

Supporting innovative clients through the clinical trial process



How can we help you meet your study goals?

PharPoint is a **US based contract research organization (CRO)** that has supported over 1,000 clinical trials for clients of all sizes with various needs. Our services include:

- Clinical consulting
- Site feasibility
- Project management
- Clinical monitoring
- Site management
- Medical monitoring
- Data management
- DMC coordination
- Biostatistics & statistical programming
- Medical writing

PLANNING

Work with our experts to mitigate risk & prepare for a successful clinical trial.

- Preparation of regulatory package content required for trial start-up, inclusive of:
 - Protocol development
 - Investigator's brochure
- Creation of a clinical development plan
- Strategic site identification and enrollment predictions
- Sample size planning and power calculations

START-UP Quickly and effectively operationalize your study plans.

- Site activation, including:
 - Site identification, selection, & qualification visits
 - Budget & contract negotiations
 - Essential document collection and review
 - Management of IRB submission
 - Study team alignment, including:
 - Kick-off meeting
 - Study team training
 - Investigator meetings
- Vendor selection, including:
 - Quality assurance (QA) audits
 - Contract negotiation

- Development of strategic study plans & materials:
 - Data Management Plan & Case Report Forms (CRFs)
 - Project management & clinical plans
 - Informed Consent Form template
 - Medical Monitoring Plan
 - Randomization Plan
- Development of study tools, including:
 - Electronic Data Capture (EDC) build
 - Clinical Trial Management System (CTMS) and electronic Trial Master File (eTMF) set-up

CONDUCT

Keep your study on track and in compliance with real-time reporting.

- Experienced, attentive Clinical Research Associates (CRAs) to conduct site initiation and monitoring visits
- Ongoing data cleaning & reconciliation
- Medical coding
- Early statistical support, inclusive of:
 - Interim analysis
 - Statistical Analysis Plan (SAP) development
 - Development of shell Table, Listings & Figures (TLFs) for expedited analysis
- Vendor management
- Patient narratives & profiles
- Data review committee (DMC, DSMB, DSUR, SRC) participation, member recruitment and administrative support
- Project management and centralized site management, including real-time reporting on performance
- Medical monitoring
- Site payment processing

CLOSE-OUT

Get results one month faster than industry average.

- Efficient site close-out visits
- Expedited database lock
- Rapid top line results
- Timely Clinical Study Report (CSR)

Work a with a flexible CRO with a consultative approach to meet your needs.

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