



GRAVITY is an Integrated Electronic Trial Master File (eTMF) and Electronic Investigator Site File (eISF) system developed to facilitate every stakeholder in a clinical trial in their everyday document management.

GRAVITY provides the highest level of performance, quality and visibility to the users. This in turn ensures that Sponsors and CROs can gain the required access and control of the documents and oversee the clinical trial in real-time, Site can be sure that the documents available to them are current and accurate at all times and Auditors can access the study, when authorised to review the documentation.



A complete Document Management System (DMS)



Being an **integrated eTMF and eISF system**, GRAVITY becomes a complete cloud-based electronic DMS, serving as a window for Sponsors, CROs and Sites. However, GRAVITY can also be deployed and utilized for each individual entity alone.

Regulated & Controlled



It is compliant with **21 CFR Part11** and developed based on the **TMF reference model**, GRAVITY stands fulfils the industry requirements of document management in clinical trials. Role Specific access ensures that the system is controlled for every user and security is maintained.

QC System Logics



It is important that documents uploaded to GRAVITY are correct and accurate and so we have employed a 2 level QC check for each document. It is **Smart and Logical**..

CRA Verification Process



Users **check and verify** if documents have been saved and shared appropriately in just few simple clicks. Monitors can verify the availability of accurate and current documents within the eISF in-house thereby **reducing the time** in reviewing paper documents on-site.

Real-time Logs & Forms



When everything else is electronic, why not the logs and forms. GRAVITY hosts an array of logs and forms used in clinical trials. For example, site visit log, patient screening and enrolment log, Informed consent log, training log etc. **Real-time completion and verification** of these logs contributes to the quality of trial at all levels.

Smart Notifications & Alerts



Whether a new document is available or a document is pending acknowledgement. GRAVITY ensures that **system notifications, reminders and alerts** are provided to the users prompting timely reviews.

Integrated SUSARs system



Safety is a key in any clinical trial. And so are safety documents. GRAVITY holds an in-built **SUSARs management system** which ensures that safety information is available to the site **in real-time** and is acknowledged by PI (**e-signature**). This assures that every site is aware of the safety implications of the study on an on-going basis. **Robust tracking and report** generation specific for SUSARs helps in avoiding the use of multiple systems for safety management.

Essential document tracking



When a site is selected for conducting a clinical trial, documents starts to flow in, however, the initial pack of essential documents requires maintenance, for example, CVs are only valid for two years. It is time consuming and expensive to track these manually. GRAVITY incorporates a unique feature of **overseeing the essential document management** and alerting the users of expiring documentation ensuring documents are up-to-date.

Tracking & Reports



What gets in to GRAVITY does not escape it without a trail. And that is the mark of an effective system. GRAVITY produces **dynamic trackers and reports** for every activity performed within the system providing consolidated information in few clicks.

Easy access & use



Now your documents can be accessed through **any browser / device, any location, any time. No need to install any software or hardware** and no need to go through hassles of technical specifications. All you need is your username and password. Its design makes GRAVITY easy to navigate and work with.

System Migration Assistance



If you are looking to migrate from paper or from another electronic system, be assured that GRAVITY can become **your best choice**. We are able to assist you with the migration of documentation at all levels irrespective of the size of the trial.

Archiving



Paper documentation consumes a large volume of space, time in QC and preparation and cost in storage. GRAVITY can greatly reduce these by being **99% electronic** across all user groups.

Support



We continuously monitor the performance of our system to ensure that systems across the world is synchronised and are performing at an optimal level. Whether it is IT, training or QC. GRAVITY has a dedicated team to serve you and resolve your questions / issues **24/7**.

The Edge with Gravity

eTMF

Developed based on TMF reference model, in-line with ICH-GCP and regulatory requirements

Efficient uploading, sharing, maintenance, review, tracking, retrieving and archiving

A single access for all functionalities

Reduces time and resources in document management both on-site and off-site

Dynamic reporting system

Logical flow and user-friendly

eISF

Unique and similar to the management of paper based filing. Hence user-friendly.

Assures that site has access to the correct study documents at all times

Utilizes dynamic logs and forms, reports and trackers

Reduces time and resources in document management

Role specific access and e-signature

Easy but controlled access. Assures security

ALWAYS AUDIT READY



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