Simplifying Clinical Trials

PPCE
rely on us

A division of Phoenix Progressive Certifications Enterprise Pvt. Ltd.

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Company Overview :

PPCE is an efficient functional service provider of Clinical Data Management, Biostatistics and Medical Writing services for global pharmaceutical and medical device companies.

Working on a number of fully validated clinical data management platforms, we cater to mid-size pharmas, while also being the partner of choice for organizations ranked amongst the Top 5 global healthcare companies.

Established in 1997, PPCE's business began with providing internationally recognized management system certifications in the areas of GMP, Good Hygiene Practices, Quality Management, Environment Management, and Occupational, Health and Safety Management for Pharmaceutical companies and clinical laboratories, oil & gas, construction, food and a number of other high risk industries.

With a sound understanding of systems, processes and regulation, in 2010, PPCE diversified to offer services to the Clinical Trials industry. Our focus is to maximize value to a trial through the interface between the crucial elements of Data Operations, Biostatistics and Medical Writing.

Global Perspective :

We understand that multi-center research cannot rely on the style of a single country. Rather, it must reflect the practices of the countries involved and conform to the regulatory guidelines, laws, customs and regulations that are unique to each country.

In keeping with this philosophy, PPCE's teams have exposure to international projects and an in-depth knowledge of international regulations, modern infrastructure, validated systems, CDISC data models, and flexible business models to suit different operational requirements.

Clinical Data Management

Because the outcome of a study is critically dependent on the quality of clinical trial data, our Data Operations teams work closely with other study stakeholders, from the beginning of a study in order to ensure efficiency in areas that will affect biostatistical analysis and submissions.

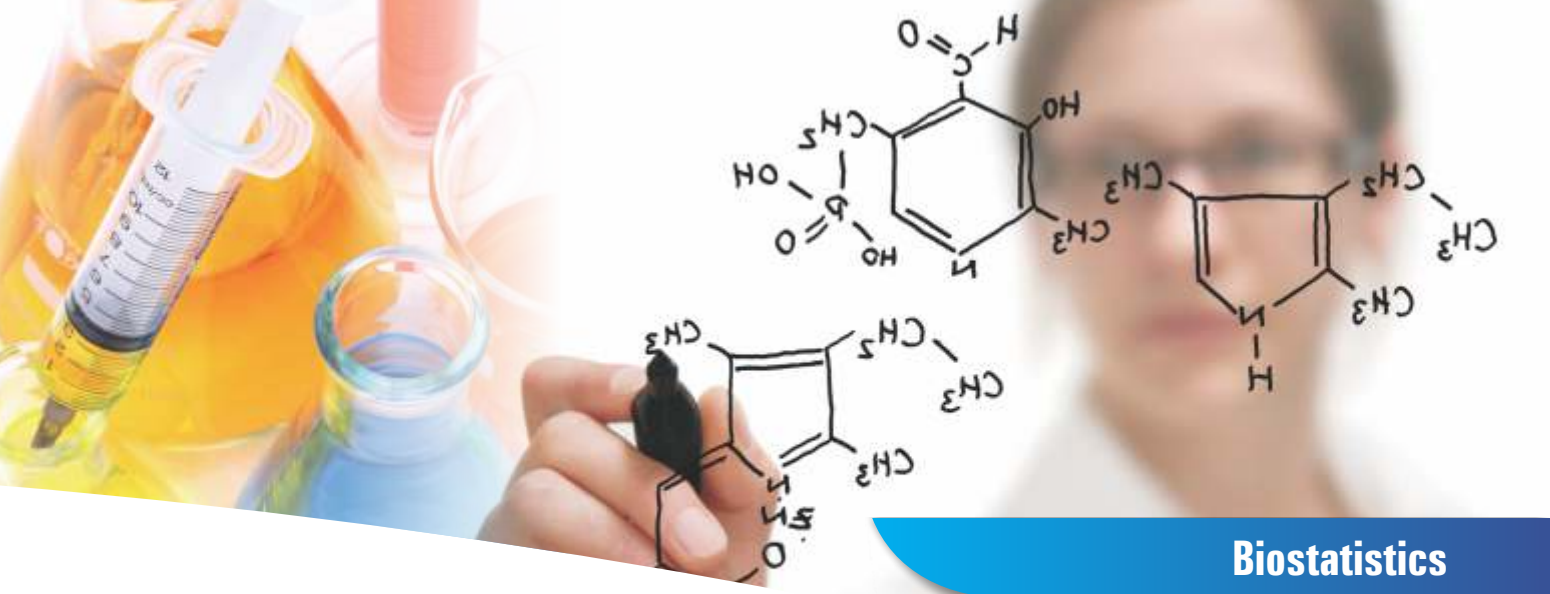
In this way, we are able to fashion workflows right from the start to ensure minimal rework, which translates into assured results and greater cost savings for both parties.

