FreshGravity™
Driving Digital Success®

www.freshgravity.com

Clinical Data Platform

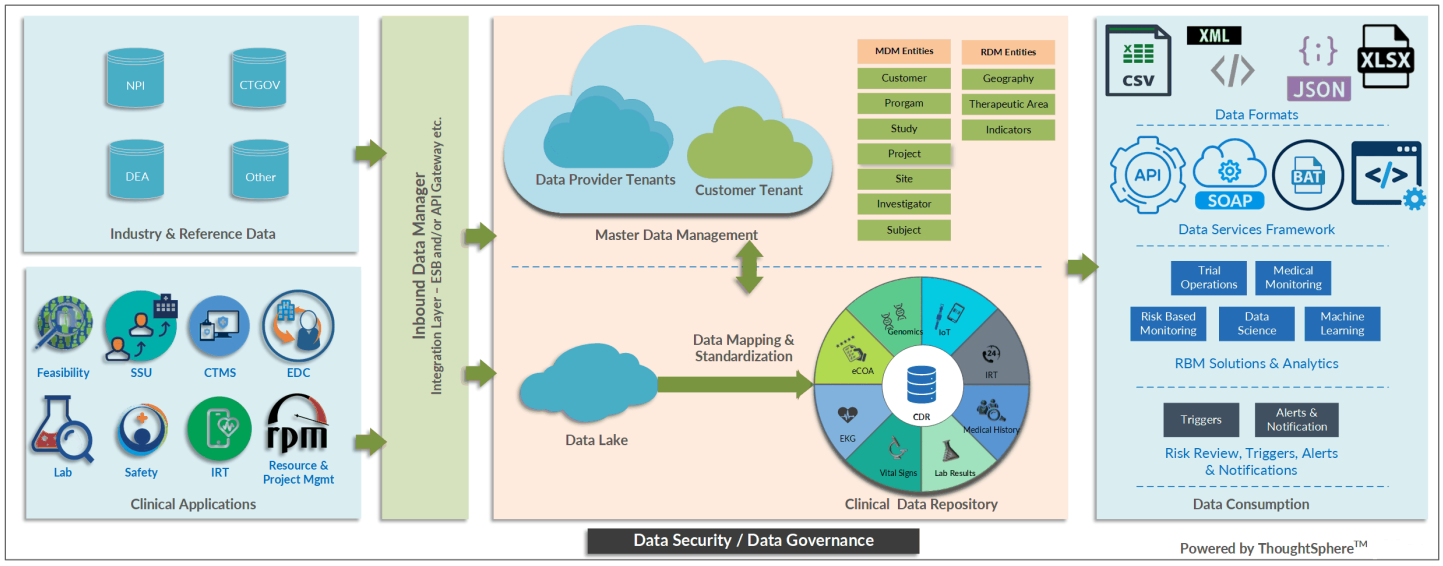
An end-to-end platform fueling agility, effectiveness and efficiency in clinical research through seamless access to holistic clinical information

As the focus increases on difficult-to-treat rare diseases and life-threatening conditions, biopharmaceutical organizations are consistently making large investments in clinical research. However, a majority of clinical trials see incessant delays owing to data-related challenges, leading to drug development delays and millions of dollars in losses.

Today, the pressing **clinical data-related challenges** are as follows:

- Poor integration and management of **voluminous data** (structured and unstructured) from globally dispersed research sites, multiple source systems and platforms which in turn are generating **information silos** and increasing **data redundancies.**
- **Lack of access to real-time clinical trial and operational data** is causing latency in critical functions.
- **Poor data visibility** is preventing early detection and mitigation of clinical and operational risk.
- **Poor quality of clinical trial data** is a challenge for regulatory compliance and hinders trial completion.
- The **tedium of manual and legacy data systems and processes** are taking time away from monitoring operational and medical outcomes.
- **Broken flow of critical information** is hindering effective budgeting and automated payments.

