



Clinical Research platform

BizNET-CTM, an end-to-end platform for clinical trials; right from Early phase, Late phase, Oncology to Registry to Post approval trials.

Better –

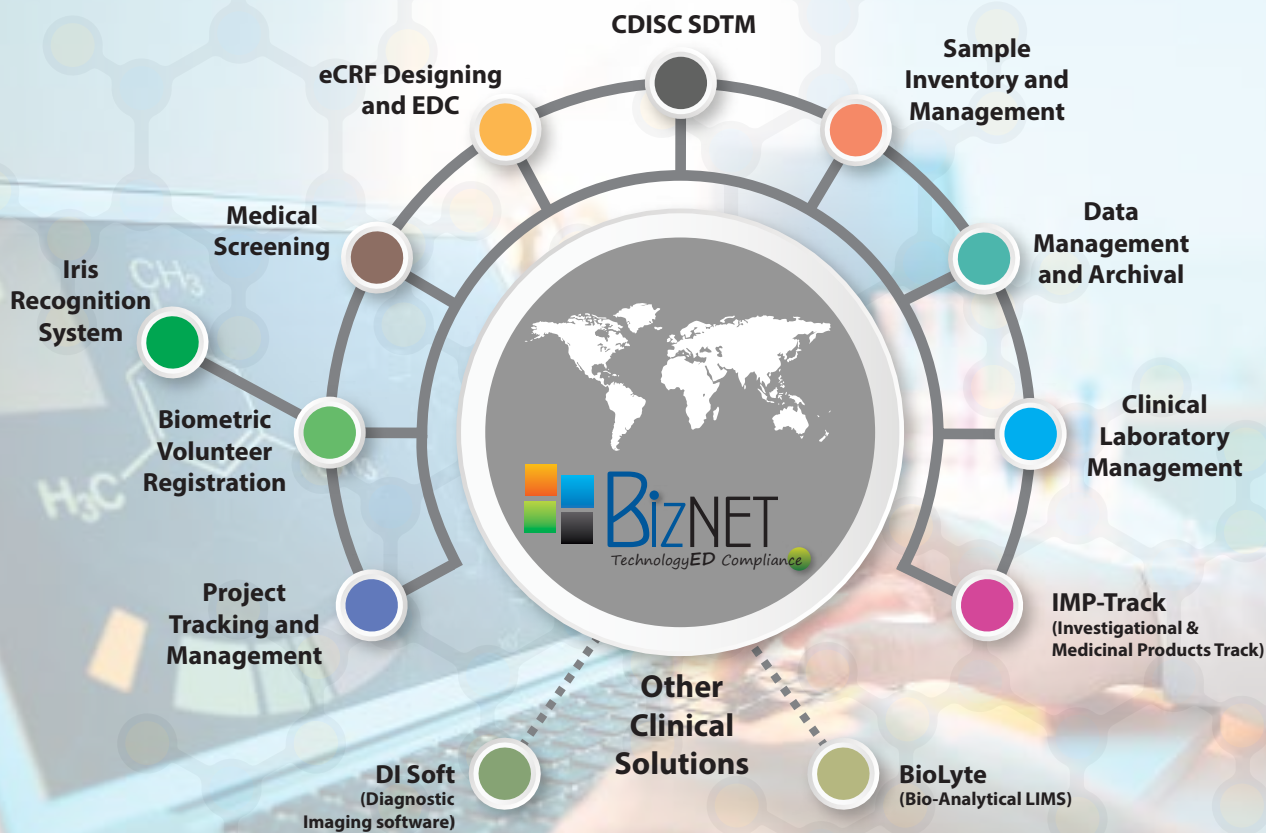
The use of the BizNET-CTM tracking, reporting and data integration efficiencies help streamline regulatory & audit procedures; reduce research & development costs.

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 - Supply Chain and Distribution pharmanet.sarjen.com

- ✓ Sales & Distribution/Order Processing
- ✓ Purchase and Inventory Management
- ✓ Forecasting and Demand Planning
- ✓ Warehouse Management
- ✓ Distributor Management System

FForce - Sales Force Excellence and CRM fforce.sarjen.com

- ✓ Salesforce Automation and Excellence
- ✓ Field Sales Information System
- ✓ eDetailing System
- ✓ Customer Order Management System
- ✓ Field Training and Recruitment
- ✓ Field Service Procurement

QEdge - Enterprise Quality Management qedge.sarjen.com

- ✓ Quality Processes; CC, Deviation, CAPA, Others
- ✓ Document Control; SOPs, WI, Others
- ✓ Training Records and eLearning
- ✓ Audit Management

Process XE - Smart Manufacturing process-xe.sarjen.com

- ✓ Electronic Batch Records; eBMRs
- ✓ eForms and eLogbooks
- ✓ eLabNote books
- ✓ Dispensing management
- ✓ Manufacturing Execution (MES)

PvEdge - Drug Safety Database pvedge.sarjen.com

- ✓ Human PV Safety Database
- ✓ Product Enquiry Trail and Response
- ✓ Veterinary Vigilance
- ✓ Multisource Case Inbox
- ✓ EV Triage and Inbox
- ✓ PV Training

KnowledgeNET - Dossier Publishing & Management knowledgenet.sarjen.com

- ✓ eCTD Publishing and Lifecycle viewer
- ✓ CTD/Paper Submission
- ✓ RIMS
- ✓ ISO IDMP
- ✓ SPOR Database
- ✓ APQR

About Sarjen

- ✓ Journey of IT consulting for business and technology since 1998
- ✓ Domain expertise in Pharmaceutical, Life Science and other domains
- ✓ Subject Expertise in SCM, CRM, SAP, QMS, PV, Clinical, eCTD and MES
- ✓ Client presence in 50+ countries; mainly in UK and rest of Europe
- ✓ Partnerships with Microsoft, Apple, Amazon, Azure
- ✓ Members of, Nasscom, Gesia, Pharmexcil
- ✓ Proprietary Technology Stack
- ✓ Proficient in cGxP, Part 11, GDPR compliance
- ✓ In-depth knowledge of Computer System Validations (CSV)



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