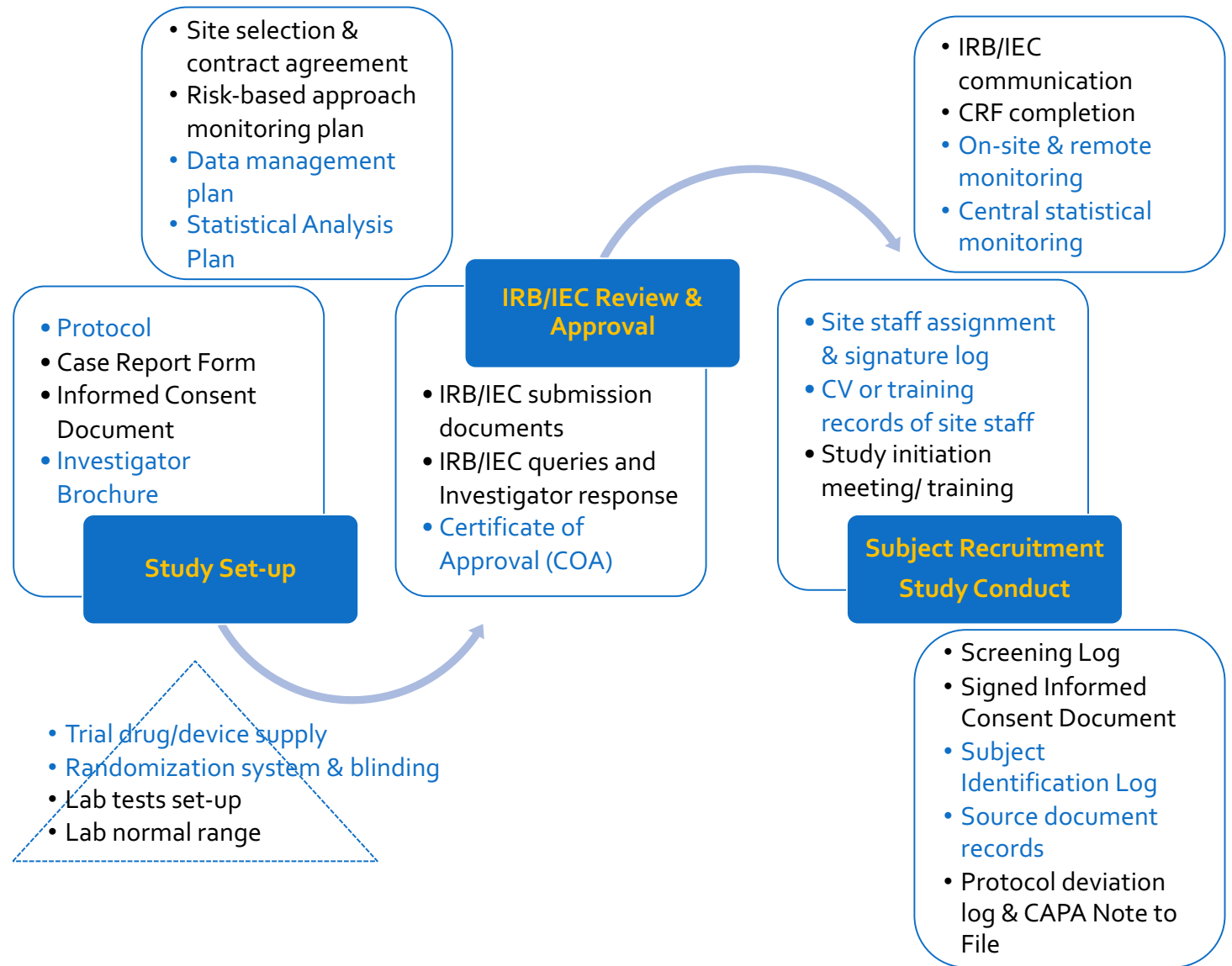


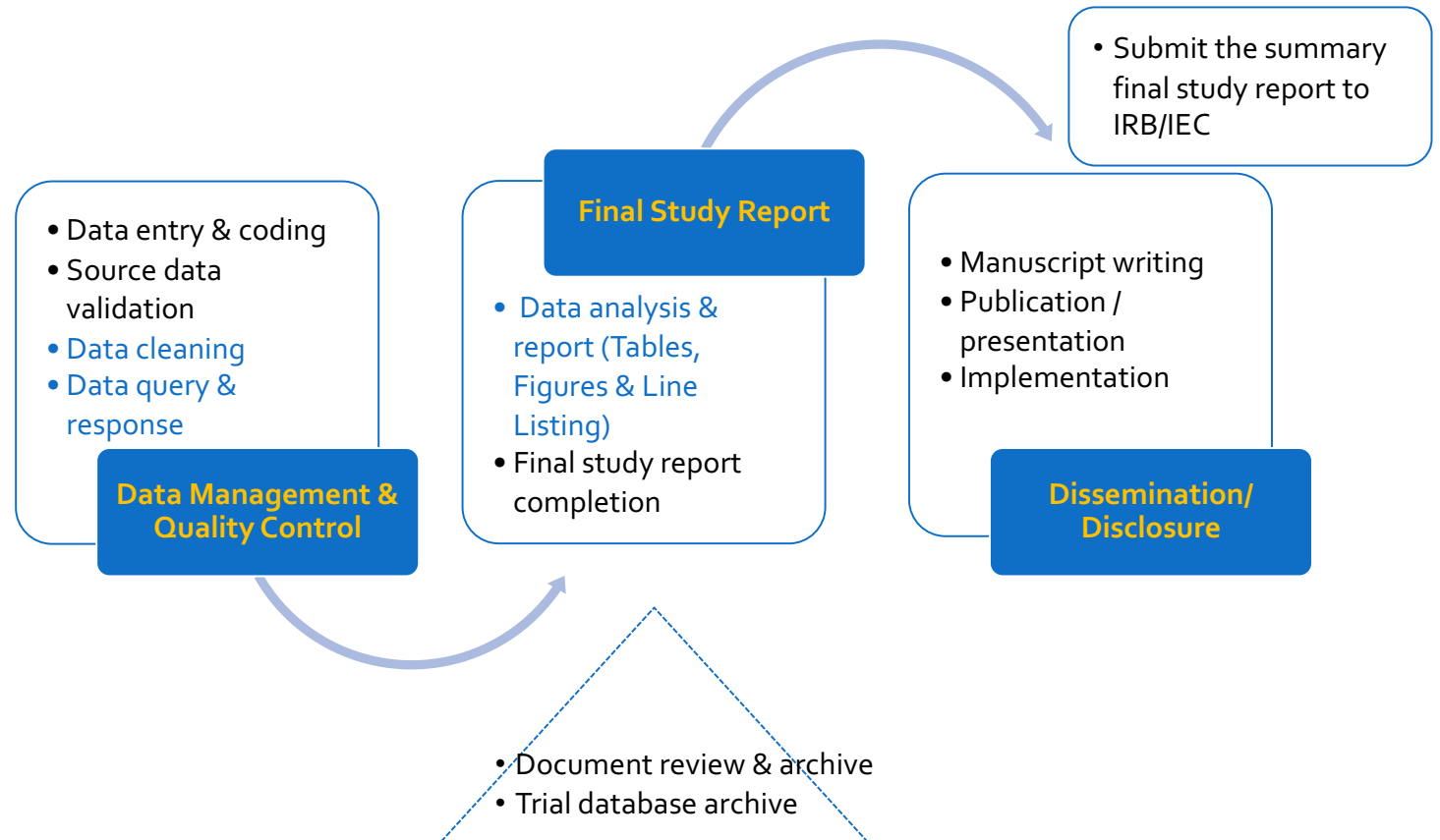
Essential Tools for Conducting a Clinical Trial

