Reducing Manual Data Entry for CRCs and Maximizing Data Availability with CLEHR

Client Overview & Business Requirement:

A medical device company conducting a surveillance study aimed to reduce the manual data entry burden on study sites

The company's long-term surveillance study to track quality of life outcomes and safety events in patients using their devices, required access to medical care data following device implantation. Given the large volume of required data, the client sought a more efficient solution to replace manual extraction and entry into their EDC systems, reducing site burden and long-term operational costs.

Challenge

The existing manual data abstraction process was labour intensive, error-prone, and time-consuming, requiring significant effort from study sites to extract and enter data into EDC systems. This caused delays in data availability, data inconsistencies, increased operational burden, and staff burnout, ultimately limiting the client's ability to derive timely insights.

400+ study fields made manual EDC data entry time-consuming and labour intensive	**~ 5–7 hours** spent/ patient on manual data entry, delaying data availability and increasing site burden	Manual data entry was r**estricted** to predefined **EDC fields**, limiting access to broader data	CRC's had to manually **search** for the **correct** values from the **vast data points**	Identifying the correct value often involved **subjective decision making**, reducing data reliability	Resolving discrepancies took **~10 minutes/ query**, adding up to significant time lost in source data verification

Solution:

To address the client's challenges with manual data entry, ***"CLEHR***" a FHIR-enabled eSourcing Solution was leveraged for reducing burden of manual data capture. Key components of the solution included

- A FHIR-based interface extracted patient records directly from EHRs, eliminating the need for manual abstraction
- Automatically identified potential study participants and verified eligibility based on study criteria, and sent de-identified patient data to the client's EDC system
- The solution captured a significantly larger volume of data compared to requested EDC fields, increasing data availability and accessibility while minimizing manual effort
- HIPAA- and HITRUST compliant cloud environment, ensured secure storage and encrypted data transfer while maintaining strict regulatory compliance
- Automated batch updates were scheduled to refresh patient data at 30, 90 days, and 1 year, ensuring timely and accurate data availability
- Established processes for quick site set up & integration that enabled coverage for ~60M patients across multiple sites

This end-to-end automation eliminated manual inefficiencies, enabled access to expanded datasets, and ensured high-quality data transfer to EDC system for generating real-world insights.

Graticule's Value Add

In collaboration with the client and research sites, Graticule implemented CLEHR at 5+ sites, to streamline EHR-to-EDC integration. This automation resulted in:

Direct and secure transfer of **~70% of EDC data fields**, eliminating transcription errors and improving research integrity	**Reduced data entry time by 45 minutes** or more/ case, saving staff hours of repetitive work and improving efficiency	Capture of **3,826 data points/ patient**, compared to just 30 with manual entry, ensuring a more complete dataset	**150x more data points/ EDC data field** compared to manual entry (eg; 290 BP values vs 2 with manual abstraction)

Interested in learning more? **Reach out to us at info@graticule.life**