Blind Data Review in Clinical Trials

Abstract

Blind Data Review

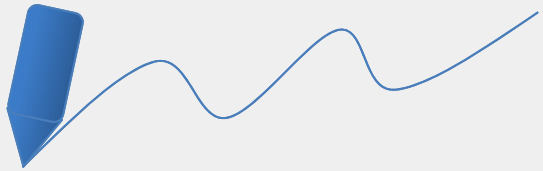
- an important procedure in clinical trials;
- help identify the issues, review protocol violations and examine explorative trends;
- from first patient visit to the breaking of blind.

How do **more efficiently**?

SEE OUR EXPERIENCE !

Previous hurdle

- Data checking process NOT clear
- TIME COST of data checking
- Data quality IMPACT
- Appropriateness of the design assumptions
- Worry efficacy trend
- Misunderstanding



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Check List

- Visit
  Missing
  AE
- Baseline Information
  Dose Compliance
  Disposition
- Outlier
  Efficacy
  Cross Check with Ref. Study

Merits

- Feasibility
- Template
- Automatic Check

Automatic SAS Codes Based on Macros

Output

Focus

- Data Quality Check
- Assumption Check
- Show Trend
- Protocol Violation

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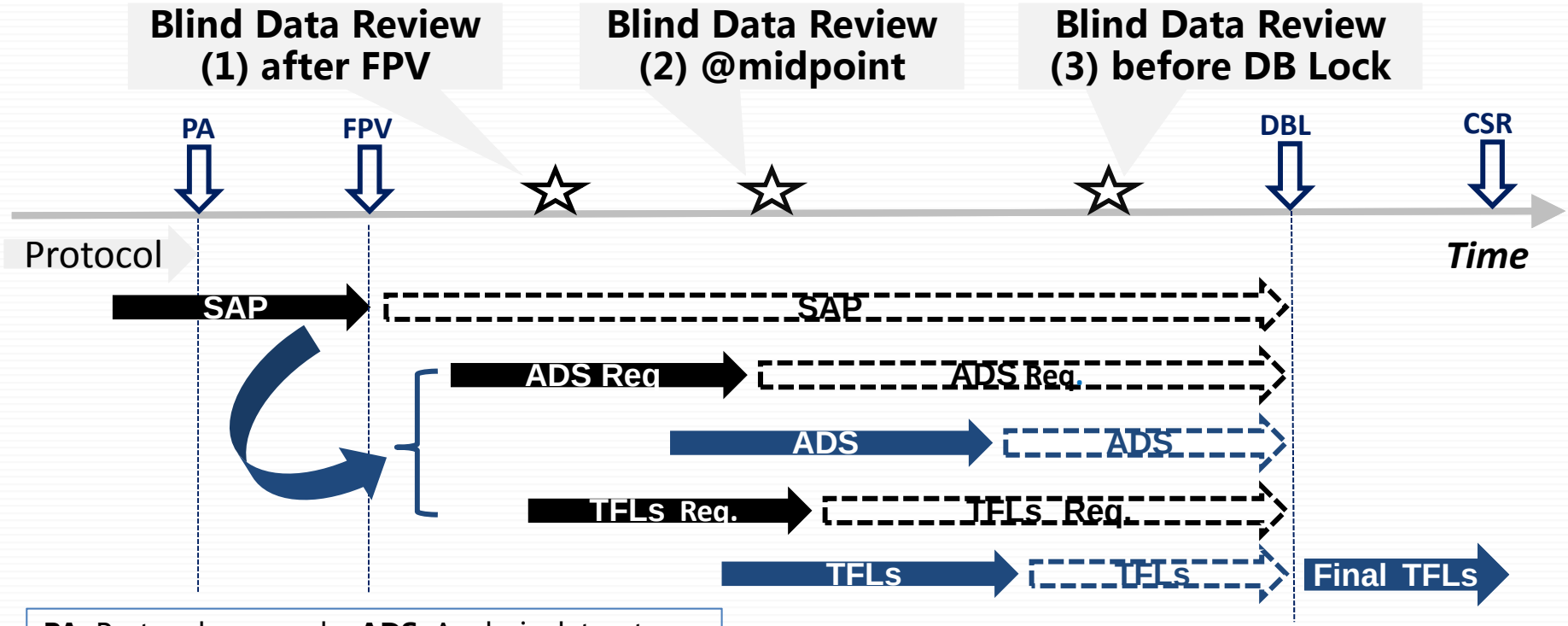
When we do?



PA: Protocol approval **ADS:** Analysis datasets
FPV: First patient visit **Req.:** Requirement

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Achievements

- Data checking process clear
- Reduce time cost
- Enhance data quality
- SAP update
- Similar trend
- Reduce misunderstanding

CDO: Clinical Data Officer
CTM: Clinical Trial Manager
SA: Statistical Analyst
PS: Project Statistician