ancillarie
passion for research

ABOUT US

We aspire to render clinical support services to Pharmaceutical, Biotechnology and Contract Research Organizations since 2012. Emphasizing the utilisation of modern technologies to ensure utmost quality and assist our clients to achieve their goals.

MISSION

Our Mission is to be branded as a pioneer in clinical support services to our partners by delivering the service on time to meet the business goals.

VISION

Our Vision is to be the Trustworthy Global clinical support company with quality services in area of Drug Development and Clinical Research.

GOAL

Our goal is to provide professional clinical support to our clients from all over the Globe with investment in modern technologies and development of individuals supporting us and our partners.

WHY CHOOSE US

We are an ISO 9001 certified global clinical support service company with a decade of experience aiming to provide quality driven services to our clients.

- ☑ We prioritize client expectations
- ☑ We strive to deliver quality service output
- ☑ We aspire to implement ‘Innovation in Business’
- ☑ We stand by our values

OUR SERVICES

Biostatistics

Ancillarie team assists in providing inputs on protocol and study design, sample size and power calculation, CRF design and review, randomization procedure and statistical analysis plan, through study level analysis of TLFs. SAP is one of the crucial document which describes the intended clinical trial analysis. We ensure regulatory process compliant submission with CDISC compliant dataset.

CDISC Implementation & Mapping

We at Ancillarie, offer our clients a range of CDISC services and are experienced in mapping to CDISC standards. We follow SDTMIG 3.1.2 to SDTMIG 3.1.3 and ADaMIG 1.0. and perform Creation of CDISC compliant CRF, CDASH and SDTM annotated CRF, Trial design compliant Dataset, SDTM and ADaM compliant Dataset, Generation of Define.xml, rtf and pdf, ADaM metadata, Utilization of Open CDISC.

Clinical Data Management

Ancillarie's experienced CDM professionals provides inputs from database selection depending on client needs and budget. We assist in CRF/eCRF Development, DMP, Annotated CRF (CDISC standards), Database design and consistency check programming, Data Entry, Data Cleaning and Query Management, Medical Coding, SAE reconciliation, External Data Management, Database release, Data Transfer, Quality Control, Interim analyses, DMC, Project Data Management.

Clinical Operations

Our Clinical Operations service portfolio includes site feasibility, evaluation and site selection, site training, vendor evaluation and management, regulatory submissions, developing study specific documents, risk-based monitoring and SDV, IP accountability and query management.

Medical Writing

To support clinical development programs as a whole we offer medical writing services, including, protocol development and amendment, clinical study report, safety narratives, Integrated Summaries of Safety (ISS),Integrated Summaries of Efficacy (ISE), Clinical Section of Common Technical Document including Module 2.5 Clinical Overview, Module 2.7.3 Summary of Clinical Efficacy (SCE), and Module 2.7.4 Summary of Clinical Safety (SCS).

Pharmacovigilance

We assist in improving client profitability by supporting various Pharmacovigilance related services, that involves, mailbox handling, case entry and medical coding, medical review, submission and distribution, triage, narrative writing and quality control

Quality Management

Our Quality Management (QM) Department ensures high quality of work.

Our QA team covers all aspects, including GCP consultancy services, study document audit, root cause analysis and handling of for-cause situations, mock inspection and inspection readiness training.
Our QC team ensures data integrity throughout trial by performing quality checks, technical and document QC, process QC and improvements, process development for SOPs and policies.

Resourcing

We offer comprehensive service options that involves functional service provider (FSP) programs to Project Based Service (PBS), Activity Oriented Service (AOS), Resource Replacement Service (RRS) and Contract Staffing (CS) for variety of services, including Biostatistics, Clinical Data Management, Medical Writing, Quality Management, Clinical Operations, Statistical Programming and Regulatory Affairs.

Statistical Programming

Statistical Programming team works closely with Biostatistics team to carry out planned analyses. We cover aspects including Statistical Programming Services, Programming of CDISC SDTM and ADaM submission ready dataset, Programming Tables, Listings and Figures, Interim analysis support.

Message from CEO

Amiit Keshav Naik

Founder and Chief Executive Officer

"To build a team of passionate researchers"

CONTACT US

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