

Providing premium clinical trial management support, with on-time and in-budget project delivery.



## SERVICES OFFERED

### STUDY SUPPORT

#### Start Up

From project kick-off to site activation, our team will work with yours to complete all required start-up activities by helping:

- Assist with protocol review or finalization
- Create project plans or manuals, study binders, PSV, SIV, IMV, COV and remote visit slides, annotations and letter templates
- Provide vendor and IRB oversight
- Perform contract/budget negotiation with selected vendors or sites
- Conduct site and country feasibility assessments
- Plan and conduct virtual or in-person Investigator Meetings
- Build timelines to meet FPFV targets and design successful mitigation strategies

#### Close Out

Assistance with the study finalization process and closure activities involves:

- Database locks and data cleaning
- Return of study drugs and supplies
- Preparing the clinical study report
- Final eTMF and finance reconciliation

### STUDY RESCUE

Did your study fall off track? We can help save your study by:

- Determining where the study went wrong
- Assessing if and how the study can be corrected
- Formulating a clear action plan to move forward with the remainder of the study

#### Maintenance

When monitoring and overseeing an activated study, we ensure timelines are met and the study remains on track through:

- Site activation, recruitment, and retention strategies
- Risk mitigation
- Vendor management
- Data management, including query, data entry and DM metrics oversight
- Interim analysis planning and execution
- eTMF maintenance
- Training or subsequent Investigator Meetings as needed

### CUSTOMIZED SUPPORT

We are happy to customize a plan based on your needs! Individualized support may include:

- Planning
- Task management (short and long term)
- Review of study procedures, plans, and/or protocol design

Successful clinical research begins with high standards and a strong foundation.  
Together we can collaborate to integrate best practices, improve efficiencies, and put patients first!

— TIFFANY ASHTON —