Algorics

GLOBAL CLINICAL DATA MANAGEMENT

Business problem

Biopharma and biotech companies invest significant effort to design, plan, and execute clinical trials. The output of all this effort is the clinical data which is collected, validated and analyzed to confirm the defined clinical outcomes. Clinical data management is therefore a significant part of the clinical development effort but with increasing complexities in clinical trials, it is not straight forward and if not done well can delay time to market, thus denying life-saving treatments to patients

Algorics approach to data management

Sixty percent of data collected today is from non-EDC / external sources, trials have become more complex and technology plays an increasing part in the modern clinical trial, making data collection, cleaning and management much more challenging. Algorics have built out a broad data management ecosystem which allows us to be the sole "clinical data" partner for biopharma and biotechs, so as the clinical operations are delivered by a variety of partners, we provide a single global approach to data operations across all of a client's studies.

This approach with a single point of ownership and set of processes, ensures our clients have complete control over their data end-to-end while being effectively supported by the most appropriate technology, and expert teams.

Our clinical data management portfolio includes:

Services
End-to-end data management services

People
Resourcing across levels for data management and oversight

Processes
Dedicated SOPs and customization of workflows based on study and client needs

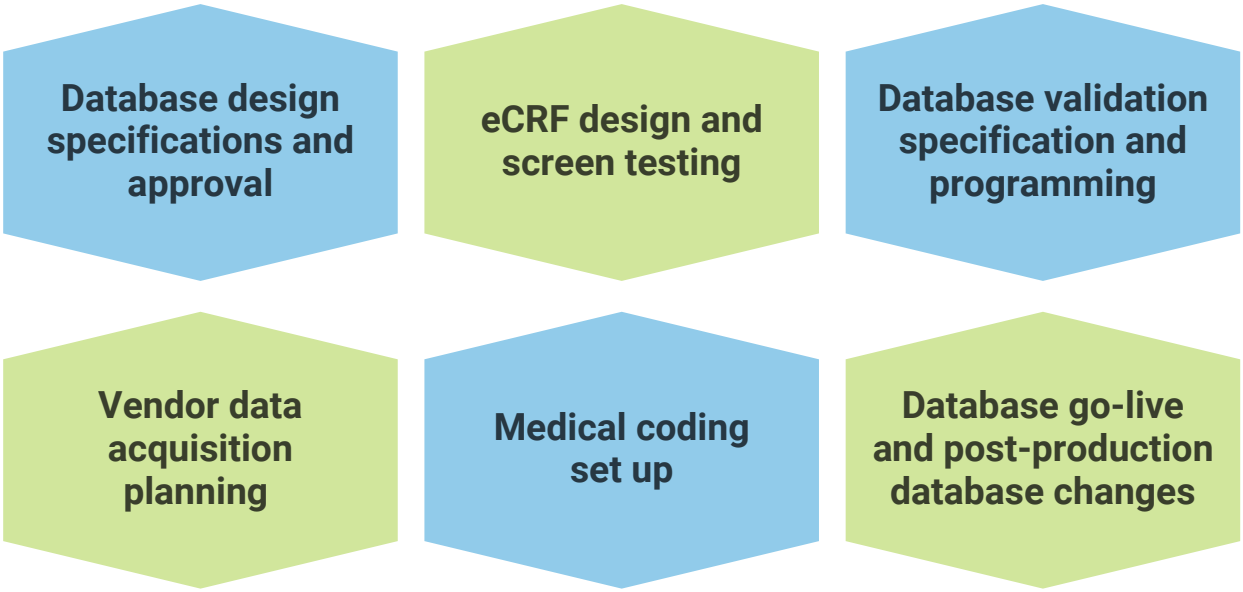
Technology
Implementing the right systems for data management and risk and quality oversight

Study start up: Data acquisition

The most critical part of any clinical study is getting the data acquisition right. If the foundation is strong, execution until close out can be a lot simpler.

We enable this with strong data base design and validation expertise with 270+ preconfigured CRF design and edit checks library.

Study start up services include:



EDC Partners

Preferred EDC Partner

Vault CDMS

Other EDCs Supported

medidata Rave

medrio

ORACLE HEALTH SCIENCES

crucial DATA SOLUTIONS

In-progress: Data review

For in-progress data reviews, we bring in our proprietary technology, Clarity which has powerful data visualizations to access, review and monitor data. This enables near-real time data reviews to identify data anomalies ahead of the curve and have mitigation strategies in place. In addition, Clarity also supports automated data review solutions to reduce manual listings and vendor reconciliation efforts.

