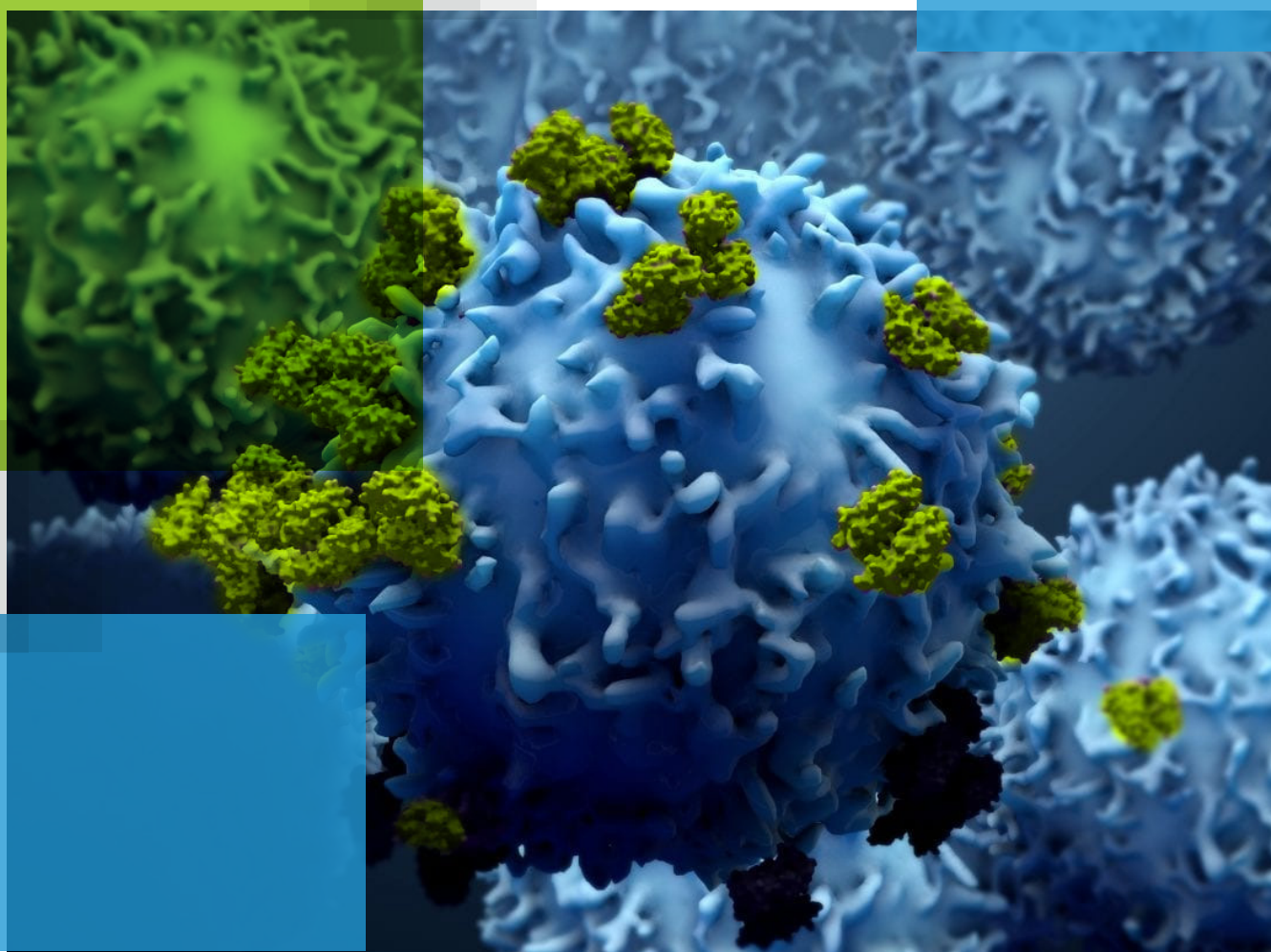
Algorics

VISUALIZING THE PATIENT JOURNEY

How Patient Profiles Enable Better Clinical Research



A visual patient profile combines data on an individual trial participant ranging from a simple data extract or text summary to more informative, sophisticated tools that incorporate graphics and several views of the data to meet the needs of various stakeholders involved in clinical development.

