

TransCelerate: a global collaboration across biopharmaceutical R&D to accelerate and simplify new medicines development

Lynn Marks

GlaxoSmithKline, TransCelerate BioPharma Inc., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, USA

Abstract: As the economic pressures increase on healthcare systems around the world due to aging populations, chronic diseases, expanding patient populations in emerging markets and advances in medical technology, it is crucial that we focus on developing and delivering innovative and quality medicines with true medical value to patients around the world in a more collaborative, quality-focused and cost-effective manner.

An important component to this mission across the biopharmaceutical industry is identifying and solving common issues that compromise the success of a clinical development program – the shared pathway to safer and more clinically meaningful medicines. However, subject recruitment challenges, data collection and follow-up issues, identification of high-quality trial sites, and lack of successfully achieving study timelines continue to stress clinical trial operations teams across companies. Although there has been progressing across this range of roadblocks by individual companies, the underlying economics continue to threaten the research and development (R&D) business model.

Failure to solve these key issues will affect all parties involved in the clinical trial enterprise: patients, clinical investigators, health authorities, academia, tax-payers and the sponsor companies. The question remains whether a deep and broad collaborative effort that stretches across the clinical development arena—one that is charged with a common goal of improving quality, enhancing the investigator and patient experience, reducing costs and sharing data—can be a catalyst for success. With encouraging signs already realised, the operation of TransCelerate BioPharma Inc., a non-profit organisation created to improve the health of people around the world by accelerating and enhancing the R&D of innovative new therapies will test this premise.

Keywords: clinical trials, research and development, risk-based monitoring, clinical data transparency, comparator drugs, quality management system, site qualification and training, GCP training

Correspondence to: Lynn Marks, GlaxoSmithKline, TransCelerate BioPharma Inc., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, USA; Email: media@transceleratebiopharmainc.com

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1. Introduction

Since its launch in 2012, TransCelerate BioPharma's membership has grown to include 20 biopharmaceutical companies: AbbVie^[1], Actavis + Allergan^[2], Amgen^[3], AstraZeneca^[4], Astellas^[5],

Biogen^[6], Boehringer Ingelheim^[7], Bristol-Myers Squibb^[8], EMD Serono^[9], GlaxoSmithKline^[10], Johnson & Johnson^[11], Eli Lilly^[12], Medgenics^[13], Merck^[14], Novo Nordisk^[15], Pfizer^[16], Roche^[17], Sanofi^[18], Shionogi^[19], and UCB Pharma^[20]—all with a shared vision of accelerating and enhancing the research and

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development (R&D) of important new therapies. Bringing such highly recognised organisations together into an environment where collaboration for the betterment of all is the focus, promises to create a greater outcome than if we all worked in silos.

As a group, we are listening to pain points that are common across all of our organisations and finding ways to solve them together. The challenge is not in recognizing that there are many areas of opportunity for improvement in clinical development, but rather in identifying which specific areas can we truly make an impact in a positive manner, while respecting the fact that we are fierce, independent competitors. One example of our focus is to alleviate the duplicative burdens we place on clinical trial sites and their patients. Although TransCelerate does not represent the entire biopharmaceutical industry, we still feel that we have the ability to effectively address some of these challenges given the vast array of talent, practical experience, and knowledge derived from the number of clinical trials its members have conducted and the influence that a group comprised of such thought leaders will likely have.

2. Critical Issues and Unmet Needs

TransCelerate was conceived while the clinical trial business model was under intense pressure. As many in the industry understand, the status quo for clinical trial operations has not been sustainable for a very long time: it costs more than \$2.6 billion dollars^[21] to bring one new medicine to physicians and patients. This cost structure is negatively impacting the industry's ability to produce new drugs and maintain or increase drug quality. Although most companies have initiated their own program to reduce cost and improve quality, the status quo remains an inefficient model for all parties involved in the clinical study of medicines.

TransCelerate has focused on improving the relationships in the clinical development space and systematically addressing issues that an individual company could not take on by itself. The list of potential ways to influence and impact efficiency, quality, safety, and cost, are boundless. However, with a multi-year strategic road map in mind, TransCelerate sought a path to strategically deliver solutions that could improve the clinical trials execution paradigm serially and in parallel.

