



## Clinical Trial Management

**BizNET-CTM** is a comprehensive, end to end regulatory compliant Clinical Trial Management solution for Pharmaceuticals and Contract Research Organizations (CROs)

### **Better –**

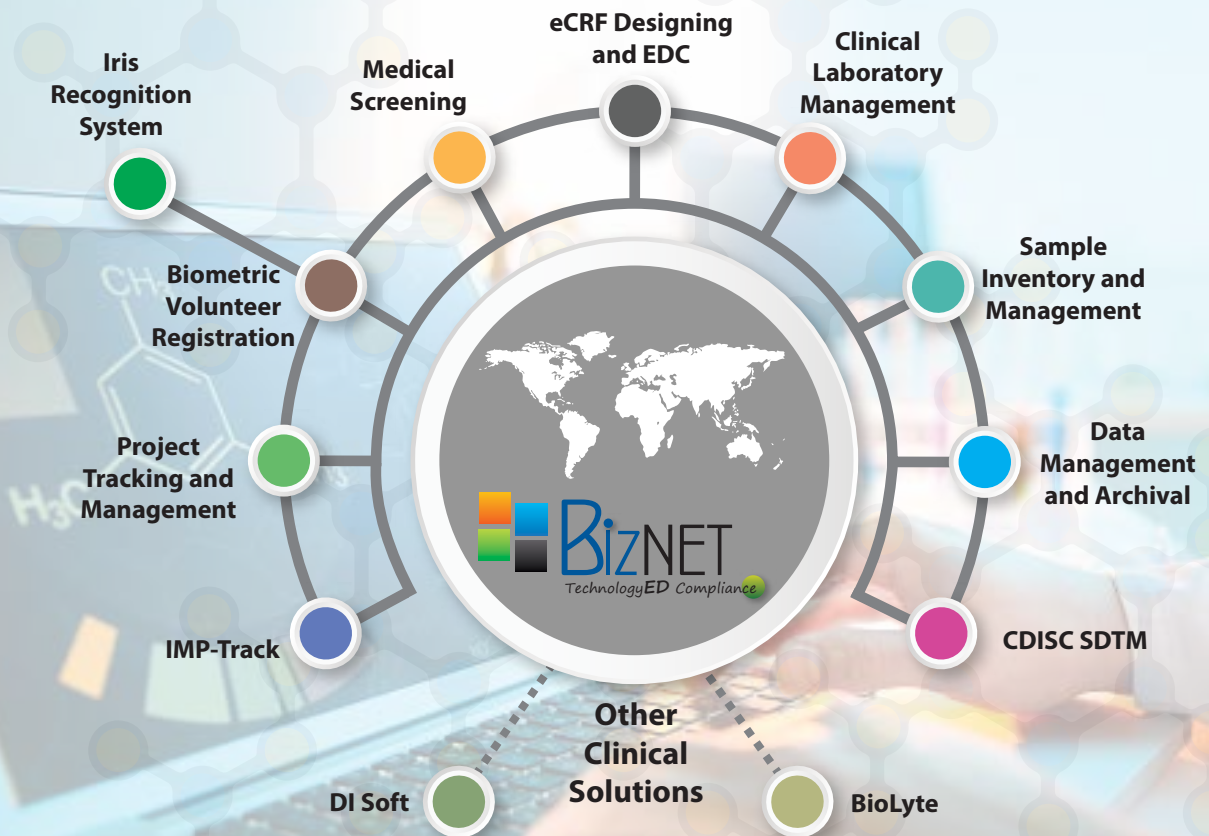
The use of the BizNET-CTM tracking, reporting and data integration efficiencies help streamline regulatory & audit procedures; reduce research & development costs.

### **Faster –**

New challenges call for innovative approach, keeping in track the management level operations the system helps complete the work in time.

### **Dashboard –**

Availability of key points and measures of each project helps in better, smarter and faster decisions by project managers, investigators and helps getting down to the essentials from large data clutters.



## Project Tracking and Management

- ✓ Manages various projects (includes BA-BE, Clinical trial, Registries, etc.)
- ✓ Tracks multi centric, multi period projects and visits
- ✓ Auto-scheduling and slotting of bio-equivalence study
- ✓ Allows project duty delegation
- ✓ Auto e-mail and dashboard tracker

## Iris Recognition System

- ✓ Utilization of "Iris recognition" during screening, registration
- ✓ Complete audit trail of verifications
- ✓ Higher consistency rate in differentiating
- ✓ Iris stands unchanged throughout the age
- ✓ Characteristics are universality, uniqueness, collectability, permanence, acceptability, circumvention

## eCRF Designing and EDC

- ✓ Intuitive CRF designing tool to best suit the protocol
- ✓ Reusable template library, online validation and edit checks
- ✓ Manages eCRF version history with complete audit trail
- ✓ Electronic data capture through barcode and data transcription
- ✓ Online review process and discrepancy management

## Biometric Volunteer Registration

- ✓ Verification based on biometric records
- ✓ Captures fingerprint, signature and photograph
- ✓ Attachment of volunteer identity and address proof documents
- ✓ Online volunteer booking management
- ✓ Audit trail of captured details

