



Pioneering science delivers vital medicines™

Challenges Facing the Programmer in Observational Research

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Agenda

- Background
- Introduction
- Types of Observational Research (OR) Study
- Data Format and Collection
- The Changing Environment
- Compliance to Standards
- Conclusion

Background

- Developing new drugs is getting harder
- OR becoming increasingly important
- Evidence regarding
 - Disease
 - Costs
 - Utilization patterns
 - Real world data (safety and effectiveness)

Background (cont ..)

- Demand from Regulatory Agencies
 - Pharmacovigilance
 - Risk/Benefit
- Demand from Reimbursement Authorities
 - Health Technology Assessments
 - Comparative effectiveness

Introduction

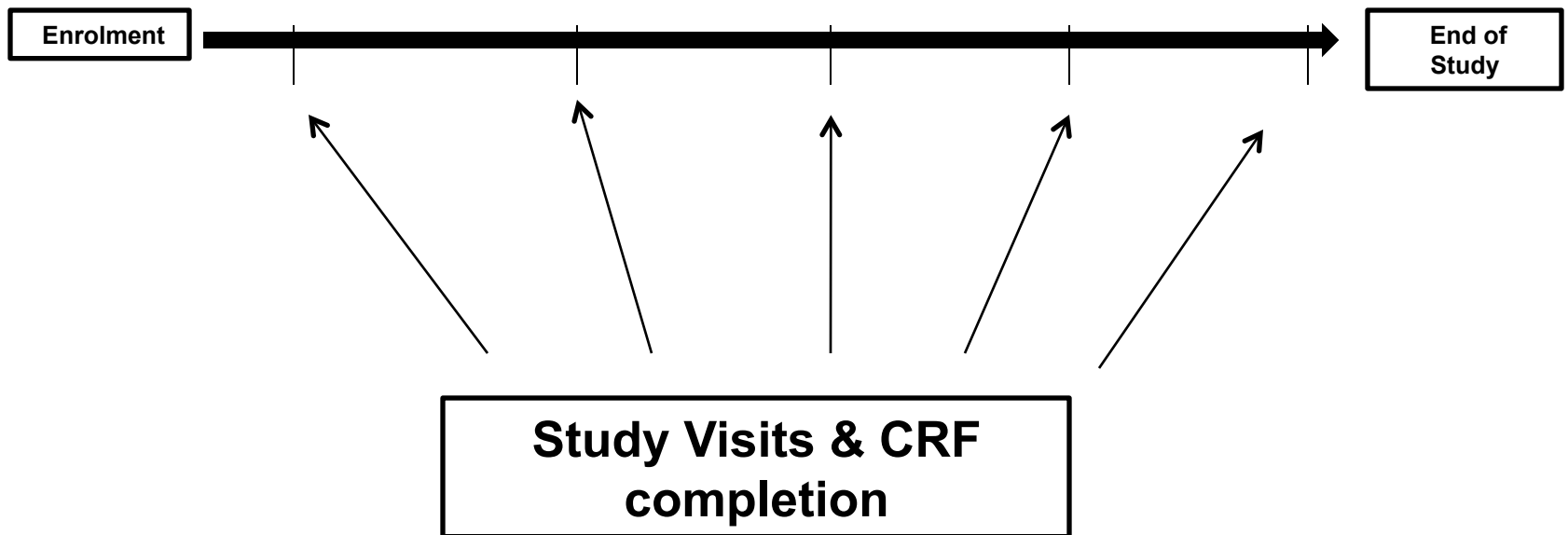
- How are Statistical Programmers affected?
 - Familiarity with phases I-IV
 - Different study designs
 - Challenges

Types of Observational Study

- Many Types
- Reasons for Choice
 - Data required
 - Practical aspects of data collection
 - Timelines
- Schedule of assessments vs Routine clinical care
- Prospective vs Retrospective

