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Four Major Trends in Oncology Clinical Trials

Introduction

Cancer treatments are improving what is possible for patients, with the use of technology in clinical trials bringing breakthroughs a step closer to becoming a reality.

In this document we will outline four key trends within oncology and highlight the importance of biospecimens, which are becoming an increasing feature of clinical trials to treat cancer. Expert input will be provided by pharma logistics specialists, Oximio, based on experience of keeping biospecimens at the strict temperatures required.

Generative AI

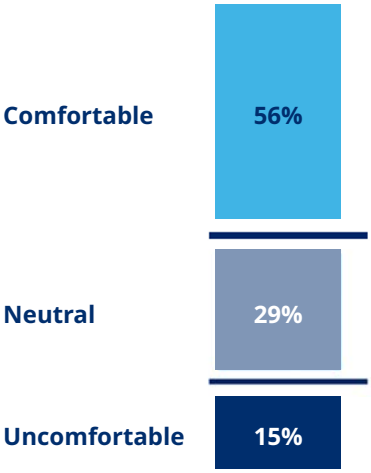
Generative artificial intelligence (GenAI) is being increasingly used to improve clinical trial processes and it has much to offer oncology. The capacity to quickly spot patterns and analyse vast volumes of data has been effective in cancer diagnostics, particularly in the crucial early stages.

A case study from Massive Bio, a US oncology solutions startup, shows the use of a ChatGPT-powered chatbot platform to transform the way cancer patients, referring physicians and principal investigators engage with and access clinical trial information.

The platform includes two main personas: AskFiona AI and DrArturo AI. These serve as informational resources for cancer patients exploring clinical trials, and act as virtual oncology tools for oncologists and haematologists, respectively.

However, GenAI must be implemented responsibly due to concerns over bias, privacy risks, and reliability and accuracy, while the technology is new and developing. Nevertheless, there is a willingness among patients to embrace it. A survey on clinical practice by GlobalData found 56% of the cancer patients questioned were comfortable with visiting a medical practice that used AI.

GlobalData survey of cancer patients on how comfortable they are with AI being used by medical practices they attend.



Source: GlobalData

Immuno-oncology and cell therapy

Immuno-oncology (IO) is the science of harnessing a patient's immune system to recognise and attack cancer cells. This is done by stimulating the immune system or by administering modified products with oncolytic properties.

As of April 2023, there were more than 4,400 industry sponsored clinical trials investigating IO, with 703 drugs in clinical development.

IO agents, which are used against solid tumours, have transformed cancer therapeutics, driving long-term remission in patients who historically had limited options. They include the classes of immune checkpoint modulators, cell therapies, bispecific antibodies, oncolytic viruses, therapeutic vaccines and cytokines.

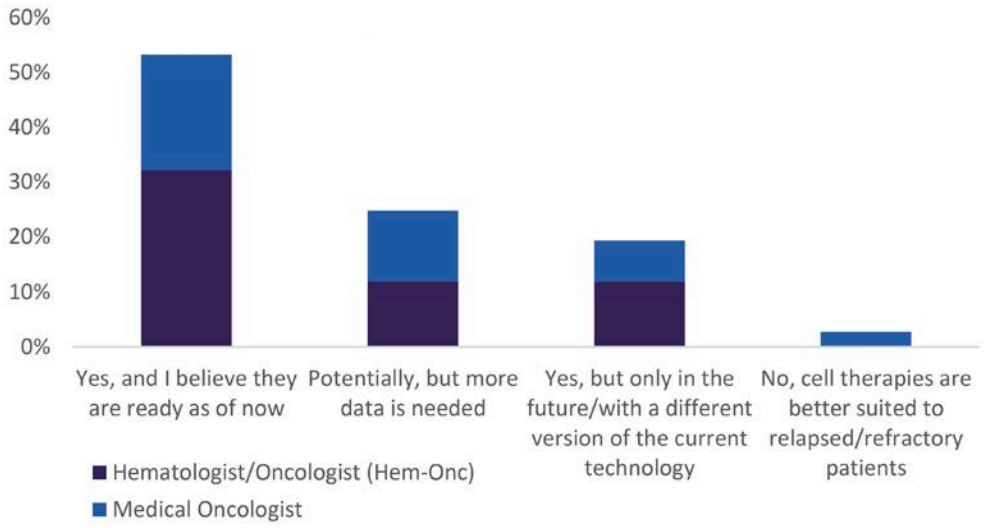
The most widely used are immune checkpoint inhibitors (ICIs), which work by blocking the inhibitory interactions between tumour cells and T-cells, facilitating an anti-tumour immune response. There are more than 20 approved, marketed ICIs. While initially only approved for metastatic disease, ICIs have now moved into earlier disease settings, reducing the risk of progression and relapse.
However, IO therapies have a high price tag, typically exceeding $100,000 in the US, while cell therapies can top $400,000. Patients and healthcare facilities often find it difficult to get these agents reimbursed.

