ORACLE
Health Sciences

UNIFYING ACTION, ACCELERATING RESULTS.

FALL 2019

ChromoReport

Study Startup Around the World
A preliminary view from Oracle Health Sciences

As the debate over reforming the nation's healthcare system rages on, there's at least one goal all sides can agree on: bring costs down. Reducing the amount of money and time spent on clinical trials is a priority, as the amount spent to develop any drug depends mostly on what it costs to conduct studies to prove its safety, efficacy, and secure regulatory approval.[1,2]

Study startup, encompassing all steps required to initiate a study is a very complex and recognized bottleneck whose functions are performed by multiple people in multiple locations at the sponsor, Contract Research Organization (CRO), and site levels, all of whom need to communicate and share data.

ORACLE

A dedicated study startup system integrated with other eClinical technologies which streamlines bottlenecks allowing stakeholders to better adhere to established timelines and budgets, cutting runaway costs and speeding the delivery of life saving medicines to those in need is therefore essential.

Globalization is adding to this complexity and the pursuit of global trials is increasing. A recent report by SCORR Marketing and Applied Clinical Trials[2] examined the reasons why companies are pursuing global clinical trials and the challenges they face in conducting them. The top two reasons cited for trials exiting the U.S. and Western Europe and moving to other regions were high costs and patient recruitment difficulty. Over 80% of respondents believe that the trend toward globalization of clinical trials will continue.[3] Other research cites the benefits to sponsors in overcoming regulatory barriers for drug approval in countries where large populations offer the promise of access to growing markets.[4]

Recent data from clinicaltrials.gov shows that of its more than 318,000 registered trials only 34% are taking place in the US exclusively.[5] Moreover, research suggests that the 20 largest US-based drug makers conduct approximately one-third of their Phase III clinical trials outside the country.[6]

Globalization has an obvious impact on organizational structure of clinical operations teams. Do centralized groups outperform non-dedicated groups? A comprehensive study conducted by Tufts Center for the Study of Drug Development (CSDD), *Start-up Time And Readiness Tracking (START) II*, [7] concluded that there was no conclusive evidence that centralizing the function of site identification through to activation achieved significant improvements in terms of cycle time reductions. Irrespective of organizational structure both groups face similar challenges and see the same opportunities for improvement.

But what do the industry metrics have to say about cycle time performance of multi-country vs. single country studies? And economies of scale in clinical trials?

Performance Metrics: Key to Study Startup Optimization

The sharpening focus on quality management is fueling greater use of standardized metrics to optimize clinical trial performance. That's why targeted performance metrics that measure the many details of clinical trial operations are essential. And for study startup in particular, performance metrics are critical, given that it is one of the most complicated parts of clinical trials [8] and one of the most crucial to meeting site activation timelines and study completion milestones. Yet, its performance scores lag other stages of clinical research.[9]

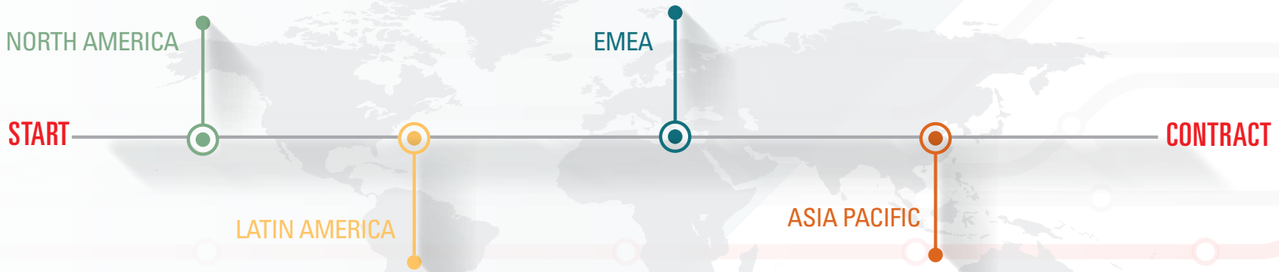
As the industry leader in study startup, Oracle Health Sciences is well positioned to standardize across multiple data sets, to provide a single view of the real-world metrics and cycle times for study startup. Study startup cycle time beginning, and end points have been defined in alignment with the multiple starting points defined by our customers. These are dependent on an organization's SOPs where, for example, the events *Activated*, *IP release*, and *Site Initiated* could be synonymous. This supports our ability to provide an industry wide view of the cycle times important to study startup.

