Rapid Rise of Decentralised Clinical Trials

As the world continues to adapt to the impact of the pandemic, a lasting legacy has seen the evolvement of varying approaches to how clinical trials are designed and deployed.

There has been a rapid rise of decentralised clinical trials (DCT) which brings benefits and poses potential challenges in equal measure.

Clinical-trial sponsors are increasingly looking at alternative ways to make trials quicker, more cost effective, while improving the experience of patients and medical teams involved.

The rapid rise of DCT has become more prevalent and increasingly the pharma space is seeing the introduction of different products and services to help encourage enrolment, improve patient participation retention rates and enhance the reliability of data collection and results.

COVID-19 has been a major accelerator and catalyst in the move to DCT offering valid alternatives to the traditional clinical trial model, whereby the patient was expected to attend a site to be able to conduct the research and work with the investigators.

The clinical trial sector had to adapt accordingly as the world was subject to multiple lockdowns with restrictions including limitations on travel, during the COVID-19 outbreak. Home-based, patient centric trials, which were in their minority pre-pandemic, became more popular particularly as they negated the need for patients to travel to a trial site.

New scalable solutions were needed and dispersing trial sites globally provided a more convenient service for participants, existing and new. The rise in DCT meant new more diverse populations could be reached, which helped encourage patient enrolment rates and led to increasingly insightful results.

Changing Face of Clinical Trials

Increasingly biotech and biopharma businesses are adopting decentralised or hybrid models over traditional trials.

It's anticipated the industry will continue to see a significant shift this year to decentralised and hybrid designs and according to GlobalData analysis approximately 1,300 trials with a decentralised and/or virtual component are anticipated to start in 2022, representing a 28% increase from 2021 and a major 93% boost from 2020.[1]

While there will always be that need for the traditional clinical trial we will continue to see a more hybrid approach within the clinical trial space.

Clinical trials employ a number of different models including:

- Depot-to-patient model – the medicinal drug is shipped straight from the depot or the pharmacy to the patient. Favoured from a reach and speed perspective if drugs need to be delivered quickly. Negates need for patients to travel to a site.
- Site to patient model – drugs are shipped from the depot to the clinical site and then from the study site to the home of the patient.
- Hybrid model approach encompasses elements of both of the above.

The prevailing patient centred approach aims to build a positive in-house, at home participant experience and a softer hospital approach. Some people don't like going into a clinical environment. That is removed with the patient-centric approach, which in turn provides the opportunity to involve a larger patient pool, including more of a diverse population.

The traditional approach allows for the important patient/investigator relationship to stay strong because if participants return to the same site and see the same people they build a good connection. Conversely, if you have a different person visiting a patient's home each time that might potentially demotivate the participant over time.

Protective Packaging Innovations Boost Trial Success

The clinical research and drug development industry, alongside selected suppliers involved throughout the trial process, have had to evolve to ensure DCT are successful and encourage enrolment.

Specialist packaging suppliers operating in the clinical trial space play a pivotal part in ensuring the success of DCT and the service offered overall needs to be as holistic as possible. Thermal shipper solutions deployed for clinical trials are vital; however, all facets are key including storage, distribution and return logistics.

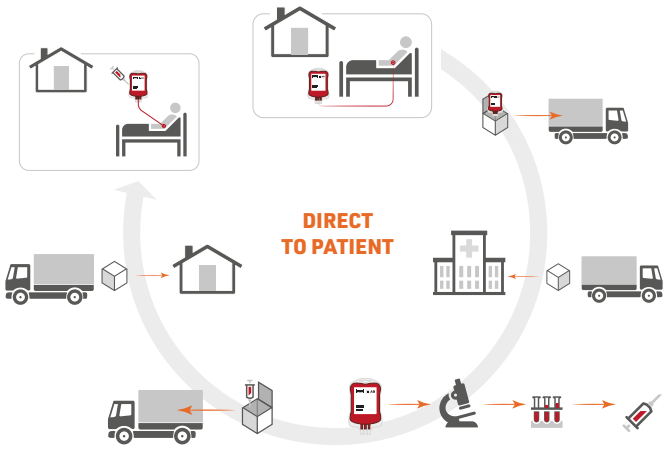
From a packaging perspective it's critical to be able to supply an entire solution that is tried, tested and meets the high-quality standards and risk-averse nature of the pharma sponsors. Currently there are only a handful of thermal packaging suppliers that can provide this specialist service worldwide.

