Optimise trial supplies and post-trial patient access

New therapies and treatment options are a lifeline to many patients across the world. Yet, increasing complexity puts clinical trials at risk. Working together with a partner, such as **Clinigen**, that can provide tailored guidance on clinical supplies management and manage treatment access post-trial, considering both the needs of the sponsor company and the patients, can make the difference.

The increasing adoption of more patient-centric, decentralised approaches is one of the factors that is making efficient supply chain management critical. Risk-based optimisation of clinical trials can not only help reduce costs and minimise waste, but ensure treatment continuity. Managed Access Programmes (MAPs), which can be used in a range of circumstances from post-trial access to commercial withdrawal, expand the provision of treatment to patients.

Risk-based optimisation and technology provides a holistic picture of global clinical trial supplies.

The power of insights

Increasing complexity means more waste as, for example, safety buffers are introduced to manage uncertainty. Risk-based optimisation and the use of technology provides a holistic picture of global clinical trial supplies, ensuring informed decisions can be made about drug allocation. As a result, inefficiencies are reduced.

It also makes it easier to determine the amount of clinical trial material overage, define the best supplies management strategy for the trial, monitor the supply forecast, and adapt the strategy based on real-time data.

Risk-based optimisation not only minimises drug waste and reduces costs, but it enhances patient service levels and accelerates timelines.

Deliver access when a trial ends

MAPs go beyond providing a particular medicine for patients who reached the end of their trial participation, or are part of a trial that has concluded, and have benefited from the treatment. They open up access outside conventional parameters, address the unmet medical need that exists prior to regulatory approval and before commercial launch, or provide access to a product that has been discontinued commercially. MAPs are also designed for patients who are not eligible for a trial or have exhausted other treatment options and, therefore, can be run alongside an existing trial to benefit more patients.

A cost-effective solution to continue the provision of treatment when outsourced to partners with dedicated expertise, they free up internal resources while enabling supportive real-world data insights, which can facilitate the progress towards commercialisation.

A strategic approach

Working with the same service provider for both clinical trial supplies and post-trial treatment access can be an advantage, especially for late phase studies or large and complex phase III studies. Why? Often, they have already shipped the drug to the same clinical trial site, are familiar with the regulatory landscape, and the needs and risks involved. They also have the clinical, operational and logistics expertise to supply a drug, and the healthcare professionals on-site are already used to working with it.

Speed, flexibility and efficiency

Running a clinical trial and successfully navigating increasing complexity is easier with an experienced partner that proactively manages risks and can ensure access to a drug throughout its life cycle: From clinical supplies management, including sourcing comparators, packaging and labelling supplies for clinical studies, to making a product available outside of clinical trials through unlicensed and commercial channels, globally and regionally.

Clinigen is a flexible global partner committed to meeting the specific needs of each trial sponsor and patients worldwide, and has been providing quick and broad access to critical medicines for over 30 years. ●

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