RWD103

The ICEBERG Study: Patient Right of Access Pathways as a Novel Method for Longitudinal RWD Generation in Clinical Research

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Background and Objective

- Observational clinical studies often rely on manual chart abstraction from single institutions of care. While these site-specific records provide granular detail, they fail to capture the fragmented nature of healthcare.
- Rather than relying on a single institutional record, this research utilizes Patient-directed Right of Access pathways (the legal right to obtain copies of one's health information) to aggregate a comprehensive RWD set from across the patient journey.
- Primary objective is to characterize the scope, detail, and completeness of combining complete payor claims and EMR data to understand where valuable study insights are uncovered.

This poster presents an interim data readout of the ICEBERG study

Methods

- **Study Cohorts:** Two cohorts were created from the ICEBERG study for this interim readout and analysis. Cohort A (n=202) is all participants who enrolled in Q2/Q3 of 2025. Cohort B (n=33) is a sub-cohort of A for whom the data was additionally normalized and structured for this interim readout. Participants were recruited from a generally healthy population.
- **Data Acquisition:** 1) Claims data was collected from insurance carriers for at least one year pre-enrollment; and 2) Electronic health records from the self-reported locations a participant had care were collected via API or centralized offline methods.
- **Data Completeness and Comparative Analysis:** Claims and EMR Data gathered from Cohort B was analyzed over one year prior to enrollment to quantify: 1) Distinct medication classes in claims not represented in the EHR. 2) Distinct diagnosis categories found in claims but absent from EHR data. 3) Emergent care episodes detected in claims.
- **Characterizing the Longitudinal Patient Journey:** There was an expert review of the claims and EMR records of participants in cohort B. The investigators identified a series of events and care encounters that show gaps in the patient journey when viewing EMR records alone. When paired with claim records over the same period, relevant procedures and diagnoses were discovered.

Results

Cohort A (n = 202): Data Collection Cohort

Table 1: Data Collection Success

Metric	Value
Percentage of participants with data collected	99.50%
Percentage of participants with payor claims collected	98.17%

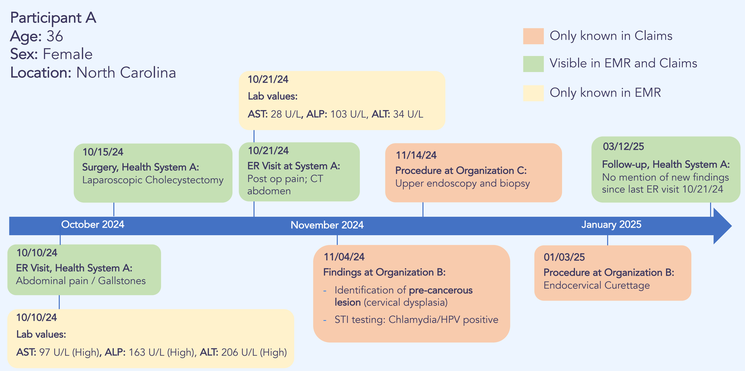
Table 2: Cohort Statistics

Metric	Value
Number of participants in cohort	202
Median time to enroll	12m 32s
Number of US states represented	38
Number of distinct insurance carriers*	110
Number of distinct EMRs listed	251
Participant mean age (years)	40.6

*Including Medicare, Medicaid, and Commercial Plans

Highlighted Patient Journey

Figure 1: Timeline of relevant care based on EMR and payor claims data



- This case highlights a significant gap in data completeness caused by the fragmentation of healthcare records. While the participant's primary EMR effectively captures surgical events and lab values, it presents a critical blind spot regarding specialty care. **Claims data revealed that the participant sought services at an external health system where findings included a pre-cancerous lesion (cervical dysplasia)**
- If this participant were part of a drug safety cohort or a retrospective study using only her primary system's EMR, **the discovery of the pre-cancerous lesion would be entirely missing.** The claims data provide the necessary information to identify an oncology signal and a significant change in the patient's clinical baseline.

Cohort B (n = 33): Data Analysis Cohort

Figure 2: Claims data show a single center is blind to many emergent care events

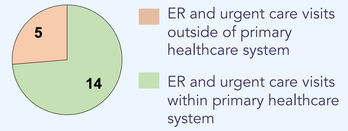


Table 3: Cost of care data

	Paid costs	Patient Responsibility
Mean	$31,808	$903
Max	$657,300	$12,330

Table 4: Detailed statistics of claims data

Count of…	Mean	Max
Medical services	243	2973
Pharmacy fills	10.2	79
Diagnosis codes or descriptions	31.3	115
Medication codes or descriptions	14.12	91
Distinct providers	5.97	25

Figure 3: Combination of claims and EMR are necessary to capture comprehensive diagnoses

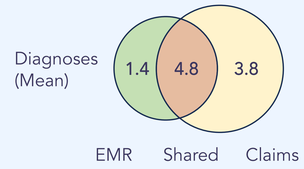
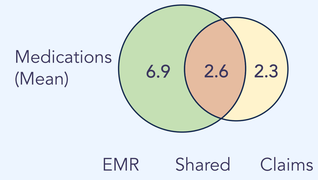


Figure 4: EMR alone inadequately captures actual medication exposures



Conclusions

- **New Methods Offer Comprehensive and Longitudinal Access to RWE for a Full Cohort of Enrolled Participants:** This readout demonstrates that leveraging federal Patient Right of Access mandates is an effective vehicle for closing the gaps in RWD. Interim results demonstrate the uniquely comprehensive capabilities of this model, demonstrated by 99.5% of enrolled participants with data collected.
- **The Combination of Claims and EMR Delivers More Insight than the Sum of its Parts:** EMR data and claims data each have biases for overreporting and underreporting when used as standalone data assets, but when used in combination a complete picture emerges. Where claims data provides a "table of contents" of all healthcare encounters, EMR data sheds light on the rich clinical detail. This pairing ensures that critical study insights can be consolidated into a single, comprehensive record.
- **Success Requires a Purpose-built Solution:** While advancements in interoperability have brought efficiencies to data access, complete data capture still requires methods that hybridize technology with traditional offline data capture. After aggregation, the normalization and structuring of the data is a complex task requiring deep medical informatics expertise. Crescendo Health has developed a unique solution for sponsors that pairs comprehensive, longitudinal data access with sophisticated medical informatics to simplify these complex processes for sponsors.