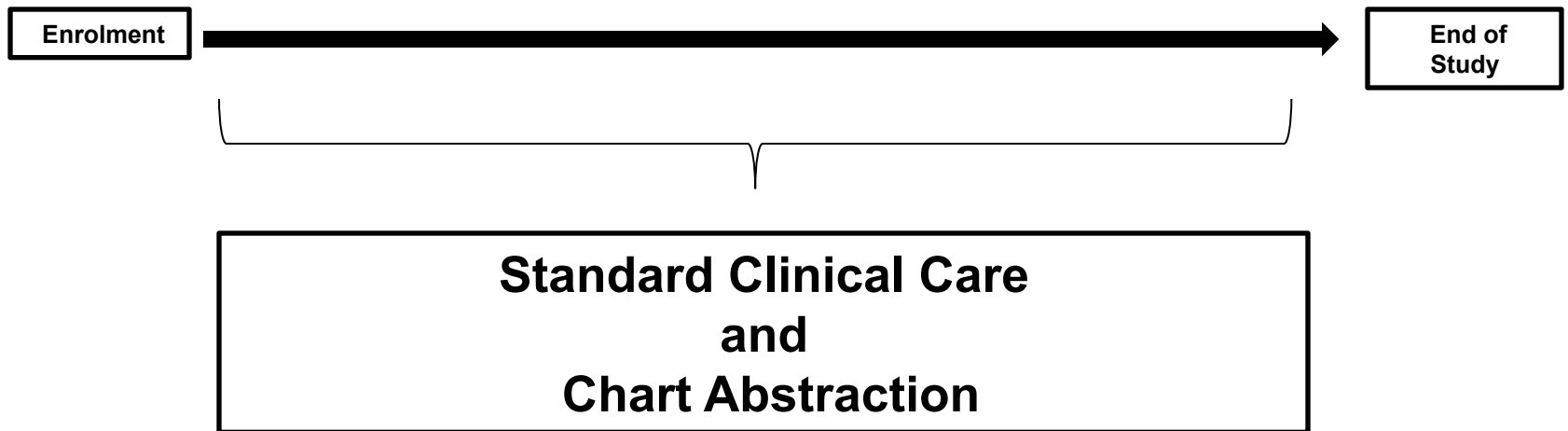
Prospective Studies

- Registries (Longitudinal Cohort Studies)



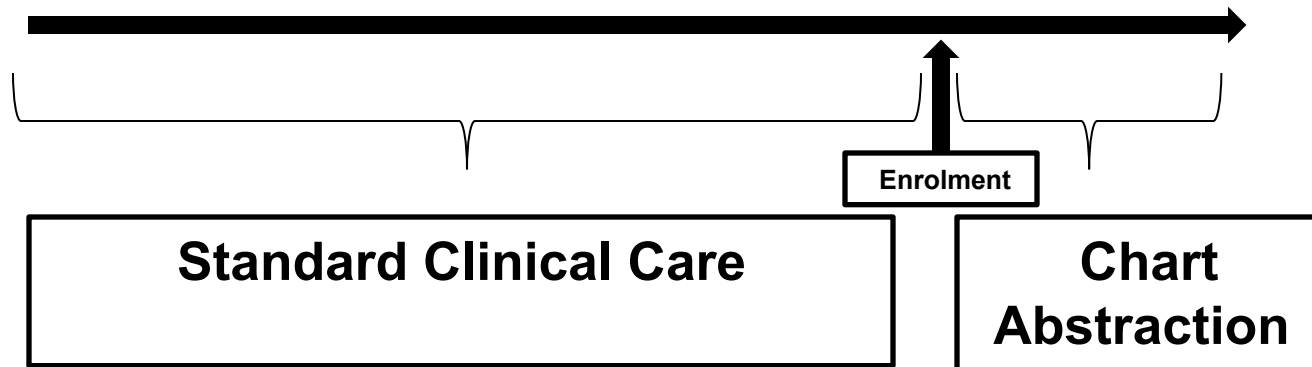
Prospective Studies (cont ..)