3. Accelerating a Paradigm Shift in R&D

One of TransCelerate's greatest strengths is the collective experience, knowledge and passion of the participating Member Companies and the people working on initiatives such as Clinical Data Standards^[22], Site Qualification^[23], Risk Based Monitoring^[24] and more. We are proud to engage top R&D leaders from each of the Member Companies who provide different experiences, diverse backgrounds and the ability to develop innovative concepts to address shared industry challenges.

Since inception, three of the earliest TransCelerate's initiatives have received significant acknowledgement: launching a framework for mutually recognised Good Clinical Practice (GCP) training, establishing a recommended method and approach to high-quality Risk Based Monitoring (RBM), and supporting the development and launch of industry-wide Therapeutic Area Data Standards^[25] through a collaboration with the Clinical Data Interchange Standards Consortium (CDISC)^[26], Critical Path Institute (C-Path)^[27], National Cancer Institute – Enterprise Vocabulary Service (NCI-EVS)^[28] and the U.S. Food and Drug Administration (FDA)^[29] as part of the Coalition for Accelerating Standards and Therapies (CFAST)^[30].

In addition, TransCelerate has launched a Drug Comparator Network^[31] that allows Member Companies who chose to participate, to purchase approved drugs directly from each other for clinical trials, thereby ensuring a safe, secure and reliable supply of comparator drugs. Later this year, TransCelerate will launch the Shared Investigator Platform^[32], a portal that will revolutionise communication between sites and sponsors, by providing a single sign-on capability for clinical investigators to access study-related information across multiple sponsors. This will create significant improvements in the communication channels between sites and sponsors, by easing the burden of site staff and improving quality through more harmonised IT solutions.

4. Key Milestones

Over the last three years, the RBM Initiative^[33] has been one of the areas where we have made a significant impact within the industry. RBM is an adaptive approach to clinical trial monitoring that directs the focus of monitoring and activities to the evolving areas of greatest need with the most potential to affect patient safety and data quality. Supporting infrastruc-

ture helps to enable RBM within Member Company's organisation by using common tools and triggers to identify risk, as well as the standard categorisation of low, medium and high risk trials. With uniform, industry-wide guidelines and supporting infrastructure for risk reporting, RBM's Methodology can both enhance patient safety and ensure the quality of clinical data.

Each participant of the clinical trial continuum will experience the benefits of RBM. Sponsors are able to allocate resources more efficiently and ensure subject safety, data integrity and GCP compliance, while patients are provided a safer clinical trial environment due to focus from sponsor and site on critical data and processes. By reducing the mass generation of queries issued months or years after data was originally generated, we decrease site personnel time checking data elements and allow them more time to focus on their patients. Regulatory bodies also potentially benefit from working closely with each other to ensure alignment on guidance documents. Before TransCelerate took on this challenge, no model framework that enabled organisations to successfully deploy and scale RBM existed.

Most recently, TransCelerate released RBM's Volume 3 Monitoring Update^[34] which outlined three publications that further the understanding of RBM, quantitative performance metrics, external engagement updates and 2015 deliverables. The volume 3 publication reflects TransCelerate's commitment to continuously refining and improving this and other initiatives for optimal results to the industry.

Another TransCelerate initiative that is addressing the burdens placed on clinical investigator sites is the Site Qualification & Training Initiative^[35]. Traditionally, clinical trial investigators and sites—for each company and often for each trial—are required to complete questionnaires, forms and similar training courses to prepare for trial participation. GCP training and collection of non-study specific information are pain points for investigators and sites as well as biopharmaceutical companies. Rather than going to the investigator and training them in GCP methods multiple times, in multiple ways, we can now cross-recognize different pharmaceutical companies' trainings and not duplicate efforts. The mutual recognition of GCP training^[36] allows clinical trial investigators and other site personnel who have completed any GCP training program that meets minimum criteria based on ICH principles^[37], to have that training be accepted

by participating Member Companies.

As of last year, TransCelerate completed the evaluation of 130 professional GCP training courses from over 110 unique providers meeting the minimum criteria^[38] across the participating TransCelerate Member Companies. We also launched a feature on the TransCelerate website to simplify the self-attestation process^[39] for training providers. By reducing time spent on GCP training, we are working together to improve study start-up times, streamline sponsor collaboration with sites and ultimately improve clinical trial site quality.

