GLOBAL SUPPLY CHAIN FOR CLINICAL TRIALS

DELIVERING CARE ACROSS THE GLOBE

OXIMIO

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ABOUT

Oximio

Delivering care for almost 20 years, Oximio is proud to play its part in improving the health and wellbeing of countless individuals worldwide. Our commitment to excellence combines our 'best-in-class' depot network with a highly experienced and qualified workforce. Our extensive knowledge and expertise encompass both global and local procedures for clinical trials ensuring the highest standards of operation. This has made us a trusted partner for CROs, CDMOs and biotech innovators for the provision of reliable clinical trial logistics services.

In this eBook, we invite you to discover the benefits of partnering with Oximio in each of our locations. We are here to support you in your journey towards improving healthcare outcomes and look forward to the opportunity of contributing towards the success of your vital research.

GEORGIA

Georgia's Rising Status as a European Clinical Trials Destination

With the on-going conflict in Ukraine, some clinical trial sponsors are turning their attention to other European countries to conduct their research. Georgia is rapidly emerging as a key alternative providing excellent potential for the biotechnology and pharmaceutical industries. In recent times there has been significant investment in the country's health system with the creation of several new facilities and programmes in addition to an increase in the number of experienced physicians.

Exploring the untapped benefits of Georgia as an emerging destination for multinational clinical trials in Europe.

FAST START-UP TIMELINES

Whilst neighbouring countries experience lengthy waits for clinical trial application reviews, in some cases up to six months, this can be awarded in a shorter two-month timeline from submission to the start of studies. A further advantage is that there is no need to obtain import licenses for IMP. Additional approval is needed for comparators and medical test systems such as urine or pregnancy tests, no need for lab kits and biosamples. Georgia benefits from a population of almost 4 million, offering timely patient recruitment opportunities.

GROWTH POTENTIAL

With therapeutic areas across oncology, the central nervous system, infectious disease, gastrointestinal disease, and immunology, Georgia is already well established as an excellent location for clinical trials.

There have been over 100 clinical trials in Georgia since 2020.

The bulk of these came from international sponsors with a strong focus on managing Phase II-III multinational trials. With a growing potential, the country boasts 172 registered investigational sites, with 16 of these managing 20 clinical trials.

An added benefit is that most Eastern European CROs already have experience in clinical studies in the territory in addition to registered offices within Georgia.

Other benefits include:

- Full compliance with Good Clinical Practice (GCP) guidelines.
- Clear regulatory requirements including Good Distribution Practice (GDP) and simplified process of document submission.
- Highly qualified and motivated medical investigators providing high quality data inspected and approved by the European Medicines Agency (EMA) and US Food and Drug Administration (FDA).
- Availability of site teams and patients.
- Proven track record with internationally recognised standards for disease treatment and prevention.

LEADING THE WAY WITH CLINICAL TRIALS SERVICES IN EUROPE

Oximio has been providing clinical trials services within Georgia since 2017. From its dedicated GDP/ISO certified depot in Tbilisi, along with a courier fleet, it can provide a quick distribution service including direct to patient deliveries.

A key requirement for many sponsors is temperature control, particularly when it comes to biological samples. Leading the way, Oximio provides dedicated support for the storage and distribution of investigational medicinal products and clinical trial materials. Coupled with regulatory and customs experience, sponsors can access quick customs clearance and are assured of shipment integrity at all times.
A second depot in Georgia, which is located in a Free Trade Zone, enables supply, storage and distribution to multiple Caucasus countries from a regional depot. Oximio is well placed to provide unique access to patient populations in Eastern Europe via their GxP-compliant depot network covering Georgia, Hungary, Turkey, Israel, Serbia and Ukraine.

https://oximio.com/depot-network/europe/georgia/

TÜRKIYE & ISRAEL

The Emergence of Türkiye & Israel as Popular Clinical Trials Destinations

As clinical trial participant groups reach saturation levels worldwide, it has become crucial to venture into different countries to facilitate the development of new medical treatments, enhance research diversity, and promote international collaborations.

