

Resource Guide for the course on

Clinical Trials Data Analysis

using



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Course created and instructed by:
Aslam Khan

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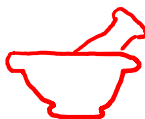
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Getting started with Clinical Trials



Molecule/ Compound



IND= Investigational New Drug



Approved Drug

- ☐ Components of the pharma industry
- ☐ Phases of Clinical Trials
- ☐ SAS as a tool for Data Analysis and Reporting
in Clinical Trials
- ☐ Types of data in Clinical Trials

Clinical Study Documents



Protocol



Informed
consent



Inclusion/
Exclusion
Criteria



Statistical Analysis Plan
(SAP)



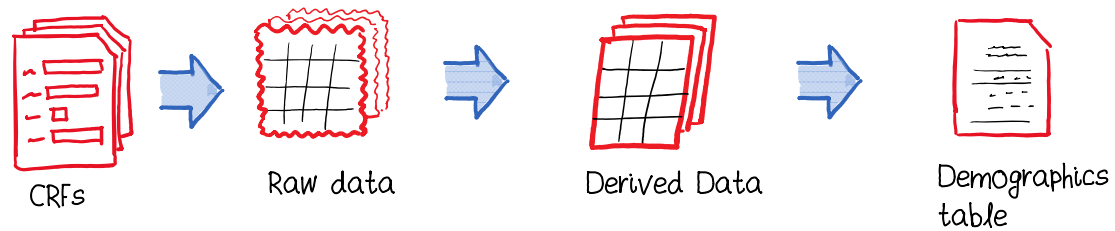
Mock shells



Case Report
Forms (CRF)

- ☐ Clinical Study Protocol
- ☐ Informed Consent
- ☐ Inclusion-Exclusion Criteria
- ☐ Mock Shells
- ☐ Case Report Form (CRF)

Building the Clinical Study Reports





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