



# Saama's SDQ Speeds COVID-19 Vaccine

## Customer

### Top 10 biopharmaceutical company

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~ VP of Data Monitoring  
& Management

After a clinical trial or trial phase ends, it can take more than 30 days for patient data to be "cleaned up" for scientists to analyze the results. This tedious, manual process involves inspecting massive data sets to check for coding errors and other inconsistencies that naturally occur when collecting tens of millions of data points.

This Top 10 biopharmaceutical company set out to accelerate this workflow by inviting companies to a Breakthrough Change Accelerator, a novel "incubation sandbox" designed to help the company solve complex research challenges. This hackathon approach replaces months of legal negotiations and technical assessments with an abbreviated contracting framework that protects patient data.

According to their Vice President and Head of Data Monitoring and Management, the challenges that led to the hackathon were two-fold. "On the operational side, this is a highly resource-intensive activity and being able to bring innovation to it and automate as much of it as possible really simplifies the work," he says.

The second part of it is tactical, in the sense of being able to pre-program and enable more than 1,000 edit checks per study and make sure they're all implemented.

The executive says that "it's part of our strategy to ... take the human factor out of certain redundant, repetitive activities because we know the tool will do it. And that will allow us to focus a smaller, more nimble team onto the data that matters, the most critical data."

### A Winning Solution

Within six weeks, the inaugural competition was won by members of Saama's AI Research team, who came up with a solution they called Smart Data Query (SDQ). The team was selected for a variety of factors, including its level of engagement, spirit of collaboration, speed and flexibility, and, most importantly, the accuracy of the outputs.

"Developing such technology normally would take a long time, but in six weeks they solved it and produced a viable tool," says the data management VP. "From there, we collaborated with them to build it out to meet our needs."

SDQ ensures data quality and accelerates data clean up by automating query management, using machine learning to predict discrepancies, identify the reasons for those discrepancies, and auto-generate query text with 'human-in-the-loop' oversight.

Thanks to SDQ, the COVID-19 vaccine clinical trial data was ready to be reviewed a mere 22 hours after meeting the primary efficacy case counts. The technology enabled the team to maintain an exceptional level of data quality throughout the trial, leaving minimal discrepancies to resolve during the final steps.

"It saved us an entire month," recalls the data management VP. "It really has had a significant impact on the first-pass quality of our clinical data and the speed through which we can move things along and make decisions."

*Thanks to SDQ, a major COVID-19 vaccine clinical trial data was ready to be reviewed a mere 22 hours after meeting the primary efficacy case counts.*

While the biopharmaceutical company and Saama continue to evaluate the performance of SDQ, and while the AI engine continues to get better as it's trained on more data, the preliminary results were impressive:

#### **High-Volume Reconciliation**

More than 105 million data points were reconciled in just 4 months.

#### **15X Time Savings**

Median calendar days, from data capture to query generation, were reduced from 25.4 days (for all vaccine studies) to just 1.7 days. The total time saved in reviewing data and automating query text is estimated to be between 2,800 and 3,500 hours.

#### **Unstructured Text Analysis**

Using natural language processing, more than 750,000 free text sentences and phrases were successfully processed, to help detect adverse event signals and reconcile them with medical histories and case report forms.

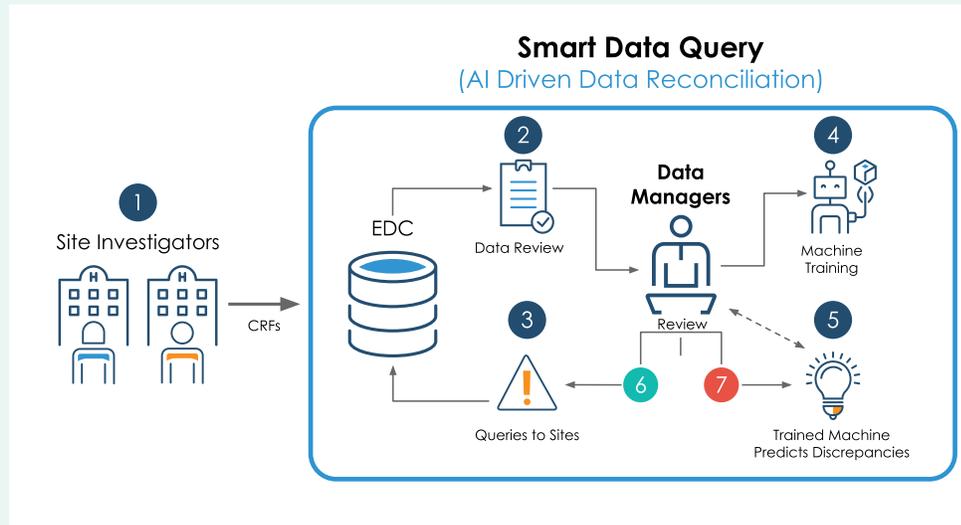
The data management VP and his team have high hopes for the application of artificial intelligence technologies in the clinical operations realm. "The potential we see in this project is not simply in making it more cost-effective to do the data validation," he says. "It's going to accelerate the speed by which data is themed as fit for purpose ... and should allow more real-time decision making."

To learn how SDQ can help you accelerate data cleaning, speed time to query, and resolve open queries more efficiently, contact Saama today for more information or to request a demo.

## An AI-Enabled Workflow

The entire process from eCRF entry to auto-query generation and review takes just minutes and gets faster as more clinical data is passed through and reviewed in SDQ.

1. Site investigators feed information via eCRFs into the sponsor's EDC system, which is integrated with SDQ. The AI immediately reviews the data and makes predictions, which data managers can review for accuracy.
2. Queries are automatically generated as eCRFs in the EDC and sorted by confidence interval, with links to data discrepancies.
3. Data managers can view each discrepancy and AI-generated response in the SDQ user interface; if the AI response is correct, the data manager signs off on the change (step 6) and the query is raised in the open state to the eCRF in the EDC.
4. Meanwhile, the SDQ AI recognizes that its suggested query text was correct/ appropriate, and the underlying SDQ algorithms improve.
5. If the auto-generated query text is either partially correct or incorrect, the reviewer can edit the response (step 7) before raising the query. In either case (outright rejection or amendment), the SDQ learns from the reviewer's feedback and gets better at generating automated responses.



## Related Resource

- [Smart Data Quality Landing Page](#)

## Get Started with Saama Today

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