When selecting a clinical trial site, numerous considerations come into play. The suitability of a location is influenced by various factors, such as favourable regulatory approval timelines, the size and diversity of the local population, the track record of patient retention in past trials, the presence of established research infrastructure, and the overall state of the country's healthcare system.

Discover the growing appeal of Türkiye and Israel as popular destinations for testing new medicinal products.

TÜRKIYE'S CLINICAL TRIALS GROWTH

The Turkish Medicines and Medical Devices Agency (TMMDA) oversee the management of clinical trials within the country. The governing body has successfully adopted globally recognized guidelines and aligned its procedures with European Union directives, guaranteeing adherence to the highest standards of good clinical practice (GCP). Through its efforts, the TMMDA has introduced measures to simplify the approval process, resulting in reduced timelines and improved communication channels between researchers and regulators. These optimized procedures significantly enhance the speed and efficiency of setting up and running clinical trials in Türkiye.

In addition to this, the Turkish Government, in an effort to incentivise local and overseas sponsors, offers financial support, grants and tax incentives. These actions are pivotal in enabling collaborations across academia, industry, and healthcare institutions.

"We have a favourable investment environment, robust growth in the sector, and opportunities in sub-sectors as well. Türkiye has a strong international presence," explains Gunes Yildirim, managing director for Türkiye at Oximio. "We have favourable demographics, with a dynamic, young, and secure talent pool supporting the industry. And we also have a rising life expectancy and increasing spending on healthcare."

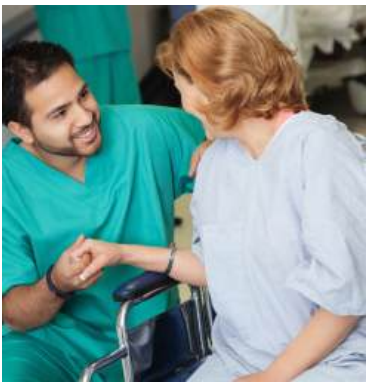
Robust collaborations in the realm of clinical trials are pursued eagerly by both Israel and Türkiye. These partnerships not only enhance our understanding of science but also stimulate economic development and cultivate strong bonds between local and international entities. A growing number of pharmaceutical companies, contract research organizations (CROs), and academic institutions are acknowledging the immense potential of Israel and Türkiye as highly favourable locations for their research.

ISRAEL'S CLINICAL TRIAL LANDSCAPE

Israel has become an increasingly attractive hub for conducting clinical trials, drawing substantial international sponsorship. According to GlobalData, from December 8, 2012, to March 8, 2023, a remarkable 75% of clinical trials carried out in Israel were multinational in nature. This popularity among global investors can be attributed to various factors, including a diverse population and a strong national healthcare system that offers comprehensive long-term health monitoring and medical records.

EXCELLENT PATIENT POOL

The ease of recruiting and retaining patients, is one of the major benefits that Israel can bring to clinical trials. "The recruitment and retention of patients are very important because you know you can get a trial to be initiated and stay on track and remain within the timeframes of the recruitment period, which makes for



successful clinical trial outcomes" says Zayheda Khan, chief commercial officer at Oximio.

Moreover, due to the diverse origins of Israel's population from multiple global countries, it presents a distinctive advantage for recruiting such a diverse population of patients for clinical trials and sometimes is unmatched in other international locations.

"In a small environment, with a population of just over nine and a half million, we have a community that has genes from all over the world," explains Dror Sukenik, managing director for Israel at Oximio.

“The Israeli population is nationally health insured, we don’t see people moving to another country, like in Europe, so our patient database is tracked and monitored easily.”

FAVOURABLE REGULATORY ENVIRONMENT

The Israel Ministry of Health (IMOH) is responsible for supervising and authorizing clinical trials within the country. To ensure timely review and approval, it has established streamlined procedures.

The government actively promotes and supports clinical trials through a range of initiatives and incentives, such as financial assistance and grants. One notable collaboration is with the Israeli Innovation Authority, which works closely with pharmaceutical and biotech firms to provide financial support and necessary resources for conducting clinical trials within the country.