- Prospective Chart Reviews



Retrospective Studies

- Retrospective Chart Reviews



- Retrospective Database Analysis

Data Format and Collection

- (e)CRF data
- Adjudication data
- PRO data
- Spreadsheet data
- Adding value

Data Quality

- Completeness of data
- Cleanliness of data
- Rate of incoming data
- Database analysis

Coding Techniques

- Efficient coding
 - Generally desirable
 - Not usually critical in clinical trials
 - May become more important in OR
- Techniques (in SAS) include
 - Avoiding PROC SORT's where possible
 - Using 'WHERE' instead of 'IF'
 - Creating Indexes
 - Testing programs using a subset of data

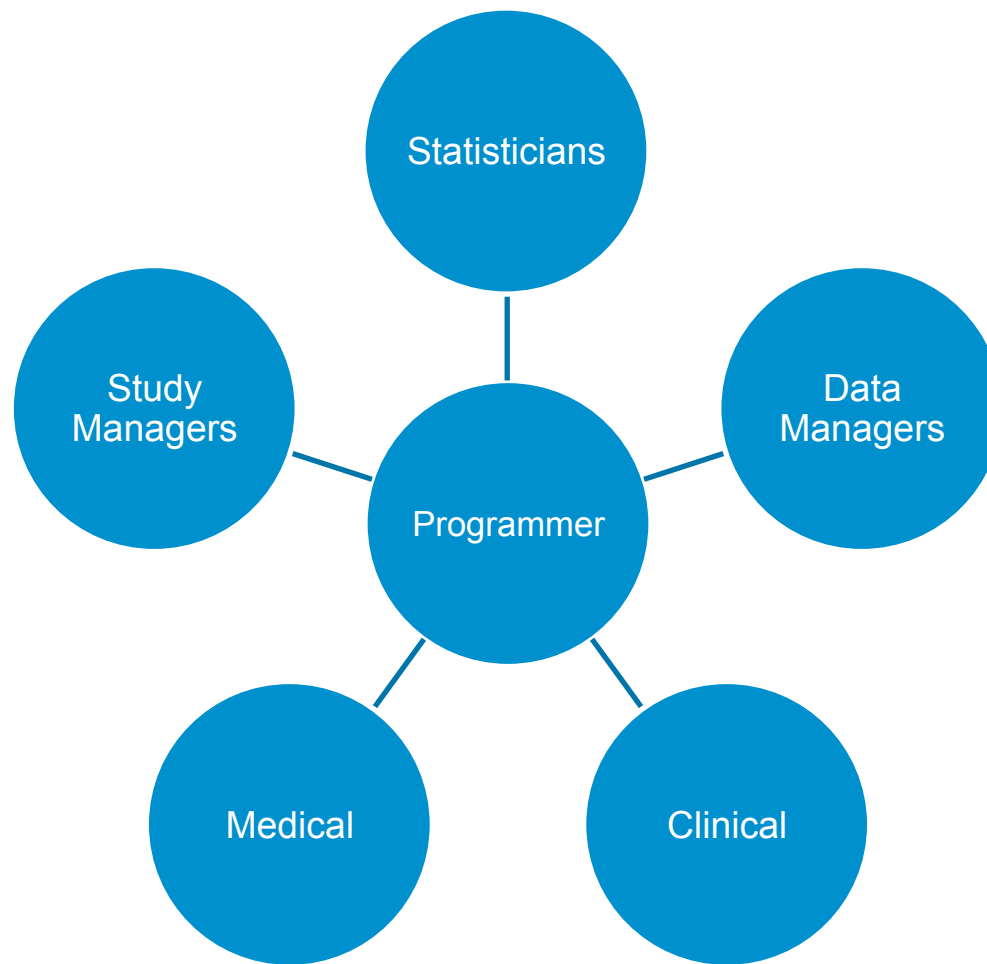
The Changing Environment

- Goals and Objectives
- Evolution of ideas during study
- Pre-specification / ad-hoc work
- Programming team may need to work differently
 - Planning vs Flexibility
 - Timelines and resourcing
 - Risks to quality

