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ChromoReport

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

Despite ongoing efforts to bring new treatments to market the time taken to get a clinical trial up and running hasn't improved,[1,2] with research showing that Phase II and III studies now taking a full month longer than the average seen 10 years ago.[3]

The focus on technology as a driver of performance improvement in clinical trials is intense, but despite years of valiant efforts, study execution remains far from optimal. For study startup, the data are dismal. Results of a 2017 survey conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD), *Startup Time And Readiness Tracking (START) II,*[4] found that 80% of respondents who have invested moderately or heavily in study startup technology reported time savings. Moreover, respondents who stated that their startup technology is adequate have cycle times that are 30% shorter that those with inadequate technologies.

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Study startup is a complex business, composed of country selection, pre study visits, site selection and initiation, regulatory document submission, budget and contract negotiations, patient recruitment initiatives, and enrolling the first patient.[5]

Thorny budget and contract negotiations between sites and sponsors are the single greatest cause of delays in starting clinical trials.[6] Contracting has two distinct components – pre- and post-contract sent to site, as documented in the Metrics Champion Consortium (MCC) contracting standard (Fig. 1).[7]

The *draft contract sent to site* is the first task that can be controlled by the contracting group, whereas the drafting/authoring of the contract is controlled and dependent on different organizational groups/functions, into which the contracting group has minimal impact or insight.

This scenario generally leads to the contracting group backward planning the *contract to be sent to the site* from the *SIV data*, resulting in the contract being on the critical path for *site activation*. But does it have to be? How could a risk-based management approach be utilized to optimize contracting?

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Figure 1. Metrics Champion Consortium Contracting Standard

Performance Metrics: Key to Study Startup Optimization

The sharpening focus on quality management and efficiencies is fueling greater use of standardized metrics to optimize clinical trial performance, a practice that is routine in most other industries but not in the initiation of studies.[8] 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[9] 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.[10]

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. 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.

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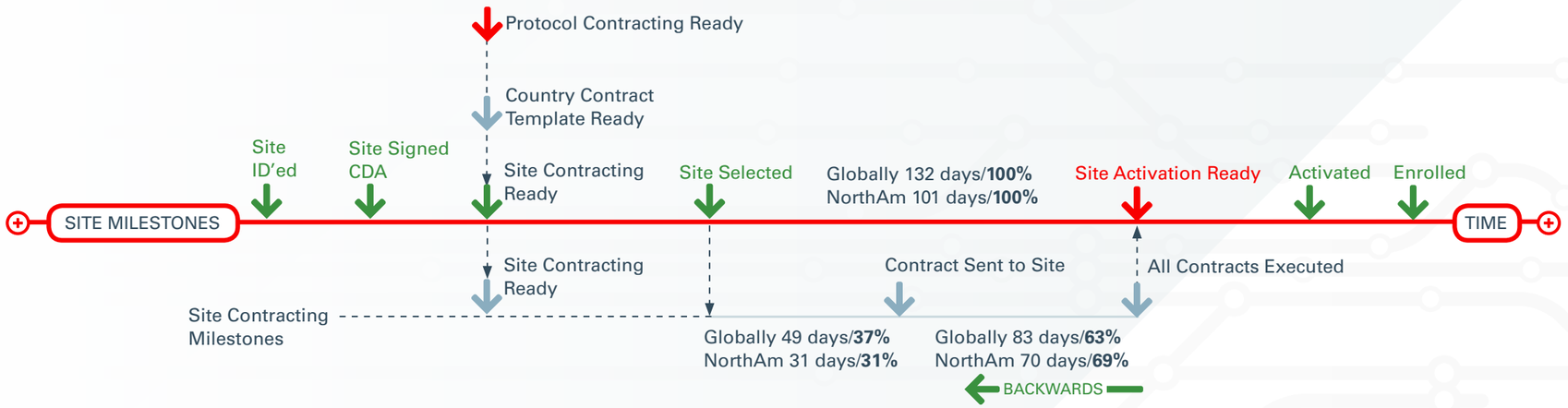
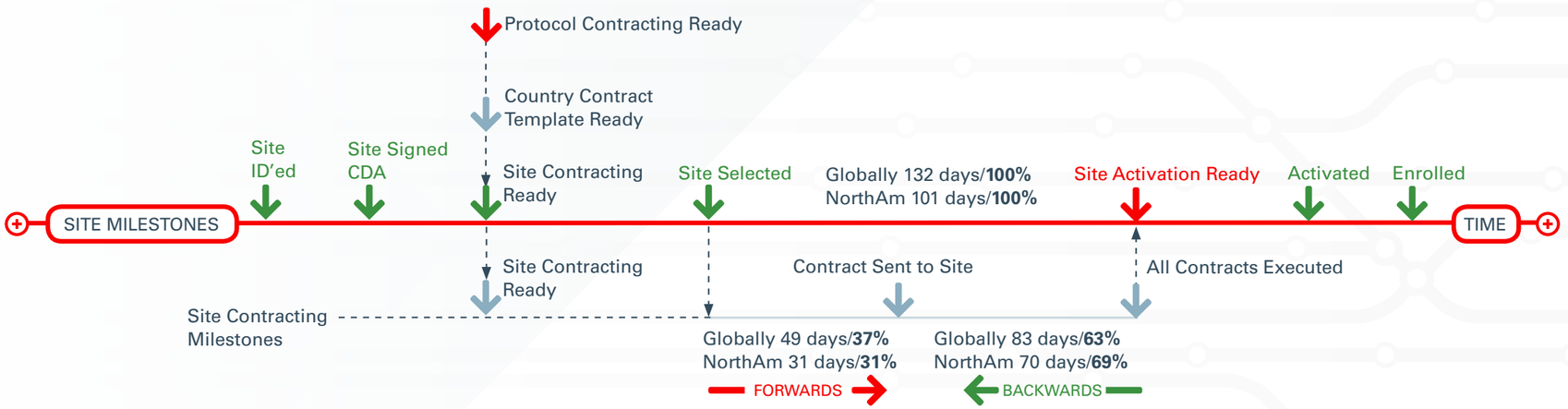
Focus on Contract Optimization