Data sources can be as follows but not limited to:

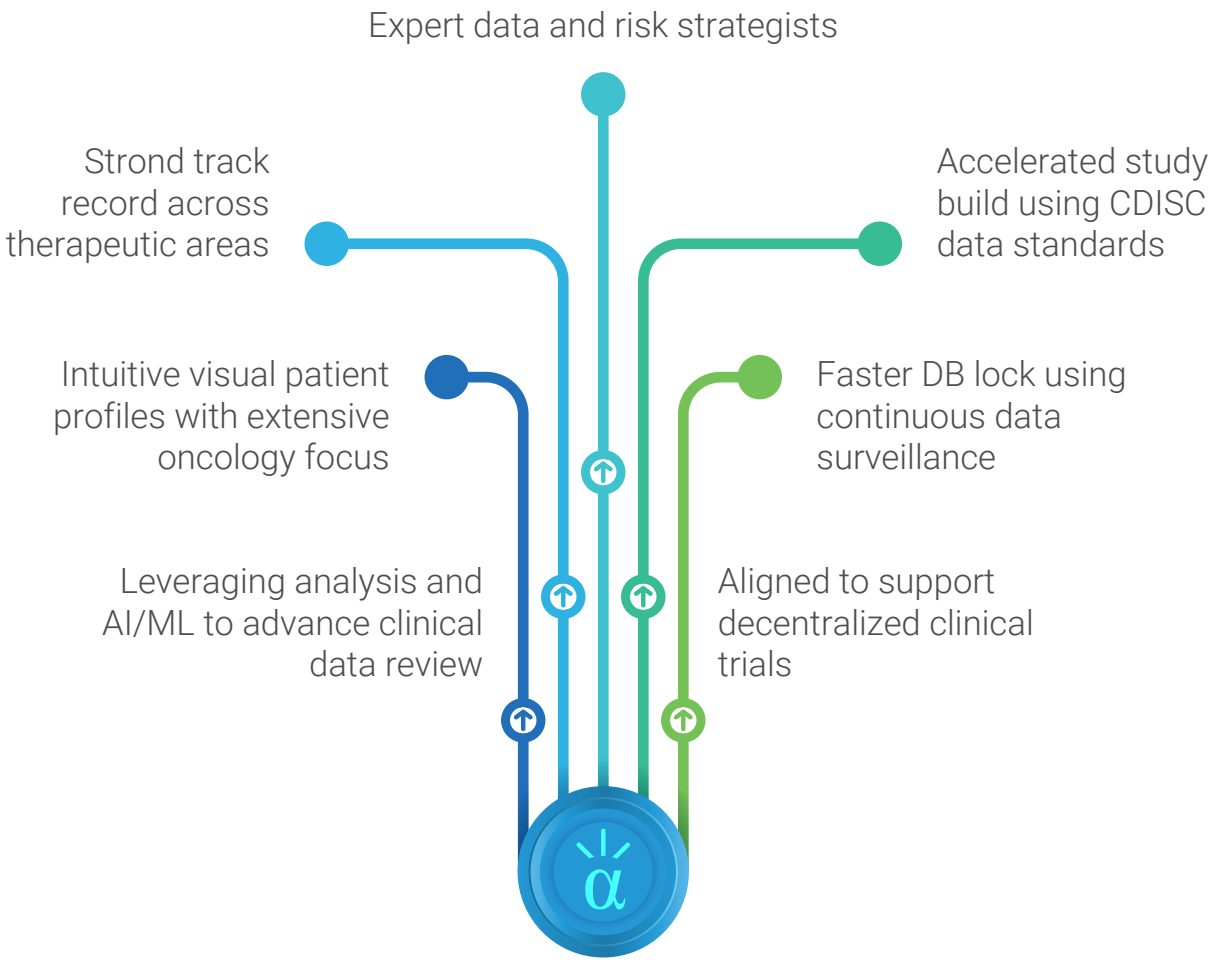
EDC data	Central reader	eConsent
ePRO/eCOA	Laboratory data	IP data
IVRS/IWRS	Patient sensors/ wearables	Digital data

Study close-out
Database lock and closures

We belive if the first two parts are executed smoothly, faster database lock can be ensured. Irrespetive of where your sites are and how complicated the study is, we ensure a smooth study close out with activities including:

- Completing database lock checklist
- Quality review prior to database lock
- Database lock form review and approval
- Database lock
- Post database lock/unlock
- Site closures
- Data transfer and site archival

Why Algorics?



Our teams will be happy to have a conversation to understand your current data management needs, and share how we can support you effectively.

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