5. Future Opportunities for Clinical Trials

5.1 Clinical Data Transparency

A major movement that we are experiencing and will expand upon in the coming years is increasing transparency when sharing clinical data. Cooperation across sponsor companies, investigators, academia and clinical research organisations is widely recognised as a key indicator in the acceleration of drug development. Indeed, biopharmaceutical companies and thought leaders in the field are coming out in support of this. The Institute of Medicine released a report in January titled "Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk,"^[40] that provided the value of data sharing and guidelines and roles required for success. TransCelerate has positioned itself to be a leader in this space with several initiatives that aim to make it easier to prepare, review, interpret, access and share clinical data such as Clinical Data Standards^[41], the Shared Investigator Platform^[42], Placebo and Standard of Care Data-Sharing^[43] and Clinical Data Transparency^[44].

5.2 Technology Advancements

Technology advances bring new opportunities for cost reduction, improved decision making and multi-channel communication between researchers, sponsors, investigators and patients. It is expected that a majority of biopharmaceutical companies are researching on how best to integrate mobile, social, cloud and big data in order to help revolutionise R&D divisions. TransCelerate is integrating some of these technology opportunities through initiatives such as electronic labels (eLabels)^[45]. Today's labelling information provided with investigational medicines are not leveraging the range of technologies currently available that can provide truly engaging content for patients. What

TransCelerate is aspiring to do with the e-Labels Initiative, is to leverage the different ways in which information can be delivered through the use of technology, such as mobile, where it is easier to consume—whether it is the printed word, or multimedia or otherwise^[46]. Ultimately, the e-Labels Initiative will work to enhance label quality and utility for patients, provide more consistent labelling approaches for clinical trial sites, potentially reduce clinical labelling timelines and provide cost efficiencies for sponsors.

5.3 Collaboration

Historically, R&D in the biopharmaceutical industry has been on a linear plot: companies identify targets, select candidates, review toxicology, test for the first time in humans, establish proof of concept, move through research phases and so forth. The information learnt along the way is not optimally utilised to improve the processes—even within individual companies. As some have recognised, if sponsors had shared key learning, then the information received, coupled with real world data and evidence from our clinical trials, could reinforce circles of learning. In fact, a recent article from Deloitte highlighted some of the key areas of collaboration between biopharmaceutical companies that substantially impacted processes, such as pooling resources to share R&D costs and improve time to market for new drugs by standardising development cycles from early trials through commercialisation; filling gaps in product pipelines by co-developing innovative products and sharing costs and profits evenly; hedging R&D-related risk in discovery and early stage development by forming alliances; and working with companies outside the traditional life sciences industry to offer a better and more well-rounded standard of healthcare^[47]. As such, TransCelerate provides a platform that can foster and facilitate these and other initiatives to increase the development of new drugs through more efficient R&D processes.

6. Conclusion

To date, TransCelerate has benefited from an unprecedented sense of purpose among its member companies, as well as clear leadership. The formula driving TransCelerate forward is because we are comprised of some of the most passionate and innovative thinkers in R&D, from some of the world's most successful biopharmaceutical organisations, who have fundamentally recognised that working together can often be

much more productive and efficient than working apart. However, our mission would prove unsuccessful if it were not for our partnerships with a large array of external stakeholders that enabled us to create value for the biopharmaceutical industry^[48].

The joint efforts have resulted in an ongoing dialogue in over 20 countries, and engagement with major health authorities around the world. We are truly witnessing global momentum and are poised—excited and ready—for the next phase of our mission.

Although our focus has been on improving the way clinical trial sites operate and how investigators and staff function to make a clinical trial as efficient and safe as possible, in the future, we will look to expand our horizon. While our interface with patients is not direct, we are now increasing our efforts in defining needs for patient-centred activities during clinical trials. Lastly, we see an opportunity to extend our remit and hope to successfully take our approach to the non-clinical space of R&D.

Conflict of Interest and Funding

The author is the Corporate Secretary of TransCelerate and Senior Vice President, Projects, Clinical Platforms & Sciences at GlaxoSmithKline.

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