Global Study Startup Cycle Times by Single vs. Multi-Country Studies

Two global milestones *Start to Contract* and *Start to IP release* were used for comparison purposes. *Start to Contract* is defined as the cycle time from site selected through all contracts executed and/or regulatory approval, whereas *Start to IP release* is defined as the cycle time from site selected through to investigational product release.

In a sample of 13,000+ sites we have found that sponsors/CROs and sites utilizing Oracle Health Sciences goBalto Activate Cloud Service have the following average study startup times (duration in weeks.) The total global and total regional cycle time metrics are representative of *all* therapeutic areas.

NO. OF COUNTRIES IN A STUDY	1	2-5	6-10	11-20	20+
GLOBAL AVERAGES	12.58	16.23	18.84	20.81	18.69
REGIONAL BREAKDOWN	12.80	15.57	17.11	19.03	19.14
	Insufficient data	Insufficient data	19.96	28.45	17.55
	Insufficient data	19.36	20.98	22.56	17.86
	8.67	16.24	21.52	20.13	19.02



NO. OF COUNTRIES IN A STUDY	1	2-5	6-10	11-20	20+
GLOBAL AVERAGES	14.47	19.81	22.53	24.36	22.46
REGIONAL BREAKDOWN	14.68	18.99	20.38	22.16	22.97
	Insufficient data	Insufficient data	26.47	37.16	24.23
	Insufficient data	24.16	25.25	26.57	21.85
	10.61	18.44	24.20	21.79	21.31

Data generated from clinical trials started after Jan 1, 2017

In Summary

Irrespective of the reasons driving globalization of studies, multi-country studies regardless of geographic region were found to have longer cycle times than single country studies. The data shows that as organizations scale the number of concurrent global studies there is a gradual increase in overall cycle times, however cycle times drop for studies spanning 20+ countries. Conducting clinical trials in places with unfamiliar regulatory pathways, cultural and language differences, and limited infrastructure is highlighting the value of technology that streamlines key bottlenecks, allowing stakeholders to better adhere to established timelines and budgets.

References

1. Herper, M. The Cost Of Developing Drugs Is Insane. That Paper That Says Otherwise Is Insanely Bad. Forbes, October 16, 2017. https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#48b299dd2d45
2. Sullivan, T. A Tough Road: Cost To Develop One New Drug Is $2.6 Billion; Approval Rate for Drugs Entering Clinical Development is Less Than 12%. Policy & Medicine. March 21, 2019. https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html
3. Global Trends Survey Report. SCORR Marketing and Applied Clinical Trials. August 21, 2017. https://www.scorrmarketing.com/resources/global-trends-survey-report/
4. Lang T, Siribaddana S. Clinical trials have gone global: Is this a good thing? PLoS Med. 2012;9(6). Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3373653/pdf/pmed.1001228.pdf
5. ClinicalTrials.gov Trends, Charts, and Maps https://clinicaltrials.gov/ct2/resources/trends
6. Examination of Clinical Trial Costs and Barriers for Drug Development. U.S. Department of Health & Human Services, ASPE Office of the Assistant Secretary for Planning and Evaluation, July 2014. https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development
7. Harper B, Wilkinson M, Lamberti MJ, Getz KA. Tufts CSDD-goBalto Site Selection Market Research (START II). June 30, 2017. https://go.oracle.com/LP=80941?elqCampaignId=203519
8. English RA, Lebovitz Y, Giffin RB. Transforming clinical research in the United States: Challenges and opportunities. Workshop Summary. Institute of Medicine. 2009. https://www.nap.edu/catalog/12900/transforming-clinical-research-in-the-united-states-challenges-and-opportunities
9. Adelglass, J. The critical elements of study startup. CenterWatch. June 29, 2015. Available at: http://www.centerwatch.com/news-online/2015/06/29/the-critical-elements-of-study-startup/.

LEARN MORE

+1 800 633 0643

healthsciences_ww_grp@oracle.com

www.oracle.com/lifesciences

Oracle Health Sciences

Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes to bring new drugs to market faster. As a leader in Life Sciences technology, Oracle Health Sciences is trusted by 30 of the top 30 pharma, 10 of the top 10 biotech, and 10 of the top 10 CROs for managing clinical trials and pharmacovigilance around the globe.

CONNECT WITH US

blogs.oracle.com/health-sciences

facebook.com/oraclehealthsciences

twitter.com/oraclehealthsci

linkedin.com/showcase/oracle-health-sciences

ORACLE