AliraHealth

Statistical Consulting & Data Science

Our team of experienced statisticians and data scientists develop, implement, educate and advocate innovative methods to optimize the development of products across therapeutic areas for both medical devices and drugs.
Our integrated approach allows us to incorporate regulatory, market access, financial and patient considerations from pipeline strategizing to the design of individual trials in all phases.

Innovative Designs

> Innovative and efficient early phase designs for hypothesis, population, dose selections
> Seamless and adaptive designs
> Bayesian group sequential designs
> Bayesian adaptive designs with historical borrowing
> Hybrid designs
> Post-marketing or Early Access Program trial designs
> Real World Evidence data collection strategies and analyses
> Trial designs under master protocols

Innovative Approaches for Trials with Complex Endpoints

> Adaptive designs with longitudinal and time-to-event endpoints
> Multiple endpoints – providing best way to handle multiplicity
> Digital endpoints including images and signals
> Adaptive designs for diagnostic validation studies
> Thorough considerations for estimands
> Go/No-Go analysis based on historical/external data
> Hierarchical composite endpoints for CVD and acute care trials

Data Science Innovations

> Machine learning (ML) models applied to images, signal, omics and clinical data
> Biomarker discovery analyses
> Development of ML algorithms for diagnostic devices
> Landmark event prediction (Bayesian and Frequentist)
> Data Mining

Consultancy and Collaboration

> Data Monitoring Committees / Data Safety Monitoring Boards
> Preparation and participation in interactions with regulatory authorities
> Integrated collaboration with Market Access, Regulatory, Clinical, Financial, and Patient Engagement Teams
> Preparation and participation in due diligence

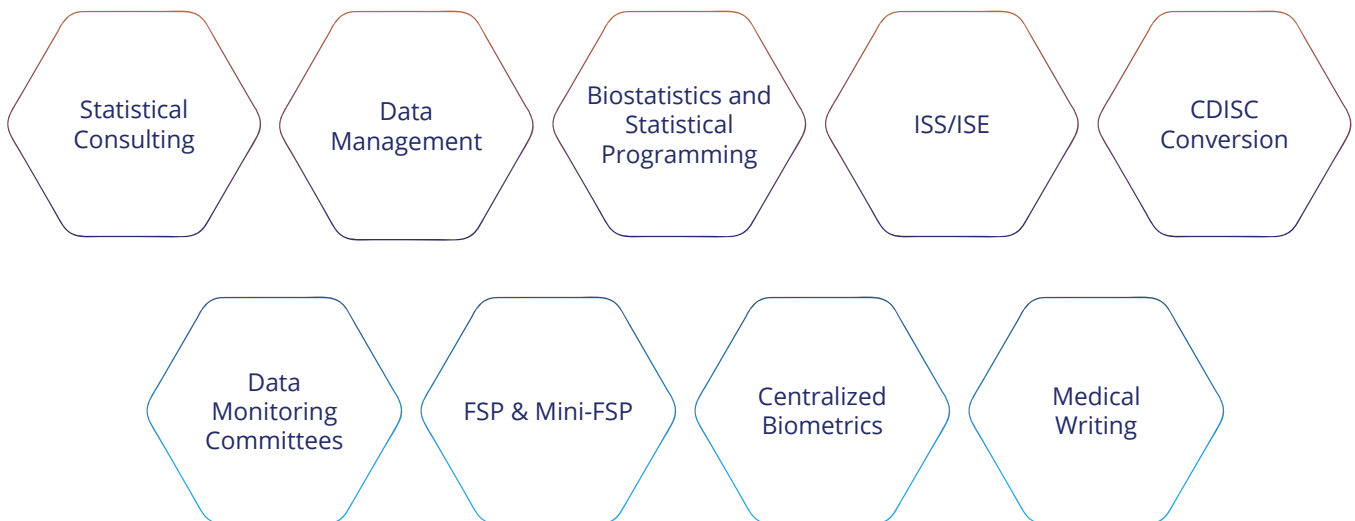info@alirahealth.com - www.alirahealth.com

AliraHealth

Delivering Innovative, Effective, Tech-Enabled Biometrics Solutions

Bringing Data to the Forefront of Your Strategy

Leveraging data as your key asset can maximize insights, increase quality and access, and decrease reporting timelines. Our team of biometrics experts works closely with you from start to finish, delivering integrated solutions and reporting for regulatory submissions.

Our Biometrics offering includes:

- Statistical Consulting
- Data Management
- Biostatistics and Statistical Programming
- ISS/ISE
- CDISC Conversion
- Data Monitoring Committees
- FSP & Mini-FSP
- Centralized Biometrics
- Medical Writing

Why Choose Alira Health?

Our biometrics team has provided expert guidance for over 500 projects, including regulatory interactions and submissions, study-based data management, biostatistics, and statistical programming. You will benefit from our:

- Leadership and guidance from an expert team of over 100 biostatisticians, data managers, statistical programmers, data scientists, and medical writers

- Dedicated, experienced in-house data specialists, with an average of over 10 years of industry experience

- Tiered governance approach designed to mitigate risks, guarantee quality, and improve efficiency of project teams.

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