



# Gold or Lead? Adjudicating Differences between CDM Data and Chart Reviews

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## Background

- Chart review is regarded as a gold standard for retrospective studies or cohort validation, but there is limited research on how to systematically understand and weigh its limitations and benefits
- Conducting time and resource efficient large-scale analyses requires careful consideration of data sources and methods for data collection
- PEDSnet, a pediatric clinical research network (CRN) which standardizes electronic health record (EHR) data into an OMOP Common Data Model (CDM)<sup>1</sup>, has conducted 10 studies that include both a chart review and CDM component
- We systematically reviewed 2 such studies, analyzing records where CDM data would have produced different results from analysis of chart review data, to:
  - Classify types of discordance
  - Identify strengths of each data source
  - Propose guidelines for leveraging the strengths of each
- The studies reviewed included\*:
  - Safety surveillance study**
    - Purpose of the study:** analyze adverse events in relation to loading dose of inpatient administration of a medication in pediatrics to support a labelling expansion
    - Purpose of the CDM:** identify patients with an administration of the medication of interest
    - Purpose of the chart review:** primary purpose to gather information about adverse events (AEs) and specific attribution of the AE to the drug of interest in physician notes. Secondary purpose to validate drug dose
  - Clinical trial**
    - Purpose of the study:** clinical trial recruitment
    - Purpose of the CDM:** identify patients who meet eligibility criteria to be enrolled in the trial
    - Purpose of the chart review:** validate inclusion criteria (e.g. diagnosis, lab results)

## Methods

- Chart review data was captured in a REDCap<sup>2</sup> case report form (CRF).
- Data elements of high importance were examined by applying checks for sensible values and/or by comparing chart review to CDM data. Important elements in the studies reviewed were:
  - Study 1:** medication dose (value, unit, timing), diagnosis date
  - Study 2:** diagnosis, lab results
- Figure 1 describes the adjudication process that we followed when discordance was realized between the CDM and chart review in order to determine the source of truth, with bi-directional arrows representing information flow and communication.
- The data coordinating center (DCC) is the hub of data flow and adjudication, requiring an understanding of source data, structure, and processes for both extract-transform-load (ETL) and chart review in order to guide and refine focus

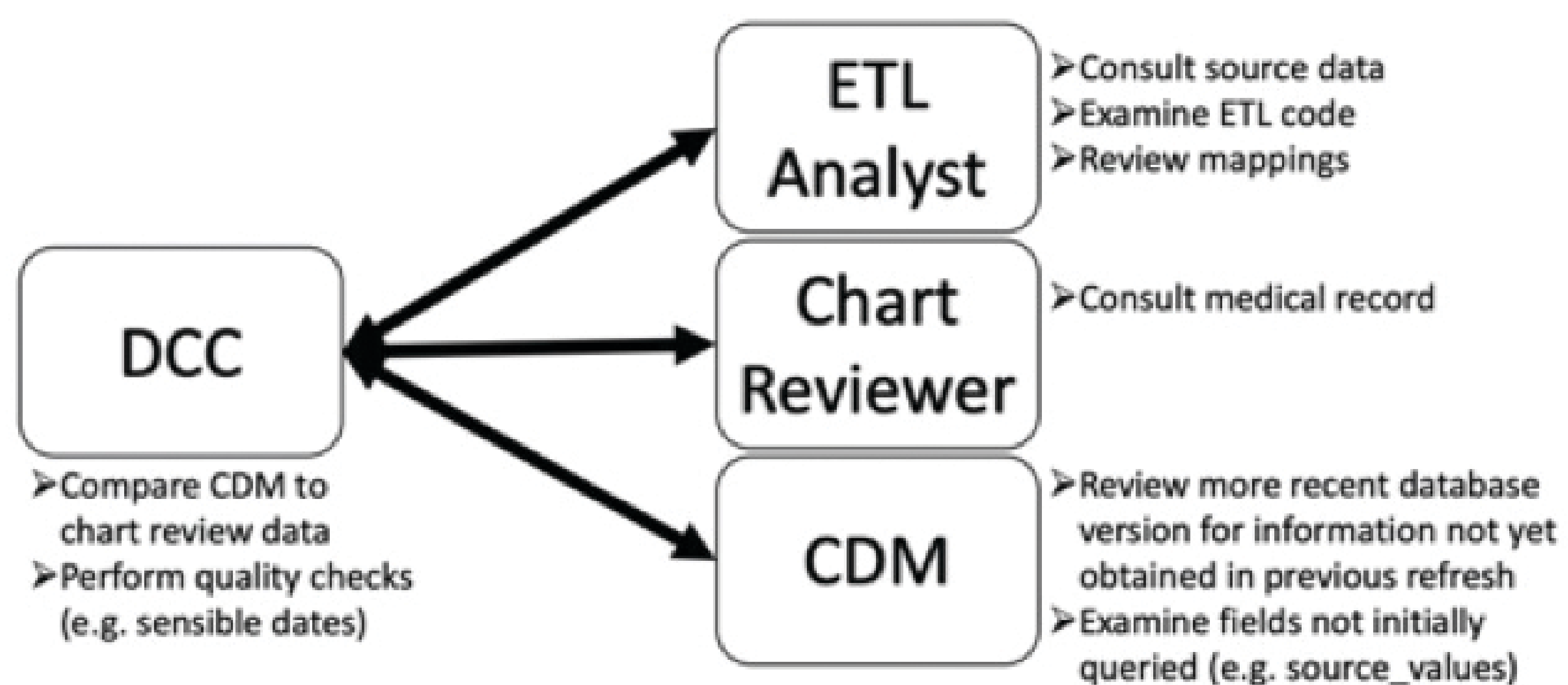
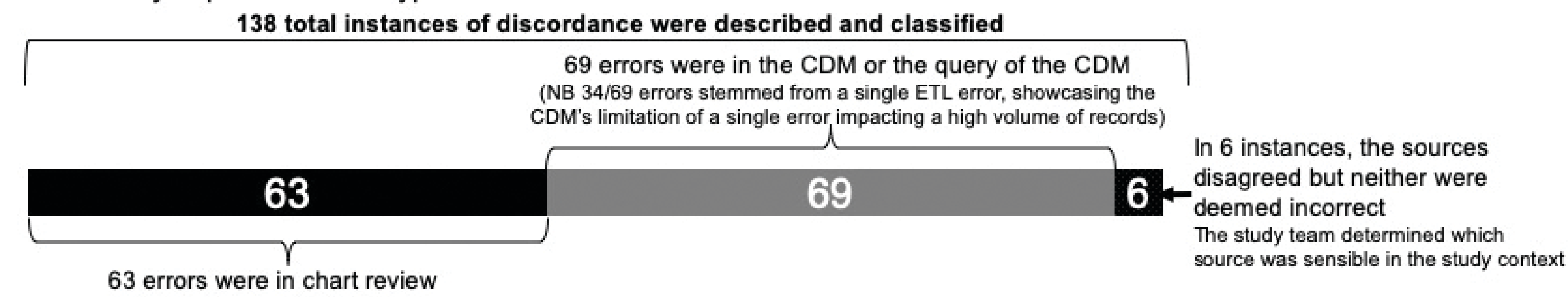


