Acurian on...

The Staggering Costs of Clinical Trial Delays and How to Avoid Them

Trial Delays May Be Costing You More than You Realize

Clinical trials can bring new innovations to the market *only* when they are completed with the required number of patients. The problem is that only 6 percent of clinical trials are completed on time, and 80 percent of trials are delayed by at least one month.[1] Additionally, 37 percent of all sites in any given trial fail to meet their enrollment targets, and more than 10 percent never enroll a single patient, meaning that such trials – and potentially helpful drugs – are stalled.[2]

Each day that a drug development program is delayed costs nearly $40 thousand USD in operational costs, and anywhere from $600K to $8M in lost opportunity costs due to delayed commercialization.[3]

A major cause of trial delays is trial enrollment planning that starts with strategies based on the research sites' *projected* contribution to overall patient enrollment, which leads to tremendous inefficiency. At Acurian, we believe strategic patient enrollment that is founded on patient-first feasibility and an *integrated* site/enrollment solution can actually help pharmaceutical companies reduce trial delays and change the trajectory of their drugs' value.

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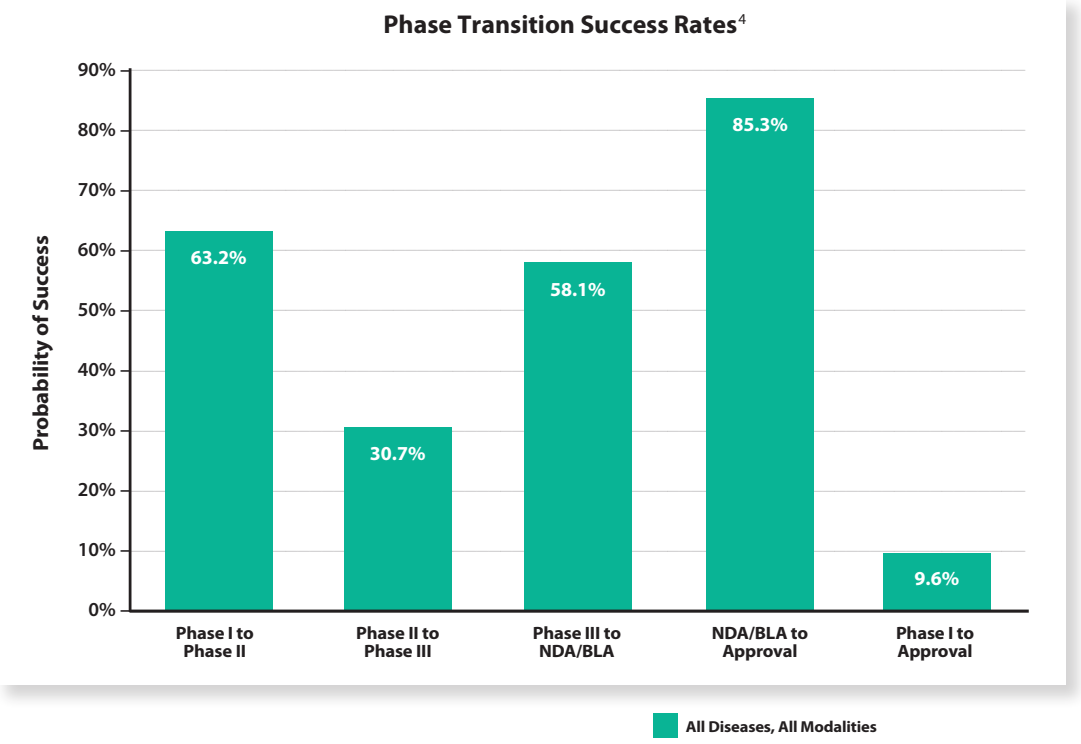
Time Is Money, and How Acurian Can Help

To understand the reason why clinical trial delays can be so expensive, it helps to look at Net Present Value (NPV), which considers the time value of money. The brunt of trial costs comes before any revenue is generated. In other words, from the onset of a trial until the drug is approved, the development cost is significant, with no immediate return on the investment. Every sponsor takes on a certain amount of risk, stemming from the harsh reality that most drug candidates fail to be approved.



