# Take the Express Toward NDA APPROVAL

Pharmaceutical manufacturers spend on average $1 billion developing a product for commercialization. With this tremendous investment, it is a pharmaceutical developer's nightmare to have its product fail during the New Drug Application (NDA) filing process due to safety concerns or lack of pharmacovigilance systems and process planning.

By developing a comprehensive and well-rounded pharmacovigilance plan early in the product development cycle using a trusted and experienced pharmacovigilance partner, pharmaceutical organizations are more likely to move faster toward commercialization of their product and turn those precious invested dollars into returns.

To understand this better, let's examine the goals of the NDA.

## NDA Goals: Three Decision Points

In no particular order, the goals of the NDA are to provide enough information to permit FDA reviewers to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

## Pharmacovigilance

Pharmacovigilance (PV), which involves analyzing and documenting all serious adverse events during clinical phases as well as both serious and non-serious adverse events during the post-marketed phase, is heavily involved in all three decisions and therefore is taken very seriously by the FDA.

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Accordingly, the slightest concerns over the filing company's PV plan, safety database, personnel handling PV operations, PV learning management system, plans for medical affairs and triage of product quality complaints, medical inquiries and adverse events, including assessment of statistics and possible signals, quality control, and regulatory reporting could have a major impact on the timing of approval.

Partnering with a company that specializes in the entirety of what the FDA regulators will be looking for is therefore extremely helpful to move through the NDA process, even if the applicant plans to split roles and handle some of the responsibility internally.

## Start Thinking in Phase I and Phase II

Despite the infrequency of serious adverse events during the earlier stages of development but post-IND, thinking ahead during this stage of clinical development (Phase I and Phase II) can significantly help the NDA process. This is especially important, given the fact that analysis of serious adverse events, and having a good handle on the cause of unexpected events, has a direct impact on labeling as well as an impact on manufacturing identity, strength, quality and purity.

From a resourcing perspective, it's also very helpful to have a detailed breakdown on the amount of time it takes to process serious adverse events and perform all of the other associated tasks, such as the preparation of periodic reports during the clinical phases. While non-serious adverse events are not required to be reported via MedWatch during the clinical phases, it is important to understand the ratios of both serious and non-serious adverse events during the clinical phases and with like-kind products in the market. Such ratios can be applied to script expectations and therefore be used in the determination of PV resource expectations. PV

Contributed by

**MICHAEL O'GORMAN** *CEO, Sentrx*

**Sentrx** *provides pharmacovigilance outsourcing service.*

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