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.

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

How do more efficiently?
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Blind Data Review in Clinical Trials

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?

Blind Data Review (1) after FPV

Blind Data Review (2) @midpoint

Blind Data Review (3) before DB Lock

Time

Protocol

PA
FPV

SAP

ADS Req

ADS

TFLs Req.

TFLs

Final TFLs

DBL

CSR

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

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