The growing importance of Israel and Türkiye in clinical trials

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Introduction

Patient pools in major global markets for clinical trials are at real risk of oversaturation, with sponsors and pharmaceutical companies finding it increasingly hard to identify and recruit participants with sufficient diversity and then retain them for the trial duration.

For example, the unfortunate disruptions that the ongoing war between Ukraine and Russia has caused to clinical trial activities in both countries and the wider supply chain has accelerated the need to focus on the other markets in the region. Concerns over regional instability and securing key supplies have also caused disruptions in nearby countries, leading to a further decline in clinical trial activities.

As a result, there is a need for the clinical trials sector to focus on alternative markets for hosting both single-country and multi-country trials that combine large populations of potential participants with robust regulatory regimes and existing clinical frameworks of sufficient quality.

The countries that have the potential to increase clinical trials must also possess the necessary expertise and infrastructure to expand activities and develop into key markets for hosting more trials.

To address this need, Israel and Türkiye have steadily emerged as attractive candidates as these markets still have significant potential for growth, with both countries possessing multiple benefits for clinical trial sponsors.

Firstly, both countries have highly developed healthcare ecosystems with well-established regulations, modern medical facilities, well-educated healthcare professionals, and advanced technological resources.

Crucially, both nations possess large or diverse population pools that are well-suited to clinical trials, with Israel's population of 9.6 million being drawn from multiple ethnic backgrounds. While Türkiye's rapidly growing population of 84 million consists of a working-age population that currently stands at approximately 56.5 million and is only rising, according to FRED economic data.

Both countries have also made clear efforts in recent years to streamline and harmonise the regulatory frameworks and bureaucratic processes for clinical trials to align them better with global standards, making them more attractive to potential trial sponsors and pharmaceutical companies from these larger locations.

As the economies of Israel and Türkiye continue to grow, and clinical trials continuously need to tap into new markets, these two countries are likely to emerge as important locations for the future of the sector.

In the following pages, we will profile the clinical trial environments of both countries, with expert input from Oximio.

Country profile: Israel

Key Information

1,509

Number of clinical trials completed from 9 December 2012 to 8 March 2023, recorded by GlobalData