Patient profiles are important data points gathered on individual clinical trial subjects enabling investigators and sponsors in tracking the subject's data journey through clinical development.

In other words, this profile is a complete collection of patient data covering domains such as, the subject's demographics, vitals, medical history, treatments, lab test results, related medications, adverse events and others, that are included in the clinical database.

Typically, statistical programmers leverage SAS to generate listings and graphics that serve as patient profiles while preparing the data for review and reporting. This long list of output is often unmanageable and confusing for reviewers.

Thus, simplifying the visualization of a patient profile plays an important role in effective data analysis, allowing scientists to better comprehend and analyse large amounts of data, derive meaningful insights and expedite important research outcomes.

How are patient profiles leveraged?

In the recent years clinical trials have increased in complexity with a variety of endpoints and outcomes to reach. At the same time, patient enrolment and retention has become more and more challenging. Thus, it has become critical to extract maximum value from every data point gathered. Thus patient profiles across therapeutic areas serve a particularly important role.

User-friendly subject level data in the form of patient profiles immensely help reviewers gain richer insights about subject data, monitor safety signals and events, as well as mitigate risks.

Patient profiles also enable medical writers take an early look at the incoming data before listings, figures, and tables are produced from the analysis datasets, increasing efficiency, and allowing the creation of patient narratives before the clinical study report. This facilitates faster identification of any data anomalies so researchers can more efficiently monitor potential safety trends, which are critical in protecting the interests of patients in ongoing trials.

Typical Challenges Faced

The increased complexity of protocol requirements and diverse data sources are key challenges in the current clinical trial landscape and are likely to continue in the post pandemic era as well. Thus, sponsor companies are consistently looking for innovative technology solutions to effectively manage these challenges and the need of the hour is customized viewing of the patient profiles, which drives higher utility with stakeholders. With the right tool, patient profile visualizations can be tailored as per study needs and therapy areas to facilitate periodic review and evaluation to monitor participant safety, study conduct and progress as well as eventually efficacy.

At Algorics, our goal is to offer a comprehensive solution that delivers a strong visual framework allowing multidimensional data visualization of patient data from multiple domains, with differentiation of standard and study specific domains.

