SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

Building Blocks of Efficient IMP Supply and Distribution Strategies

In an era of constant growth in the scale and complexity of clinical trials, planning properly for efficient manufacturing and distribution of investigational medicinal products (IMPs) is more important than ever. With many constraints and dependencies inherent in clinical supply chain management, waste, overages, or shortages are costly propositions in terms of overall study schedules and budgets. Consider the driving trends in clinical research:

- Research takes place at more sites and in more countries than ever before
- Study designs are increasingly complex, with many different treatment arms and drug types
- Movement restrictions and regulatory complexities related to the global coronavirus pandemic add new logistical difficulties
- Newer models of study conduct emphasize the location of participants rather than sites

All of this can make studies involving products that are expensive, limited in supply, or short on shelf life such as those for oncology, much more difficult. Signant's Clinical Supplies (CS) team spearheads the technology and logistical strategy for thousands of such research programs, and offers these first-hand insights to help sponsors build risk mitigation strategies.

1. Include the clinical supplies team early in study planning

While this may seem obvious, clinical supply chain considerations can easily get lost in the fold when study teams are focused on the many other aspects of clinical research design, planning, and execution. However, it is often the most critical link in the chain. If there is a delay upstream, it falls to the CS team to make up for lost time and flawlessly execute extremely complicated and interdependent operational processes. Allow the CS team to establish the strategy and perform risk assessments early.

2. Develop a granular picture of supply needs

When forecasting supply needs for a study, sponsors may opt to plan around "worst case" assumptions, but this model does not account for variables that ultimately dictate the actual needs of an active trial and can result in shortages or overages. Once underway,

be sure to deploy an RTSM that can manage inventory in a way that accounts for each patient's specific position in the trial based on visit schedules, visit-specific dispensing windows for each kit type, country-specific lead times based on sites' locations, country-specific lookout windows, and varying do not ship values. You can use this data to ship earlier-dated study drugs for shorter visits and longer-dated materials for longer visits. In our experience, this approach reduces supply waste due to expiry events.

3. **Take a campaigned approach to re-supply and distribution**

Often, formulations and packaging designs can change after a study has launched, prompting the need to update kit types mid-trial. Initial manufacturing and labeling plans are created prior to launch based on anticipated enrollment rates. If your plan does not account for the factors outlined in number two above, there is high risk of interrupting the trial or wasting materials when not enough or too much material is produced and shipped. A campaigned re-supply plan allows clinical supplies teams to manufacture fewer kits initially. This prevents waste but it requires granular supply predictions to allow ample time for production and distribution.

4. **Consider a pooling strategy**

Drug pooling at the depot-level allows products to be shared across studies that utilize the same compound. This drastically reduces the amount of inventory needed, simplifies logistics and administration, and provides study teams with the flexibility needed to direct supply to sites or patients dynamically in response to factors such as staggered study timelines, unexpected delays, or changing priorities.

5. **Know your RTSM system well, or partner with those who do**

Everything is carried out in the RTSM system – from managing patient demand to building out the study's logistics and resupply strategy – it keeps operations running smoothly. Therefore, it's imperative to have both the technology as well as specialized expertise support complex clinical supply manufacturing and distribution operations.

As clinical trials become more complex and investigational medicinal products become more expensive, sponsors benefit from employing more advanced systems that can handle the inherent challenges of today's clinical research and that are poised for innovation to accommodate new challenges in the future.

To learn about Signant's innovative SmartSignalsTM RTSM, contact us to speak to our experts.

Signant Health

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently generate quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 400 sponsors and CROs of all sizes – including all of Top 20 pharma – have trusted Signant Health solutions for remote and site-based eCOA, eConsent, IRT, supply chain management, and data quality analytics.