Data Reliability in Retrospective Chart Review Studies: Results and Considerations from a Novel Data Review Methodology

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Neil R. Brett[1], Luke Safarcyk[2], Elizabeth Donahue[2], Marielle Bassel[1]

[1] Thermo Fisher Scientific, Montreal, Canada; [2]Thermo Fisher Scientific, Waltham, MA, USA

Background

- Retrospective historical cohort studies (chart review studies) are generally efficient designs to generate longitudinal observational follow-up data.[1]
- For data review and abstraction verification in clinical studies, source data verification (SDV) may be thought of as the gold-standard.[2]
  - However, the potential use of SDV in chart review studies may face challenges in implementation, site interest, data protection, and timelines.
  - Thus, chart review studies generally use remote data review (without source documents); however, this method can result in data reliability/accuracy issues for studies.
- There is a need for data review methodology that is realistic for efficient implementation in the chart review context, yet still with additional rigor compared with traditional remote data review.

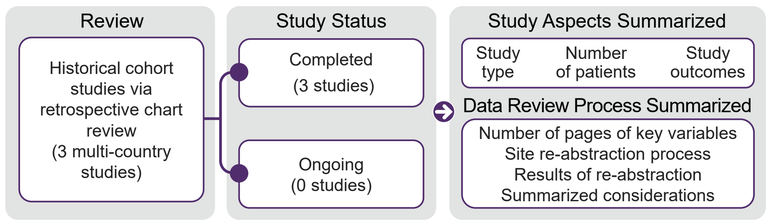
Objective

- **The objective was to describe an alternative method for data quality review and highlight key considerations.**

Methods

- We performed a review of the three historical cohort studies via retrospective chart review.
- The summary of study status and key evaluations conducted are presented in the **Figure 1**.

Figure 1. Three historical cohort studies via retrospective chart review

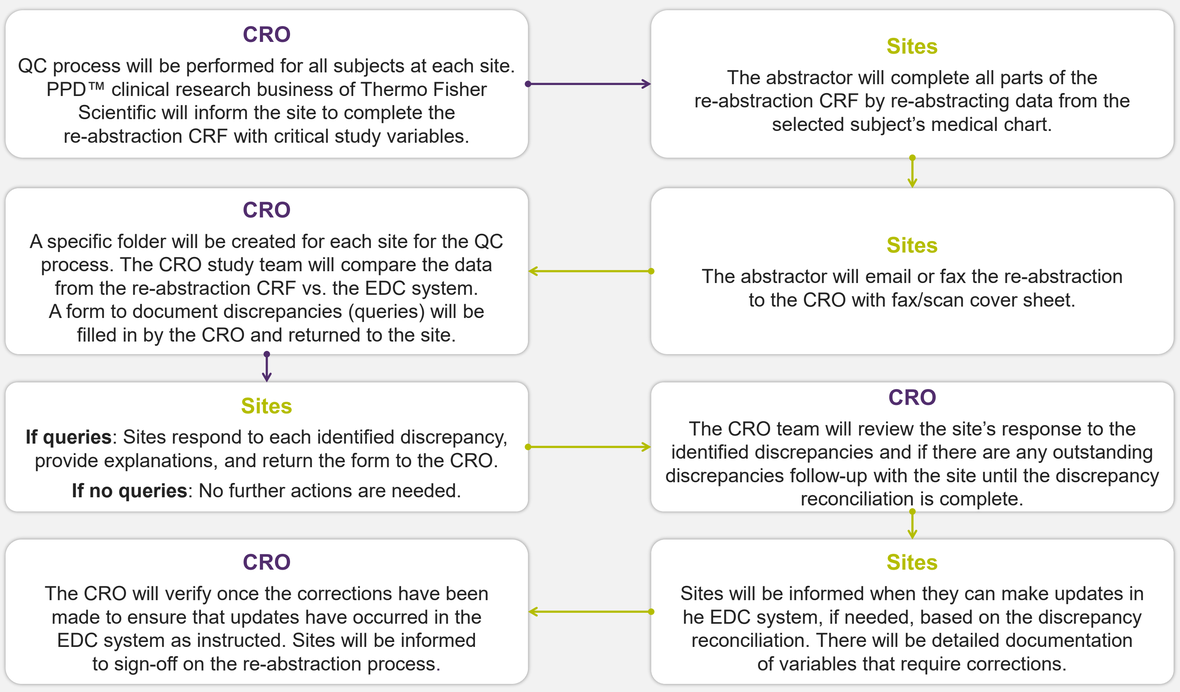


Results

Table 1. Overview of Study Types, Populations and Key Outcomes

Site-based or De-centralized	Study Population and N	Therapeutic Area	Type of Chart Review Study	Types of Data Collected
Site-based	Adults, n=227	Gastroenterology	Natural History Study	Medical history, treatment patterns, clinical outcomes
Site-based	Pediatrics, n=30	Rare Disease	Label Expansion	Patient demographics, medical history, initiation of treatment, clinical outcomes
Site-based	Adults, n=18	Immunology	Drug Utilization	Patient demographics, medical history, treatment patterns including adherence, laboratory tests