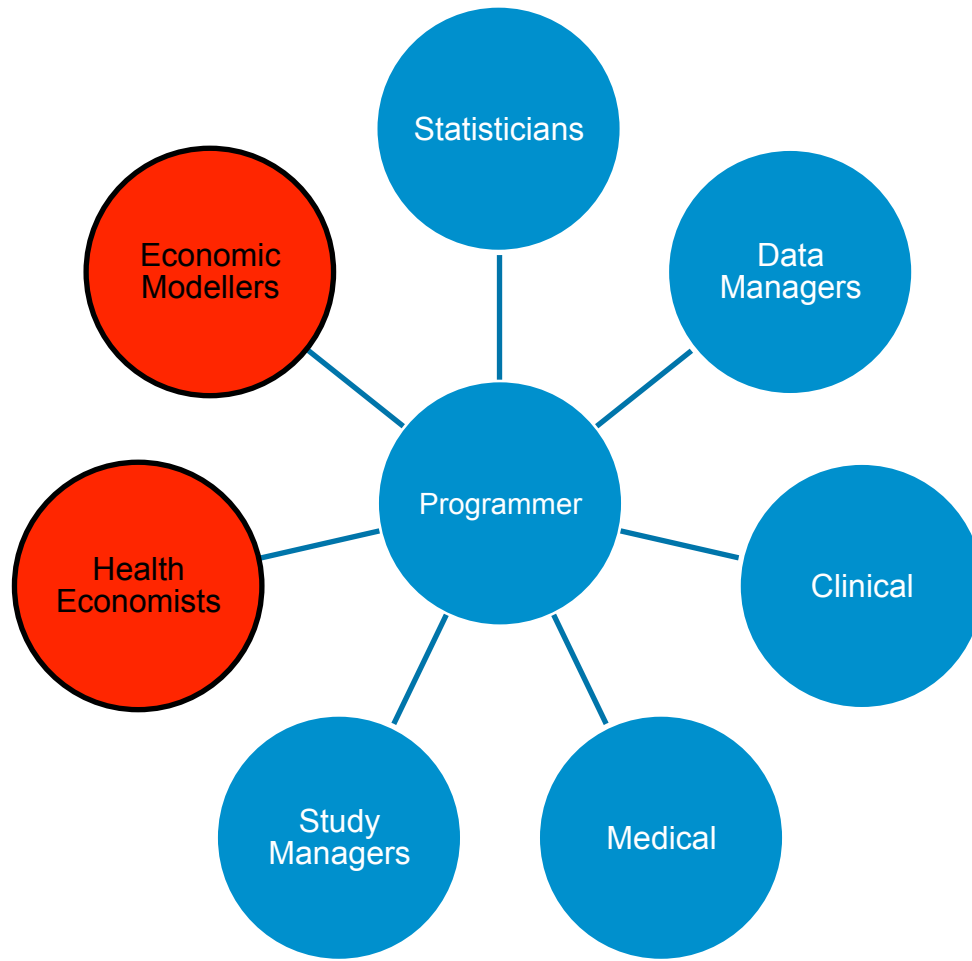
Use of Output

- Clinical Research
 - Derived Datasets/TFLs usually final deliverables
 - Clinical Study Report, Submission
- Observational Research
 - Derived Datasets/TFLs may be part of a process
 - Costings
 - Economic Modelling
 - Publications / Posters

Functional Interactions



Functional Interactions (cont ..)



Compliance to Standards

- SDTM
- ADaM
- Project Standards

Conclusions

- Increased demand for OR studies
- Presents new challenges for programmers
 - Knowledge
 - Study designs
 - Data considerations
 - Interactions
 - Flexibility
 - Project management
 - Technical
 - Communication

Questions