There are 74 marketed IO products in US, Germany, France, Spain, Italy, the UK, Japan and China. Cytokine products lead, with 30 approved products, followed by checkpoint modulators with 22.

The cell therapy market is expected to surge, according to GlobalData, to generate more than $52bn by 2029, up from nearly $3bn in 2022, showing a compound annual growth rate (CAGR) of 51%. There is increasing confidence among medical professionals about cell therapy as a first-line treatment, according to responses in a GlobalData survey.

One of the most promising cell therapies for cancer is chimeric antigen receptor (CAR) T-cell. By genetically modifying a patient's own immune cells to kill cancer cells, CAR-T therapies have shown promising results, especially for certain types of blood cancers. It is the only genetically modified cell therapy to have received regulatory approval.

Are cell therapies ready for use in first-line?



Source: GlobalData

Gene therapy

Gene therapy offers hope to numerous patients living with serious medical conditions that have limited treatment options.

While the impact of gene therapies has so far been limited, with only 39 marketed as of June, it is expected to be a far more influential treatment in the coming years, as more than 4,450 drugs are currently undergoing preclinical and clinical trials globally, according to GlobalData's Drugs database.

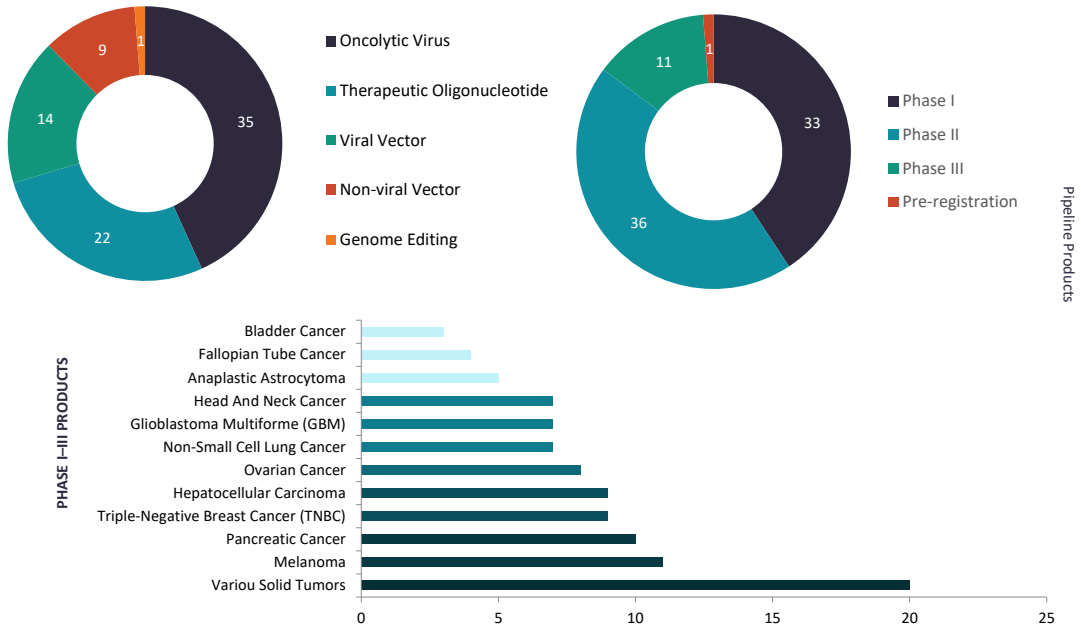
GlobalData expects gene therapies to generate nearly $54bn in sales by 2029.

With cancers, the therapy is more likely to be used to modify gene regulation in tumorigenic pathways and expressing genes in cells that cause them to be recognised as foreign, or to elicit an immune response to tumorigenic cells.

In April 2021, GlobalData recorded more than 80 gene therapies undergoing clinical trials to develop treatments for a range of cancers. Targeting solid tumours was the leading area, followed by melanoma and pancreatic cancer.

While gene therapy is in the early stages of developing treatments for cancer, the potential for patients is immense. There are currently three gene therapies marketed for oncology. Oncolytic viruses have two approved drugs and viral vector gene therapies have one. Viral vector gene therapies could be a one-time, curative treatment in the future, but they are expensive, which restricts patient access.

Gene therapy pipeline candidates in the 8MM



Source: GlobalData

Decentralised clinical trials

From technologies and revolutionary treatments to the model of clinical trials, one of the major changes accelerated by restrictions on movement during the Covid-19 pandemic was the adoption of decentralised clinical trials (DCTs).

Clinical trials had to get treatments to patients' homes and monitor their progress remotely. Wearable technologies such as heart-rate monitors can be used to send crucial data to CROs.

