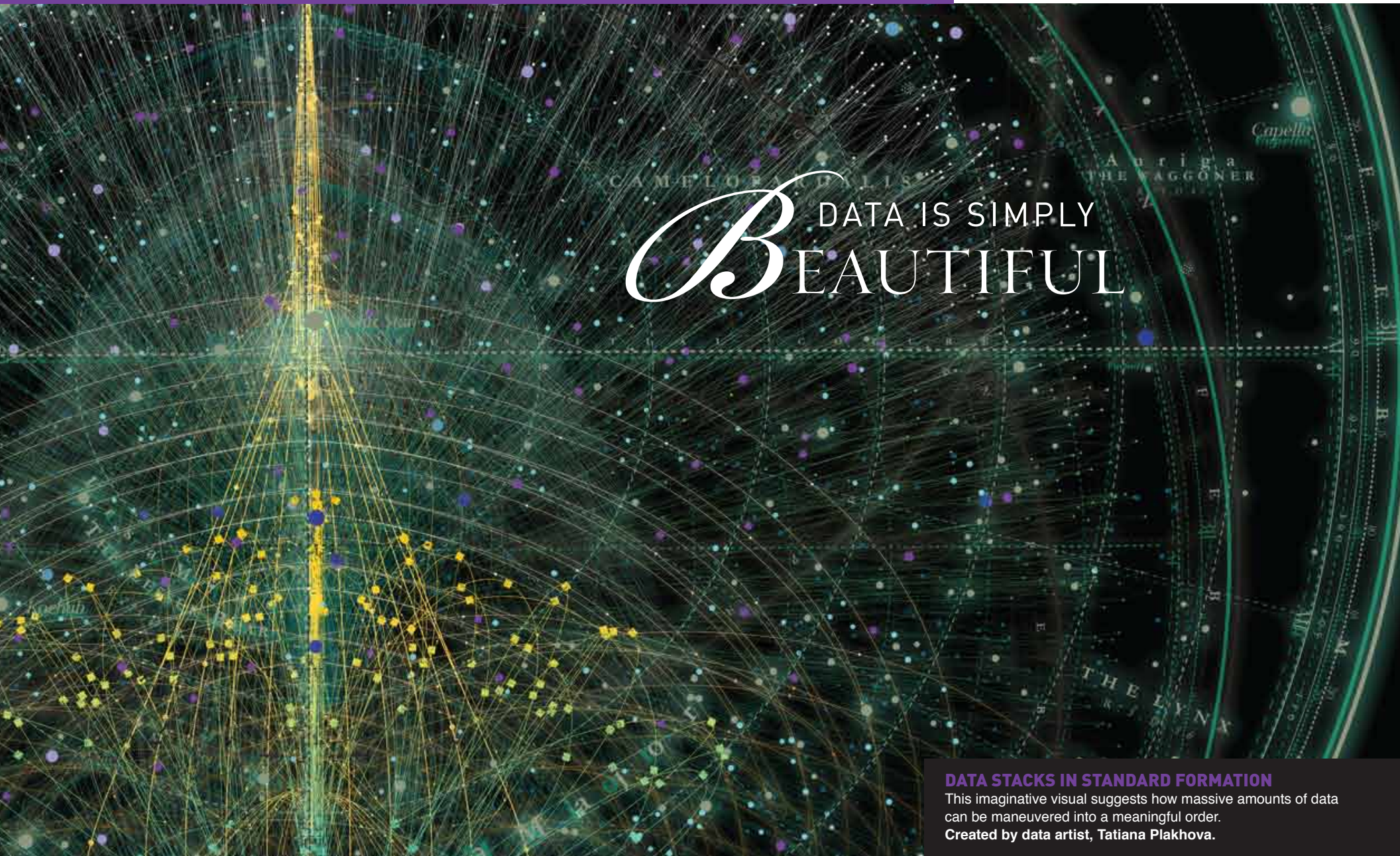
CLINICAL DATA MANAGEMENT

Bringing Order to Your Clinical Data

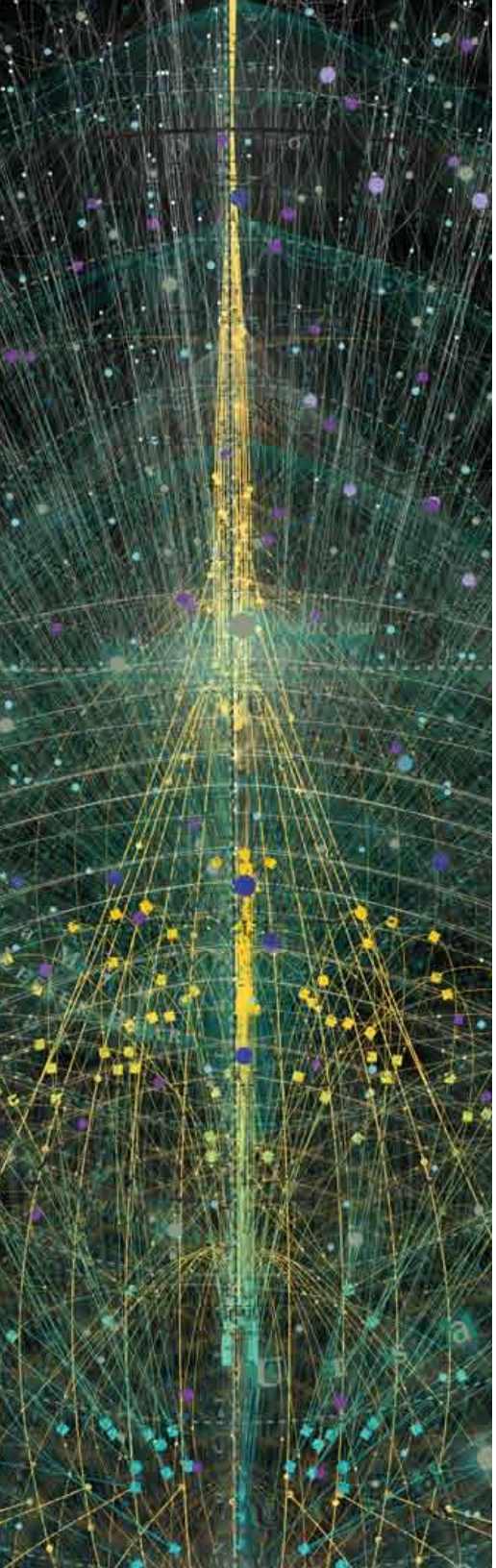
Making it Manageable and Meaningful

eclinicalsol.com

eClinical Solutions



DATA STACKS IN STANDARD FORMATION
This imaginative visual suggests how massive amounts of data can be maneuvered into a meaningful order.
Created by data artist, Tatiana Plakhova.



Data Processing vs. Data Management

Our vision of data management is very different than what has become the standard in the life sciences industry. The majority of small- to mid-size biotech and pharmaceutical companies utilize data management services as an autonomous engagement specific to a trial. Within this narrow view, data processing has become synonymous with data management. The utilization of multiple service partners across trials invites sole focus on a specific trial engagement, but it doesn't create an overarching clinical data strategy. The byproduct of this approach may satisfy an immediate objective, but leaves organizations without the ability to maximize the use of one of its most valuable assets: clinical data.

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than what has become the standard

Data Management as a Foundation of Clinical Development

eClinical Solutions was formed to help life science organizations maximize the value of their clinical research data. We do so by making its acquisition, standardization, aggregation, and analysis absolutely simple and easy. We believe that establishing a repeatable process for subsequent efficiencies; defining and using data standards; and providing complete data access for visualization and use should not be exclusively reserved for large pharmaceutical companies. We've empowered emerging organizations by introducing them to what we believe data management should be—a strategy that becomes a cornerstone of the clinical development plan and one that can offer brilliant insights simply by making data accessible and usable.

We have empowered

emerging organizations

Building the Foundation

Our process starts by developing a plan around two key aspects: standards and re-usability. We use the term standards in regards to defining and establishing data standards. Our knowledge and use of CDISC standards is leveraged to ensure data can be used for needed analysis and also for submission to regulatory authorities without time consuming and costly effort after the fact. We use the term re-usability in regards to establishing standardization in technologies and process that will be leveraged for subsequent trials. It dramatically decreases the time to start a trial and shortens the development timeline as a result.