The Algorics
Solution

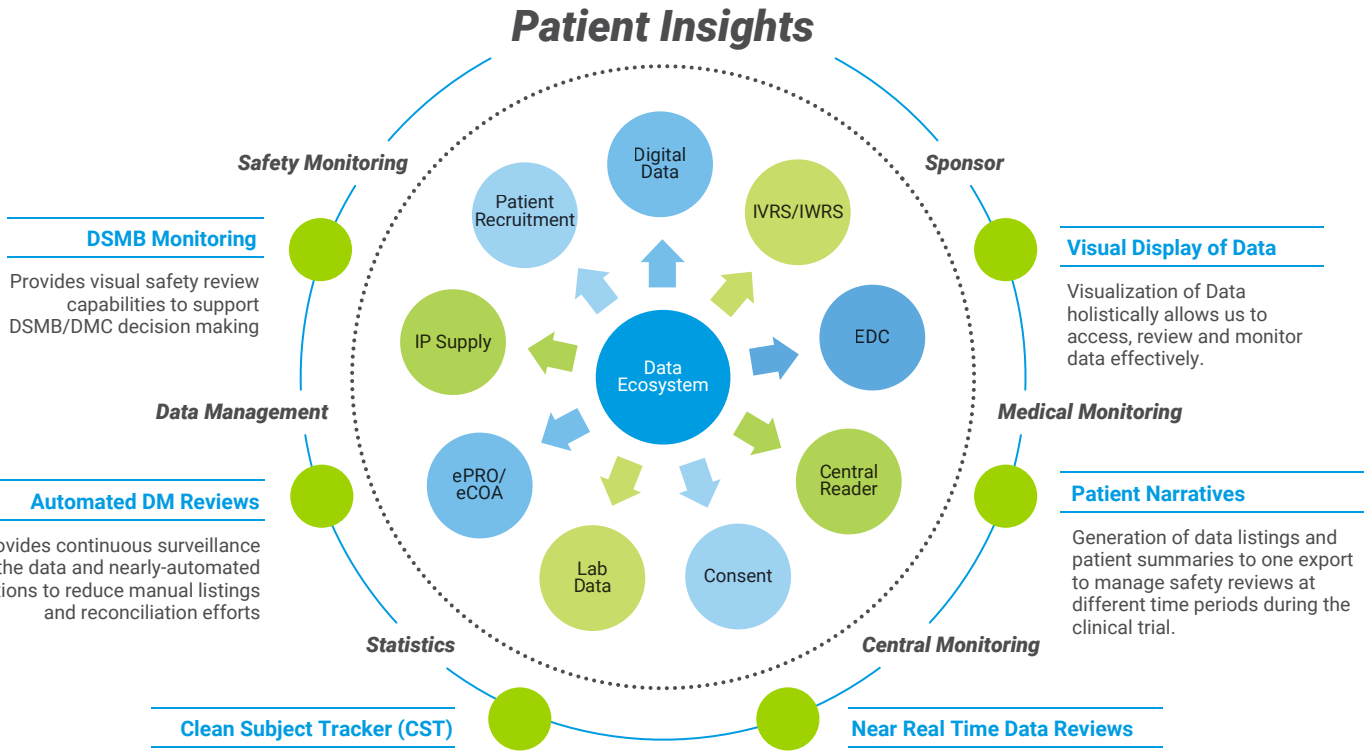
Patient profiles can be challenging to create from scratch and involve mapping non-standard input data to a format like that of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) standards. Without a patient profile tool, it falls upon the study statistician to provide suggested formats or templates for data presentation. This manual approach is not only time consuming but also inefficient. Several off-the-shelf solutions are available, but these may not always allow the integration of diverse data sources and limit generation of insights.

Our Patient Insights visualization suite integrates data from diverse data sources, utilizes industry data standards such as CDISC SDTM, and offers distinct views with a complete visual framework that can differentiate standard and study specific domains (critical data domains).

To support our biopharma, biotech and CRO clients, Algorics has built a comprehensive Visual Patient Profile called “Patient In-sights (PI)” using Business Intelligence tools (E.g., Tibco)

Our Comprehensive

Visual Patient Profile Framework



DSMB Monitoring

Provides visual safety review capabilities to support DSMB/DMC decision making

Visual Display of Data

Visualization of Data holistically allows us to access, review and monitor data effectively.

Automated DM Reviews

Provides continuous surveillance of the data and nearly-automated solutions to reduce manual listings and reconciliation efforts

Patient Narratives

Generation of data listings and patient summaries to one export to manage safety reviews at different time periods during the clinical trial.

Clean Subject Tracker (CST)

Keeps track of patient data cleaning status and ensures CSR are monitored for milestones (E.g Interum lovk)

Near Real Time Data Reviews

Provides an ability to review the data nearly real time for early identification of data anomalies that will helps timely resolution

What makes us Different?

Risk-Based Approach Adoption

As the industry shifts towards a risk based approach with ICH-GCP E6 revisions, our solution is built to make the adaptation of a risk-based approach easier and compliant with regulatory requirements

Customization

Though our model is ready to use that aligns with the requirements of most clients, we also provide customization as per study needs and support flexible usage

Seamless Data Integration

Our Data Integration facility brings together all non-standard and standard data domains from various data sources to enable multidimensional data visualization. By bringing in data from different systems, reviewers can build a more holistic view of the patient journey connecting standard domains (e.g., AEs, drug accountability) and study specific domains (e.g., PK, ePROs, and eCOA)