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https://oximio.com/depot-network/middle-east/israel/

AFRICA

Unleashing the potential of the new superpower in clinical trials

Africa remains a largely untapped market for clinical trials, with data showing that the continent has a history of running significantly fewer clinical trials than other regions globally. But it has much to offer pharmaceutical companies in trialling new drugs. And the key to opening up the market lies in expertise in managing the supply chain and overcoming the varying regulations across 54 countries.

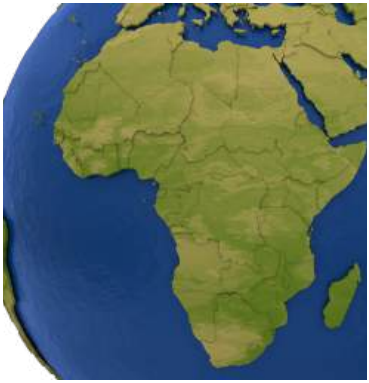
The continent offers considerable advantages and opportunities for trialling investigational medicinal products that, if pharma companies can correctly harness, will turn the continent into a superpower for clinical trials.

Africa has the potential to transform into a superpower for clinical trials.

Across 54 countries, the continent accounts for approximately 17% of the global population, and the total number of people living there is projected to surpass two billion within the next five years. The population is also considerably diverse ethnically. It also possesses the greatest disease burden in the world at around 25%, which includes serious diseases such as HIV/AIDS, malaria, tuberculosis, acute respiratory infections, and diarrheal diseases, which all have high mortality rates.

Rates of non-communicable diseases such as hypertension, cardiovascular disease, chronic respiratory diseases, diabetes, and cancers are also considered high throughout Africa. Research suggests that sub-Saharan Africa is expected to see one of the largest global increases in mortality rates caused by non-communicable diseases.

These high rates of diseases in largely untapped patient pools, present invaluable opportunities to trial new drugs



that can help people living with chronic conditions and battling serious illnesses. Crucially, Africa is projected to have the largest working-age population globally by 2050 and its importance for clinical trials is only predicted to increase in future.

“Africa offers effective, innovative and cost-effective ways to execute clinical trials,” explains Rob van den Bergh, Managing Director of Oximio’s sub-Saharan Africa division, which delivers comprehensive services in clinical trial logistics. “It’s home to the highest genetic diversity of humans on the planet and it’s filled with potential participants who are more and more urbanised and eager to be part of the clinical trials.”

However, Africa currently accounts for a very low percentage of global clinical trials, with estimates putting it at approximately 2.5%. While there is clearly a strong pool of patients, there are obstacles and misconceptions that persist in limiting the number of potential clinical trials across the continent.
“There is a misconception that diseases in the Western world are not prevalent in Africa. This is completely incorrect because we know the medications for all therapeutic indications,” says Zayheda Khan, Chief Commercial Officer at Oximio. “The patients exist in Africa, as do the high-quality infrastructure of clinical trial management that are available in any other country or global region.”

CLINICAL TRIALS DATA FOR AFRICA

Globally, research has found that 62.2% of patients who take part in clinical trials are from a Caucasian background, which rises further to 84.2% in the US. The average representation of other ethnic groups in the US is very low, with 7.3% being African American, 3.4% Asian, and 2.8% from a Latino background.

Therefore, the available patient pool of a majority Black population in Africa represents an invaluable opportunity to develop medical products for patients with unmet clinical needs.

According to GlobalData figures, the worldwide percentage of clinical trials started and completed in Africa between 9 December 2012 and 8 March 2023 was 2.2%. Yet of the 5,071 clinical trials during the period studied, the majority were in Egypt with 2,910. Counting just the clinical trials in sub-Saharan Africa, the amount comes to 1,925 – or 1.45% of the global total. Within sub-Saharan Africa, the most trials were recorded in

South Africa with 930. Nigeria was the next highest with 169, followed by 163 in Kenya, and 160 in Uganda.

