TransCelerate BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

SOLUTION IMPLEMENTATION

When Benefits Come to Life

These testimonials have been shared with TransCelerate by companies who have used TransCelerate solutions to realize benefits with stakeholders across the R&D ecosystem.

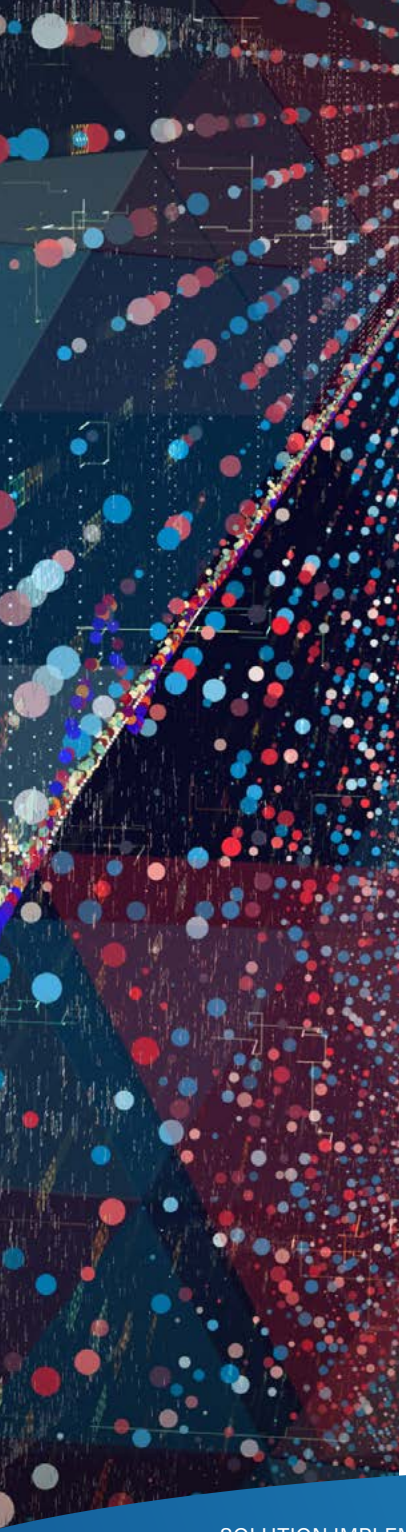
- Patient input leads to study design change reducing patient burden
- Successful implementation of Robotic Process Automation (RPA) in the Individual Case Safety Report (ICSR) management process leads to enhanced ability to protect patients
- Patient technology toolkit helps advance a sponsor company's patient-centric objectives in clinical trials

Patient input leads to study design change reducing patient burden

As part of our feasibility processes for a large breast cancer oncology clinical program, our study teams used parts (elements) of the **P-PET toolkit** to engage with patient advisory groups (patients, survivors, and co-survivors) about a number of planned clinical trial designs. Early draft study protocols (prior to receiving patient advisor feedback) required that all patients undergo a pre-screening biopsy in order to qualify for study participation. The unanimous feedback from the patient advisors reflected in the patient panel read-out reports helped study teams to better understand the impact and burden of this "additional" invasive procedure as well as its impact on a patient's desire or willingness to consider participation in a clinical trial. The clinical program directors were able to document the rationale for the need to modify this study requirement (inclusion criteria) across all related studies within the clinical development program, whenever possible.

As a result, the study teams made broad protocol design modifications allowing patients willing to share their diagnostic samples and where possible to substitute required pre-screening biopsies with the flexible option of using their "archived scientifically optimal diagnostic biopsy samples."

This new study inclusion option designed to reduce patient burden, requires that patients have access and be willing to share their archived tumor samples. Patient advisors clearly indicated that this type of flexibility would bring them closer to being shared decision makers in their own health care.



Successful implementation of Robotic Process Automation (RPA) in the Individual Case Safety Report (ICSR) management process leads to enhanced ability to protect patients

Through the data presented within TransCelerate's **"Interactive ICSR & Automation Technologies Tool" (IATT)**, our member company was able to adjust our short-term automation strategy for pharmacovigilance. By examining the IATT's data for the maturity of automation implementation using robotic process automation (RPA), we had a strong case for utilizing RPA to achieve quick wins on process improvement across several steps in the ICSR process.

We implemented RPA into the ICSR intake process late last year (2020). A bot took over the duplicate check and import of E2B cases received from a business partner. This implementation of RPA automation led to a reduction in effort to manage cases and subsequently reduced cost. These improvements were fully realized with a relatively low investment of programming and validation, but at the same time, increasing the efficiency in these workflow activities.

The use of RPA in the ICSR Management process supports managing repetitive tasks and can be combined with other functionality such as optical character recognition (OCR). We added OCR into production with a second bot supporting another business case within the ICSR intake process.

Our two use cases show a savings of approximately 5-7 minutes processing time per ICSR, and the bots completely replace the human interaction for those activities. The free capacity (time and effort) in the case intake could be re-distributed with our CRO partner to work on ICSR activities with higher value and greater complexity. Overall, our use of RPA has dramatically improved our capability to process safety data faster and enable our people more time to examine more complex safety data, which will enhance our ability to protect patients.

Patient technology toolkit helps advance a sponsor company's patient-centric objectives in clinical trials

The Clinical Innovation (CI) team within our company is responsible for the implementation of digital patient-facing technologies (DPFT) in the clinical studies. CI worked closely with two study teams who were interested in leveraging DPFTs. CI utilized the **patient technology implementation framework** as a roadmap to avoid redundancy while accelerating internal due diligence processes and overall timelines.

The two assets that were utilized the most were: the patient technology discussion guide & the patient considerations. These assets helped study teams and CI to leverage technology while underscoring a patient-centric mindset. The patient technology discussion guide was leveraged by CI to think strategically while having an inclusive and detailed plan when working with internal and external stakeholders. This document enabled the users to wear multiple hats while determine the best technology to be used by patients in the study. It also helped CI to think not only on the patients' needs but also in the investigators and site staff's needs as well. By following this guide CI made sure that technology did not impose significant work in participating sites nor patients. Finally, incorporating this document in our processes helped us to expedite the internal vetting process from months to weeks.

In reference to the patient consideration asset, it entails a list of questions that study teams must leverage to make sure that any potential technology being incorporated in the study brings true value to patients, diminishes burden, and does not impact negatively their safety nor compliance with study procedures. CI used this asset to secure that the potential DPFT to be included in the study is actually bringing true value to participating patients. This was accomplished by asking multiple questions to study teams and their stakeholders that came directly from patients. Hence, this approach reinforcing that the voice of patients are truly being heard and implemented by the sponsor in their DPFT solutions. Finally, CI used these questions to put together a survey during the duration of the study for gathering insight from participating patients. This questionnaire will be an important source of data to perform any necessary changes to the DPFT to secure it fulfills its patient-centric objective.