Apart from delivering a high-quality solution, that will maintain product integrity, it's critical to be able to pivot and be flexible in the space. With more decentralisation sites popping up on a global scale, organisations need to be agile in their strategy to bring a trial through implementation and for it to be successful.

For specialist thermal packaging providers having a global standardised Standard Operating Procedure (SOP) in place is crucial to maintain good best practice, instil confidence in the sponsors and the clinical sites. It's essential all organisations involved are abiding by the same standards.

High performing protective packaging is vital in the trial process where patient safety is paramount. When deploying drugs from a clinical site to a patient the integrity of the pharmaceutical product is critical.

Well-engineered thermal packaging helps mitigate temperature excursions, ensuring when the drug is administered to the patient it is at the right temperature and maintains its efficacy and potency. This improves the success rate of the trial and treatment administered.



Having the ability to provide premium thermal solutions that remove the risk of thermal excursion is essential.

Within clinical trial models there can be variations in geographical reach. This requires flexibility and protection across different distances, climates, and transportation modes.

Encouraging and retaining patient enrolment is key to the clinical trial industry. Patient-centric solutions should convey convenience alongside simple to use systems. The clinical trial industry utilises innovative packaging products which don't require conditioning or complex packing instructions. This means the user can easily prepare the box themselves with no expert intervention.

This ease of use is key from a Direct from Patient standpoint, whereby a biological sample needs to be sent back to the lab, so having an easy to use and activate shipper solution to hand, that doesn't require any refrigeration or conditioning activity at the patient's home, is important.

Therefore, selecting a packaging vendor who has a breadth of products is important to fulfil both DtP (Direct to Patient) and DfP (Direct from Patient) program requirements from one thermal packaging supplier.

Also crucial is having breadth of thermal performance, having flexibility in terms of cost and being able to offer a thermal solution that can be conditioned by the client site or prepared by the packaging vendor with the capabilities to offer a preconditioned service.

Offering reusable packaging solutions that can easily be returned and reused is also important from a sustainability standpoint. Choosing vendors who can provide packaging that can be tailored to the trial's requirements is an advantage. There is a move toward agile, adaptable packaging whereby the shipper solution offers the option to flex the product and have the ability to scale the size of the box to fit the requirement.

Whether grouping cartons of multiple treatments, or shipping a single medical device or diagnostic kit, enlisting packaging suppliers whose product portfolio enables you to fit the box tailored to product requirements, reduces shipping costs and the number being shipped helps lower carbon footprint.

DCT Challenges, Benefits and Future Developments

Potential challenges linked to DCT involve the transference of information, which is imperative in any trial. The data collection and data security involved in the decentralised processes is a major consideration.

With the DCT model a lot of new virtual/mobile technology is being used at patients' homes that would usually be held at the clinical site. It's essential to ensure data is stored, accessed and requested in the right framework to make sure rules/regulatory requirements are being met from a data integrity and security perspective.

The DCT model offers benefits including the opportunity to involve a more diverse patient population, which leads to accessibility to more rich data. When collecting the data and opening the trial up to a bigger geography it allows access to a larger data set to draw insights from different populations and combined populations. That accuracy and intelligence and learning behind that data pushes the analysis further and we learn a lot more from it.

Going forward it's anticipated the future growth in clinical trials will see a more hybrid approach and greater digitalisation across the entire supply chain when it comes to data gathering and data security.

There will be future developments, especially within the cell and gene space tying the patient to the shipment with real-time GPS tracking of shipments, providing greater visibility and the progression of the at home hospitalisation experience will grow.

Patients like the convenience DCT offers, which hopefully will increase attendance and enrolment rates. This is particularly vital as a significant percentage of clinical trials fail due to patient dropout rates which are estimated at; Phase 1: 60–70%, Phase 2: 40–50% and Phase 3: 30–40%.

Reducing those rates will ultimately benefit clinical research results and help bring new drugs to market.

REFERENCES

1. K Parkins and A Hillman: 2022 forecast:decentralised trials to reach new heights with 28% jump – https://www.clinicaltrialsarena.com/analysis/2022-forecast-decentralised-trials-to-reach-new-heights-with-28-jump/

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