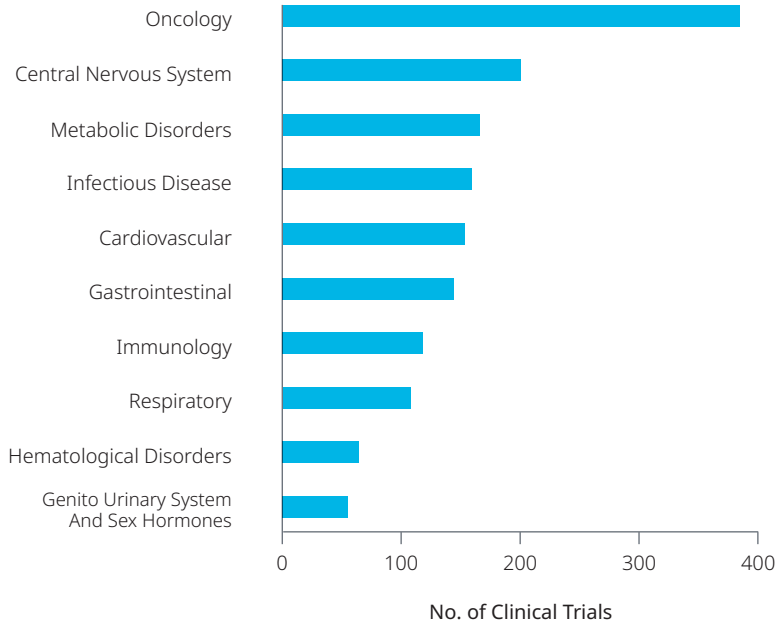
TOP SPONSORS

Novartis AG, Merck & Co, The Chaim Sheba Medical Centre

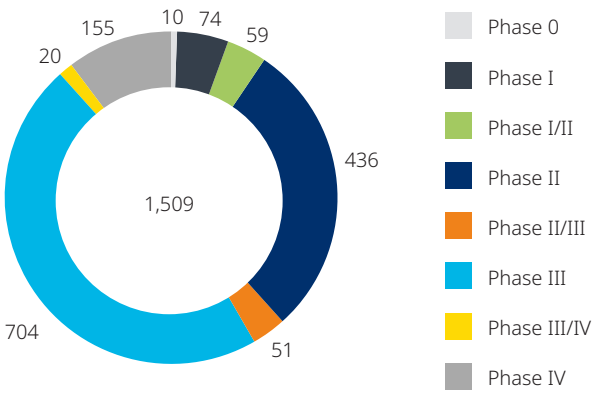
$2.4bn

The size of Israel's pharma market in 2018, according to GlobalData

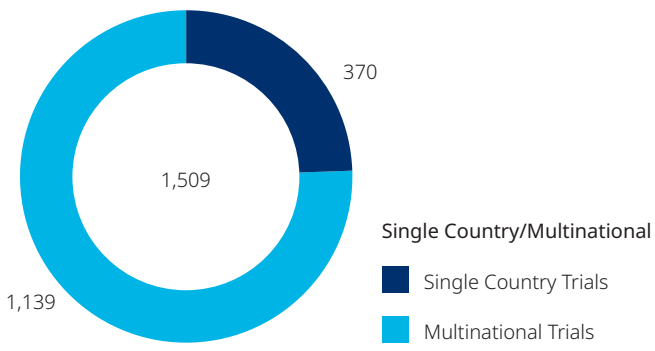
Top Therapy Areas



Trial Phase



Location Type



Israel has emerged as an increasingly attractive market for conducting clinical trials due to several factors that make it a favourable destination for pharmaceutical and biotechnology companies.

In a sign of its attractiveness to international sponsors, multinational trials made up the vast majority of clinical trials completed between 8 December 2012 and 8 March 2023 with 1,139 or 75%, according to GlobalData, compared with 370 for single-country trials or 25%. The highest therapy area was oncology with 384 clinical trials.

In the period covering the start of the pandemic and recovery between 30 March 2019 and 8 March 2023, multinational trials have continued to dominate even further. Of the total 1,105 clinical trials running or completed, 903 or 82% were multinational, compared with 202 or 18% for a single country.

The clinical trials environment

From its advanced healthcare infrastructure to its robust research ecosystem that includes internationally renowned universities, Israel offers numerous advantages for clinical research.

Israel's highly developed healthcare system provides top-quality medical services to its population. The country boasts state-of-the-art medical facilities, advanced technology, and a highly educated healthcare workforce. Israel consistently ranks among the top countries in various health indicators, such as life expectancy and healthcare outcomes. This strong healthcare infrastructure is crucial for conducting clinical trials, as it ensures that participants receive optimal care and monitoring throughout studies.

> **"The recruitment and retention of patients are very important because you know you can get a trial to stay on track and remain within the timeframes of the recruitment period, while the patient experience is enhanced at all stages of the process which is as an outcome is great."**

"The quality of the healthcare system in Israel is very high," explains Zayheda Khan, chief commercial officer at Oximio. "It is every bit as robust as in other leading countries, and I think that gives a lot of confidence in choosing Israel for single-country or multi-national clinical trials."

Of particular value is the fact that the country's entire population is part of a national health insurance scheme, meaning that the medical history of individuals is recorded over time to provide a key advantage in monitoring the long-term health of trial subjects. Similarly, Israel's small geographic size and centralised healthcare system offer a further advantage for clinical trials, facilitating efficient patient recruitment and enrolment, as well as allowing easy access to potential trial participants.

