ALMAC

Partnering to Advance Human Health

Guide

Getting started: three steps to implementing an effective JTM strategy

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By 2050, the number of people over 80 is predicted to triple from its current total of 143 million to 426 million[i]. Not only are we living longer but there's more of us too. In fact, estimates suggest the world's population (currently 7.7 billion) will rise to more than 9.8 billion over the next 30 years[ii].

That's a lot more patients, placing a lot more demand on drug developers. The good news is, the pharmaceutical industry is rising to these challenges. Investing billions in research and development of next generation cell and gene therapies, biologics and pushing boundaries to develop new or more effective treatments for a huge array of disease types.

Yet advancements that have huge potential to positively impact global human health aren't without obstacle. For instance, shifts towards larger and more complex molecule drugs, which by nature have relatively lower yields and are more expensive to develop, create pressure to systematically drive down costs, without sacrificing operational efficiencies or causing negative patient impact. Likewise, the evolving need to operate clinical trials on a global scale to expediate enrolment, minimise costs or target specific patient populations, can create untold complexity for sponsors tasked with safeguarding product integrity and timely supply, whilst effectively mitigating waste and controlling costs.

Just in Time Manufacturing (JTM) is a tried and tested strategy sponsors can rely on to overcome many of the obstacles associated with the manufacturing, packaging, labelling and distribution of clinical supplies in this new clinical trials' landscape.

A firm favourite of big pharma and smaller, entrepreneurial sponsors alike, Almac's JTM offering, Almac Adapt, has been designed to reduce waste and nurture a patient and site-centric approach to meet variable demand. Other benefits include the ability to maximise viability of pooled supplies, quickly effect label change, reduce study start up times, process drug orders quickly and maintain access to dedicated cGMP suites, covering all processing temperature conditions.

Sounds good, right? But where to begin on your journey to leaner, more optimised clinical supply chain management?

Plan your JTM strategy with plenty of time

Proper project planning and execution is critical regardless of the type of packaging and labelling strategy utilised. Yet the most common pitfall sponsors face is initiating the planning process too late to allow the necessary time to review, prepare, procure and release items so they are ready for distribution to sites or depots.

Incorporating your production strategy into a study's planning phase and engaging with vendors at the earliest opportunity to assess and qualify the process is key to success. Having a fundamental understanding of the end to end process and the critical path items, and timelines within that process, will promote successful study execution and minimise the need for reactive expedited responses that may jeopardise patient dosing.

A good rule of thumb would be to engage with a vendor several months in advance of the study start to allow for an audit of the JTM process, study level consultation and completion of items on the critical path, such as release/delivery of primary drug, regulatory submissions and approvals, kit and label design, component item procurement, development of production and distribution instructions.

Align people, partners, process and technology

For JTM to run optimally it's important that sponsors involve internal stakeholders charged with managing the study, such as clinical trial managers, as well as their quality unit, and any stakeholder responsible for development/input into the IRT build.

It's equally important that sponsors select the right vendor and place value on creating partnerships rooted in strong, open, collaborative communication. This will allow proactive course correction that will avoid impact to sites and patients versus reactive measures that increase risk of impacting patient dosing.

Almac ONE™, Almac's unified clinical trial supply solution provides the perfect solution to align the right people, partners, processes and technologies to achieve optimal results for sponsors' JTM study. The solution creates alignment between the digital and physical supply chain to create a responsive end-to-end process that bridges the gap between the physical and digital connect resulting in enhanced visibility and accuracy throughout the lifecycle of a trial.

Continuously review and adapt

Once up and running, JTM strategies must be regularly reviewed and fine-tuned to continuously safeguard efficiencies.

As part of Almac's project services the project leader will conduct a weekly or biweekly touchpoint with the sponsor to review the daily study activities, as well as short-term and long-term developments in the study that may require a shift in packaging and labelling strategy.

It's possible for sponsors to change between standard batch manufacturing to JTM and vice versa during a clinical trial, but some considerations will need to be assessed to determine impact on quality agreements and IRT configuration. Working with an experienced vendor will assist with this impact assessment and assure continuous, cost-effective resupply to patients.

To find out more about how Almac One and Almac Adapt can safeguard supply for your clinical trial contact us at **info@almacgroup.com**.

References

[i] https://www.un.org/en/sections/issues-depth/ageing/

[ii] https://www.worldometers.info/world-population/#table-forecast

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