- **eClinical Solutions has been an active member of CDISC since 2007**
- **We build all our studies to conform with CDASH and SDTM standards, saving our clients valuable time and budget when planning data acquisition, analysis, and submission activities**
- **As a seven-year accredited partner with Medidata, we're able to leverage and support its Rave® platform. The eClinical Solutions team is highly experienced in configuring the software for clinical trials as well as developing global libraries for our clients—reducing cost and development time for subsequent trials by 30 percent**

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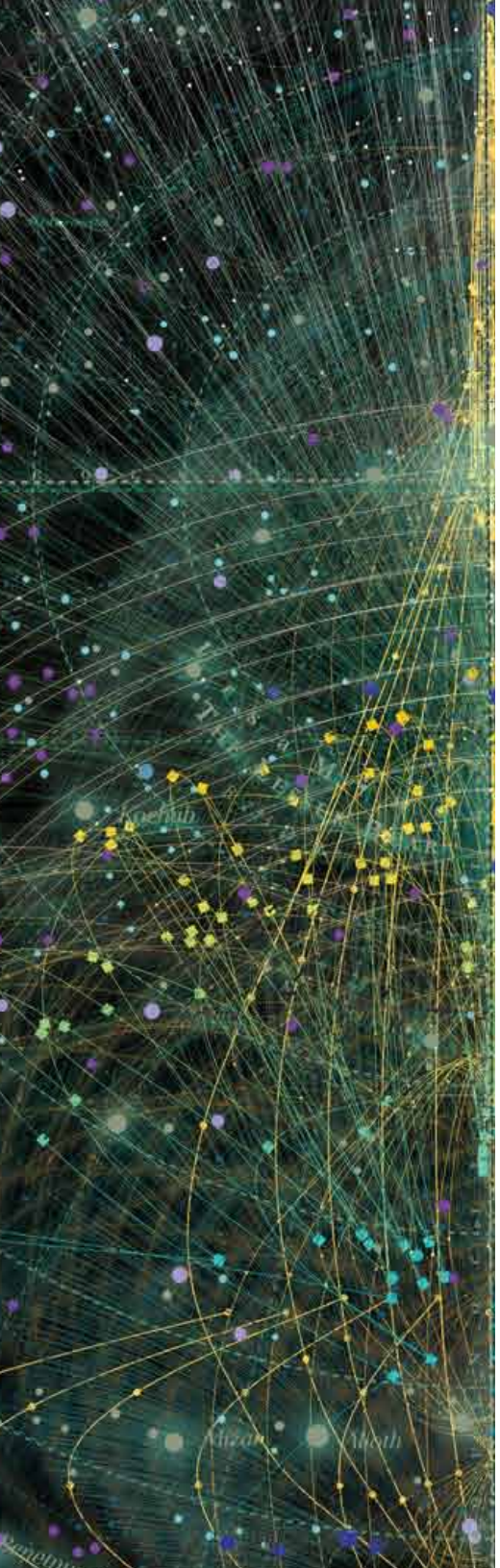
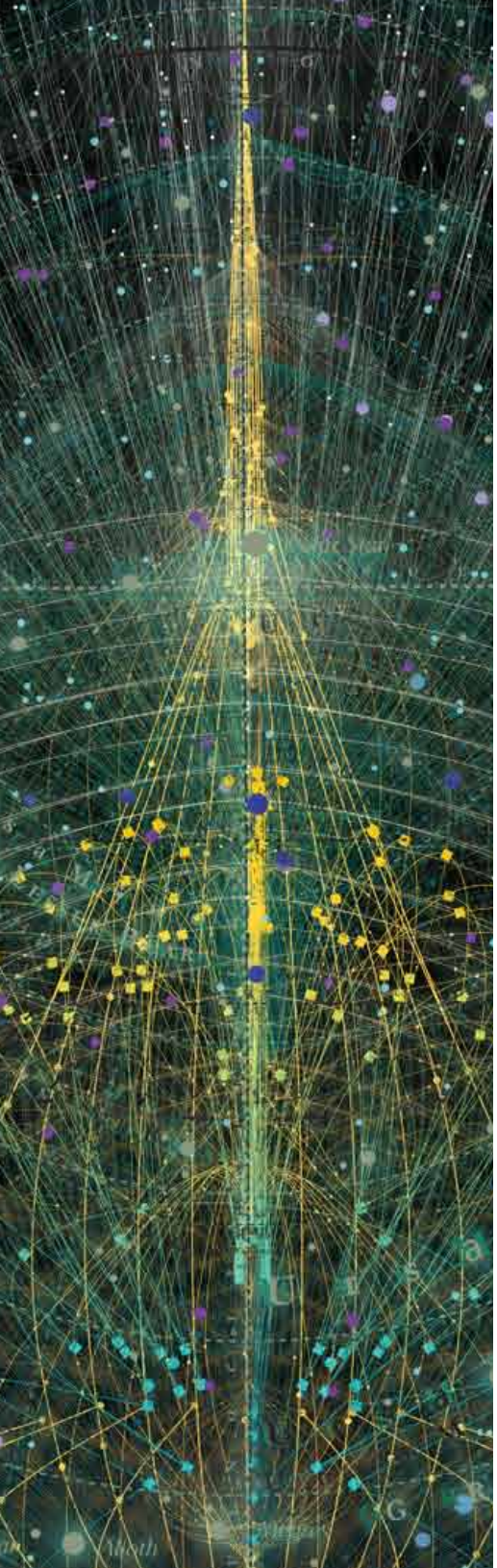