Pravich Tanyasittisuntorn, MD

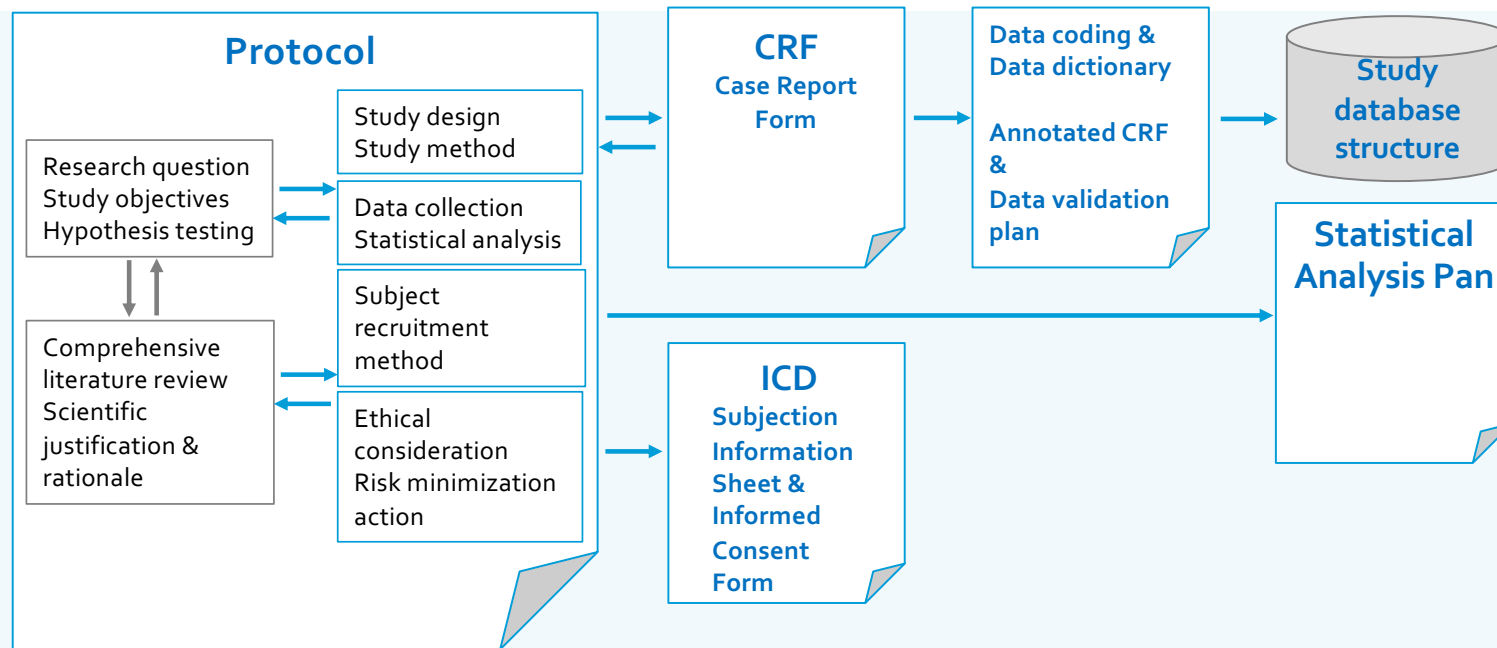
Essential Tools & Documents



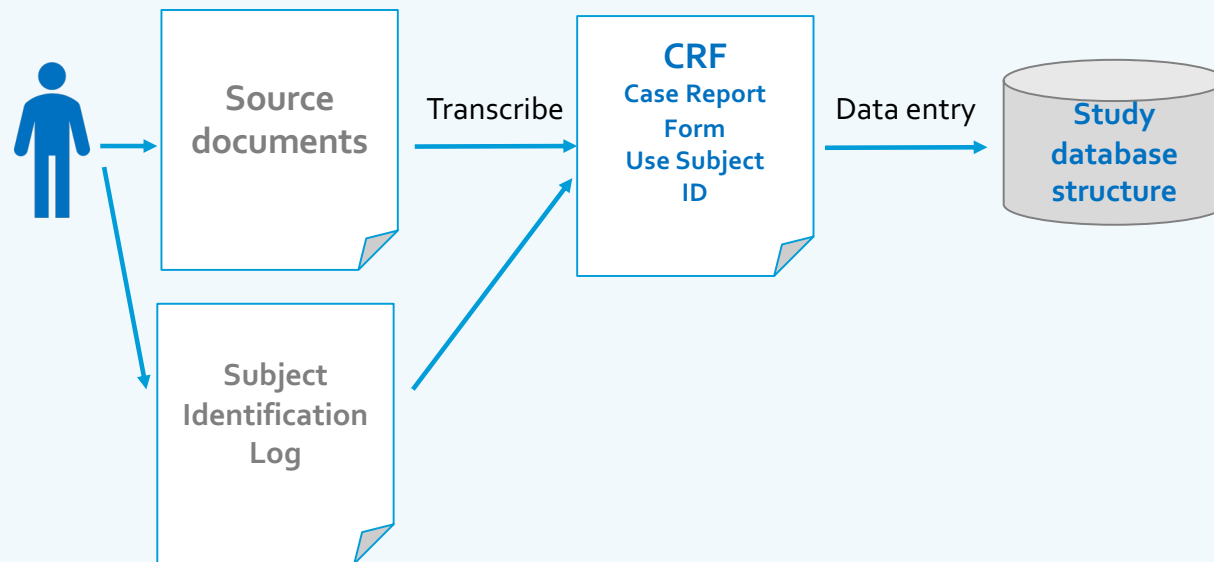
Essential Tools & Documents



Protocol (Clinical Investigation Plan)



Case Report Form & Source Document



Essential Document Filing & Archiving

- Trial master file
- Investigator file
- Available for audit and inspection
- How long to archive?
- Sponsor determine when to destroy