



# Biometrics Services

## for Digital Clinical Trials

a premier provider of digital clinical data services for trials from acquisition through submission.

### **eClinical's Biometrics Services**

Data Acquisition

Clinical Data  
Management

Biostatistics  
& Statistical  
Programming

Submission  
(ISS/ISE)

### Adapting Technology to the Unique Needs of Your Trials & Programs

Data is the currency of life sciences. At eClinical we help clients maximize the value of every data point. Our expert team members utilize modern technology and streamlined processes to deliver successful trials. We help you optimize the participant site experience to ensure the sponsor and CRO team always have the right data to ensure safety and integrity.

## Provider of Digital Trial Services Using Modern Technologies

eClinical's Biometrics Services provides experience unmatched in the industry. We have over 10 years' experience of delivering data services across therapeutic areas.

Our team of biometrics professionals averages over 15 years' experience in the life sciences industry. Their deep domain knowledge spans therapeutic areas and phases, reflecting the industry's research priorities, including strong experience in oncology and rare disease indications.

We are also technical experts in a number of clinical systems which allows us to pivot as needed with every clinical trial that we are a part of. The flexibility of our team means that you can rely on us and our expertise to help you navigate through any trial, at any phase, to ensure that you are working with high-quality

### Metrics that Out-Perform Industry Standards

- Kick-off meeting to database Go-Live in < 12 weeks
- DB Go-Live to illuminate Operational - < 2 weeks
- LPLV to DBL - < 4 weeks
- DBL to Final Stat Package - < 8 weeks
- # of findings Post - DB GoLive - 0
- High-Risk CAPAs - 0

### Our Team

Clients come to eClinical Solutions because of our digital expertise and stay with us because of our team. We share enthusiasm for maximizing the value of technology for high velocity and high quality clinical development. We know data is the currency of life sciences

and collecting data involves numerous stakeholders in clinical development. Our goal is to optimize the participant and site experience and ensure the sponsor and CRO team continuously have the data needed to ensure safety and integrity.



# eClinical's Biometrics Services

## Data Acquisition

- Unique eCRFs
- Database release
- External data integrations
- Rave module implementation

## Biostatistics & Statistical Programming

- SAP and mocks
- Randomization schedules
- Submission ready SDTM package
- aCRF.pdf
- Define.xml
- Study Data Reviewer's Guide (cSDRG)
- Pinnacle 21 report
- Submission ready ADaM package
- Analysis Data Reviewers Guide (ADRG)

## Clinical Data Management

- Database builds using Rave
- CRF design
- Data management plan
- Integrated data review and oversight plan
- Medical coding
- External vendor reconciliation
- SAE reconciliation
- Data review and query
- Listing review
- Trending/outlier identification
- Database lock activities

## ISS/ISE

- TLFs
- BIMO



*Having a data management-specific service provider that has standardized on the Medidata Rave technology has been a benefit to both the data management organization and the company as a whole. The eClinical team are experts on both the data and Medidata Rave clinical cloud.*

**Liz Thompson, Data Management Director**



## Portfolio Approach

As clients grow, we have adapted our resourcing model to grow with them. Dedicated team members stay with clients over time to shepherd their data from early phase through submission.

Our unique approach to your entire data portfolio allows for oversight of all your data with an allocated team for your studies. We have portfolio leads, statisticians, and technical architects who will work with your teams across your portfolio.

They work with study-specific teams to maximize efficiencies in the implementation of illuminate as well as global libraries, EDC, DCT and beyond! We work with you to establish portfolio standards for submission and downstream efficiencies and support you with submission planning.

## Why eClinical's Biometrics Services for Your Trial

Over the last ten years we've worked with over a hundred biopharmaceutical and medical device companies across therapeutic areas, the reasons they select and continue to work with the eClinical team include:

- Center of Excellence Approach for data related tasks of digital trial development and execution:
  - Medidata Clinical Cloud Build and Optimization
  - Decentralized Clinical Trial Builds
  - Data Standards
  - External Data Integration
  - Statistical programming
- Senior team of credentialed data specialists with years of clinical data management and design experience
- Ability to aggregate data from all studies for real time insights regardless of clinical CROs used for the studies (via illuminate)
- Dedicated to optimizing Sponsor's data assets and maximizing the value across programs

[Learn More](#)



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