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BUSINESS BRIEF

Automation, Standardization, and Collaboration in Clinical Trials

Commentary on results from a clinical data management snap poll

A common set of goals exist for all who touch a compound, drug, or clinical study: bring safe, effective treatments to patients quickly, and keep costs down while doing so.

A recent poll addressed just one component of managing and executing a clinical trial: the data. With a goal to further understand how efficiently and cost-effectively massive amounts of data are shared between trial sponsors and CROs, we asked three questions:

1. From request to receipt, how long does it take to get clinical trial data from your CRO partners?
2. How much does it cost you each time you ask for a data pull from your CRO partner?
3. Do you feel like you have a single source of truth for your trial data?

Understanding that data moves between CROs and trial sponsors, as well as around a company to various stakeholders, in a variety of formats, we wanted to look at the time, cost, and risk associated with the movement and sharing of clinical data.

Real-Time Access to Clinical Data: Truth or Legend?

In responding to our first question, over 65% of poll respondents indicated that it took 5+ weeks to get trial data from their CRO partners. With that lengthy turn-around time, how is it possible to respond quickly to any problems with the data? And, if you're working on a set of data, it's highly unlikely that you have the most recent cleaned, validated data. In those situations, how can you ensure that you're able to respond quickly to challenges when you can't be confident that you have the data you need, when you need it?

One respondent indicated that they had reached the Holy Grail: real-time access to data for both the CRO and the trial sponsor. If all trial

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CID/2018/04.19

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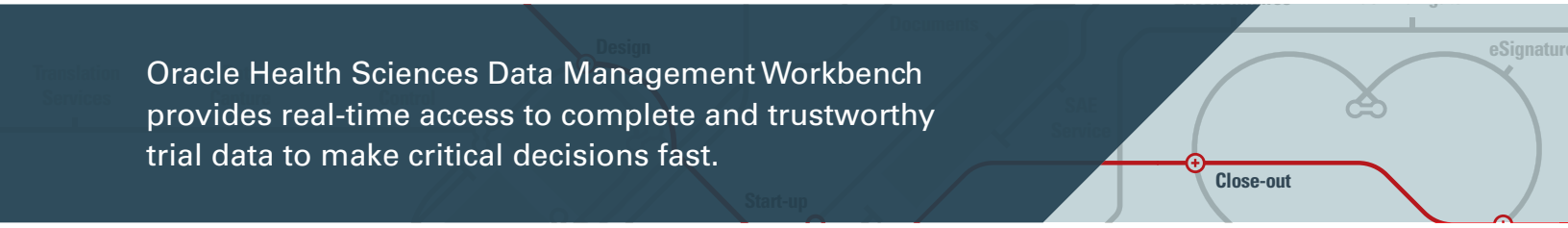

sponsors had that kind of access to their data, imagine the efficiencies they would gain, and the reduction in costs.

Requesting Clinical Data: What's the Cost?

Our second question asked about the cost of sharing data. With increasing budget pressures (and decreasing budgets!), we wondered if sharing and acquiring data was as cost-prohibitive as we thought. A handful of our respondents weren't sure of the cost of sharing data with their CRO partners, but more than 50% indicated that it cost between $10k and $30k *every* time they requested data from their CRO, and 13% shared that it cost more than $30k for each data request.

The caveat: a certain number of data requests are written into the trial sponsor/CRO contract. Ad hoc requests are a different story; and those can add up, especially as data moves around the organization and additional data points are needed to help support the clinical trial. If you have to request data multiple times, waiting five weeks *each* time, the trial faces delays and the associated cost of both the data *and* the trial delay grows and grows. What if you could access data real-time, at no additional cost? Simplifying end-to-end data flow, because your CRO partners aren't the only stakeholders with an interest in the clinical data, will lead to lower costs, higher quality data, and less risk.

Clinical Data Volume and Variety: What's the Truth?

Finally, we asked about a single source of truth. Fifteen percent indicated that they feel they have a single source of truth for their clinical data, though 82% shared, sometimes accompanied by laughter, that they do not. One response noted that by source or data point that they do, but not one source for all data. That brings up an important point: in addition to traditional data sources, there's mHealth, EHR, and RWE data that provide invaluable information to a data scientist. This data comes in a multitude of formats and needs to be aggregated and then standardized to actually be useful. If you could do this automatically, imagine the potential ease in making important clinical decisions quickly.

As the variety and volume of data increases with the addition of data sources like mHealth, EHR, and real-world evidence, and as the number of people touching the data in a clinical trial increase, technology needs to adapt. To aggregate, clean, standardize, and trace the lifecycle of a data point, and to then deliver and share data with a single-source-of-truth, advanced clinical data management techniques and tools must be leveraged. Luckily, this technology exists today, so you can address these challenges now for immediate, positive impact on cost, timelines, and mitigated risk.

82%

Complex clinical trials mean a large volume and variety of data, and 82% don't have a single-source-of-truth.

"Research shows that content is growing by as much as 200% per year, and the risks of not managing it effectively are growing even faster."

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