Real Differentiators

How can an organization increase the intrinsic value of data collected from various sources across all their clinical trials? Simple. Make it accessible and meaningful to end-users so they can make critical decisions. One of our core directives is to empower our clients to have complete access to all their collected data, and allow visualization and analysis across trials—down to the patient level—simply and easily. In our pursuit of this, eClinical Solutions has developed elluminate™. It enables both our partners and data managers to see collected data in a new light—both during the trial and after database lock. We configure and implement elluminate for use during the trial, which allows access to advanced analytics, brilliant visualizations and reporting for both data managers and clients.

Every functional team within an organization has different objectives and goals for utilizing data. We bridge the gap between the source and the data given to these functional teams by providing business intelligence views that allow the data to tell a story. A story that can be easily analyzed and acted upon.

We provide business intelligence views that allow data to tell a story



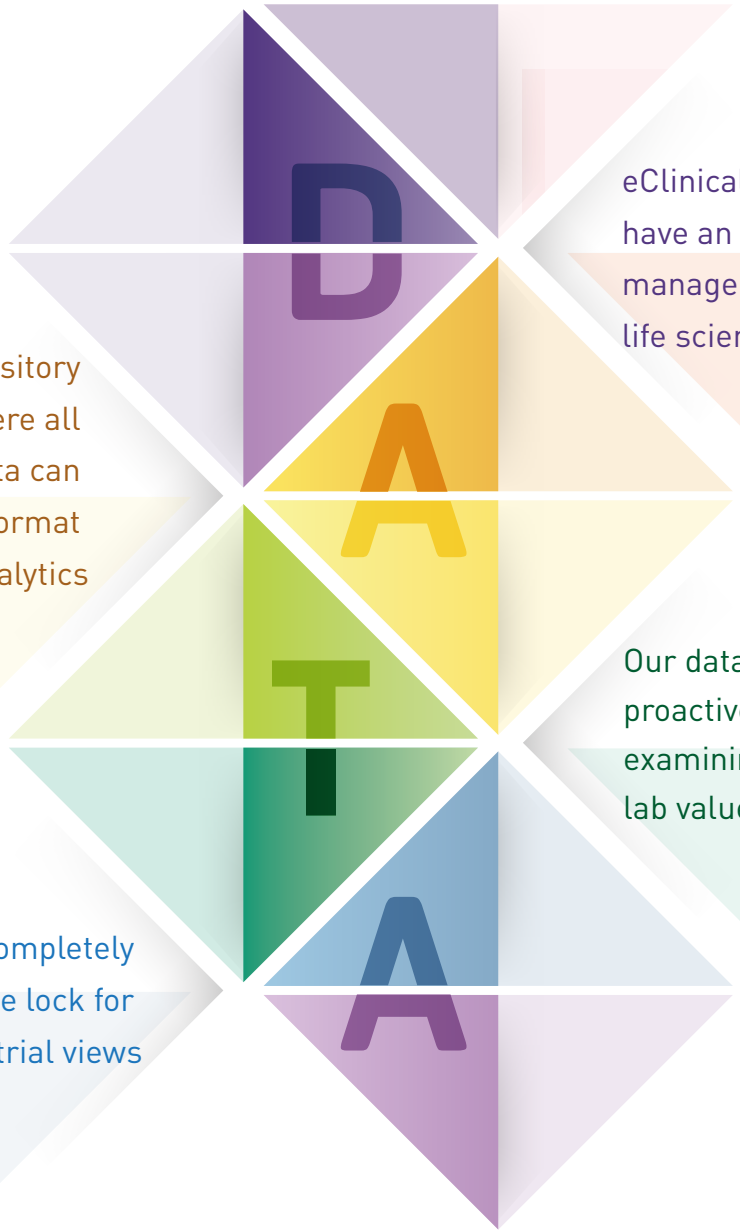
Real Differentiators

Now an organization can access and analyze all their clinical data in a standard format at any time, across trials, during or after a study is completed. In addition, data management teams can access elluminate for proactive data management and help other stakeholders make critical decisions by:

