FreshGravity™
Driving Digital Success

Bringing Innovation to Pharma R&D and Clinical Trials

Life Sciences Offering: Solutions for Pharma R&D and Clinical Trials

Molecule to Market (R&D)

A Comprehensive master data management solution that includes all entities from drug discovery to drug commercialization. It includes mastering the medicinal product that is primarily focused on IDMP compliance. Our solution connects all the identifiers of the medicinal product, from substance to the commercial drug tracking its way from R&D to commercial. Some of the use cases enabled by this solution include managing pharma label changes, drug safety, regulatory, and R&D searches of past experiments.

Site Intelligence

Site and Investigator Selection, and Site Startup, are some of the key tasks in starting clinical trials. The solution components include a mastered registry of investigators and sites sourced from internal CTMS and other applications, as well as externally procured data from subscriptions like Citeline, DrugDev, CTgov etc. The registry of investigators and sites is enriched and ranked with performance metrics from internal and external data. It also provides workflows for conduct ing feasibility analysis and performing the investigator and site selection for upcoming studies.

Automation of Clinical Study Builds

Generating eCRFs from protocols is a tedious, lengthy and time-consuming activity in study startup. We have automated this process by using NLP and Machine Learning. The solution components include a clinical metadata repository (MDR) for storing metadata standards, questionnaires and scales and eCRF libraries (CDASH, therapeutic area specific forms, past studies etc). The NLP/ML engine takes the protocol document as input and automatically creates the required forms/ items and edit checks based on the study design; a comprehensive review and approval workflow; and the conversion to EDC specific study builds files for direct uploads.

Comprehensive Clinical Data Repository Platform

A comprehensive clinical data repository that is capable of ingesting data from applications and sources like EDC, CTMS, LAB, IVR, EMR/EHR etc. standardizes the data into SDTM/ OMOP or other target formats; and built-in analytics/ dashboards for ClinOps, medical reviews, risk-based monitoring, triggers, and alerts.

Analytics Enabled Curated ClinicalTrials.gov Data using Knowledge Graphs

Readily available and up-to-date data from ClinicalTrials.gov is standardized and loaded in a semantic knowledge graph. This platform also provides natural language query and semantic search capabilities to assist in complex queries, feasibility analysis, researching trials and outcomes for previously conducted experiments in specific areas of interest.

Synthetic Controls in Drug Development

Extending the usage of the Clinical Data Platform mentioned above, and bringing together top researchers from MIT and Columbia University who have been researching in the areas of synthetic controls and interventions, we have a fully baked solution to augment real-world data (RWD) into clinical trials data, with synthetic cohorts. We use ML and AI to create synthetic cohorts from RWD, and then render comparisons and end-point analysis. The solution is aimed at bringing in heterogeneity to the clinical trial through real-world evidence (RWE), reducing the recruitment burden for the control arms in a randomized controlled trial (RCT), and providing useful analysis and comparisons between the experimental drug and RWE for standard of care interventions.

Solutions for Safety and Pharmacovigilance

Safety/Pharmacovigilance – AI Driven Case Intake and Case Processing

We have applied AI/ML and cognitive solutions to –

- Automate data ingestion and extract from structured and unstructured sources
- Perform auto-triaging, acceptance and data book-in
- Prioritization of cases
- Review hard and soft checks, follow-up process (with automated letter generation, reminders and auto-ingestion)
- Duplicate identification, and dictionary coding

The system integrates with safety systems like Argus and can generate regulatory reports like E2B R2, E2B R3, CIOMS and MedWatch. Our solution also enables structured reporting at source from web and mobile platforms (for clinical trials, study programs, HCPs, MOPs, Sales Representatives etc.). The offering is highly customizable and can adapt to your reporting needs without code changes. The solution is also compliant with HIPAA and 21 CFR Part 11 regulation.

E2B R2 to R3 Conversion for Safety Data Submission

The E2B backward-forward compatibility (BFC) adapter enables conversion from E2B R2 to R3 and vice-versa. From year 2022, E2B R3 will be the format that will be used for safety data reporting. With the deadline fast approaching, migration of safety systems to E2B R3 compliant versions is an important but also time-consuming and expensive effort. Our E2B BFC adapter is a perfect solution to ensure compliance and address this problem effectively. The BFC adapter can act as a wrapper around the E2B R2 compatibl e safety system and can ingest/produce E2B R3 f iles.

About Fresh Gravity

At Fresh Gravity, we help Life Sciences companies with their digital transformation journeys. One of our core competencies lies in the R&D and Clinical Data side of Life Sciences. Our mission is to bring innovation using modern technologies to the industry. We have built several solutions to solve some of the challenging problems in the industry. To know more about us and our Life Sciences offerings, contact us at info@freshgravity.com.

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