In pursuit of shorter time-to-market, cost-effectiveness in drug development and enhanced process efficiency, organizations are constantly seeking ways to minimize the data-related inefficiencies in clinical research and optimize the entire clinical trial lifecycle. An effective way to do so is Fresh Gravity's Clinical Data Platform, powered by ThoughtSphere™.



Clinical Data Platform: An Ideal Solution for Multiple Use Cases

Clinical Data Aggregation:

- **Study Data Collection and Aggregation:** ingest, transform and standardize structured or unstructured data from disparate source systems such as EDC, central labs etc. into clinical data hub.
- **Standardized Data Sets – SDTM, E2B, ADaM:** transform data into standard datasets leveraging CDISC SDTM or user configured target data models.

Master Data Management:

- **Data modeling and creation of golden records** for clinical entities (customer, program, study site, investigator, subject, and subject visit).
- **Reference Data Management** for therapeutic lists, disease indicators, country lists.
- **Contact information management, cleansing and standardization** of addresses, **validation** of phone numbers and e-mail's.
- **Data enrichment** from external sources such as National Provider Identifier (NPI), Drug Enforcement Administration (DEA) and others.

Data Review and Reconciliation:

- **Integrated Data Review:** create rules to easily identify discrepancies and give data managers the ability to perform complex relationship checks to ensure cleaner, quality data.
- **Data Reconciliation:** reconcile data across EDC and external data sources such as Safety, Lab etc.
- **Discrepancy and Query Management:** alert users when there are discrepancies in the data set, review the discrepancies, create queries, and take action to close the discrepancy in real-time.
- **Serious Adverse Event Reconciliation:** facilitate superior SAE reconciliation with a data lake approach.

Risk Based Monitoring (RBM) Solution and Analytics:

- **Study, Portfolio and Quality Oversight:** effectively monitor site and study performance. Multi-vendor (CRO) oversight at the study and portfolio level.
- **Subject Review and Patient Profile:** medical monitoring reviewing congruency of data across various parameters at subject level. Interim reviews.
- **Holistic RBM with Central Monitoring:** remotely monitor risks and analyze data to proactively identify and prevent inadequate site behavior and processes.

Budgeting and Planning:

- **Budget Planning:** plan study budget and categorize scenario options around fixed and variable costs.
- **CTA Management with Site Collaboration:** define contract and payment terms and generate CTAs and facilitate site/ investigator collaboration through a portal.
- **Investigator / Site Payments:** initiate automated payments to sites based on events and support payment terms at various level e.g. visit, resource, patient or procedure.
- **Data Quality Linked Payments:** automate site payments based on meeting data quality thresholds.

Fresh Gravity Clinical Data Solutions: The Key Benefits

- Transform your clinical data into manageable form, and actionable insights.
- Leverage the power of AI, ML and deep learning techniques to reduce data redundancies and process latencies, achieve end-to-end optimization and drive clinical research outcomes.
- Accelerate site selection, clinical trial startup, patient recruitments, trial execution and payments.
- Ensure regulatory compliance and industry standards adherence.
- Get customized solutions built with accuracy for your unique data management needs.

How Can Fresh Gravity Help?

Fresh Gravity is a business and technology consulting firm that assists enterprises with their digital transformation journey by using state-of-the-art technologies. Our core strengths lie in Enterprise Data Management, Data Engineering, Data Science, Artificial Intelligence and Enterprise Integration. Fresh Gravity's clinical data experts have decades of hands-on experience helping pharma companies and CROs implement technology solutions to solve complex data and analytics problems. This makes us uniquely qualified to help our clients to solve their clinical data problems.
For more information, visit **www.freshgravity.com**

Corporate HQ — San Francisco Bay Area
2901 Tasman Drive, Suite 222,
Santa Clara, CA 95054, USA

www.freshgravity.com

Washington DC
1100 Wilson Blvd., Suite 1005
Arlington, VA 22209, USA

Raleigh, NC
120 Preston Executive Drive,
Suite 200 Cary, NC 27513

Melbourne
L4, 152 Elizabeth St.,
VIC 3000, Australia

Pune
A-801 & 802, Teerth Technospace,
Baner, Pune - 411045, India