Figure 1 Adjudication process diagram

- Each instance of discordance was recorded along with metadata such as domain impacted, process for discovering the source of truth, outcome of investigation, and whether the CDM or chart reviewer was ultimately deemed correct.

## Results

- We quantified and classified each type of discordance, creating categories based on commonly occurring themes and adding new categories for those that did not fit into existing categories. As we review additional studies, we will continue to expand the list categories exhaustively capture all error types



Theme	Definition	Incorrect Source	Common Examples	Frequency
Incorrect	Erroneous values in the CRF, EHR, or CDM	Chart Review	<b>Typo:</b> Erroneous entry of diagnosis date in CRF <b>Source data error:</b> Physician mis-typed diagnosis in notes which was then transcribed by chart reviewer	24
		CDM	<b>ETL error:</b> Incorrect mapping of dose units <b>Source data error:</b> Inpatient drug administration time entered incorrectly into Epic. Chart reviewer noticed that administration time was prior to the medication order time	49
Missing	Information overlooked in EHR or not present in CDM	Chart Review	<b>Oversight:</b> Chart reviewer did not search the medical history field for a diagnosis	9
		CDM	<b>Latency:</b> Patient admitted during ETL cycle, causing lack of visit_end_date <b>Non-standard capture:</b> death_date reflects date of organ donation. Chart reviewer found actual date patient was declared dead within physician notes	15
Mistranslation	Error in logic or interpretation	Chart Review	<b>Logic lapse:</b> Chart reviewer searched for diagnoses "within" ( $\leq$ ) 6 months instead of "at least" ( $>$ ) 6 months prior to an anchor event <b>Question misalignment:</b> Diagnosis was on the patient's Problem List, which chart reviewer had not considered a true diagnosis	30
		CDM	<b>Logic lapse:</b> Patient was transferred to another inpatient unit with a new visit_occurrence, which the CDM query had not taken into account	5

Table 1 Description of themes

## Conclusions

Leveraging the utility of CDM and chart review can help ensure accuracy and efficiency in study conduct, and elements to extract from each based on priority of element and ability for best capture should be considered during the study design process.

	CDM	Chart Review
<b>Strengths</b>	+ Efficient for large volumes of information + Uniform application of a definition across all patient records	+ Incorrect information in source EHR can be supplemented with context from unstructured fields or with comparison with nearby events + Up-to-date information can be viewed and extracted
<b>Limitations</b>	- Single ETL error could impact a large volume of records - Erroneous entry into source data less easily recognized through ETL process - Latency introduced by CDM refreshes and ETL processes	- Manual process - Time intensive - Expensive - Human error - Fatigue for a large volume of records - Ambiguity in CRF question interpretation

Table 2 Strengths and limitations of CDM and chart review

\* Specifics of studies such as project sponsor cannot be disclosed due to regulatory agreements

### References:

- Christopher B Forrest, Peter A Margolis, L Charles Bailey, Keith Marsolo, Mark A Del Beccaro, Jonathan A Finkelstein, David E Milov, Veronica J Vieland, Bryan A Wolf, Feliciano B Yu, Michael G Kahn, PEDSnet: a National Pediatric Learning Health System, Journal of the American Medical Informatics Association, Volume 21, Issue 4, July 2014, Pages 602–606. <https://doi.org/10.1136/amiajnl-2014-002743>
- Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.