For therapy areas during the period analysed, infectious diseases had the most trials with 944. Oncology and cardiovascular therapies were relatively low with 132 and 118 trials respectively. For indications such as viral infections topped the list with 445 trials, followed by parasitic diseases with 330, and 259 for HIV/AIDs.

One of the many segments where sub-Saharan Africa could lead the world in clinical trials is therapies for sickle cell diseases, which disproportionately impacts Black people in far higher numbers than other racial groups. Yet in the period analysed, GlobalData recorded just 24 clinical trials for sickle cell diseases in the region. In the US, there were 91 clinical trials for sickle cell therapies in the period studied. As the US often struggles to attract enough African American trial participants, sub-Saharan Africa offers a viable solution to test treatments on a much larger population.

SHRINKING PATIENT POOLS IN THE REST OF THE WORLD

Africa also holds a solution to addressing the issue of shrinking populations of patients with noncommunicable diseases in the US and Europe. This is because many patients in these regions already have access to comparable drugs.

Consequently, there are relatively small patient pools for non-communicable diseases such as cancer, diabetes, heart disease, and Alzheimer's. Furthermore, Africa offers a population that is more receptive to taking part in clinical trials.

"You have a drug-naïve population in Africa. They don't have great access to commercial or prescribed drugs and there's the affordability issue of those," says Mark Woolf, Chief Business

Development Officer for Oximio.

“Therefore, they are open to clinical trials, because of the lack of costs that they have to put towards it. They need to have that assistance of access to clinical trials.”

OVERCOMING CHALLENGES WITH CLINICAL TRIALS IN AFRICA

Africa is made up of 54 countries, which potentially means 54 different sets of, not only rules and regulations for customs and operations, but also how they are interpreted on the ground. For clinical trials, this represents considerable complexity that is typically impractical to manage from outside the continent. Then there are the many different languages spoken and understood across Africa. Historically, these factors have discouraged sponsors from conducting wider clinical trials in Africa, or just repeatedly using one or two African countries that they are familiar with. However, it is possible to navigate these factors effectively by using local experts.

To address all these issues, Oximio has built a coalition of experts in regulatory and logistics across Africa, often based in the countries themselves, to better understand and adopt more advanced supply chain risk management practices.

“In 80% of the countries, we have a regulatory expert who is familiar with the local Department of Health and Ministry of Health processes,” says van den Bergh. “They handle the import licence application on behalf of all the sponsors or investigators in that country. We have one entity that expedites approvals through regulatory, customs and border control getting it to the site twice as fast.”

Oximio handles the end-to-end supply chain process to mitigate any risk or quality concerns sponsors may have in dealing with multiple parties across several countries and borders.

“We go right to either end: to the patient, to the site and the investigator” adds Khan.

"Everything is maintained to the highest quality standards and all shipments inbound and outbound are traceable from source to end destination. So, that's a huge added potential value to ensure products are delivered on time without any delays and some circumstances cost saving too."

ENSURING THE CORRECT CHAIN OF CUSTODY FOR SHIPMENTS

Clinical trials can only be effective if the drug has followed the correct chain of custody, which is secure in terms of temperature maintenance and handling. This can be particularly challenging in the hot climates and remote locations of Africa for biopharma drugs for example, that need to be kept in strict temperatures not only during transit-time and storage, but also once they reach the trial site to dose patients.

Central to Oximio's services in sub-Saharan Africa is a top-of-the-range, customs bonded distribution facility in Nairobi, Kenya, which provides state-of-the-art storage and distribution operations – strategically located to serve all areas within sub-Saharan Africa, both to the west and the east. The facility is essential in maintaining the clinical supply chain across all African states, which also offers substantial cost benefits.

"Providing research companies with centralised distribution and procurement and the added value to rapidly move clinical trial material, manage biospecimen transportation, perform re-labelling and so on, will most definitely contribute positively to clinical supply chain outcomes," comments van den Bergh.

