

Get back - Managing your Return Logistics for Clinical Trials



Over the last ten years, the way that the pharmaceutical industry is expected to deliver new drug products to market has seen symbolic change. This shift in process has been driven by a number of significant factors.

In the next five years the industry is expected to lose around \$290bn in revenue from branded prescription medications going off patent (the patent cliff) and overall drug development timelines are coming under continued scrutiny. Internal and external pressures mean traditional approaches to drug development are difficult to sustain and speed to market is paramount to success.

R&D costs are continuing to grow aggressively; it is estimated that an investment of at least \$1.3billion is now required to successfully initiate a new drug to market¹, in some instances ranging up to in excess of \$5 billion for some of the industry's leading firms², whilst bringing a new molecule from laboratory to approval can take up to 12 years. These factors, coupled with approximately only 1 in 5000 drug candidates which enter preclinical testing making it to market³, the industry's focus is on developing quality drug candidates and getting them through clinical development as quickly, efficiently and cost-effectively as possible.

Upfront study planning is crucial to ensuring that planned clinical studies are executed in a timely fashion, however, the end of the trial and the final milestones are often not given as much consideration.

Investigational clinical studies have continued to evolve and have become more complex. Today a clinical trial will involve a substantial amount of logistical challenges to guarantee successful project execution. Sourcing developmental drug product, the development and interpretation of study protocol, coordinating language translations, labelling and executing packaging, sourcing comparator drug product, and executing monitored logistics in getting IMP drug to investigational sites around the globe are activities best left to the experts, and even then there can be unforeseen and unanticipated challenges.

With the notable use of emerging markets being used



for the execution of clinical studies, countries such as Russia and Eastern Bloc countries, Asia Pacific countries, China, or South America present a large number of unique cultural and regulatory challenges that have to be considered. As such, due to the complex nature of planning and executing such studies, it is often true that the preparation for the end of the study and the return logistics of unused drug product are not always given consideration until it is upon the sponsor company.

IMP regulations mandate that all unused study medication must be returned and accounted for at the completion of each study.

Reverse logistics back to the sponsor or designated returns vendor may involve hundreds or thousands of packages to be returned and individually accounted for. For some studies, this may involve accountability down to the individual dose level. For example, controlled substances require meticulous reconciliation to the tablet. Detailed records must be maintained and returned drug must be efficiently processed.

To significantly ease the returns process, sponsor companies can clearly outline and agree the process for receipt, reconciliation, notification (to sponsor) and destruction of study materials at the outset of their study. By providing clear and concise instructions to investigator sites at the onset of the study and mandating the process by which samples should be returned, sponsors can ensure a smooth returns process, which is vital for a study's success. Clear expectations should also be provided for the parties providing the returns management service to ensure prompt processing of returned product. Returns may of course begin to be received ahead of the conclusion of a study, as investigator sites often have very limited space for storing study materials; sponsor companies need to be aware of this and ensure it is planned into their study process. Prompt and efficient handling of returned study material is best accomplished by a dedicated returns management team who have the necessary skill and training required for this type of precise and essential service.

Ensuring a clear and concise communication plan between



all parties is critical from the onset of a study, namely how frequently communications should be expected and by what mechanism. Increasingly, this requires data entry and returns accountability confirmation via common cloud-based electronic third-party IVR/IRT systems. Choosing the most appropriate IT system when setting up a study will have a tremendous impact on the returns management process agreed throughout the lifecycle of a study. Having an effective and user-friendly returns module in the IVR/IRT system can expedite information reporting timelines and data processing. Non-user-friendly systems encumber the returns process and can prevent timely resolution of discrepancies.

Timely processing and communication is vital to ensure decisive resolution of any potential discrepancies between what was thought to have been sent from the investigator site and what the returns processor has actually received. Investigator sites and returns processors need to understand the implications and ramifications of discrepancies that may arise. Valuable time and resource can be wasted whilst looking to reconcile any discrepancy and potentially inhibit the sponsor's ability to formally close the study. It is important to ensure any discrepancies found upon return are communicated to the sponsor, documented and closed out so that there aren't any gaps in the chain of custody. If this piece is clearly defined up front in the process set-up, there are fewer issues down the road.

Product un-blinding is also a potential issue in the returns process; as such both the investigator sites and the returns processors need to understand the potential impact that this can have on the integrity of the study. It is also important to understand that the study's integrity must be maintained for the duration of the project, which can often be as long as three years. This timescale underscores why a returns management strategy that maintains study blinding is essential.

Giving forethought as to what the process for when returned drug product is received and processed will also ensure significant benefits for the sponsor company. By determining whether product should be immediately destroyed, or stored and catalogued until the completion of that study/phase allows

a sponsor to establish cost estimates and budget for the returns at the onset of the project. A lack of these conversations upfront can lead to project creep and unexpected costs at the end of a study. Returns management service providers help mitigate these additional costs by working with clients to create dialogue on potential options and industry best practices.

A returns management provider must work with customers early in their study development to ensure they avoid the frustrations common to sponsors in the latter returns management process. This helps clients focus their energies on the next phase of their development and ultimately successful commercialisation of their lifesaving therapy.

References

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3. www.medicinenet.com- "Drug Approvals - From Invention to Market ... A 12- Year Trip."



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Based in Treforest, South Wales, Gavin works to develop and implement effective strategies for storing, processing and shipping supplies to

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Gavin joined PCI in Dec 2009 after working with both DHP Ltd and Bilcare as logistics manager.

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