In 2012, GlobalData recorded only 250 DCTs globally, which was expected to surpass 1,420 in 2022, representing an increase of more than 470%.

For oncology, DCTs offer the opportunities to recruit more diverse patient pools and actively target groups from different ethnic backgrounds that may otherwise be underrepresented in clinical trial data.

Global estimates state that 62.2% of clinical trial patients are from a Caucasian background, increasing to 84.2% in the US. DCTs offer the chance to broaden diversity by overcoming barriers to participation.

According to the GlobalData Clinical Trial database, DCTs for oncology have been taking place for gastric cancer, metastatic renal cell carcinoma, and head and neck cancer. To run a successful DCT, reliable partners are required in pharma logistics.

Furthermore, with the biospecimens increasingly used in oncology clinical trials, transporting these fragile biological samples at the optimum temperature is of paramount importance.

Transporting biospecimens

When transporting biospecimens, or biosamples, it is essential to work with trusted partners who have experience with regulations and how they are interpreted by officials at borders.

"If you're using a trusted carrier that the different customs authorities are familiar with, who knows what they're doing, and are familiar with all the documentation and processes, then things will go more smoothly," says Mark Woolf, chief business development officer at Oximio.

"But, if you're using a carrier that is less familiar with customs, there will be more scrutiny to ensure the carrier is compliant with everything that the Transport Security Administration and other agencies require."

Across Oximio's operations in Africa, dry-ice packaging is a vital tool in overcoming the technical challenges of transporting samples over long distances in high temperatures. Using CryoSure's dry-ice shipping solution allows the company to keep samples below -70°C for up to 21 days during transit. This offers superior environmental performance as less dry ice is required, because it dissipates at a slower rate, while it is also reusable and lightweight.

"Normally, when you transport a dry-ice shipment, you also have to ship additional dry ice to top it up during transit. This brings additional cost and complexity due to the fact that dry ice is dangerous cargo," says Woolf.

"But, with the system we have, the dry ice lasts a lot longer and dissipates more slowly, so we don't need to recharge it during transit. That makes things a lot easier."

In addition, CyroSure can help save invaluable time for biosample transportation. Even if there are delays at borders or during transportation, the capabilities of the technology to maintain low temperatures for prolonged periods help ensure that the biospecimens remain in their optimum storage conditions.

Case study

Delivering vital biospecimens from Ukraine to three separate sites in record time

The challenge:
Oximio was tasked with ensuring the safe and secure delivery of three biosamples from Ukraine to three different locations in the UK, Switzerland and Belgium. Each sample had to be delivered to its end location within 72 hours, and it needed to be kept at a temperature of between 15°C and 25°C during transit.

Execution:
Oximio's team formulated a detailed plan, factoring in the optimal transportation routes, customs procedures and temperature-sensitive requirements. Each biosample was carefully packaged and placed in temperature-controlled containers. The team's expertise ensured a seamless process at every stage, from sample collection to secure storage during transit.

Outcome:
Oximio exceeded expectations by delivering all three biosamples within the stipulated 72-hour window, with some of the goods reaching their destination within just 48 hours. The samples maintained the required temperature range throughout transit, ensuring their integrity for subsequent analysis.

Importance:
Oximio's success underscored the significance of rapid, reliable and compliant transportation in critical medical endeavours. The project highlighted the connection between clear planning, expert execution, and in-depth knowledge of geographical nuances, regulatory intricacies and logistical challenges.

Conclusion:
Oximio's delivery of biosamples from Ukraine to the UK, Switzerland and Belgium showcased its ability to navigate complex international logistics, emphasising the critical role of precision, efficiency and expertise in ensuring the secure and swift movement of sensitive materials, while adhering to stringent temperature requirements and regulatory protocols.

"The war in Ukraine has impacted many things, but there is still a huge portfolio of ongoing clinical trials within the country. While there is no air transportation, there are logistics on the ground. So, we've utilised that as a solution and been able to manage the export of biosamples from Ukraine to Europe," says Zayheda Khan, chief commercial officer at Oximio.

"We are a leader in the export of biosample solutions from Ukraine, especially since the war started. It has been on our radar. It shows that when there is a challenge, Oximio creates a solution."

About Oximio

Oximio is a leading provider of logistics and transportation solutions, specialising in serving the global clinical trials industry. With a comprehensive global network, the company offers a wide range of services, designed to meet the specific needs and challenges of clinical trials and medical research.

The company's global network spans six continents, allowing it to offer seamless logistics solutions for clinical trials on an international scale, ensuring biospecimens arrive at their intended destination in the optimum conditions.

Moreover, Oximio's team of experts provide personalised support to clients, collaborating closely to provide tailored solutions that align with the specific requirements of each clinical trial and the biospecimens needed.

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