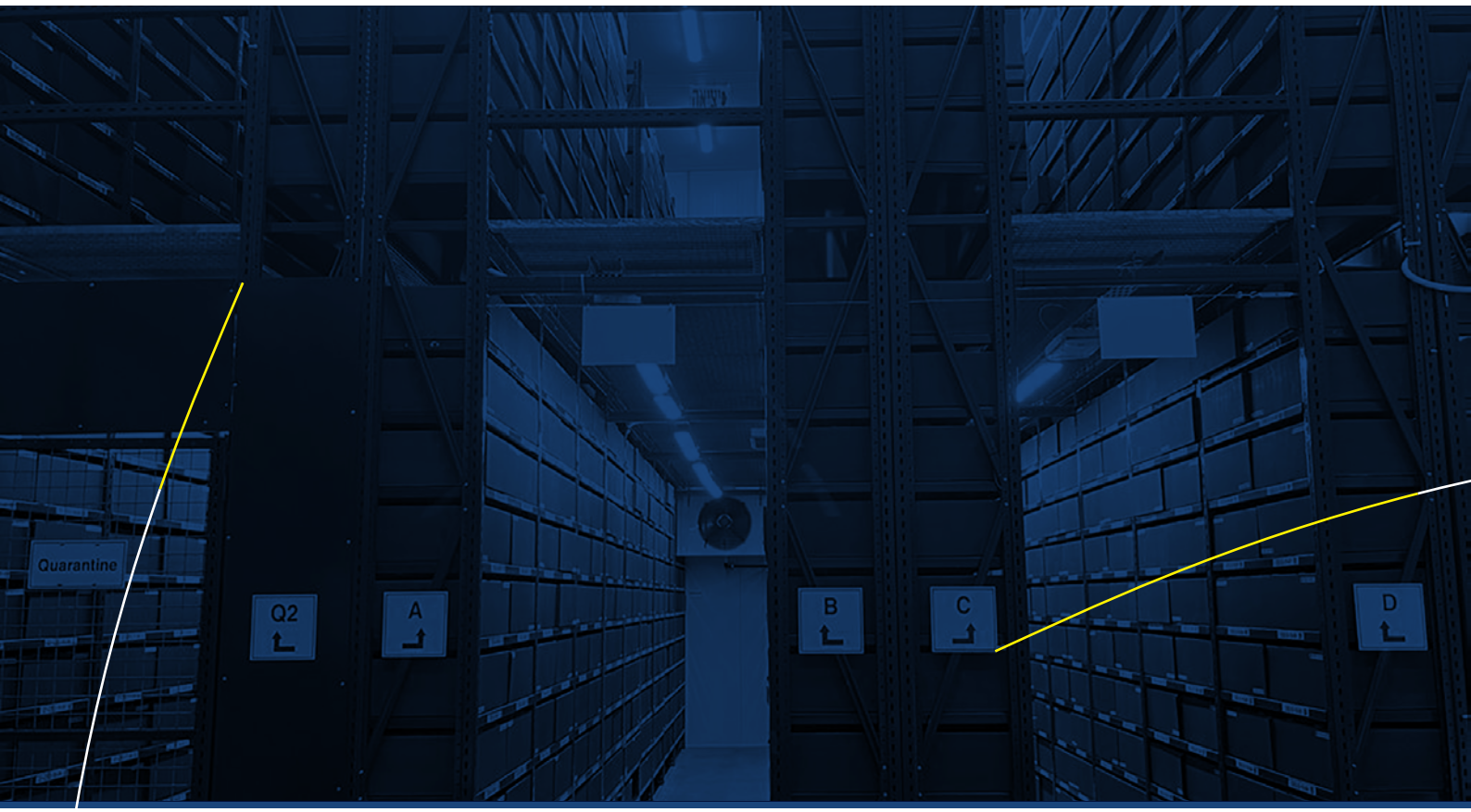
"The recruitment and retention of patients are very important because you know you can get a trial to stay on track and remain within the timeframes of the recruitment period, while the patient experience is enhanced at all stages of the process which is as an outcome is great," adds Khan.

Israel's unique population composition is another key advantage for clinical research. The country has a diverse ethnic and genetic makeup, resulting from the immigration of individuals from different regions globally. This diversity provides researchers with an invaluable resource for conducting trials that require a varied patient pool.

“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 can be tracked and monitored easily.”

Moreover, Israel has a well-established research infrastructure that promotes innovation and collaboration. The country is home to renowned academic and research institutions, including leading universities and hospitals. These institutions often collaborate with industry partners to conduct clinical trials, providing access to world-class expertise and facilities. The strong network of researchers, scientists, and physicians in Israel supports the design, implementation, and analysis of clinical trials, ensuring high-quality research outcomes.

This is evidenced by the fact that the country has a rapidly growing biopharma industry alongside a flourishing life sciences start-up sector where two-thirds of companies are less than a decade old, according to the Israel Advanced Tech Industries Group. Israel also reportedly has the highest proportion of medical device patents per capita globally.



In addition, Israel has a favourable regulatory environment for clinical trials. The Israeli Ministry of Health (MoH) is committed to promoting and furthering clinical research while ensuring participant safety and ethical standards. The MoH has implemented efficient and transparent regulatory processes, offering a streamlined pathway for trial approval. The MoH has also established a dedicated unit, the Israeli Clinical Trials Registry, which serves as a centralised database for trial information and further enhances transparency in processes.