In addition, the time-savings

by this facility in the clinical supply chain are considerable. “You’re talking about a regulated environment that manages and controls conditions, can import and export under custom-bonded status, which means that research companies can bring investigational products into the African continent, it can be held there and then moved to other nations across sub-Saharan Africa area rapidly, more cost effective with low risk.“

Certificates of Origin (COAs) which take 14 to 28 days to be granted. Whereas in Ghana, while approval only takes 8 to 10 days, additional permit fees and a Valid License of Importer must also be submitted.

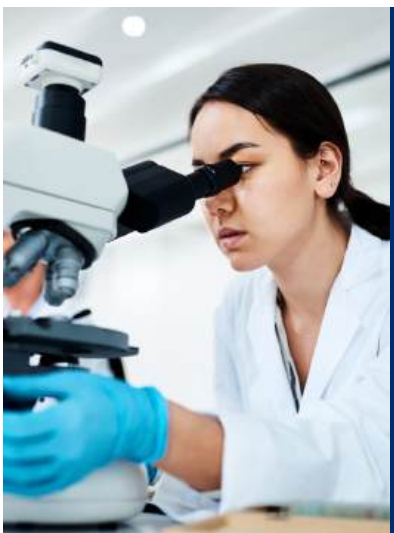
https://oximio.com/depot-network/africa/

SERBIA

Oximio in Serbia: The Gateway to Clinical Trials in Europe and Beyond

In recent years Serbia has emerged as a prominent and enticing destination for clinical trials research. With its flexible approach, enhanced regulations and cost-effectiveness it is able to offer quick, agile solutions for clinical trials and is rapidly becoming a preferred choice for many pharmaceutical and biotech companies over many other European Union (EU) countries.

In this article, Andras Orisek, Managing Director of Oximio in Serbia highlights some of the key factors making Serbia an attractive hub for conducting clinical trials.



Serbia - An attractive hub for clinical trials.

REGULATORY APPROACH

Serbia has made significant strides in enhancing its regulatory framework for clinical trials. The pharmaceutical industry is a priority for the government to drive economic growth. It has been proactive in aligning its regulatory procedures with EU standards making it easier for companies to conduct clinical trials within the country ensuring compliance with international requirements. It has also made efforts to simplify bureaucratic procedures for clinical trials which has resulted in shorter timelines for regulatory approvals, minimising delays. Typical clinical trial approval application timelines are 60 days.

COMPETITIVE COSTS

Serbia offers cost advantages compared to many other EU countries whilst still maintaining high-quality standards. It has one of the lowest labour costs in Europe, investors benefit from generous incentives and free-trade arrangements with EU and other markets. This affordability is a significant attraction for sponsors.

Typical clinical trial approval application timelines are 60 days.

STRATEGIC LOCATION AND DIVERSE POPULATION

Serbia benefits from an excellent, central, European geographic location serving as a crossroads for East and West. With excellent transport links and infrastructure, it is an easily accessible location.

The country has a diverse population of over 7 million people. This offers a valuable advantage for clinical trials as researchers are able to access a wide patient pool covering a range of genetic backgrounds and medical conditions which enhances the representation of their patient studies. The opportunity for patients to take part in a clinical trial means that they can gain access to pharmaceutical products which are limited or may not be available under state-funded programs.

These factors have resulted in efficient patient recruitment capabilities reducing the time and resources needed to enrol patients into clinical trials. This is crucial in expediting trial timelines.

EXPERIENCED WORKFORCE

Serbia boasts a well-educated and highly trained workforce including clinical research professionals, investigators and site staff. Healthcare providers deliver high quality clinical trial data derived under GxP guidelines and can facilitate reduced study timelines. This expertise, combined with a patient-centric approach, ensures that studies run smoothly adhering to quality international standards.

OXIMIO IN SERBIA

Oximio's Serbian facility is situated in Belgrade, an excellent gateway to the Balkans, Asia and Western Europe. Supported by a global distribution network, Oximio Serbia, has a worldwide reach.

Boasting an overall storage capacity of 385 m2, this includes a customs bonded warehouse. Complete with WDA Licence, the facilities provide increased efficiency, a centralised supply chain governance, and in some instances, cost savings of up to 50% compared to other direct-to-site models.

