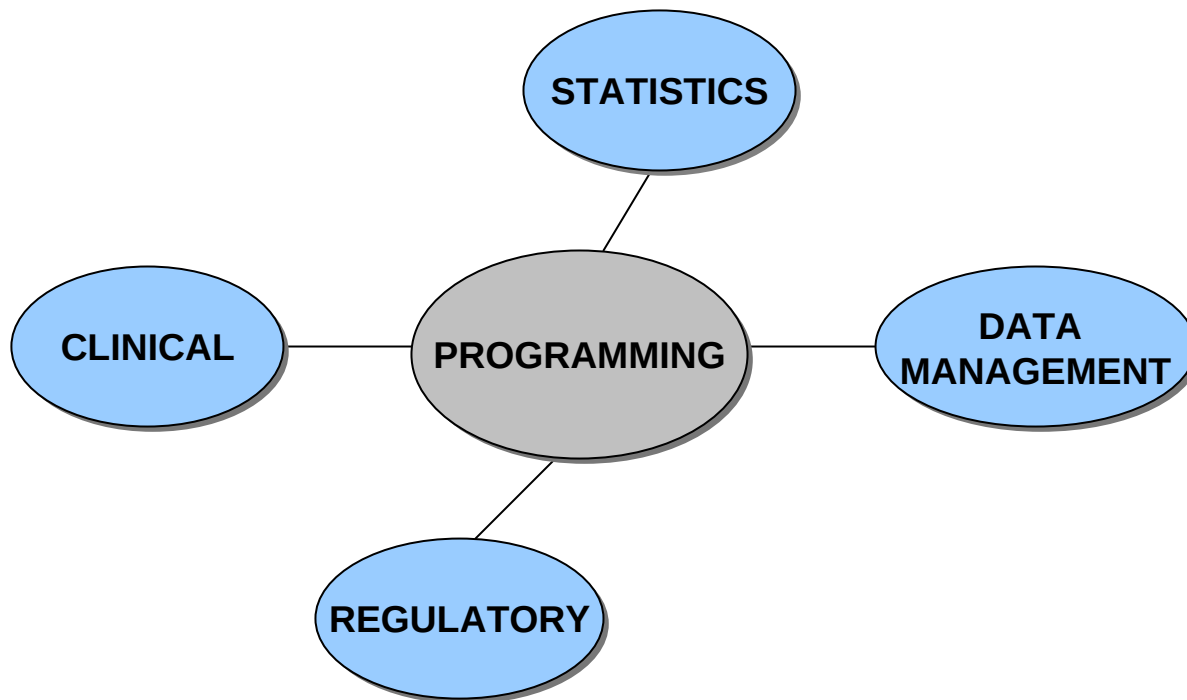






Roles and Responsibilities of a Statistical Programmer

Functional Relationships



Relationship of Functional Areas

- **Our Customers**
 - Statisticians
 - Clinical Department
 - Regulatory
 - Medical Writers
 - Etc
- **Our Suppliers**
 - Data Management
 - Clinical Programming
 - Clinical Data Analyst
 - Statisticians
 - Etc

Statistical Analysis

- **Statisticians Write Statistical Analysis Plans (SAPs)**
- **SAP Drives**
 - **Requirement Documents**
 - Table Shells and Annotated Table Shells
 - Data Definition Tables
 - Statistical Programming Plans
 - **Planned Analysis Package**
 - Analysis Datasets, Tables, Listings and Graphs (TLGs)
 - **Validation Plans**
 - Validation programs
 - Validation Documents
- **Ad-Hocs**

Thank You

- **Contact Info**

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