Furthermore, the Israeli Government actively supports and encourages clinical trials through various initiatives and incentives. The government provides financial support for clinical research, offering grants and funding to attract both domestic and international sponsors. Additionally, the Israeli Innovation Authority collaborates with pharmaceutical and biotech companies, providing financial support and resources for conducting clinical trials in Israel. These government initiatives demonstrate a commitment to strengthening the environment for clinical research and incentivising sponsors to choose Israel as a destination for clinical trials.

While from a logistics perspective, Israel is well-connected through international airports and an extensive road network.

Oximio in Israel

For companies looking to enter or expand their activities within the Israeli clinical trials market, Oximio's experienced team of on-the-ground experts provide an ideal mix of global industry best practice insight and local expertise. Oximio's Israeli depot is located near the city of Caesarea on the Mediterranean coast, a 45-minute drive north of Tel Aviv.

Having operated a depot in Israel since 2011, and led by managing director, Dror Sukenik, the company provides a one-stop-shop for clinical trial support services.

"We have a fully dedicated and professional team, taking clients by the hand and providing them all the knowledge that they need in order to start up the trial easily," adds Sukenik. "We go over everything. Having a diverse population speaking a variety of languages, we also assist with translation, labelling, or whatever needs to be done to provide our client with a full coverage of service."

Providing the full range of import and export licence support and operating its own local depot, Oximio can transport controlled drugs, genetically modified organisms, cytotoxics and many other sensitive pharmaceutical products and materials. Capable of transporting goods in ambient conditions all the way to deep frozen temperatures of -80°C, the company is leading the way in direct-to-patient deliveries in Israel.

"The Israeli depot is agile and able to mould itself to suit clients' needs – such as a QP Release on site," says Sukenik. "Having a local partner to assist you, who knows the local bureaucracy and regulation, and who can speak the local language is vital. So, having us as a partner, who can provide all the right licences and raise the right flags at the right time is valuable."

Country profile: Türkiye

Key Information

1,728

Number of clinical trials completed between 9 December 2012 and 8 March 2023, recorded by GlobalData

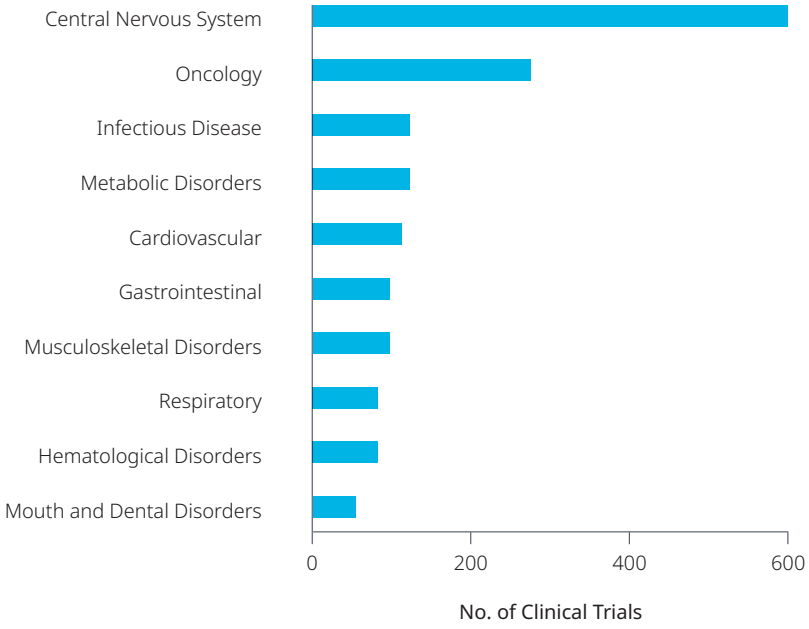
TOP SPONSORS

Novartis AG, Sanofi, Pfizer, GSK, MSD
Istanbul University, Ataturk University

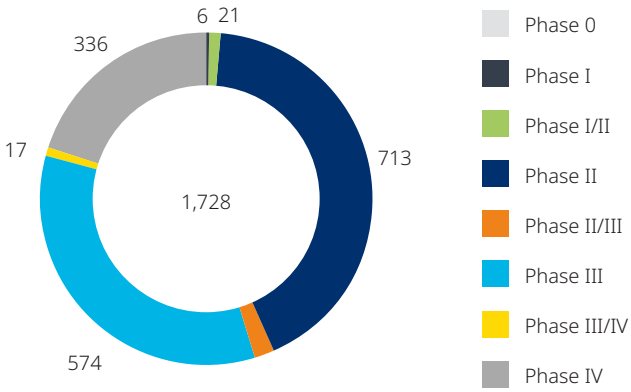
$327.7m

Total economic annual value of clinical research in Türkiye as of 2019, according to GlobalData

