



Making Life Easier for Investigators: A Shared Solution for Smarter, Faster Clinical Trials

The industry's Shared Investigator Platform significantly reduces the time and cost of clinical trials, simplifying work for investigators and bringing promising therapies to market more quickly.

Executive Summary

Life sciences companies are under continual pressure to reduce clinical trial costs and the time it takes to bring a new therapy to market. Clinical trial challenges include subject retention, medical adherence and managing the huge volume of administrative documents and tasks required of investigative sites. The administrative work necessary for startup and management represents approximately 30% of the activities required for any given study.

Individual biopharma companies have attempted to address administrative inefficiencies by using Web-based portals to streamline information flow, document exchange and data access among study teams and investigative site staff. It is well-recognized that investigators complete the same administrative documents every time they work on a study for a sponsor. What's more, clinical trials increasingly require dynamic, interdependent relationships among sponsors, investigators and regulators – relationships that must be better managed to increase study efficiency and productivity.

Finally, new technologies ranging from social media to smartphones offer new capabilities that offer the opportunity to influence the clinical trial process and reshape the study experience for patients and investigators.

With the goal of improving clinical trial efficiency, a group of pharmaceuticals companies is supporting the development of a new technology platform that can be shared among multiple sponsors, with the goal of streamlining how investigators interact with biopharma companies across the industry. The new platform will enhance organizational productivity by providing investigators and site staff with a more centralized access point to clinical trial information, enhancing accuracy and reducing study startup time. It will also help pharmaceuticals companies improve quality, regulatory compliance, process visibility and capacity, while reducing investigator efforts related to training, document exchange and support.

In the future, the platform may provide regulators with an efficient electronic audit process and better insight into clinical trials, as well as func-



tionalities that match investigators and patients with studies that are the best fit. This white paper details a cross-industry effort to create a collaboration platform to help biopharma companies better facilitate their interactions with clinical trial sites, thereby accelerating and simplifying the research and development of new therapies.

Clinical Trial Operations: Streamlining a Shared Burden

The vast majority of delays in clinical trials is related to the need to log into various clinical systems and complete administrative documents and tasks for financial and trial management, as well as to fulfill regulatory requirements. Investigators often feel out of touch with sponsors and are burdened by redundant tasks and the management of multiple user names and passwords for systems and tools, known as “trial fatigue.” At the same time, sponsors struggle to make decisions with incomplete data and slow information flows. These factors make it more difficult for biopharma companies to quickly bring effective treatments to patients.

Fortunately, biopharma companies now have the technologies and tools to transform clinical trial processes and practices. These technologies have been used by individual life sciences companies to create information portals for their own investigators. Yet these individual efforts have had little impact on trial costs and efficiencies for several reasons:

- An individual portal does not enable a biopharma company to reduce duplicate efforts by its sites related to clinical research and recording-keeping, which contributes to trial inefficiencies and costs.
- Investigators still must log into multiple sponsor portals and systems, each with its own user name and password and a different user experience.
- Individual portals don’t effectively support the increasingly complex web of connections now required to bring a proven therapy to market.

Studies involve a wide variety of stakeholders beyond patients and investigators, including multiple business partners, such as contract research organization (CRO) and regulatory bodies. Addressing these issues as part of a shared industry solution enables improvements in clinical trial management, communication and

stakeholder collaboration. In essence, technology can now help resolve many of the persistent pain points that plague clinical trials.

In essence, technology can now help resolve many of the persistent pain points that plague clinical trials.

Developing such a tool requires an understanding of which processes can be simplified and streamlined across the industry to improve the experience of investigators.

A shared platform should:

- Strengthen the relationships between biopharma companies, investigators and regulators, both online and offline.
- Support near real-time communication between investigators and sponsors.
- Improve the investigative site experience.
- Simplify and optimize clinical trials.
- Streamline access and integration of clinical trial data.
- Create collaborative solutions across stakeholders focused on efficiency and value.
- Increase data reliability, transparency and regulatory compliance.
- Improve efficiency and scalability.

Accelerating New Therapies with Shared and Simplified Clinical Trial Management

The life sciences industry is working toward such a solution with the Shared Investigator Platform (SIP), conceived by TransCelerate BioPharma, Inc. TransCelerate is a nonprofit industry group composed of the world’s leading biopharmaceutical companies, and formed with the vision of accelerating and simplifying the research and development of innovative new therapies. The SIP provides a common workspace to simplify the clinical trial process, enable sponsors to collaborate more effectively with sites, and share data and clinical trial information between a sponsor and its clinical sites. The platform is designed to provide a faster, more cost-effective means to manage clinical trials by improving interactions between sponsors and investigators (see Figure 1, next page).

Data and user privacy is paramount to any cross-industry portal. With SIP, general information about investigators will be shared among member companies, as appropriate, while maintaining the security of each company's proprietary information and safeguarding the investigator's privacy rights. Clinical operations data is secured within the company's firewalls. Clinical teams set up a study workspace, sharing forms and templates for ethics review, as well as the trial master files that reside at the site and with the sponsor.

