Algorics

Early Signals

Starting stronger with early evidence generation

While making the transition from the lab to clinic, the pitfalls of early development are widely known to derail clinical development plans. Quite often called “The Valley of Death” results that are promising in the lab can often produce confusing results in early phase studies. As you embark on the early development journey, robust scientific planning to ensure you capture and evaluate evidence signals early for informed decision making, gets you ahead of the curve.

Business problem

As emerging biotechs go through early-stage development, they are typically faced with the critical decision of either continuing development, staging the program or killing the program. These decisions are usually hinged on poor scientific planning, overlooking critical safety signals, and overestimating or underestimating the potential of a drug candidate, resulting is very expensive late phase failures. This not only impacts the cost of development but also the loss of time to market and reduced valuation of the product.

How does Early Signals help?

As the name suggests, Early Signals is a highly focused group of expert biostatisticians leveraging your data and our technology to generate early evidence insights. Right from the point of designing your early phase study, defining the sample size, SAP and SAR creation to delivering the final trial analysis, our team collaborates with you every step of the way. Enabled by a wide spectrum of experience across study types and designs, we also support PK/PD analysis and reporting, helping you derive important evidence from early PK data.

End to end portfolio of solutions:

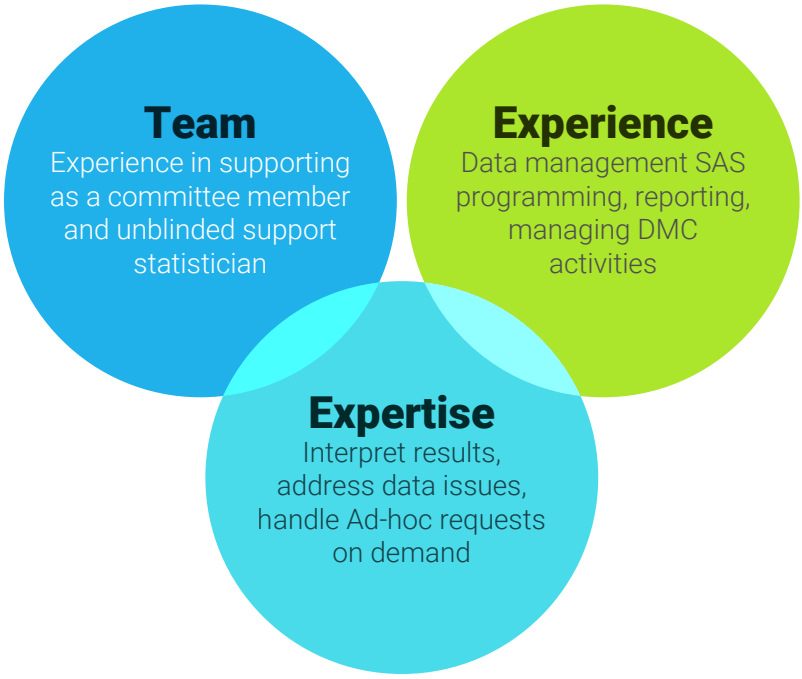
Biostatistical solutions	PK / PD solutions
• Input To Protocol/Synopsis • Study Design Inputs • Sample Size Estimation/Justification • Randomization Specification Writing/Review And Generation (Blinded/Unblinded/Open Label) • CRF Input And Review Edit Checks Specification Review/Non-CRF Data Guideline Review/ Data Issue Discussion and Handling • Study Timeline Discussion and end to end execution • Statistical Analysis Plan (SAP) Creation/Review Along with Mock Shells. • DMC/DSUR/Interim SAP and Shell Creation/Review • DMC Statistician (Unblinded) • Statistical Independent Review Of SDTM/ADaM Specifications. • TLFs Specification Review • 100% Review of Outputs Generated • Query Resolution	• Inputs to CRF as per the PK/PD endpoints • Working closely with DM for preparing the NON-CRF guidelines for PK/PD • Input to SAP/DAP for the PK/PD sections. • PK memo for the blinded data review/Dry runs/Interim(s) • Preforming Reconciliation between EDC and Vendor data • Assisting PK Non compartmental analysis. • Developing intermediate input dataset for PK analysis • Developing CDISC complaint (SDTM and ADaM) dataset for PK/PD. • PK TLFs programming and validation • Performing statistical analysis of the PK/PD parameter as per the SAP/protocol • Working closely with Medical Writer (MW) for the result interpretation and compilation of the CSR.POP **POPK:** • Creation of NONMEM POPPK dataset • Developing the Exposure Safety (ERS) and Exposure Efficacy (ERE) dataset for POPK modelling

Revolutionizing DMC support

Data Monitoring Committee (DMC) services are required to monitor safety and/or efficacy for many early clinical trials but mostly delivering timely and accurate results is challenging. With strong experience across data management and SAS programming, we provide data and program quality reports as well as manage DMC activities.

Additionally, our risk-based quality management system, Clarity is a modular and fully integrated technology solution has an in-built DMC dashboard that enables to you to corroborate data points for DMC submissions and track the entire journey.

Our strengths in DMC services:



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If you are in early development and early evidence generation is your goal, we would be happy to share more on how we can assist you with it.
Reach us at **hello@algorics.com**

www.algorics.com