

Can you please get me a ballpark estimate for this study by the end of the week?

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Recent estimates for the growth of the pharmaceutical market points to a figure exceeding five percent per year. This growth is fueled by significant advances in innovator products and strong demand for products to address a diverse spectrum of diseases, many rare. While this level of demand is creating a healthy outsourcing ecosystem projected to achieve over 11% CAGR¹, it is generating strain on a system that is propped up by old processes and even older approaches to clinical trial budgeting.

Over the last several years I have heard many customers lament about the push and pull between the development of ballparks to satisfy clinical development planning and the annual budgeting process and the need by many service providers for one to two weeks to complete these bids. While the length of time may seem outlandish - Surely, they have these numbers at their fingertips, right? - creating, verifying, approving, and delivering even a "ballpark" estimate is extremely labor intensive and time consuming using existing tools (i.e., Excel).

To further illustrate this predicament, let's consider that a total of 245 999 clinical trials (interventional studies) were started between 2000 and 2019, of which 135 144 (54.9%) were completed.² Among completed trials, 5113 (3.8%) were sponsored by the NIH or a US government agency, 48 668 (36.0%) by industry, and 81 363 (60.2%) by other sources.² Now let's assume this number of industry-sponsored trials will grow at 11%, or roughly 5300 plus new trial growth per year. Surveys show that on average, it takes ~20 hours to create a study ballpark in Excel, with accuracy < 50%. This means **we're looking at more than 1 million hours of effort!** I'm not even going to calculate the spend. Do you see the resource push and pull now?

Compound this growth with the fierce employee recruitment challenges impacting the marketplace, the need for experienced talent and of course, the great resignation³ and the opportunity for a new process, a new tool to support clinical trial budget development becomes ever clearer.

The team at Strategikon has been working double time to generate a solution to this problem, Clinical Maestro PORTFOLIO. PORTFOLIO is highly intuitive, enabling clinical operations professionals to quickly design a study budget without financial modelling, advanced Excel skills, or dependence on CRO provided budgets. It automates all pre-RFP budgeting and clinical study scenario modeling needs of clinical drug development. When it comes to ballparking, the effort is reduced from 20 hours to something more like 15 minutes per study. The savings in effort and labor costs are profound, and the accuracy is increased to 95% or better...

Reach out to me now at bkelly@strategikonpharma.com to learn more or checkout our website.

Let me show you how we can help you create reliable and accurate study estimates in minutes, not weeks, without hiring a resource or relying on your providers for help.

¹ <https://www.fortunebusinessinsights.com/industry-reports/contract-research-organization-cro-services-market-100864>

² <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769830>

³ <https://hbr.org/2021/09/who-is-driving-the-great-resignation>