## Medical Screening

- ✓ Manages both generic as well as project specific screening
- ✓ Stores volunteer screening and medical history
- ✓ Electronic test requisition form and online review
- ✓ Attachment of ECG, X-Ray, lab reports
- ✓ Online review of lab reports and marking CS, NCS
- ✓ Export/Print facility of Medical screening records

## Clinical Laboratory Management System

- ✓ Allows test requisition for all safety samples
- ✓ Bi-directional transfer of data between machine and system
- ✓ Electronic review of lab results and report generation
- ✓ Color codification of "Out of Range" and "Critical Value" results
- ✓ QC check of the parameters



## Sample Inventory and Management

- ✓ Creation of PK sample batches
- ✓ Maintenance of centrifugation, sample separation, freezer logs
- ✓ Request and retrieval of PK sample for analyses
- ✓ Manages sample verification and sample discard log

## Data Management and Archival

- ✓ Designing, processing, managing clinical data
- ✓ Data cleaning and validation edit check
- ✓ Allows medical coding from standard dictionaries
- ✓ Lock and archive/retrieve of clinical data
- ✓ Dynamic multi-level review process

## CDISC SDTM – New curve in eClinical Data Integration

- ✓ Standardized library
- ✓ Accelerate your clinical data for FDA Submissions
- ✓ Clinical data mapping of CDISC SDTM Standards with BizNET application
- ✓ Easy to design and Implement
- ✓ Smooth data generation for submissions
- ✓ Updated with FDA standards

## IMP-Track (Investigational & Medicinal Products-Track)

- ✓ Real-time report of test product movement for projects
- ✓ Complete paperless inter department communication
- ✓ Pharmacy reporting for monitoring monetary essentials
- ✓ IWRS facility for real-time team notifications
- ✓ Projects, sites and study specific report generation
- ✓ Quality check, stock tracking and archival process

## Other Clinical Solutions

### BioLyte (Bioanalytical LIMS)

- ✓ Automatic sequence generation & plan runs on LCMS-MS
- ✓ Request form for sample retrieval for analyses
- ✓ Data printing & export from LCMS-MS to BioLyte
- ✓ Easy sample submission, review and data lock
- ✓ Data collection, validation, authentication
- ✓ Easy Data compilation for analysis and export
- ✓ Easy integration with various LCMS machines

### DI Soft (Diagnostic Imaging Software)

- ✓ Medical image viewer for CROs and hospitals
- ✓ Manage multi-site studies on web based dicom viewer
- ✓ Fast image transmission from site(s) to center
- ✓ Independent review provision for multiple radiologists
- ✓ Quick generation of data for statistical analysis

Committed to deliver comprehensive, user friendly and innovative solutions into Clinical and Business Industries. Readily available solutions are an online and offline web-based tools that backs all aspects of site management and monitoring.

## Other Products

### PharmaNET - Sales and Distribution pharmanet.sarjen.com

- ✓ Sales & distribution
- ✓ Inventory Management
- ✓ Demand Planning & Supply Chain Management
- ✓ Accounting - collection adjustment
- ✓ Expiry management
- ✓ ERP connectors
- ✓ India, Europe, USA specific deployment

### QEdge - Enterprise Quality Management System qedge.sarjen.com

- ✓ Quality processes automation (CRF, Deviation, Investigation, CAPA, OOS, OOT, Audit, etc.)
- ✓ Document control (SOP, Specification management, Other documents etc.)
- ✓ Training records keeping and management

### PvEdge - Drug Safety Database pvedge.sarjen.com

360° pharmacovigilance solution which covers Post marketing, Clinical, Medical devices, Vaccine, Veterinary Pharmacovigilance. Enabled with Literature automation and Signal detection modules, Ethics committee functioning and SAE management, xEVMPD and Product License management.

### FForce - Field Sales Excellence Platform fforce.sarjen.com

- ✓ Distribution Management System
- ✓ Electronic Order Management System
- ✓ Sales Force Automation System
- ✓ eDetailing
- ✓ Field Sales Information System

### Process XE - Electronic Batch Records process-xe.sarjen.com

- ✓ Covers entire cycle starting from MPCR preparation to approved BPCR archiving
- ✓ Managing related SOPs, equipments' validation and calibration status
- ✓ Compatible with devices and OS - helps in utilizing Process XE on shop floor

### KnowledgeNET - Dossier Publishing Solution knowledgenet.sarjen.com

KnowledgeNET is a robust, featured-packed, well established dossier submission and life cycle management solution. It has great adaptability of compiling dossiers with various global regulatory standards in distinct publishing formats like CTD, eCTD, NeeS, ACTD, GTD, vNeeS and the regional formats.

## About Sarjen

- ✓ Over 19 years' journey of IT consulting for business and technology
- ✓ Domain expertise in Pharmaceutical, Life Science and other domains
- ✓ Expertise in SCM, CRM, QMS, PV and Dossier Publishing solutions
- ✓ Client presence in 40+ countries; mainly in UK and rest of Europe
- ✓ Partnerships with Microsoft, Apple, HP, IBM
- ✓ Solutions built with own IP; adoptable to meet business challenges
- ✓ Solutions compliant with 21 CFR part 11, Annex 11 and GxP
- ✓ In-depth knowledge of Computer System Validations (CSV)



ISO 9001:2015 certified company

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