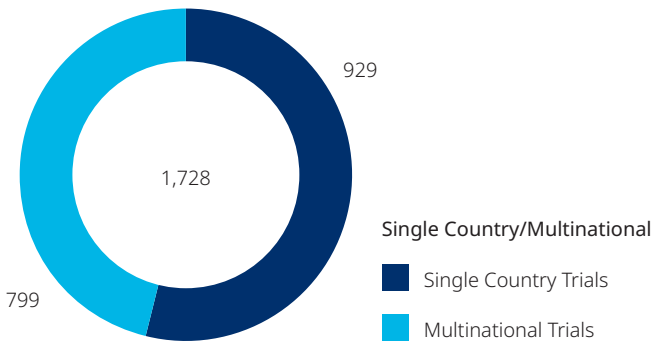
Top Therapy Areas



Trial Phase



Location Type



Türkiye is rapidly becoming one of the most attractive international markets for running clinical trials, with the nation's government having identified the sector as a key growth priority within its 2020 investment report.

Türkiye was ranked 26th for clinical trial activity globally in 2020, and the Association of Research-Based Pharmaceutical Companies (AIFD) believes that the country can increase the number of trials by threefold to reach the top ten within a relatively short period.

And the signs are looking highly promising. There have been substantially more clinical trials running in Türkiye in a recent 12-month period than the combined total over several years. For example, from 1 January 2022 to 8 March 2023, GlobalData recorded that 311 clinical trials were running. This is compared with 222 running for the entire period from 25 February 2012 to 30 March 2019.

Unlike Israel, there has been a more even split between multinational and single-country trials. In fact, according to GlobalData figures, there was a small majority of single-country trials completed in Türkiye between 9 December 2012 and 8 March 2023 with 929, amounting to 54%, compared with the 799 being multinational trials – or 46%. The highest therapy area was for the central nervous system products.

The clinical trials environment

Türkiye has established clear and efficient regulatory processes for obtaining clinical trial approval. The Turkish Medicines and Medical Devices Agency (TITCK) is the regulatory authority responsible for evaluating and approving clinical trials in Türkiye. The TITCK has implemented measures to streamline the approval process, reducing timelines and facilitating efficient communication between researchers and regulators. These streamlined procedures enhance the speed and efficiency of initiating and conducting clinical trials in Türkiye.

Explaining how the regulations and procedures have served to enhance Türkiye's international standing, Gunes Yildirim, managing director for Türkiye at Oximio, says: "All our regulations are aligned with international and EU regulations and standards like PIC/S GMP, ICH GCP, and ISO."

Furthermore, the government actively supports and encourages clinical research through various initiatives and incentives. The Turkish Ministry of Health collaborates with academic institutions, research centres, and industry partners to promote research and innovation.

The government offers financial support, grants, and tax incentives to attract domestic and international sponsors to conduct clinical trials in Türkiye. These incentives not only reduce the financial burden on sponsors but also stimulate the collaborations between academia, industry, and healthcare institutions, contributing to a vibrant research ecosystem.

"There could be direct additional funding from the government to support the companies actually running their clinical trials in Türkiye," says Khan. "They will obviously have to have a local presence and there is the risk of inflation, but there are certainly the strategies available to make it worthwhile and especially if they already operate within the country."

One of the key factors that make Türkiye's growth prospects so attractive is its substantial patient population. With a population of more than 84 million, Türkiye provides access to a large pool of potential participants across various age groups, ethnicities, and medical conditions. Additionally, Türkiye's population is characterised by its relative youth, making it particularly well-suited for clinical studies as populations age around the world, while also serving to benefit the industry from a business perspective.

"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."