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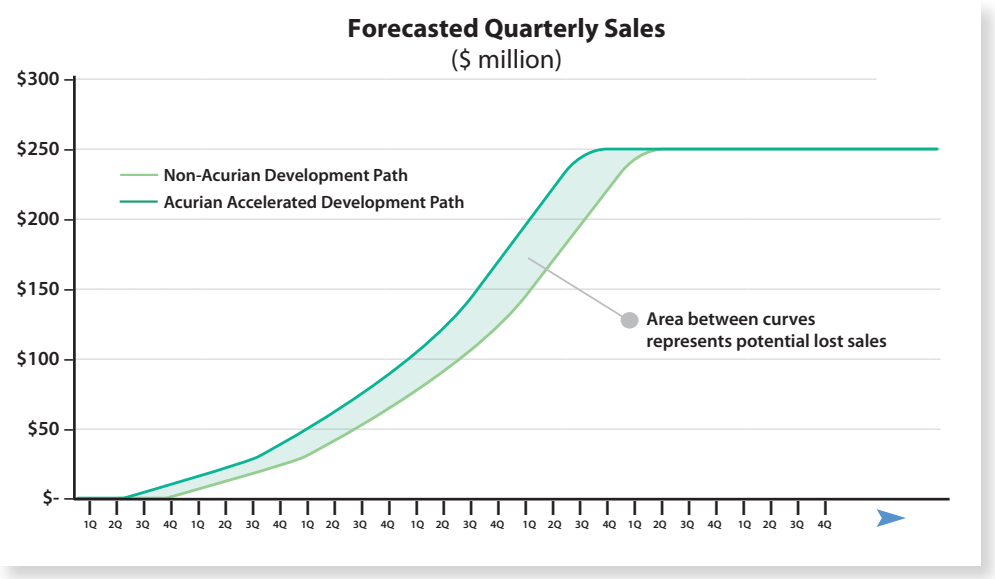
Assuming months – if not years – for each of the stages shown, the speed in arriving at a "go or no-go" decision on their drug is the most powerful initial driver for sponsors. Then, once that decision is made, the faster the drug moves on to approval, the longer they will have to achieve maximum revenue before patent expiry. All of this contributes to the risk-adjusted NPV.

Clearly, time-to-launch is a significant factor when sponsors are valuing potential new drugs. A huge opportunity to gain time is during the patient enrollment stage of the trial.

Potential Value of Acceleration with Acurian

Example: Accelerated Enrollment for a Phase 3 Program

Using basic assumptions, the risk-adjusted net present value (NPV) associated with a 6-month reduction in time-to-launch for a compound with $1B sales potential is >$200M.



As shown above, accelerated patient enrollment with Acurian can have a major impact on the NPV of a new drug innovation. Such time savings can be achieved, without sacrificing patient referral quality, through a strategic combination of site and enrollment capabilities.

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Some Ways to Avoid Trial Delays and Their Added Costs

SynexusPlus – an integrated site/enrollment solution from Acurian and Synexus – can optimize both speed and volume of patient enrollment from output to randomization. This acceleration can be executed in several ways using a highly productive site network together with a supercharged enrollment engine.

• Streamlining study start-up

Quite often, the final site selection itself eventually becomes a rushed process, whereby hundreds of investigators/sites across the globe are selected over a short span in an attempt to hasten trial start-up. As a result, poor selection of productive sites becomes a problem during trial conduct, and reportedly increases the cost of clinical trials by at least 20 percent.[5] In a typical Phase III study, this can translate into $2.25 million in expenses for non-active and under-enrolling sites. The cost of initiating a site (which is the largest chunk of site start-up cost) has been estimated at $20,000 to $30,000, and trial delays can add to this cost.[6]

Compare this to an integrated model encompassing all site-based and enrollment costs, in which the sponsor simply pays a per-patient fee. With SynexusPlus, the study also benefits from faster site start-up, simplified project management, improved site productivity, and more consistent, high quality trial data.

• Increasing efficiency of enrollment

Acurian's patient-first feasibility combines tens of millions of proprietary patient data points and the sponsor's protocol design to accurately predict how and when patient randomizations will occur. This feasibility model uses study-specific enrollment algorithms rather than relying on what sites say they can deliver. The result is the maximum volume of patients moving through a trial without sacrificing referral quality. By tapping into a pre-qualified pool of patients to increase likelihood and efficiency of enrollment, SynexusPlus can fulfill the complement of required patients faster.