The data shows the industry 'status quo' adoption of backward contract planning, which limits opportunities to optimize the process and often relegates contracts to the critical path to *site activation*. This assessment is based on the Oracle Health Sciences contracting predication model which utilizes the clinical trial agreement (CTA), first version with no amendments, which are the most likely component to impact *site activation*.



The 1-2 months authorship strongly points to backward planning, with contracts often a bottleneck on the critical path to *site activation*. The reasons contracts are often found on the critical path are related to complexity and lack of transparency, that is, the contracting group does not have the information available to identify which contracts will:

- Be more complex (contract language and budget negotiations) and therefore require more time to complete
- Know how early a site can be contacted without wasting effort on a site not being selected
- Which contract to prioritize over another



Individual contracts can be executed faster if needed and therefore these do not need to be on the critical path if started when the *site contracting ready* milestone is reached. The challenges are then:

- How to identify the critical contracts to prioritize
- How to motivate parties to accept contract conditions, without the time constraints

The time from *site selected* to *draft contract sent to site* (authorship) is +1 month, indicating there are clear opportunities to engage with sites earlier, without additional resources, by simply prioritizing high-risk contracts.

How do you determine which contracts to prioritize and how early a site can be engaged?

This is where a risk-based management approach to contract optimization can be leveraged, where the key required components are:

1. Which contract components will have high impact/downstream risk (e.g., *Activation*)?
2. Which sites will have high-risk contract components (language and budget)?
3. How early can a contract component be sent to a site without wasting effort?

With the advent of study startup workflow-based tools this information already exists:

- Activation milestones: determine when contracting is ready
- Site selection tools and scoring models: determine high-risk site components
- Document and task tracking: communicate the information to contracting

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In Summary

By adopting a risk-based management approach supported by an advanced workflow-based engine, it is possible to optimize the contracting process of study startup by prioritizing high risk elements and proactivity engaging with sites when ready, without the need for additional resources.

1. Lambert, M. Clinical trials take a long time to get started. Here's how to speed it up STAT March, 2018. https://www.statnews.com/2018/03/28/clinical-trials-startup-speed/
2. Lambert, M. Wilkinson, M, Harper, B., Morgan, C., Getz, K. Assessing Study Start-up Practices, Performance, and Perceptions Among Sponsors and Contract Research Organizations. Therapeutic Innovation & Regulatory Science. January 11, 2018. https://journals.sagepub.com/doi/abs/10.1177/2168479017751403?journalCode=dijc
3. Tufts CSDD: Clinical Trial Startup Process Takes Longer Than 10 Years Ago, CenterWatch Weekly, March 12, 2018. https://www.centerwatch.com/cwweekly/2018/03/12/tufts-csdd-clinical-trial-startup-process-takes-longer-10-years-ago/
4. 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
5. Lamberti MJ, Brothers C, Manak D, Getz K. Benchmarking the study initiation process. Therapeutic Innovation & Regulatory Science. 2013;47(1):101-9. http://journals.sagepub.com/doi/10.1177/2168479012469947
6. Huggins, M. Budget, Contract Negotiations Greatest Causes of Clinical Trial Delays, New Report Shows January 26, 2017. https://acrpnet.org/2017/01/26/contract-negotiations-greatest-cause-clinical-trial-delays-new-report-shows/
7. Webcast: "Standardization Drives Transparency and Optimization of Contract/Budget Processes in Clinical Trial Startup", April 30, 2019. https://event.on24.com/wcc/r/1975788/4A4506F31AB34DAB23DD638E0BD1EEDF?partnerref=ORACLE
8. Abbott, D., Califf R., Morrison, B., Pierre, C., Bolte, J., and Chakraborty, S. Cycle Time Metrics for Multisite Clinical Trials in the United States, Therapeutic Innovation & Regulatory Science January 4, 2013. https://journals.sagepub.com/doi/10.1177/2168479012464371
9. 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
10. 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/.

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