Figure 2. Data Review Process Overview of Repeat Abstraction of Key Variables



Abbreviations: CRF = case report form; CRO = contract research organization; EDC = electronic data capture; QC = quality control

Figure 3. Details and Discrepancies for Re-abstraction of Variables

Number of pages/variables of repeat abstraction per study:

- **Study 1:** **1 page** including **13 variables**
- **Study 2:** **3 pages** including **22 variables**
- **Study 3:** **7 pages** including **61 variables**

Number of patients/sites per study included in re-abstraction:

- **Study 1:** **7 sites, re-abstraction for 1 patient per site** (7 total patients)
- **Study 2:** **17 sites, re-abstraction for all patients** (30 total patients)
- **Study 3:** **5 sites, re-abstraction for 1 patient per site** (5 total patients)

Re-abstraction discrepancies:

- **Study 1:** **4 patients** with **0 discrepancies**, **1 patient** with **1%–9% discrepancies** and **2 patients** with **30%– 40% discrepancies**
- **Study 2:** **26 patients** with **10%– 39% discrepancies**, **4 patients** with **>40% discrepancies**
- **Study 3:** **0 discrepancies for all patients**

Figure 4. Considerations for Repeat Abstraction of Key Variables Data Review

Study-specific quality control (QC) plans should include

Specific Variables for Re-abstraction
- Focus on variables related to the primary objective
- Include variables that are complex or prone to misinterpretation
- Consider variables that have shown high variability or errors in past similar studies

Numbers of Patients
- Determine based on the study's purpose and data complexity
- For regulatory studies or those with complex data, include a larger sample size for repeat abstraction purposes should likely have greater numbers of patients
- Include the first patient(s) abstracted by each site staff member to catch early entry errors

Define Handling of Discrepancies
- Include steps for data correction, site re-training and potential re-entry of data
- Establish thresholds for acceptance error rates and actions to take if exceeded

Additional Considerations

Timing of Repeat Abstraction
- Initiate repeat abstraction soon after first patient data is abstracted to catch and correct errors early
- For studies with larger sample sizes, consider one more than one repeat abstraction to ensure ongoing data quality

Resource and Staffing
- Ensure sites have adequate resources and staff to perform initial and repeat abstraction
- Avoid having the same person perform initial and repeat abstractions to reduce bias

Study Timelines
- Integrate repeat abstraction activities into the overall study timeline
- Allow sufficient time for data review, discrepancy resolution, and any necessary re-training

Training and Support
- Provide comprehensive training for site staff on the abstraction process
- Offer ongoing support and resources to address questions and issues as they arise

Compensation
- Include repeat abstraction fees into the budget to compensate sites for the work performed
- If there are study budget constraints, consider reasonably minimizing the number of pages/variables and the number of patients for re-abstraction

Documentation and Reporting
- Maintain detailed records of all abstraction activities, discrepancies, and resolutions
- Report on data quality metrics and any corrective actions taken

- Study types that may be suitable for this methodology: Retrospective studies where on-site monitoring or source data verification may not occur.

Conclusions

- **The data review methodology of repeat abstraction of key variables demonstrates the importance of additional data QC in chart review studies, which enhances the reliability and accuracy of data abstraction, leading to more robust study outcomes.**
- **This cost-efficient methodology should be customized to each study based on study design, outcomes, timelines, and other relevant factors.**
- **Studies looking to implement this data review methodology should tailor it to be study-specific by carefully considering data abstraction complexity, study timelines, site burden, and purpose of the study.**

References

1. Saag KG, et al. Clinical Research Methods in the Rheumatic Diseases. In: Firestein GS, Budd RC, Gabriel SE, et al., eds. Kelley and Firestein's Textbook of Rheumatology. 10th ed. Vol 1. Elsevier; 2017:475–485.
2. Andersen JR, et al. *Br J Clin Pharmacol*. 2015 Apr;79(4):660-8.
3. Hamidi M, et al. *J Clin Transl Sci*. 2024 May 21;8(1):e101.

Disclosures

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