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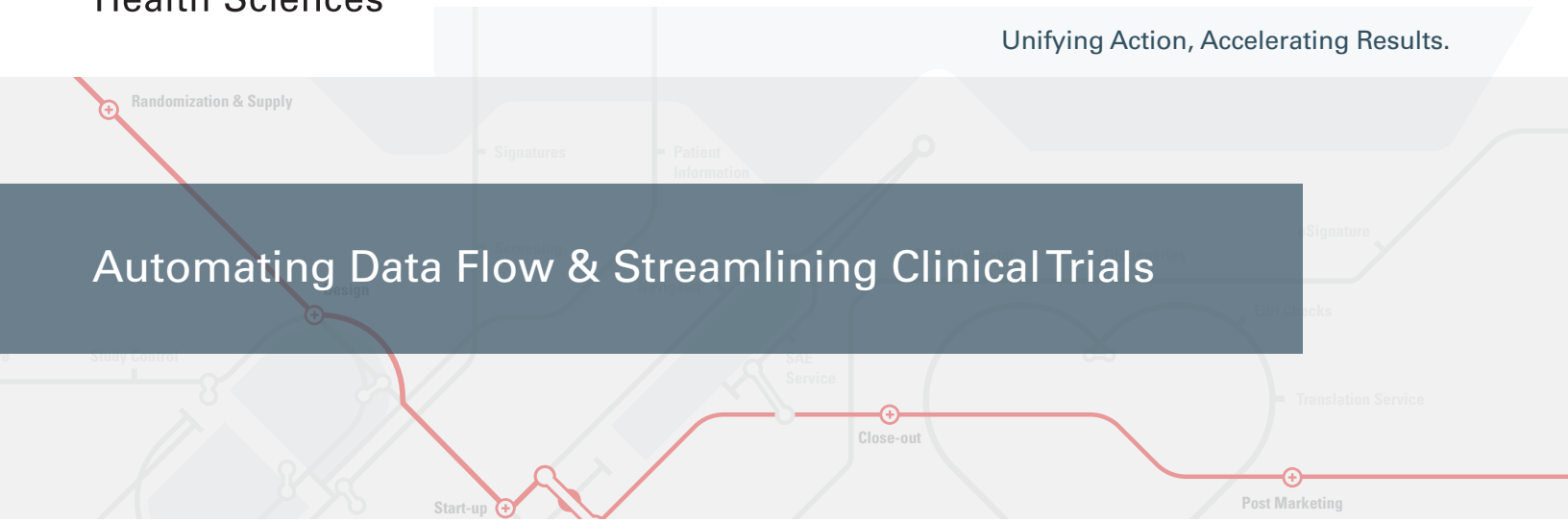

Automating Data Flow & Streamlining Clinical Trials

Ralph Russo needed to streamline his clinical tech environment. Tasked with modernizing Merck's data management platform, Russo, Director of Merck Laboratories, wanted to work with trusted partners* and proven commercial components that would help Merck simplify its clinical data flow globally, shorten cycle times, and provide all stake holders with more valuable data in real time.

Communications

Russo also understood that hand in hand with the technology changes, there would also be the necessary cultural process changes that could make or break the new implementation. So, he hired a communications expert and enlisted 200 people across the organization to promote program progress and benefits to many of the 69,000 Merck employee-stakeholders — from clinicians providing case report form (CRF) protocol requirements, to statisticians and programmers consuming data in different formats than they had before. He also enlisted international, regional, leadership support to assure that teams received and understood ongoing project updates. He also set up a hyper-teams (in China and Japan), assigning local "go to people" who could address any questions that arose from local staff.

It's All about Standards

For Merck, modernizing its data management platform meant standardizing on the obvious CDISC and CDASH standards. It also meant aligning Merck's CRF standards with the supporting structures in Oracle Health Sciences Data Management Workbench (DMW) solution to create as easy a study/build process, as was possible. Timing, though, did become an issue.

"If you think it's going to take you six months to build your standards library, you're wrong. It's probably going to take you two or three years…And, when you're redesigning all of the structures that people consume, a lot of conversation has to happen. But once you have [the standards], it does enable you to build studies more rapidly," said Russo.

> "With [a] new trial, let's say, today is the first patient, first visit. Data can be in use as soon as that happens. Those review models are finished in a couple of minutes. It's really near real time. "
>
> Ralph Russo
> *Merck Laboratories*

Oracle Health Sciences breaks down barriers and opens new pathways to unify people and processes, helping to bring new drugs to market faster.

Merck's first GO LIVE on the new system was in November 2015. Though the library was not complete, they had researched which forms were necessary.

"Now a lot of it is not so much in the build space, but again, [in] understanding [the standards specification process] — the need from the customer, how it's going to be used, and where it's going to fit in the model. That is where it takes a lot of time. So it's all about planning, not so much the execution for these objects," he added.

Today's Status

Currently Russo has eight trials running on the new system in 12 week cycle ramp-up time. Merck has set a goal of 20 percent (20%) overall reduction in cycle times. Russo intends to build out his staff and have team members get deeply familiar with all aspects of the new system so they can build studies quickly and easily.

"With [a] new trial, let's say, today is the first patient, first visit. Data can be in use as soon as that happens. Those review models are finished in a couple of minutes. It's really near real time. [The data] is consumable, once the transfer comes in form. All of those transformation programs trigger and data flows from one to the other, all the derivations run, all the validation checks run, all the queries are generated, they get pushed back to InForm in real time. That was one of the biggest benefits we saw. We don't have a CDMS [clinical data management system]. To not only have the queries fire against external and InForm collective data, but then to feed that back without human intervention to the site; it was a win-win. We couldn't pass it up," said Russo.

Benefits already seen include system gains in quality and repeatability, being able to implement processes that encapsulate all of the organization knowledge, time saved not doing manual study data tabulation model (SDTM) mapping, and lowered risk with the automated data flow process.

Russo's long term goal is what he describes as a "meta-data driven world." "We can have an MDR [metadata repository] to push out objects or have the metadata available to gain some efficiencies there. But we're not there yet…It will be an evolution."

*Merck chose Oracle Health Sciences and its clinical trial solutions including: Oracle Health Sciences InForm, Oracle Health Sciences Data Management Workbench (DMW), and Oracle Health Sciences Central Designer. Merck also joined the Accenture Life Sciences Coalition and worked with Accenture to build an Analysis Reporting Workbench (ARW).

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+1 800 633 0643

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