Following GMP best practice Oximio, Serbia offers end-to-end clinical trial logistic services and competitive, comparator sourcing.

https://oximio.com/depot-network/europe/serbia/

HUNGARY

Accelerating Clinical Trials in Hungary with Effective Compliance Solutions

When it comes to conducting clinical trials, selecting the right location is a critical decision that can significantly impact the success of your research. Hungary has long been recognised as a prime destination for clinical trials thanks to its convenient geographic location and well-established regulatory framework.

In this article we explore the key factors that make Hungary an attractive location for conducting clinical research, with a particular emphasis on the importance of GMP (Good Manufacturing Practice) certification.

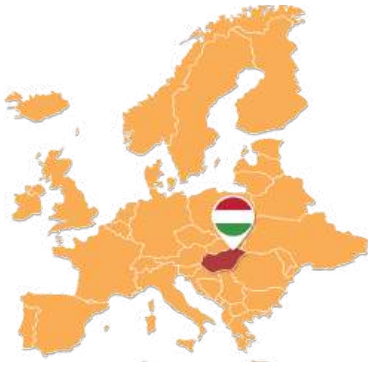
Safeguarding clinical trials in Hungary with excellent GMP

LOCATION

Hungary's central European location and extensive motorway network is a key logistic advantage for the country. Stretching 93,030 square kilometres, this landlocked country benefits from three vital European transport corridors – Mediterranean, Orient-Mediterranean and Rhine-Danube, which provide unrivalled access across Europe. Excellent road, rail and air transport provides quick and easy access to patient centres.

DIVERSE PATIENT POPULATIONS

With a population of 9.7 million, combined with its strategic location, Hungary is an ideal hub for clinical trials. Its geographical position allows easy access for Western and Eastern participants offering a diverse patient pool across various backgrounds and medical conditions. This is particularly beneficial for those wishing to run multi-country trials. It also benefits from fast enrolment.



EXCELLENT HEALTHCARE PROVISION

Hungary operates a universal healthcare program for its population which is financed through a Health Insurance Fund (HIF). In July 2023, the Government announced a further EUR 1.13bn budget investment in healthcare for 2024. Healthcare spending has grown from Euros 2.85 billion to Euros 8.28 billion over the last 10 years.

The country is home to a pool of skilled healthcare professionals, clinical researchers and investigators with extensive experience. Its modern research facilities and hospitals provide first-in-class facilities for conducting clinical trials.

REGULATORY ENVIRONMENT

Hungary's well-established regulatory framework is aligned with EU regulations, providing a smooth and efficient path to clinical trial approval. The National Centre for Public Health and Pharmacy (NNGYK), formerly OGYÉI, is responsible for the regulation of clinical trials within the country. It is their duty to ensure that the public are provided with safe and effective, quality medication that satisfies regulatory requirements.

The country places a strong emphasis on safety and compliance in clinical trials and adheres to international standards such as GCP (Good Clinical Practice) and ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use). These are obligatory and regulated by local authorities. This ensures that the highest ethical and safety standards are met.

With a clear regulatory environment and favourable study start-up timelines, the average time from submission of a clinical trial to approval is 10 weeks.

GMP CERTIFICATION

One of the cornerstones of successful clinical trials is the quality and safety of investigational products used in studies. A declaration by a QP that manufacturing sites are compliant with EU GMP certification is a requirement for the conducting of studies in Hungary ensuring that pharmaceutical products are produced in line with quality standards. In addition to the manufacturing of pharmaceuticals, it also means that other functions can be

undertaken such as kitting operations, labelling – including the extension of expiry dates, the importation of medical products into the EU from other countries as well as a range of secondary functions within the GMP licence.

OXIMIO IN HUNGARY

Established in 2020, Oximio, Hungary is conveniently located in Central Europe, a quick 50 minutes from Budapest Airport. This provides a strategic location for access between East and West Europe. The business has been accredited with both Good Manufacturing Practice (GMP) and Manufacturing and Importation Authorisation (MIA) certification. Our regional warehouse can support clinical trials across the EU and Eastern Europe with direct to site deliveries.

