

OSMOS CLINICAL RESEARCH, INC.
FAST. SMART. GLOBAL.

OSMOS



WHO WE ARE

OSMOS Clinical Research, Inc. helps our clients maximize the benefits and minimize the risks associated with conducting clinical research trials in Eastern Europe, Latin America, India and other countries around the world.

Headquartered in South San Francisco, California, the hub of biotech and pharmaceutical activity, we have been helping to advance medical breakthroughs for more than 5 years.

OSMOS was started to address a growing demand for specific expertise in setting up, management and auditing clinical research trials in Eastern Europe and Russia. Since then, we have become the leading expert group on trials in that and many other emerging clinical research regions.

In addition to our own staff of multi-cultural and multilingual specialists, OSMOS engages vendors ranging from individual consultants or small highly specialized groups, to contract research organizations with hundreds of full time employees allowing us to successfully meet the challenges of projects of any size.

Our team of experts possess unparalleled cultural understanding and in-depth knowledge of the intricacies specific to different countries' clinical research processes. This unique insight combined with years of hands-on experience in clinical project management and quality assurance means you stay informed and in control. OSMOS can ensure that your projects are conducted efficiently and to the highest ethical and scientific standards anywhere in the world.

By working diligently with our clients, we have been able to help them save months of valuable time and millions of dollars throughout the clinical development process.

[Contact us and find out why OSMOS is the most in-demand company of its kind.](#)

OUR SERVICES

At OSMOS, we believe that knowledge is paramount to smart, profitable business decisions and have spent years researching and acquiring real-life expertise in order to determine the benefits and challenges specific to each region. We also understand that change happens at lightening speed and can affect our clients' work almost immediately.

That's why we are committed to staying one step ahead of the curve by constantly monitoring and analyzing important developments and news related to clinical research regulations and activities in the emerging regions. This also means we are continuously updating our network of local and international vendors and consultants.

Our goal is to offer you the best service in the most appropriate location for your project and to achieve three main objectives:

- 1 To keep you as informed as possible before you make your most important decisions;
- 2 To give you control with thorough oversight and project-specific quality assurance measures; and
- 3 To ensure reliable results.

We offer custom-made solutions to ensure that your trials are cost-effective and compliant with all requirements and regulations. Here is a sample of our services:

PRELIMINARY ASSESSMENT AND FEASIBILITY STUDIES

If you have not yet decided where you want to conduct your clinical trial we can help you determine what are the most viable regions for your goals. Our objective assessments and in-depth reliable feasibility studies ensure that you will have all the necessary information to make an educated decision. Some of the many factors we take into consideration include: the therapeutic indication, current standards of care, the stage in the development cycle and the project budget and timetable.

IDENTIFICATION OF SUITABLE AND RELIABLE LOCAL PARTNERS

Once you have decided where your trial will be conducted, we will work with you to select the most appropriate multinational or local CRO, central laboratory and other vendors as needed for the project. OSMOS will create a detailed request for proposal and submit it to as many potential vendors as necessary. We will suggest companies from our prescreened list and can assess additional companies you might have identified. We will also help you negotiate the budgets to make sure that you will receive the best value for your money. Finally, we present the responses in a format that allows for easy comparison and ensures that you make the best decision for your project.

AUDITING CRO, SITES AND VENDORS

As a part of the selection process, we recommend that you pre-qualify your potential vendors through an audit. We also suggest that you audit your trial early in order to catch any issues before they escalate and ensure reliable resulting data. OSMOS has conducted numerous audits in the U.S., Russia, Eastern Europe and other parts of the world. We are strong proponents of performing co-monitoring and auditing in foreign countries with highly trained quality assurance professionals who are either local native speakers or fluent in the language of the country where the audit is conducted. These experts understand all the intricacies of the medical culture and documentation they are dealing with. They speak and read the language and do not rely on translations to conduct detailed, unbiased, and truly independent audits.

Over the years we have identified, trained and employed native-speaking medical and quality assurance professionals in many emerging markets around the world. This allows us to respond to our client's requests rapidly and to assure them that their projects are being monitored without the significant expenses associated with international travel and use of interpreters. OSMOS experts have the hands-on experience to deal with the most difficult situations and produce in-depth, reliable assessments expeditiously and cost-effectively.

ASSISTANCE WITH REGULATORY SUBMISSIONS AND IMPORT-EXPORT APPLICATIONS

Complying with local regulations, shipping and labeling requirements for import-export, making sure that all the documents are available and translated as required, could be difficult and costly. Local regulations may not always be clear or change unexpectedly so it is imperative to be knowledgeable and plan for contingencies. It requires specialized expertise to make sure that supplies or laboratory samples arrive on time. OSMOS can help you make sure that you are not losing time and money by being knowledgeable and avoiding potential delays. We will work with you to ensure that all the required documentation is in order, translated and ready for submission to authorities in the shortest possible time.

PROJECT MANAGEMENT OF ONGOING STUDIES

There is a saying that the vendor is as good as the people managing it. At OSMOS we have years of hands-on experience in managing successful clinical trial programs in the United States as well as internationally. Whether you want our experts to help you manage the part of your study in an emerging market location or need help with management of your global program—we will be glad to meet your needs. Our projects are delivered on time and on budget.

TRANSLATION BY PROFESSIONAL NATIVE SPEAKERS

We provide expert translation services. Our professionals are not only fluent in the native languages, but they are intimately familiar with the complex industry-specific terminology. We provide certified written translations and back translations to ensure that all the critical documents deliver the same content and message in any language.

TRAINING FOR INVESTIGATORS AND CRO PERSONNEL

It is imperative that local staff understand the details of a clinical trial and are familiar with GCP principles. However, inadequate English language proficiency may prevent study personnel from understanding all the intricacies of the guidelines and critical study documentation. We can assess their level of training and comprehension and implement corrective measures if necessary. We provide native-language help and training to Investigators and CRO personnel in ICH GCP guidelines, Standard Operating Procedures and any specifics of the trials.

[Contact us and find out how you can benefit from our services.](#)

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