- Reviewing data (i.e., lab, ECG, vital sign, efficacy) for trends, plausibility, outliers and changes in baseline through dashboards and visualization
- Monitoring adverse events and concomitant medications
- Reconciling all third party data to ensure records are as expected and data is within ranges
- Reviewing early discontinuations for safety signals
- Confirming consistency of adverse events (e.g. end points) with relevant panels across the trial
- Confirming consistency of study disposition page (reason discontinued) with adverse events or lab data as applicable

eClinical Solutions data managers have an average of ten years of data management experience in life sciences

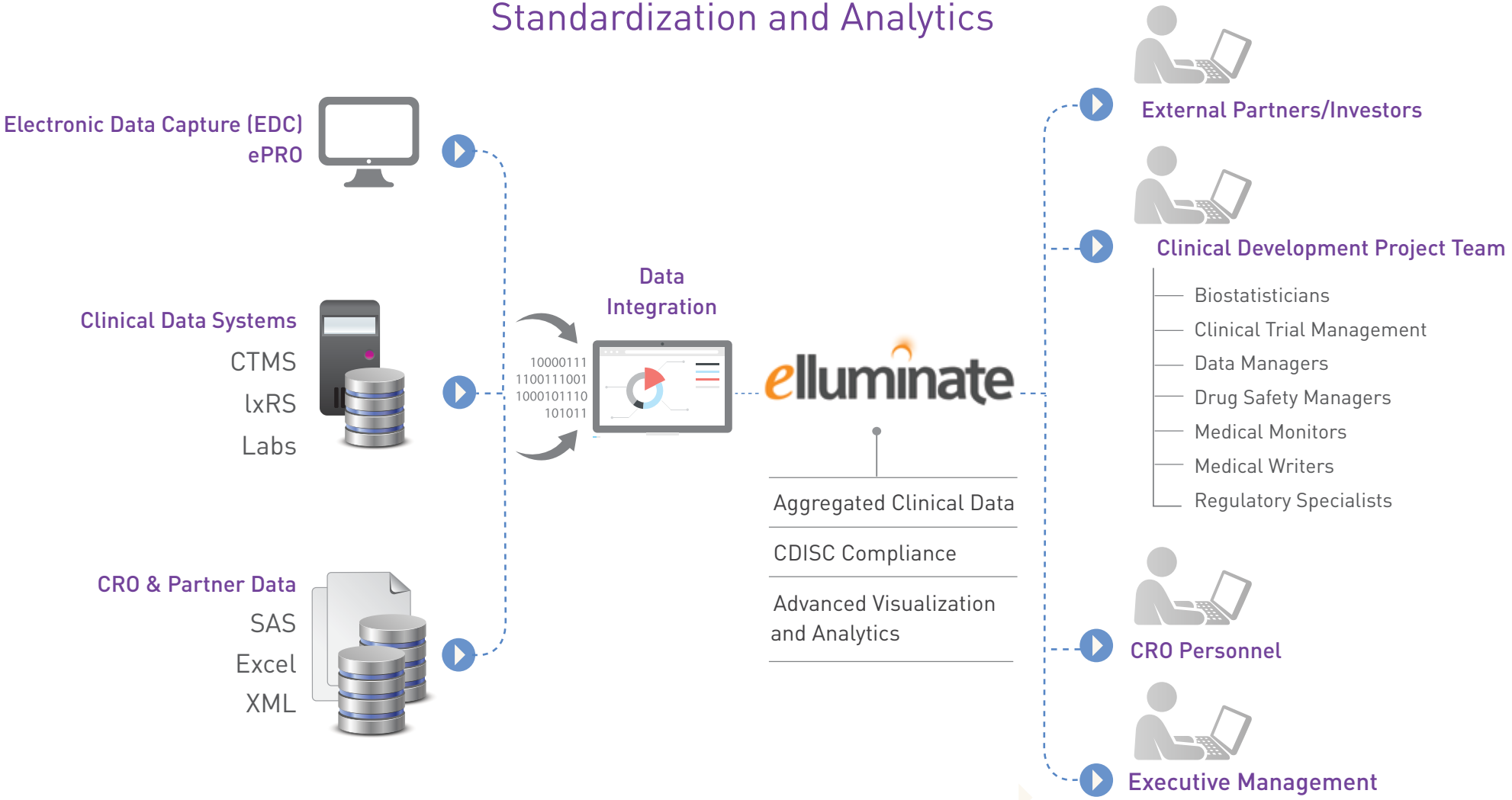
Our elluminate clinical data repository is implemented at trial start, where all of an organization's collected data can be aggregated in standardized format for powerful visualizations and analytics