Clinical Data Management services include :

- CRF Design
- DMP Preparation
- Database Build and Validation
- Data Entry
- Edit Check designing
- Medical Coding
- SAE Reconciliation
- Lab Data Transfers
- QC and QA reviews
- Database Freeze and Lock
- Raw Datasets generation
- CDISC services

The PPCE advantage :

- **Quality by Design:** A proactive approach to issues affecting data integrity
- **Ease of Control:** Single point contact until the end of a study
- **Global Standards:** 21 CFR part 11, ICH-GCP and CDISC requirements are built into SOPs and updated at regular intervals
- **Therapeutic expertise:** Experience in various therapeutic areas with a focus on oncology
- **Quality delivery:** Regular in-house audits ensure quality and timelines are on track
- **Timeliness:** High quality output and on-time delivery - no excuses!



Biostatistics

We recognize the necessity to integrate the Biostatistics role from protocol development through study monitoring all the way to the clinical study report in a study trial.

We will coordinate and manage all your biostatistics and statistical programming requirements for accurate trial outcomes.

Biostatistics services include :

- Input to Protocol / Study Design Development
- Sample Size Estimation
- Randomization Schedule
- Statistical Analysis Plan (SAP) and Shells
- PK / PD analysis
- Analysis of Safety, Efficacy Data
- Programming of Tables, Listings, Figures
- Statistical Report Writing

The PPCE advantage :

- **Stakeholder input at planning stages :** Biostatistics input at all points of a trial from design to close out allows reliable, high quality analysis.
- **Real-time data for better decision making :** Strong communication channels and quick information flows allow you to make informed decisions in a timely, cost saving manner.
- **Flexibility :** Our willingness to meet your requirements means you have the flexibility to discover a new requirement or to revisit a decision without inordinately affecting timelines.
- **Timeliness:** High quality output and on-time delivery - no excuses!

Medical Writing

Our panel of medical writing experts will ensure that scientific and medical documents entrusted to us are crisp, clear and fully compliant with regulations and best practices.

Medical Writing services include :

- Phase I-IV Protocols
- Phase I-IV Clinical Study Reports
- Manuscripts
- Informed Consent Forms
- Investigator Brochures
- Patient Safety Narratives
- Common Technical Documents
- Periodic Safety Update Reports

The PPCE advantage :

- **Customer confidence:** In-house Quality Control and Due Diligence processes ensure technical and grammatical precision.
- **Expertise:** Our writers have diverse therapeutic backgrounds with experience in the preparation of a wide range of materials.
- **Regulatory compliance:** Development of well, structured, clear documents that follow ICH-GCP and other applicable guidelines.
- **Timeliness:** High quality output and on-time delivery - no excuses!

Clinical Research Training Programs

PPCE's aim is to improve the quality of resources in the Clinical Research industry, while increasing employability.

To do this, we run, at affordable costs, an array of technical programs and internships from which to choose. Our Clinical Research programes are recognized by hospitals and universities of repute, and our modules form part of their curriculum. Developed to deliver maximum impact, our courses equip candidates with the knowledge and skill sets specifically required by recruiters.

Key Differentiators

- **Management systems :** Robust SOPs and project management practices aim at quality through the elimination of 'muda'.
- **People power :** Our team of Clinical Data Managers, Designers, Programmers and Medical Coders has extensive experience in clinical trials for pharmaceuticals and medical devices.
- **Regulations :** Core Clinical Trial services are delivered on a strong platform of regulatory expertise in GCDMP, ICH-GCP, CDISC, HIPAA and 21 CFR part 11 regulations.
- **Track record of Quality Assurance and Excellence :** Two decades in Quality Assurance services to over 1000 clients. Preferred vendor status for pharmaceutical companies in Australasia.
- **Customer Service :** You can leave the anxieties of trial management safely in our hands and remain confident in the quality of trial output. Our goal is to understand your requirements and deliver what you need, quickly, accurately and to your full satisfaction.
- **No surprises:** Strict adherence to budgets is ensured through good project management skills. Contracts are structured in clear unambiguous language.

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