With segregated storage, the warehouse offers a range of temperature control systems from controlled ambient, refrigerated to ultra-low temperatures with cryogenic storage solutions by request.

This provides storage capabilities for blood products antibiotics and cytotoxic drugs to name but a few. Providing a range of comprehensive labelling and packaging services, we can assist with secondary packaging, additional labelling, kit assembly and coding of IMPs.

Our comparator sourcing services are available for the acquisition of both pharmaceuticals, medical equipment and equipment rental. A complete return, accountability and destruction service is also provided. The Hungarian team are developing strategic services, including adaptive logistics for cell and gene therapies and bio-banking.
With a team of qualified and experienced project managers, we can support you throughout your entire clinical trial.

https://oximio.com/depot-network/europe/hungary/

UKRAINE

Clinical Trial Costs in Ukraine: Delivering Cost Effective Solutions

Ukraine has been a hub for clinical trials for many years. Offering numerous benefits to pharmaceutical, biotechnology and contract research organizations, its cost effective and efficient research environment has made it a popular destination for clinical trials.

In this article we look at some of the advantages of Ukraine as a clinical trials location and why, despite the current war, it is a leading country for clinical trials.

Despite the war, Ukraine still remains a leading country for clinical trials

LOW CLINICAL TRIAL COSTS COMPARED TO WESTERN COUNTRIES

One of the key factors that makes Ukraine an attractive location for clinical trials is its relatively low clinical trials cost compared to other countries. The cost of conducting research in Ukraine is significantly lower than in Western countries, such as the United States or Western Europe. This is due to the lower cost of labour, infrastructure, and regulatory requirements. As a result, pharmaceutical companies and research organizations can achieve cost savings while still maintaining high-quality research standards.

SAVE TIME AND RESOURCE

In addition to cost savings, conducting clinical trials in Ukraine also offers time and resource efficiencies. The regulatory framework for clinical trials in Ukraine is well-established and streamlined, with efficient processes for study approval and initiation. The

timelines for obtaining regulatory approvals and initiating clinical trials in Ukraine have recently been shortened to just 35 days from submission to publication.

Furthermore, Ukraine has a large and diverse patient population, making it easier to enrol patients in clinical trials. The country has a well-established healthcare system with a network of experienced investigators and research sites. This enables quicker patient recruitment and enrolment, which is crucial for meeting study timelines and milestones.

EXPERIENCED AND SKILLED INVESTIGATORS

Another advantage of conducting clinical trials in Ukraine is the availability of experienced and skilled investigators. Ukraine has a long history of conducting clinical research, and many investigators have extensive experience in conducting clinical trials in various therapeutic areas. These experienced investigators can provide valuable insights and expertise, contributing to the success of the clinical trial. Conducting clinical trials in Ukraine offers significant benefits in terms of cost-effectiveness, efficiency, and expertise.

The relatively low cost of conducting research, streamlined regulatory processes, diverse patient population, and experienced investigators make Ukraine an attractive location for clinical trials. If you are looking to maximize efficiency and minimize costs in your clinical trial, Ukraine may be the ideal destination.

CLINICAL TRIAL LOGISTICS AND SERVICES FROM OXIMIO

Oximio has been delivering clinical trial logistic solutions for almost 20 years. With expert industry knowledge, established procedures and dedicated teams we can help you from start to finish with your clinical studies.

Here's a taster of what we can do:

- Clinical Trials Logistics
- Sourcing for Clinical Trials
- Patient Focused Services
- Adaptive Logistics for Advanced Therapy

https://oximio.com/depot-network/europe/ukraine/

GLOBAL FOOTPRINT

A Smooth Clinical Trial Supply Chain via a Robust Partner Depot Network

When it comes to conducting clinical trials, one of the critical factors that can significantly impact the success and efficiency of the process is the establishment of a reliable partner depot network.

