Clinical Protocol Digitization

Transforming clinical trial protocols into digital formats for Analytics and insights

Background

- *A first step for any clinical trial, a protocol contains the blueprint & design for how a clinical trial should be conducted. It is used by multiple stakeholders and systems downstream to ensure success for trials manually extracted from the protocol and fed into downstream systems, thereby increasing the possibility of inconsistencies.*

- *For Life Sciences companies, it is critical to leverage digital technologies to automate the process of extracting and summarizing relevant sections of the massive protocol document & make it available for downstream systems and stakeholders.*

Current challenges with protocol documents

- **Inability to get real-time, actionable insights** – unstructured data is often recorded as free text, without limitations to format or structure making it difficult to reliably analyze and garner insights

- **Ineffective utilization of expert's time** – protocols are crafted by highly skilled clinical experts whose time is best utilized for clinical work rather than working on complex templates, formatting documents, and searching for reusable content

- **High manual administrative effort** – the protocol document often contains verbose statements that are significantly dependent on the team that formulates it, making it harder for the information to be used by others across the organization

The Solution: Fresh Gravity's Protocol Digitization Tool

Fresh Gravity's protocol digitization tool is a cloud-based solution which provides a holistic end-to-end analysis of the clinical study protocol. This tool leverages Natural Language Processing (NLP) and Machine Learning (ML) to extract content, summarize relevant sections from the clinical protocols and stores them in a structured format on a database to reduce manual effort and streamline the downstream processes.

Process Flow

Upload Protocol   ML/ NLP/ NLG   Extract Contents   Database Storage

Review Checklist   Protocol Analytics   Library   Download Contents

Ontology

Knowledge Graph

Key Features of Fresh Gravity's Protocol Digitization Tool

Key features of the solution:

- A knowledge graph database that gives a 360-degree view of the document
- Protocol Analytics that help the team analyze and relate information between multiple protocols
- Protocol extractions wherein the tool extracts related information based on the table of contents in the protocol
- Protocol Review Checklist that allows reviewing the contents of the protocol and highlights any potentially misleading information
- Ontology-based data conversion of the document from unstructured to structured format which gets stored in the knowledge database
- A content recommendation engine for the creation of new protocols that uses the existing knowledge base of all protocols across similar Therapeutic and Indication using the TransCelerate common protocol template

Benefits

- Real-time insights owing to structured digitized content in a query able format
- Optimal use of skilled resources
- Analytics tailored to the needs of users from different departments
- Quick and reliable aggregation of related content across the protocol

Protocol Analytics

Additionally, the tool is carefully designed to ensure full usability across the organization therefore allowing easy communication of information amidst groups of people conducting distinct parts of the study. By doing so, the entire clinical operations value chain will operate more effectively and give increased value at each iteration.

Following are some role-based benefits of Lifio's Protocol Digitization Tool -

- **Medical Expert** – use of AI and NLP helps medical experts speed up the process of reviewing study designs, objectives and endpoints, the selection criteria and assessment procedures
- **Statistician** – The tool enables biostatisticians to understand the previous trial designs and helps in determining the sample size and statistical analysis for better results
- **Medical Writer** – The tool suggests text for writing sections from various existing publications and interrelated sections, significantly reducing research time
- **Data Management** – This tool enables the data management team to extract schedule of events and relevant information about the list of assessments needed while designing CRFs.

Content Creation

Our tool can create and auto populate the contents of key critical clinical documents utilizing the Natural Language Generation (NLG) capabilities.

The list of documents created are:
- Protocol
- Clinical Study Report (CSR)
- Statistical Analysis Report (SAP)
- Informed Consent form (ICF)
- Publications

About Fresh Gravity

Founded in 2015, Fresh Gravity is an innovation-driven Data & Analytics consulting firm that helps businesses make data-driven decisions. We believe in the transformative power of data using technologies to help clients. To know more about us and our offerings, contact us at info@freshgravity.com