"We have a favourable investment environment, robust growth in the sector, and opportunities in sub-sectors as well. Türkiye has a strong international presence," adds Yildirim. "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."

Türkiye's well-developed healthcare infrastructure is another significant advantage. The country boasts modern medical facilities, equipped with state-of-the-art technology, and staffed by highly trained healthcare professionals. Türkiye has several internationally accredited hospitals and research centres, providing access to specialists and cutting-edge facilities for conducting trials across a wide range of therapeutic areas. This is evidenced by the fact that Istanbul University and Ataturk University are amongst its top sponsors of clinical trials.

Moreover, Türkiye's geographic location provides a strategic advantage for multinational companies looking to conduct clinical trials. Positioned at the crossroads of Europe, Asia, and the Middle East, Türkiye has a well-connected transportation infrastructure, including modern airports and highways, enabling efficient travel for shipments, trial participants and study personnel. Additionally, Türkiye's favourable time zone allows for effective coordination and communication with research teams located in different parts of the world.

The cost of conducting trials in Türkiye is considerably lower than many Western countries, offering savings for sponsors without compromising quality or patient care.

Türkiye's cost competitiveness is another significant factor that attracts clinical trials to the country. The cost of conducting trials in Türkiye is considerably lower than many Western countries, offering savings for sponsors without compromising quality or patient care. Savings are attributed to factors such as lower operational costs, infrastructure expenses, and patient recruitment expenses. These cost advantages make Türkiye an appealing option for companies seeking to optimise their research and development budgets.

Oximio in Türkiye

Operating since 2019, and led by managing director, Gunes Yildirim, the Oximio Türkiye depot is well-versed in all the nuances and complexities of running a clinical trial in the country and offers a comprehensive range of services. The country's depot is located in the city of İzmir, on Türkiye's west coast, which offers crucial access to the region's international shipping port.

From its Turkish depot, Oximio ensures that both local and international clients get their medical products and raw materials delivered at the necessary temperatures and on time.

As proof of how Oximio routinely overcomes significant challenges, the company moved into its depot when much of the world was in lockdown at the peak of the global pandemic in 2020. The company has an extensive record of using its initiative, expertise, and connections to ensure the work is done regardless of the obstacles.

"Oximio's Türkiye location is quite new, but we are not new to the sector," adds Yildirim. "We have extensive operational experience, which is our main advantage. Also, our procedures are globalised across all Oximio locations.

"We have experience in GCP, as well as GMP. We are capable of distributing to all locations in Türkiye. We have an experienced team and have built a very strong network in the country. And our quality standards are aligned with global standards and principles."

With the Turkish Government highlighting both the pharmaceutical and the clinical trial sectors as key growth areas and strategic priorities, Oximio is ideally suited to helping companies and trial sponsors capitalise on the opportunities available.

"Türkiye is another fast-growing market for Oximio and it also serves as a bridge between the Asian, European and the Middle East markets. Oximio has a very strong footprint that means we have the knowledge and can provide that link," says Khan.

Global services and facilities offered by Oximio

Oximio is a trusted partner offering a patient-centric range of end-to-end logistics services for clinical trials to streamline research processes and optimise trial timelines.

With the company's expertise and commitment to high quality, Oximio is dedicated to supporting clients at every step of the way, from study design to data analysis and moving towards regulatory approval.

Since being established in 2004 by a handful of people, Oximio now boasts a global team of experienced professionals from the pharmaceutical industry and logistics. This diverse and knowledgeable team ensures that clients receive expert guidance and support at each stage of their trial.

The company assists with study design and protocol development, optimising trials for maximum efficiency. Through its extensive network of contacts, Oximio offers access to its top-class warehouse and storage facilities using its own depots or trusted partners across Europe, the Middle East, Africa, Asia, and North America to ensure that investigational medical products are kept at their optimum conditions for as long as required.

Regulatory support is also provided, ensuring compliance with national and international regulations, as well as assisting with ethics committee submissions and approvals.

Quality and efficiency are at the forefront of Oximio's services. The company implements rigorous quality control measures throughout the trial, maintaining data integrity and meeting regulatory requirements. Streamlined processes and efficient project management ensure trials stay on track, minimising delays, and maximising success.

For those seeking reliable, comprehensive clinical trial services, Oximio has numerous strengths to be considered the preferred choice. To explore how it can support your clinical trial goals, **contact Oximio today**.

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