

AVERION



COMMITMENT



EXPERTISE



INNOVATION



WORLDWIDE

Averion
International
Corporate
Capabilities

Tomorrow starts Today

A COMMITMENT BEYOND THE ORDINARY

Averion International is a top 25 international clinical research organization (CRO) with proven expertise in designing, performing and managing drug, biologic and medical device trials.

Our clinical services support the full product development lifecycle, from first-in-man through regulatory approval and beyond.

Averion has a powerful therapeutic focus in the areas of oncology, cardiovascular and medical devices. For pharmaceutical, biotechnology and medical device companies worldwide, Averion is committed to being your trusted partner in clinical research.

Our Commitment to You.

It's a simple promise: to produce clinical trials on time, on budget, and of the highest quality.

Averion has been delivering on that promise since 1983. Today, we are a top 25 international clinical research organization (CRO) with proven expertise in supporting global clinical trials for pharmaceutical, biotechnology and medical device companies.

We offer our clients years of experience in clinical trials, extensive medical knowledge in specific practice areas, innovative thinking and technologies, and a global perspective. Most importantly, we are dedicated to ensuring that clinical trials are transparent, cost-effective and of the highest quality.

We make that commitment to every client and every project. That is why, for companies worldwide, Averion is a trusted partner in clinical research.

Averion Services for Clinical Trials

- Full-Service Phase I-IV Drug/Biologic Clinical Trials
- Medical Device/Instrumentation Programs
- Trial Design & Program Planning
- Patient Enrollment and Monitoring of Investigator Sites
- Project Management, Performance Measurement and Communications
- Database Design and Development
- Data Collection and Management
- Complex Statistical Analyses
- Writing of Protocols, Investigator Brochures, Clinical Trial Reports and Journal Manuscripts
- Data Monitoring/Clinical Endpoint Committees
- Regulatory Planning & Consulting
- Agency Applications
- Rescue Work (particularly, cleaning & analyzing data)
- Post-Marketing and Safety Surveillance Studies



The Expertise to Succeed.

Successful clinical trials depend on knowledge and expertise in many disciplines.

Averion has built a large and diverse team of professionals with direct experience in various specialties. Our expertise is a major reason behind our exceptional record of success in clinical trials.

Our therapeutic expertise includes:

Oncology – we have supported cancer clinical trials for over 25 years, guiding dozens of sponsors through more than 200 trials in virtually every solid and hematologic oncology indication and allied disorders. Averion’s work has contributed to 14 US FDA approvals in oncology.

Cardiovascular – we have conducted over 150 international studies involving new chemical entities as well as medical devices. We also have experience in the areas of gene therapy and angiogenesis.

Medical devices – we have conducted over 120 medical devices studies and helped clients gain PMA or HDE approval for 26 products, including imaging devices, bone mineral densitometers, cardiovascular devices and orthopedic implants.



CASE STUDY

CHALLENGE:

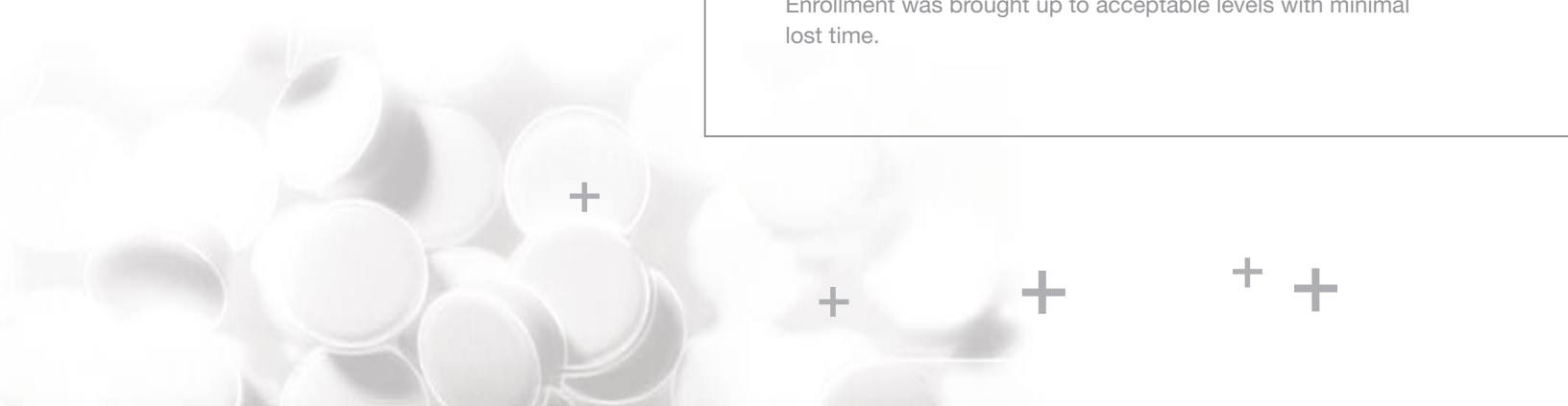
Averion was asked to rescue a program for a novel therapy in early stage prostate cancer that was suffering from languishing enrollment.