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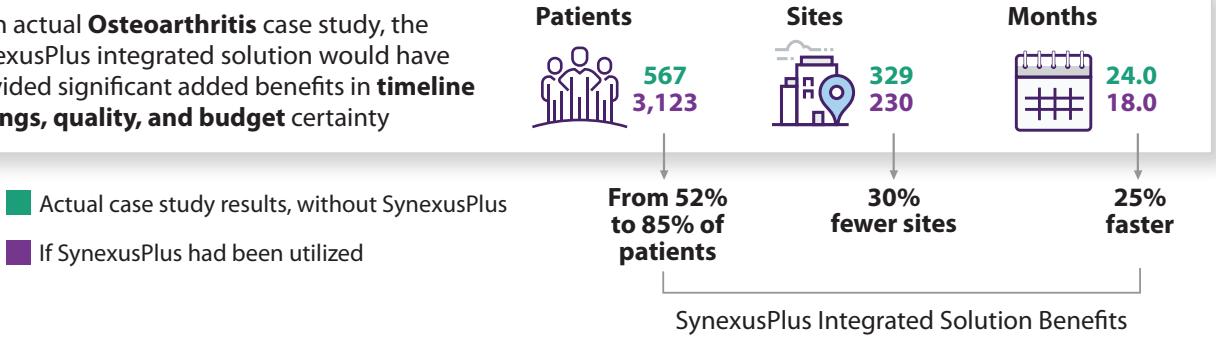
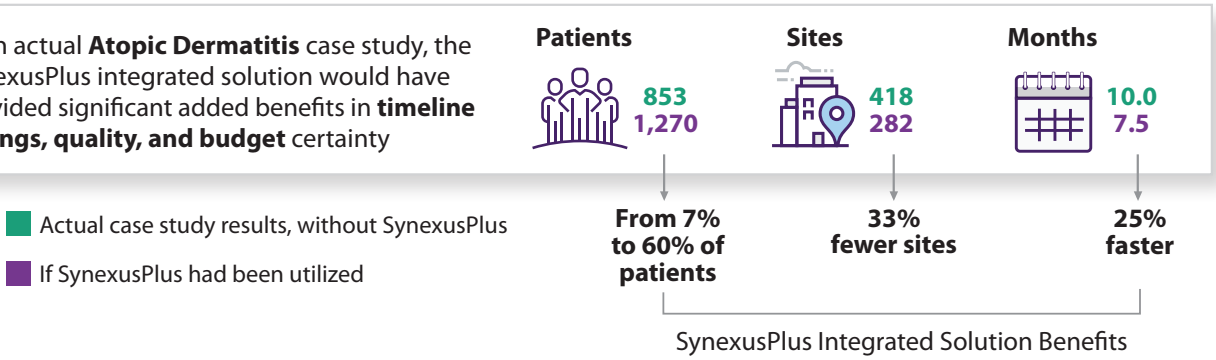
• Achieving controlled outcomes

With alignment between enrollment and site activities, an integrated solution can deliver all of the patients from fewer sites, leading to controlled outcomes (enrollment certainty, budget certainty, time certainty, etc.). Here are some examples, applying retrospective analysis to actual recruitment campaigns completed by Acurian.

In an actual **Osteoarthritis** case study, the SynexusPlus integrated solution would have provided significant added benefits in **timeline savings, quality, and budget** certainty



In an actual **Atopic Dermatitis** case study, the SynexusPlus integrated solution would have provided significant added benefits in **timeline savings, quality, and budget** certainty



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Contact us for more information

To learn more about how Acurian helps sponsors avoid the costly consequences of trial delays, please contact your Acurian representative or www.acurian.com/contact-us/. Our unique capabilities and solutions represent the new standard in clinical trial productivity and can allow you to optimize the speed, efficiency and quality of your studies.

[1] Center for Information and Study on Clinical Research (CISCRP)

[2] https://www.biosciencetechnology.com/article/2015/04/apples-researchkit-real-impact-clinical-trials

[3] http://www.pharmafile.com/news/511225/clinical-trials-and-their-patients-rising-costs-and-how-stem-loss

[4] BIO Industry Analysis, *Clinical Development Success Rates 2006-2015,* p. 7.

[5] Grom, T. Unclogging the patient recruitment bottleneck. *PharmaVOICE* www.pharmavoice.com/article/2182/

[6] Miseta, E. 2013. Bring down the cost of clinical trials with improved site selection. *Clinical Leader* www.clinicalleader.com/doc/bring-down-the-cost-of-clinical-trials-with-improved-site-selection-0001

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