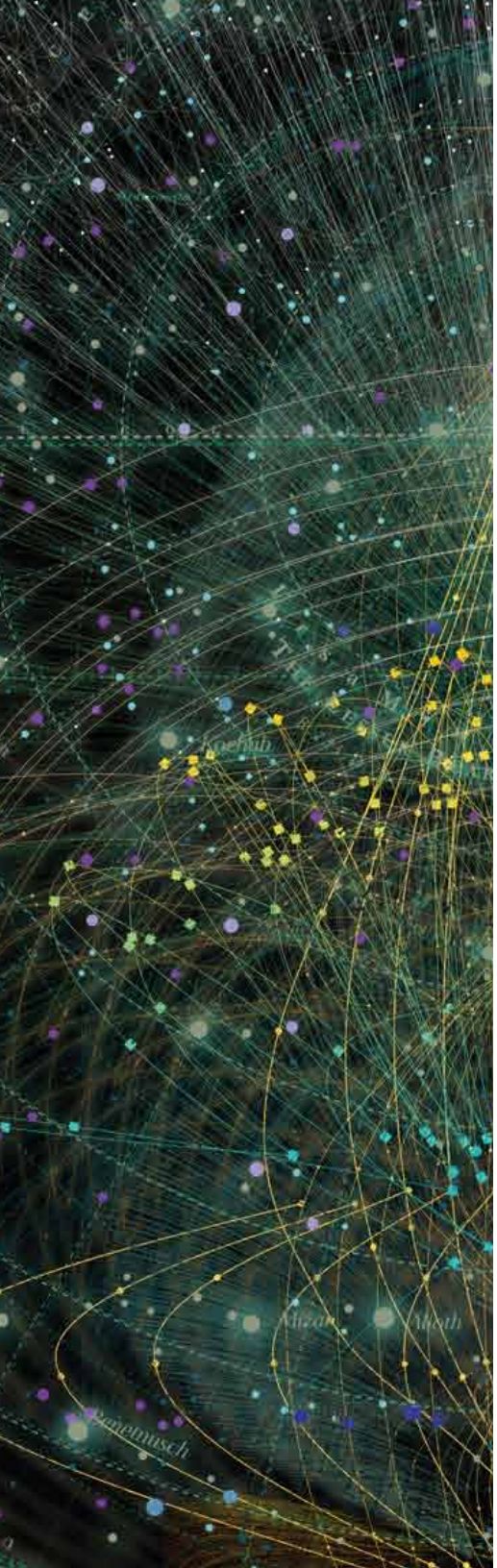


Our data managers utilize elluminate for proactive data trending and analysis, including examining safety outliers, change in base line, lab value analysis, and building patient profiles

Allows data to be completely accessible after database lock for cross-trial views

Empowering through Accessibility, Standardization and Analytics





Access as a Form of Function

During and after the study, elluminate enables stakeholders complete accessibility according to defined roles set by the organization. Gone are the days of requesting SAS datasets from service partners that charge for transfers. With all of your clinical data aggregated and configured by compound, phase, indication, therapeutic area, or any other defined label, it can be effortlessly exported in SAS, CSV, Excel, ASCII or ODM (XML) on demand—all in SDTM or Sponsor-defined standards. elluminate also enables the simple sharing of data which gives the user the ability to send exports to stakeholders directly from the platform. Additionally, it allows Sponsors to share the unique insights of one of their most valued assets.

We become a

cornerstone of your

clinical development plan

by offering standardization of clinical data, process and technologies. All the while, we provide you with unparalleled access and views of all your clinical data.

Take the first step toward truly interacting with your clinical data. Contact eClinical Solutions today for an engaging platform demonstration that will change the way you see data.

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