

Agenda: How to Improve Data Quality & Record Integrity in Your NDA, 510(k) or BLA

1. FDA Rules and Expectations

- 1.1. Pre-approval inspections (PAI) causes – data quality
- 1.2. Data quality questions asked of your submission – Preclinical / Nonclinical
- 1.3. Data quality questions asked of your submission – Clinical
- 1.4. What triggers an “inconsistency” in the mind of an FDA reviewer
- 1.5. Other considerations when collecting submission records
- 1.6. Warning letter excerpts
- 1.7. Agency enforcement options
- 1.8. Costs of approval delays

2. Defining Our Challenges

- 2.1. “Records Integrity” versus “Data Quality”
- 2.2. CDISC inconsistencies
- 2.3. Whom to involve
- 2.4. Data management committees
- 2.5. Drawing the “data integrity” box
- 2.6. Endpoint adjudication processes
- 2.7. Clinical site involvement
- 2.8. Risks of private CROs and IRBs
- 2.9. Records retention risks
- 2.10. Agency standards evolving
- 2.11. Avoiding going overboard
- 2.12. Getting maximum ROI
- 2.13. Strategic accountability

3. Cerulean’s SmarterCompliance Strategy

- 3.1. Assembling a cross-functional data management team
- 3.2. Level setting knowledge
- 3.3. Conducting an inventory
- 3.4. Defining reasonable risks
- 3.5. Determining the level of confidence required
- 3.6. Identifying controls to build in (checklist)
- 3.7. Identifying controls to add-on (checklist)
- 3.8. Identifying last-minute pre-submission controls (checklist)
- 3.9. Incorporating records retention and archival
- 3.10. Developing and Implementing an action plan
- 3.11. Monitoring and documenting proof (matrix)
- 3.12. Crafting the submission appendix

4. More Resources

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