Global clinical trial solutions. Real-world results.
A world of solutions.

Discover the power of BioClinica. BioClinica is the proven, optimal choice for your next clinical trial. We provide comprehensive clinical trial solutions and management for pharmaceutical, biotechnology and medical device companies. Our Imaging and eClinical divisions are trusted by today’s top pharmaceutical companies thanks to our passion, expertise and innovative products and processes. We have supported over 2000 studies in all phases of clinical trial development and in a broad range of therapeutic areas including Oncology, Cardiology, Metabolism, Inflammation, Endocrinology and Neurology, and more.

BioClinica believes in running more efficient, cost-effective trials and providing customer service that goes above and beyond client expectations.

Our success is based on:

• A shared set of values and a commitment to excellence
• Researching innovative technologies to improve our products
• Constantly evolving and adapting to improve internal processes
• Building strong and trusting relationships with our clients

With thousands of successful clinical trials, our team of experts knows how to bring your drug or device to market in the most efficient way possible.
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The processes and technology incorporated into our offerings are designed to provide clients with the ease of use and scalability to handle large global trials as well as the flexibility, speed and efficiency necessary to support smaller or early phase trials.

Rely on BioClinica’s extensive knowledge to support your trial at every stage:

- Upfront consultation and design
- Data collection
- Quality control
- Data Management
- Submission
- Study start-up
- Coding
- Standards support
- Data Export

BioClinica has experience conducting thousands of eClinical studies and processing and assessing millions of images.

Rely on our network of experts and strong history to support your trial.

Our specialists can supplement your staff and can help reduce training for each project, thereby improving timelines. Our strong roster of collaborative consultants, which includes board-certified radiologists, oncologists, rheumatologists, cardiologists and other therapeutic specialists, provide targeted expertise and quality results.

Our expertise has helped us successfully complete numerous client and FDA audits. Based on the large number of FDA submissions, we have participated in numerous not-for-cause, study-specific audits resulting in no 483s or other findings.
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BioClinica’s unique Office-Smart technology, can open up a new world of role-based personnel manage all the data, you stay in complete control, with accurate clinical research data, while meeting key deadlines and capturing clean and consistent data across any environment. Our Electronic Data Capture, which is a comprehensive EDC solution, adds speed and quality to every part of the clinical trial process. It provides flexible, scalable technology that acts as a central hub to coordinate and organize the collection and dissemination of clean data under any conditions. Our Electronic Data Capture Solution makes it easier to monitor protocol completion, close studies faster all while meeting necessary regulations and guidelines. Our EDC technology integrates easily with your other clinical processes and technology applications. We tailor our solutions to work seamlessly with your CRO of choice, while still having all your data and metrics in one place and keeping you in control of your trial.

Electronic Data Capture

BioClinica’s Express, our comprehensive EDC solution, adds speed and quality to every part of the clinical trial process. It provides flexible, scalable technology that acts as a central hub to coordinate and organize the collection and dissemination of clean data under any conditions. Our Electronic Data Capture Solution makes it easier to monitor protocol completion, close studies faster all while meeting necessary regulations and guidelines. Our EDC technology integrates easily with your other clinical processes and technology applications. We tailor our solutions to work seamlessly with your CRO of choice, while still having all your data and metrics in one place and keeping you in control of your trial.

Clinical Trial Supply Planning

BioClinica Optimizer is the market-leading clinical trial supply forecasting tool. The Optimizer allows you to design unlimited clinical trial supply chain scenarios and very relevant study parameters — from a global level down to a site level. The simulated results can be analyzed and modified to create the ideal supply plan. This accurate forecasting of the supply helps you reduce risks and manage costs — allowing you to accurately plan the most complex trials and help you get the right quantities to the right places in the world on tight timeframes. BioClinica Optimizer easily allows you to upload the actual data from your IVR/IVRS to use for study observation, comparison against assumptions, and further simulation and tuning of the running protocol.

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A world of technology.

BioClinica’s products are all flexible and highly customizable to meet your specific study needs.
BioClinica® WebSend is a custom designed enterprise system that provides image workflow, query, inventory, site and project management tools to automate and accelerate the process of evaluating images generated during a clinical trial. BioClinica® Bio-READ consists of hardware and software that are used to perform independent blinded reads on the image data collected during the clinical trial. BioClinica WebSend solutions improve clinical trial efficiency through the electronic transfer of images via the Internet providing faster delivery, fewer site queries, and reduced costs versus traditional paper-based processes and technology applications. We tailor our solutions to work seamlessly with your CID of choice, while still having all your data and metrics in one place and keeping you in control of your trial.

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IWR/IVRS
BioClinica® Trident, our interactive web response system (IVRS), has an intuitive user interface that empowers business users (not programmers) to quickly set up, test and deploy new protocols, and then monitor and maintain them in one easy place. This eliminates the costly and time-consuming process of setting development specifications, programming and assembling a new IVRS each time a new study comes along. All the actions performed on the web are simultaneously available on the phone via Trident’s interactive voice response system (IVRS). Trident’s IVRS single database for all clinical studies allows automatic drug scoring, viewing as a single source for reporting and standard data organization for clinical trials.

