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PHARMACEUTICAL RESEARCH SERVICES

Addressing Clinical Trials Challenges & Complexity with our EDC system: BizNET

Let's explore how BizNET addresses the unique challenges of both Early Phase and Late Phase clinical trials.

Your Trusted EDC system for Complex Clinical Trials:

In the ever-evolving landscape of clinical research, each phase of a trial presents its distinct set of challenges. Lambda Therapeutic Research's Electronic Data Capture (EDC) system, BizNET, emerges as a steadfast companion, ready to tackle the unique complexities of both Early Phase and Late Phase clinical trials.

Proven Track Record

- **Conducted 5000+ healthy subject studies & 150+ patient-based trials**
- **Versatility for Complex Studies**: Used in complex studies including replicate designs, multidose studies, and two-stage studies. Very effective for in-house Bioequivalence (BABE) and Pharmacokinetics/Pharmacodynamics (PK/PD) studies.
- **Broad Therapeutic Experience:** Extensive experience across various therapeutic areas including Oncology, Dermatology, Neuroscience, Metabolic Disorders, CVS, etc.
- **Tested & Trusted in both global and domestic patient trials.**
- **Regulatory Endorsement**: Successfully audited and endorsed by global regulatory agencies including **USFDA, EMEA, MHRA, HC, ANVISA, NMPA, and DCGI.** Extensive validation by the **EMEA**, focusing on Computer Systems Validation (CSV), further reaffirms BizNET's commitment to comply with principles of data integrity and regulatory compliance.

Efficient Data Management

BizNET excels in data management, handling the entire process from eCRF designing to Data cleaning and Validation through established edit checks. It simplifies medical coding using standard dictionaries and provides secure data locking and retrieval. With dynamic multi-level review process, BizNET ensures data integrity and accuracy, enhancing the reliability of clinical trial data. Having 24x7 system support, BizNET promises most user-friendly EDC platform.

Features	Advantages
Randomization using IWRS	• Blinded & Open label randomization procedure to prevent bias in treatment allocation. • Software-generated IP label – prevents wrong labeling issues. • Useful to manage Stratified Randomization with protocol-defined stratification criteria.
Synchronized Date & Time	• System sync with centralized clock – ensuring accurate date & time of the study activities.
Bar codes for 'auto' data capture	• Prevents redundancy in data entry related to subject identification data. • Save data entry time & efforts. Avoids data entry error • Checks accuracy of Bar Codes of PK samples, IMP dispensing unit, etc.
Database Setup	• Plug and Play kind of re-usable Data Collection Tools – complying with CDISC standards. • Simple and Faster Database development for Live data entry

Quality Assurance & Compliance

BizNET ensures top-notch quality and compliance in clinical trials. It provides features like; Standard Form Libraries, User Acceptance Testing, Mathematical Expressions & Formula, and robust edit Checks. Detailed audit trail offers transparency and accountability throughout the trial. Furthermore, BizNET eCTD dossier functionality guarantees compliance with eCTD requirements, making it a vital asset for regulatory submissions.

Features	Advantages
eCTD Dossier Functionality	• Dossier functionality provides eCTD ready Subject-specific eCRF (PDF) export. • Carries TOC & PDF specifications as per eCTD requirements
Standard Form Library	• Predesigned eCRF forms help fast build-up of the study-specific eCRF. • Periodic UAT ensures compliance status of the software.
Formula building	• Mathematical expressions help avoid manual calculations.
Edit Checks	• Edit checks can be System Checks (like range checks & not null) and Manual checks (like logical checks across pages / across visits) help to avoid data discrepancies.
Audit Trail	• Detailed Field (Attribute) level and Page (Activity) level audit trail helps understand the sequence of events. • Provides answers to Who, What, When, Why kind of questions.

Integration, Usability, and Reporting

Features	Advantages
Seamless Integration	• Prevents data redundancy and keeping similar data across all electronic platforms. • Integrated with Bioanalytical & Clinical pathology software tools. • Seamless connectivity with IWRS, CTMS, Imagine, LIMS etc. applications
User-Friendly Design & Usability	• Simple & User-friendly Clinical Data Management software. • Easy implementation and Quickly usable..
Comprehensive Reporting	• Customized reports (data listings) and exports help the study team to review and act on the data.

It's more than just an Electronic Data Capture (EDC) system; it's a complete clinical trial data management software designed to enhance the entire clinical trial process.

It streamlines the entire process, from documents and tasks to audits and trainings. This user-friendly platform provides quick database release, real-time data access, enabling efficient study tracking from start to finish. It's adaptable for trials of all types and phases.

BizNET is validated and fully compliant with regulatory guidelines (21 CFR Part 11 and GCP), ensuring transparency activities & reproducibility of steps throughout the trial.