A well-organised and comprehensive depot network plays a pivotal role in meeting regulatory requirements, managing customs clearance, ensuring appropriate transportation solutions, maintaining proper storage capabilities, overcoming language and cultural barriers, and keeping control of the budget – to name but a few.

A strong partner depot network ensuring a seamless clinical trial supply.

SATISFYING CLINICAL TRIALS REGULATORY REQUIREMENTS FROM COUNTRY TO COUNTRY

When clinical trials are conducted across multiple countries, having expert local knowledge is essential to navigate and satisfy the regulatory requirements for each jurisdiction.

Good local partners will understand the unique legal obligations in their respective countries. They will be adept at handling the required import and export licenses, managing any permits and liaising with customs authorities to expedite the clearance process. Having a local network partner familiar with local customs procedures will prevent unnecessary delays and ensures that trial materials reach their destination on time.

COUNTRY-SPECIFIC TRANSPORTATION SOLUTIONS AND INFRASTRUCTURE CONSIDERATIONS

Transportation can be a complex challenge in clinical trials particularly when operating in

countries with diverse infrastructures. A competent partner will have in-depth knowledge of local transportation networks and can design country-specific solutions to overcome infrastructural limitations. This includes selecting appropriate modes of transport, addressing any unique transportation challenges, and having access to licensed local distributors to ensure the timely and secure delivery of trial materials to investigator sites.

By leveraging their expertise in transportation logistics, a robust depot network facilitates efficient and reliable distribution throughout the trial duration.

STORAGE CAPABILITIES AND TEMPERATURE CONTROL FOR SAMPLE STABILITY AND SAFETY

Maintaining the integrity of trial samples and medicines is essential at all stages of the journey. Adequate storage capabilities, particularly for temperature-sensitive materials, are crucial to ensure sample stability and safety.

A dependable partner will offer state-of-the-art storage facilities equipped with appropriate temperature control systems. This allows for the secure storage of medicines, biological specimens, and other trial-related materials, safeguarding their efficacy and usability throughout the trial. An experienced partner will have effective temperature monitoring and contingency plans in place to mitigate any potential risks.

PACKING EXPERTISE FOR SAFE TRANSPORTATION

Proper packing and packaging is essential to protect trial materials during transportation. A proficient partner will have

extensive experience in handling a wide range of trial materials and understands the specific packaging requirements for different substances, such as hazardous materials, biological samples, or temperature-sensitive medications. By ensuring appropriate packaging, labelling, and inventory documentation, your partner will minimize the risk of damage, loss, or regulatory non-compliance during transportation.

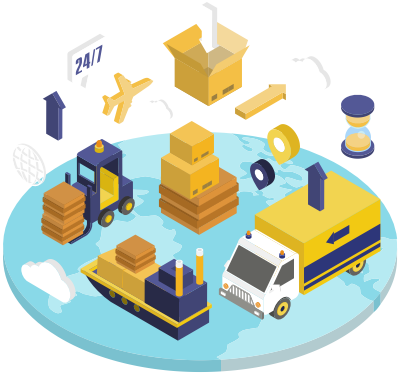
OVERCOMING LANGUAGE AND CULTURAL BARRIERS

When conducting clinical trials across borders, language and cultural barriers can pose significant challenges. A good partner, proficient in local languages and well-versed in the

cultural nuances of the regions where trials are being conducted will be able to communicate and collaborate effectively with local stakeholders, including investigators, site staff, and regulatory authorities. This will help to ensure smooth operations and compliance.

BUDGET CONTROL

Clinical trials require careful budget planning and control to ensure efficient resource utilisation. A reliable partner understands the financial aspects of clinical trial logistics and works closely with sponsors to develop cost-effective solutions. By leveraging their expertise in transportation, storage, and customs procedures, they can identify opportunities for optimisation, such as selecting the most economical transportation routes or implementing efficient inventory management strategies. Meticulous budget control means that sponsors can maximise resources and be cost-effective.



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GLOBAL SUPPLY CHAIN SOLUTIONS FOR CLINICAL TRIALS

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