SOLUTION:

Analysis indicated the prior CRO relied only on former study sites. Based on an understanding of how prostate cancer is treated, Averion was able to perform a detailed feasibility analysis to recruit additional sites, engage interdisciplinary teams at the sites for cooperative enrollment, and provide careful communication and guidance to site coordinators.

RESULT:

Enrollment was brought up to acceptable levels with minimal lost time.



Averion's record of accomplishment also includes therapeutic strengths in:

- Central Nervous System Diseases
- Dermatology
- Immunology/Hematology
- Infectious Diseases
- Nephrology
- Nutrition
- Ophthalmology
- Orthopedics
- Pain
- Respiratory
- Surgical & Medical Procedures
- Vaccines
- Women's Health
- Wound Healing



Expertise in clinical trials

Every trial is a new challenge. Whether for a new drug or a new therapeutic indication, Averion has built processes and programs that allow us to use proven techniques and provide tailored solutions for each client's specific needs. Averion knows how to design programs, deal with regulatory bodies, and coordinate site activities. We manage both the science and the processes to achieve a successful result.

Expertise in strategy and planning

As clinical trials become more complex, and the medical and financial stakes grow, partnering with Averion helps companies in developing strategies and programs. Our team can take on as much of the planning as you require. Tap into our disease-specific expertise, knowledge of domestic and international regulations, and technology capabilities to make your study a success from the start.

CASE STUDY

CHALLENGE:

A medical device company came to Averion for help gaining PMA approval for a knee injection therapy, where two existing products were already on the market.

SOLUTION:

Averion managed three pivotal studies and identified the common effectiveness advantages across the studies. A prospective ISE analysis plan was developed and statistical analyses performed, which demonstrated a higher level of effectiveness using a percentage improvement endpoint that allowed for treatment differences to be clearly seen.

RESULT:

Averion found the pathway to approval that showed a competitive advantage for this knee injection therapy. No panel meeting was required and the product received FDA approval.

Our Worldwide Capability.

More than ever, bringing a new medical product to market is a global enterprise. There are many reasons to take a clinical trial overseas—to ensure approval in international markets, to find the number of patients needed to conduct the study, and to take advantage of cost savings where possible—to name a few.

To reap these benefits, you need a research support partner with true global reach—Averion is that partner.

We have a long record of international success in clinical trials, and we have strengthened our overseas capability even further in recent years. About half of our resources are now outside of the United States, with offices in key regions including Europe, Israel, and Russia.

There's a world of opportunity in international markets, and Averion can help you take advantage of it.

Navigating the regulatory issues

Averion understands the nuances and requirements of various regulatory agencies including the FDA (U.S. Food and Drug Administration) and EMEA (European Medicines Agency). We have a specialized regulatory group focused on these agencies and their changing procedures, ensuring that every trial meets the necessary standards.

Finding the study patients

One of the most common problems in clinical trials is finding the necessary study patients. Averion has taken the lead in this area, developing local contacts throughout the world and maintaining extensive databases that allow us to plan for and recruit the needed number of subjects.



CASE STUDY

CHALLENGE:

A US-based client came to Averion with a heart failure study to be performed in the US and Europe. Patient recruitment was behind schedule.

SOLUTION:

Averion re-evaluated the client's patient recruitment plan and enrollment rates. Analysis found that patient enrollment in Eastern Europe, particularly in Russia and Poland were 3-5 times higher than the enrollment rates in the US and Western Europe. Averion re-distributed the number of patients needed per geography, so that more than half the patients came from Eastern Europe, with the remaining patients coming from the US and Western Europe.

RESULT:

Patient enrollment was completed on time and the study began without delay. The client was also pleased with the high data quality from its Eastern European sites.

AVERION WORLDWIDE OFFICES*



* Visit Averion's website for the most recent list of offices.

Qualifying the sites

Site selection is critical to delivering the necessary patients, managing the trial efficiently, and gathering data properly and accurately. Averion has developed a stringent site selection process based on our experience with hospitals and physicians around the world. This selection process is constantly refined, as we continually search for, screen and approve potential sites for future studies.

Managing the project

How do you track a study taking place in numerous locations around the world? How do you know if the trial is on schedule and within budget? Averion is an expert at managing international projects, with both local and global project managers to ensure you know where the trial stands at all times.

