



# BioClinica Express and SAS

## BENEFITS OF USING SAS WITH BIOCLINICA EXPRESS:

- SAS is the standard for data transformation and analysis in the pharmaceutical industry
- The FDA adopted SAS as a standard to analyze clinical data in 1999
- Speeds up the submission process
- Efficient data cleaning
- “One stop shop”

## SERVICE HIGHLIGHTS:

- SDTM Services
- Data Mapping and Transformations
- Submission Services



## CURRENT SAS SERVICES:

### Major Services:

- Custom SAS transformation: Converting raw data into transformed datasets based on sponsor specifications.
- Tables, Listings and Figures (TLF's): Generating tables, listings and figures per the analysis plan and mock-ups.
- SDTM Domains & Metadata: Developing a mapping specification document as per SDTM guidelines then creating the SDTM domains, metadata datasets and define in .rtf file.

### Other Tasks:

- Medical coding terms, raw data merge and LLT/ULT merge.
- External file merge: Merge any external data with Express data as per the specifications.
- Lab file reconciliation: Checking external lab files against Express data then generating discrepancy reports.
- Lab files derivations: Deriving Lab parameters from source data.
- Global Data Checks: Checking raw data with universal checks point that are applicable with any study, regardless of protocol.
- Custom Reports: Generate custom reports based on sponsor requirement in either .rtf or excel format.
- Analysis datasets and tables: Create Analysis datasets or tables as per specifications or shells from sponsor, either during interim analysis, the final locked database, or both.
- IVR/IWR checks: Checking kit data consistency between the IVR/IWR system and the EDC entered data then generating discrepancy reports.
- Custom data files: ASCII file creation containing the particular data and derivations required by sponsor.
- Sub setting the database: Subset the database as per the sponsor requirements.
- Randomization data: Create code-based randomization datasets with Treatment arms. This is based on randomization schema provided by sponsor at the time of unblinding and merged with the raw datasets.
- Data Comparisons: Database comparisons to check data consistency between any two databases.
- PROC Contents: Generate content report (with metadata) of all datasets in the study, as requested.
- CRF Annotations: Create the SDTM annotated CRFs.

## BIOCLINICA EXPRESS ELECTRONIC DATA CAPTURE

Our comprehensive EDC solution, BioClinica Express, adds speed and quality to every part of the clinical trial process. It provides stable, scalable technology that acts as a central hub to coordinate and organize the collection and dissemination of clean data, under any conditions. The performance and intuitive interface keep investigators happy while making it easier to monitor protocol compliance, close studies faster and still meet all regulations and guidelines — all at a predetermined price that helps you manage clinical trial costs. BioClinica Express integrates easily with your other clinical processes and technology applications. We can tailor our solutions to work seamlessly with your CRO of choice, while still housing all your data and metrics in one place and keeping you in control of your trial.

## TRIDENT IVR/IWR

Trident IWR's unique design provides clinical operations personnel with an intuitive way to directly set up, monitor and maintain randomization and supplies for their clinical trials, in a fraction of the time previously required. Trident gives customers the ability to build complex trials in a quicker and less costly manner than previous alternatives which require the development of custom programming for each new clinical trial. Designed from inception as a web-based system, Trident simultaneously delivers world-class IVR phone support through the same simplified configuration process. It is fully synchronized with BioClinica Optimizer, the world's leading clinical supply simulation and visualization package. Study designs simulated in Optimizer can configure Trident IWR to precisely match the optimal scenario identified using Optimizer.

## BIOCLINICA OPTIMIZER CLINICAL SUPPLY FORECASTING

BioClinica Optimizer is the world's only clinical trial supply forecasting tool that both simulates and optimizes your clinical trial. Sponsor companies find that optimization without simulation only solves half of their business problem. To identify and control situations such as supply crises, study delays and unnecessary overages before they happen. The combination of simulation and optimization is the proven best practice for planning and managing your clinical trial supply. BioClinica Optimizer is the only clinical trial supply forecasting tool that accurately eliminates unnecessary overage, minimizes drug waste and reduces trial costs, solving the entire business problem.

## BIOCLINICA CLINICAL TRIAL MANAGEMENT

BioClinica CTMS makes it easier to manage your clinical trial by providing tools that work the way you do. That's why we provide CTMS solutions which unify study software with the familiar, widely supported and simple-to-use Microsoft® Office System. Office-Smart Clinical Trial Management Software solutions from BioClinica support Office tools, business process workflow and documents within the regulated world of clinical trial applications. Organizations can leverage their staff's familiarity with pre-existing software to reduce the need for training and increase the adoption of technology. By enabling study professionals to interact naturally with their favorite Office tools, organizations can improve study team morale, increase productivity and improve quality.

## IMAGING CORE LAB SERVICES

As the world's leading independent Imaging Core Lab, our solution unifies technology, science and logistical expertise to better support the collection and management of medical image data for your clinical research. Use BioClinica WebSend to transmit and QA your images faster and more securely; it runs all the way through the trial process to our specialized systems that allows blinded images to be displayed which eliminates any potential bias. We support global studies in a broad range of therapeutic areas and are experts in nearly every available imaging modality. Our 20 years of experience and scientific depth are the preferred choice of forty out of the top fifty pharma, biotech and device companies for superior performance and reliability.

## About BioClinica

BioClinica, Inc. is a **leading global provider** of integrated, technology-enhanced clinical trial services. BioClinica supports pharmaceutical and medical device innovation with:

- Imaging core lab services
- Internet image transport
- Electronic data capture
- Interactive voice and web response
- Clinical supply chain design & optimization solutions
- Clinical Trial Management System (CTMS)

BioClinica services maximize efficiency and manageability throughout **all phases of the clinical trial process**. With more than 2,000 successful trials to date, BioClinica has supported the clinical development of many new products from early phase trials through final approval.

BioClinica operates **state-of-the-art**, regulatory compliant imaging core labs on two continents, and supports worldwide eClinical and data management services from offices in the United States and Europe.