

CASE STUDY USING AUTOMATION IN COVID-19 CLINICAL DATA VALIDATION

To accelerate timelines without compromising on data quality, one pharmaceutical company recognized the need to introduce an automated data validation solution for its COVID -19 Vaccine production processes.

OVERVIEW

In the race to overcome urgent public health challenges like the in the case of the Covid-19 vaccine development, the sponsor decided to use an automated technology supported by machine-learning. The objective was to validate the clinical data to ensure high quality, reduce time for submission and better support the sound interpretation of the study results.

CHALLENGE

Delivering high-quality validated clinical data to zero-tolerance regulators becomes a major concern when the sources are not standardized. Data may originate from different sources, in different formats, be presented in a variety of table layouts, and be dependent on manual classification by multiple programmers. Data discrepancies could significantly impact the very tight timelines.



Primary business Pharmaceutical



Headquarters **US**



Employees 10,000+



Annual revenue **\$30B**

SOLUTIONS

Based on previous experience, and since Beaconcure already trained its algorithm to validate clinical data of vaccines, the sponsor selected Beaconcure to validate the Covid-19 clinical data. The product Verify, converts various data formats in any layout into a semantic and dynamic database, to which any applicable algorithm can be applied. As a result, all discrepancies are identified automatically.

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RESULTS

By adopting an automated ML technology, data was validated within hours. The sponsor increased the accuracy and efficiency of their data validation and submission processes, avoiding regulatory delays and expediting the availability of life-saving therapies