Clinical Trial Management
BioClinica® DeVote is a fully-featured Clinical Trial Management System (CTMS) that helps life science companies manage their clinical trials within schedule and budget. Today’s study professionals face new complexities in a web-enabled world of distributed workflow teams and clinical trial applications that don’t talk to each other. BioClinica offers advanced integration techniques that consolidate operational data from clinical trial applications like EDC, IRVS and Safety systems to present one clear picture for study managers. And, Microsoft SharePoint, coupled with BioClinica’s unique Office-Smart technology, can open up a new world of web-based portals and interoperability with familiar Microsoft Office desktop applications.

Clinical Data Management
Our expert data management services make every part of the clinical data management process more efficient and predictable. Our clinical data managers minimize the risks associated with EDC and clinical data management and help you capture clean and accurate clinical research data, while meeting key deadlines and budget requirements. You’ll spend less time waiting for each project and more time running efficient trials. Although our clinical data personnel manage all the data, you stay in complete control, with continuous access to your data and the progress of the study.

BioClinica’s products are all flexible and highly customizable to meet your specific study needs.

A world of technology.
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With over 20 years of industry experience, we offer a full range of eClinical and Imaging Core Lab solutions. You can trust BioClinica to manage technology on your behalf and provide deep clinical expertise. As a full-service eClinical provider, BioClinica offers DCC, Data Management, CTMS solutions, forecasting, simulation/optimization and IVR/IWR technologies. Our independent Imaging Core Lab (ICL) offers medical image management solutions that cover the full range of imaging modalities which span the entire lifecycle of your trial. Together, these solutions make BioClinica a leading expert in clinical trials.

With thousands of successful clinical trials completed, our experienced employees and experts know how to efficiently bring your drug or device to market.
- BioClinica has over 20 years of clinical trial process knowledge including 2000 projects worldwide for over 200 clients, 11,000 sites in 88 countries (North America, South America, Western Europe, Eastern Europe, Australia, China, India).
- Our management team has over 120 years of experience combined.
- We have subject matter experts, scientists and doctors on staff.
- Our products and services are designed to help our clients operate in a manner that is compliant with applicable regulations and follows relevant regulatory guidance.

A world of quality.

Whether you need a solution to help manage your medical imaging data, or you want to take advantage of BioClinica’s combined imaging and eClinical offerings, we provide a level of quality and precision that you can trust. You can see our commitment to quality in everything we do.

For us, excellence isn’t optional. It’s our goal, every time, with every trial. It’s why we developed a rigorous multi-step process for our medical image review and why we take a different approach to eClinical technology and help manage it on your behalf. The result? Data that is not just clean and accurate, but also accessible, analyzable and actionable. This unique business model, which provides cost control and transparency not only in the budgeting process, but also throughout the trial duration, puts fiscal control back in the sponsor’s hands, where it belongs.

Quality, efficiency, and accuracy is how we deliver:
- Faster start-up
- Flexible, proven technology
- Better protocol and standards compliance
- Quality data, clean and fast
- Early and real-time access to clean data
- Faster database lock
- Predictable price
- Global Help Desk assistance 24/7
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Our Quality Control process helps you increase efficiencies, prevent back-end delays and decrease the number of queries in your clinical trial.

Our time-tested processes enhance the quality of your trial.
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To get the most out of your clinical trial, you need a proven partner who can provide reliable and flexible support. At BioClinica, we believe in making things simple for our customers. We offer an inclusive menu of services to support you with the planning and execution throughout the duration of your trial.

Our comprehensive service offerings include:

24/7 Help Desk – BioClinica has created a scalable, well-defined global support process to ensure site and sponsor issues are quickly and completely resolved. The BioClinica Support Services Department provides multi-lingual technical support to sponsors and users worldwide 24 hours a day, 7 days a week. Support requests are supported in over 150 languages by on-site employees and, when needed, an interpreter assistance service. Unlike other companies that outsource their help desk, our support teams are experts in BioClinica technology and networking, which is why we can quickly resolve site and sponsor issues whenever they arise.

Training – Our comprehensive training programs teach site, sponsor and team personnel to easily navigate our products as well as avoid common issues during every phase of the trial. We offer a variety of options including:

• Instructor-led meetings, i.e. hands-on training at investigator meetings
• Site-visit training
• Customized pre-trial programs
• Pre-recorded or live online training via WebEx
• Certifications for regulatory binders

CDISC Implementation – BioClinica is able to create CDISC CDASH conformant case report forms for your study which yields the most direct path to complete CDISC SDTM submission datasets. This reduces review time, aids in the approval of CRFs, minimizes data queries and improves data integration. Whether you need help developing CDASH forms or providing SDTM datasets, BioClinica can help and train your company to understand and meet all CDISC standards.

BioClinica provides in-depth CDISC services to help you accelerate the regulatory review process.
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