Oncology Data Enricher

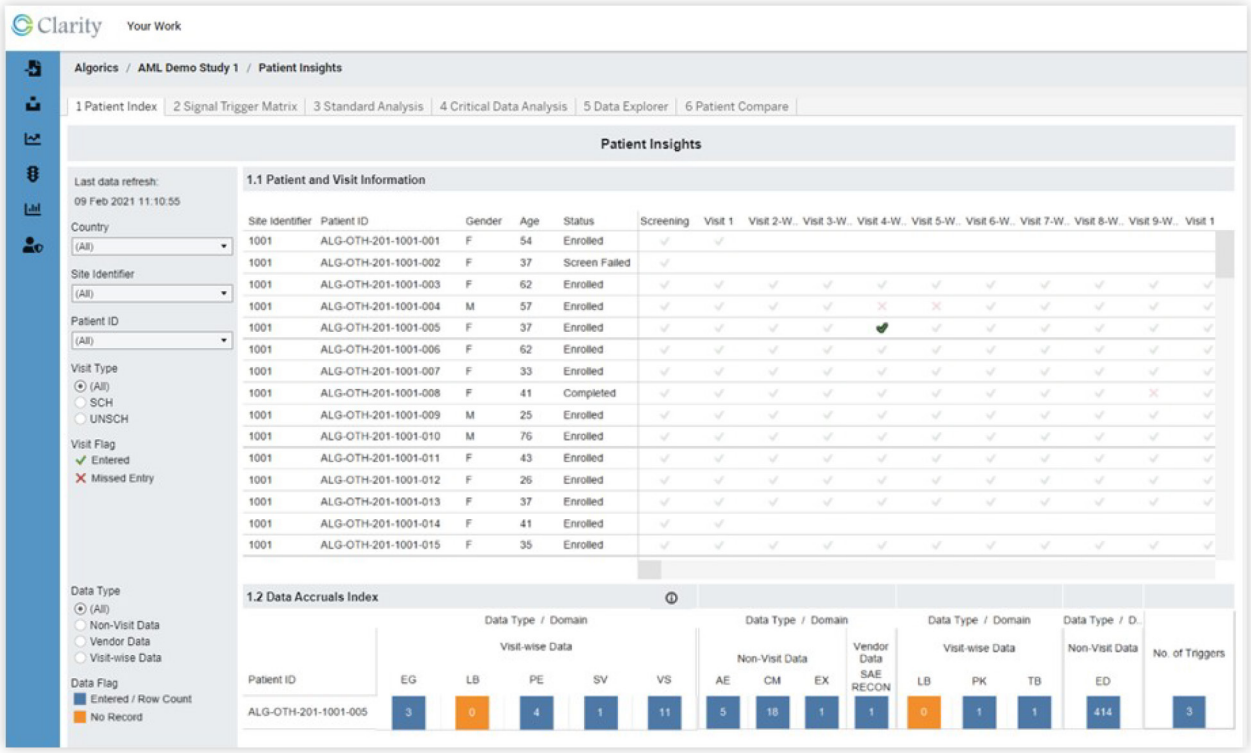
Adapting our approach to patient profiles to provide deeper insights on the subject's journey throughout the trial is a valuable endeavour that stands to improve our overall understanding of an oncology patient's experience and streamline clinical trial operations. This structure facilitates highly targeted and routine patient profile reviews depending on the study specific needs such as complex trial design adaptation. This tool is developed keeping in mind the needs focused specifically to our oncology biotech clients using Tableau and built around relevant CDISC SDTM Standards.

Support Decentralized Trials

Decentralized clinical trials are considered the next generation of clinical development today. Although one concern with DCTs continues to be the ability to integrate data coming from DCT platforms with existing data ecosystems. Algorics' Patient Insights is a unique platform that effectively allows integration and smooth conduct of DCTs

Our risk-based quality management system, Clarity is a modular and fully integrated technology solution that offers end-to-end capability to synchronize and deliver all quality management (QM) steps defined in Section 5.0 of the ICH-GCP E6 guideline. Clarity enables biopharma and life sciences research companies manage their quality framework through the clinical development process spanning from risk planning, control, surveillance, review through to reporting.

Clarity



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If this is interesting to you, we are excited to have a conversation and share more.Reach us at **hello@algorics.com** for a in depth discussion with our teams.

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