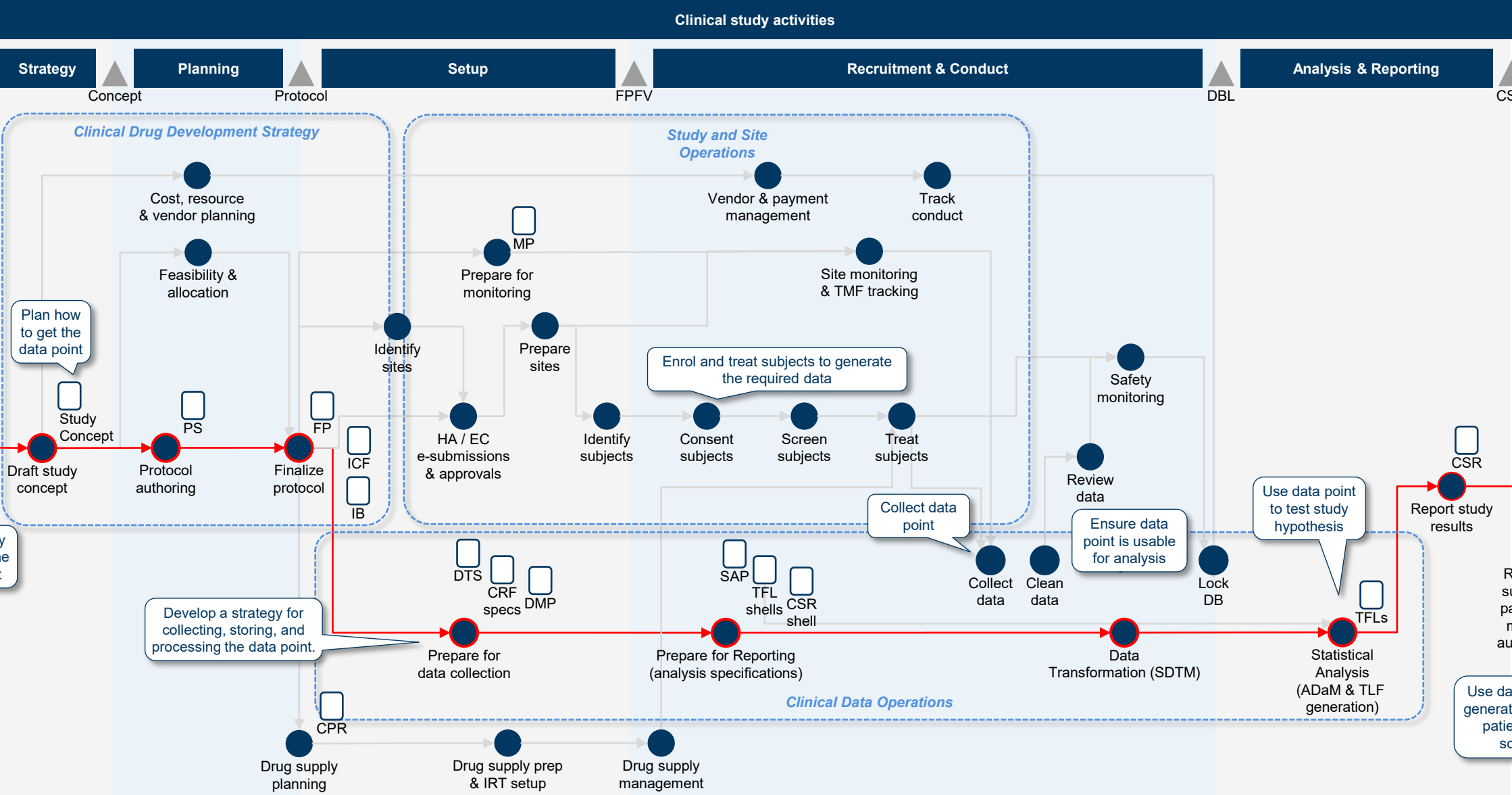


Interactions with Clinical Data Points Map



Legend:

- Key activities
- Key docs
- Lead Line function*

Abbreviations: ADaM = Analysis Data Model; CDP = Clinical Development Plan; CRF = Case Report Form; CSR = Clinical Study Report; DBL = Database Lock; DTS = Data Transfer Specifications; DMP = Data Management Plan; FP = Final Protocol; FPFV = First Participant First Visit; HA/EC = Health Authority/Ethics Committee; IB = Investigator Brochure; ICF = Informed Consent Form; MP = Monitoring Plan; PS = Protocol Summary; SAP = Statistical Analysis Plan; SDTM = Study Data Tabulation Module; TFLs = Tables, Figures, Listings; USDM = Unified Study Definitions Model