CASE STUDY

CHALLENGE:

Averion was monitoring an international study for a client who performed its own patient recruitment. All sites were behind schedule, and the client began calling each site weekly to get progress reports. A cultural misunderstanding developed at the sites in Russia and the Ukraine and patient enrollment stalled.

SOLUTION:

Averion's CRAs in Russia and the Ukraine fielded panicked phone calls from the Russian and Ukrainian sites. The local CRAs explained to the Sponsor that the sites had formed relationships with the CRAs and didn't understand why a "third-party" (really the Sponsor) was calling them. Averion developed a communication plan with the Sponsor, where the local CRAs would alert the sites of an impending progress call from the Sponsor. The sites were re-assured that there was nothing wrong with the study.

RESULT:

The client continued to call each site for weekly updates, and achieved patient enrollment on time.



Our Innovative Approach.

On average, it costs \$1.2 billion and 10 years to bring a new drug or biologic to market. At Averion, we are constantly looking for innovative ways to bring those numbers down through faster, more cost-effective clinical trials—while maintaining rigorous standards of quality.

Averion is a leader in such areas as: **Adaptive Trial Design**

Recently the FDA, EMEA and other bodies have begun accepting adaptive trials where Phase II and Phase III are conducted in parallel, making course corrections as the study develops and data becomes available. This approach saves time and costs, but requires careful planning and expertise in statistical analysis. It also requires close cooperation with regulatory agencies. Averion is an expert in all of these areas, and is helping many clients reduce their costs through adaptive trials.

Technology

Increasingly, technology is playing an important role in clinical trials, from data collection and analysis to project management and reporting. Averion has consistently been a leader in the development and application of technology for clinical trials.

- We developed our own IVRS (Interactive Voice Response System) to reduce costs and improve user friendliness.
 - We built our own web-based tools for accessing management data, real-time trial data, and other necessary information.
 - We developed our own CTMS to manage our trials in an efficient and consistent manner.
- We formed a full-time EDC review team to screen and evaluate relevant Electronic Data Capture solutions and vendors, from patient diaries and hand-held devices to scanning and other technologies. We can match the EDC solution to each client's specific trials.
 - We built our own central data warehouse that can “plug and play” with virtually any client technology, allowing our clients to have better access to more study information, including more than 250 real-time reports on trial metrics.

CASE STUDY

CHALLENGE:

Many companies come to Averion with full-service studies, including the need for IVRS.

SOLUTION:

Averion traditionally solicited bids from various IVRS vendors on behalf of our client, but found it was much more cost-effective and timely to build and validate a custom IVRS. Being familiar with the study protocol and goals of the trial, Averion specifically designed the IVRS to achieve its client's needs.

RESULT:

Our clients not only save time and money, but have a user-friendly, fully customized IVRS for their trial's enrollment and randomization processes.

Metrics

Ultimately, clinical trials are about the data. But too often, certain types of data that can be useful in managing a trial become available only after the trial is over or a schedule has slipped. Averion has pioneered the development of real-time metrics and Trajectory Reports that tell you not only where your study stands, but also how it compares to your goals and budget, and where potential shortcomings may be. This allows our staff and our clients to be proactive as soon as problems develop, before it is too late. With Averion, you can:

- View Trajectory Reports that reveal current progress measured against goals, allowing rapid real-time course corrections.
- Combine metrics from EDC, financial systems and other sources to create unified reports that capture the total picture of your trial.
- Coordinate results from all studies in all locations, pulling together data on a regular basis regardless of the number of international sites.
- Distribute information and reports to everyone who needs them—on our team and on our client's team—to enable cooperative decision-making and control.
- Use Averion's web portal to view trial status, reports and other information at any time, anywhere in the world.



CASE STUDY

CHALLENGE:

A pharmaceutical firm was frustrated by a lack of insight into their trials, often hearing of problems after it was too late to correct them.

SOLUTION:

Averion provided Trajectory Reports that told the company exactly where its trials stood in relation to schedules and costs at all times. The reports provided up-to-the-minute insights mapped against the total project goals.

RESULT:

The firm was able to immediately identify patient enrollment and budget problems, and take proactive measures with confidence.

Put Our Commitment to Work for You.

Averion is committed to providing the highest-quality, most cost-effective clinical trials in the industry. Our team is at your service to help with as much, or as little, of the project as you require. We will work as an extension of your team to help you achieve your goals.

Tell us more about your needs. We will dedicate ourselves to helping you succeed.



AVERION

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Averion is expanding rapidly to new locations. Please visit our website for the latest list of offices.



OUR GLOBAL REACH IS EXPANDING EVERYDAY

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Maryland

Massachusetts

New York

European Offices:

Austria

France

Germany

The Netherlands

Poland

Russia

Switzerland

Ukraine

United Kingdom

Rest of World Offices:

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