In the future, the platform could simplify clinical trial design with early and direct collaboration with the investigators. Clinical development teams will then be able to gain early feedback on patient populations and standards of care within the country or regions before submitting the trial design to the regulatory agencies for review and approval.

Streamlining Clinical Trial Operations

The SIP roadmap initially focuses on simplifying clinical trial startup; additionally, it adds efficiencies to ease the administrative burden for clinical investigators and makes it easier for investigators to participate and collaborate in the clinical trial environment. For example, SIP supports single sign-on, allowing investigators to register once across all participating companies for a single trial and/or for multiple trials within the same therapeutic area across companies. Single

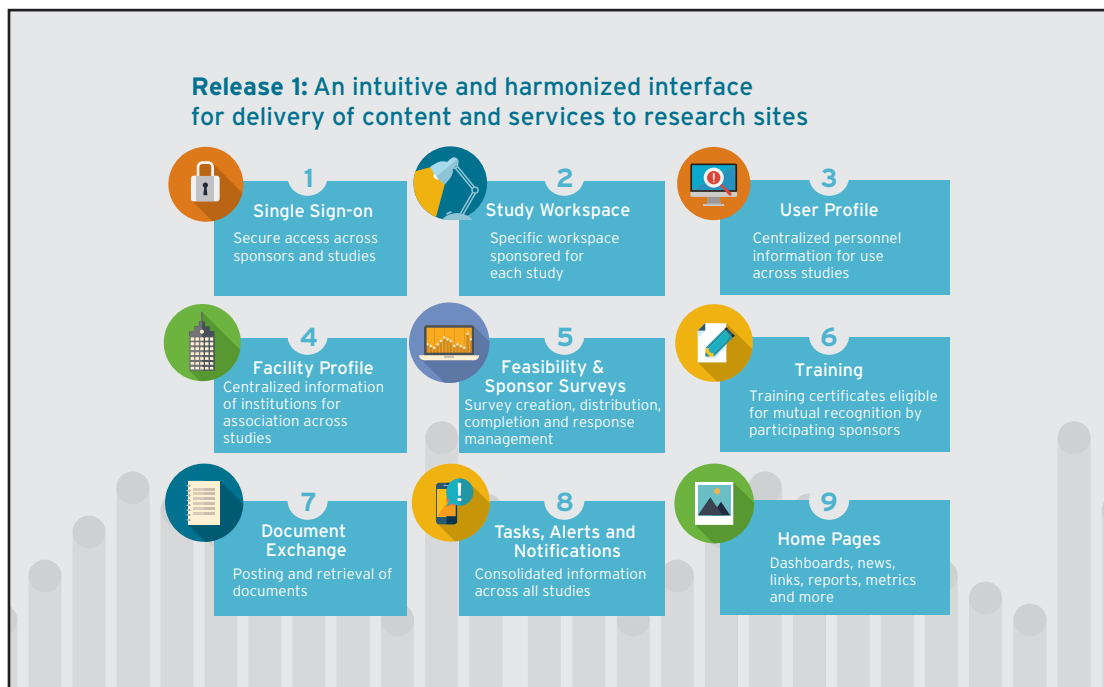
sign-on eliminates the need for investigators to have multiple user names, account forms and passwords.

Access to sponsor systems is also managed for the investigator through single sign-on. This focus on efficiency provides a similar user experience for both investigators and clinical trial sponsors, reducing clinical trial startup and completion time. These seemingly small efficiencies can result in breakthrough therapies and drugs being made available sooner, given that operational processes account for 45% to 75% of the time and cost of clinical trials.

Future SIP enhancements will focus on additional operational efficiencies, more collaboration and increased innovation using multiple digital touch-points across patients, investigators and life sciences companies. Key technologies such as social, mobile, analytics and cloud, integrated with best-of-breed capabilities, will make this possible. Areas of future focus for SIP may include:

- Drug supply ordering.
- Mentoring, training and communications for aiding patient retention and providing investigator support based on social and mobile solutions.
- Patient identification, screening and recruitment through database services and analytics.

Anatomy of the Shared Investigator Platform



- Operational services, such as paperless financial, regulatory and performance reporting data, leveraging database services, analytics and report templates.

In addition, it is also anticipated that SIP may expand to include more efficient ways to process investigative site payments according to clinical trial progress. Clinical trial recruitment metrics are another potential development priority, as is the automatic mailing of adverse event reports.

Looking Ahead: The Future Built on a Shared Vision

SIP will be the first multi-tenant, single sign-on platform through which clinical trial information, operations, administrative documents and tasks can be shared among sponsors and their sites. Several TransCelerate member companies and investigators developed the features that inform the design and development of the platform. They also provided oversight to ensure the platform provides an intuitive user experience and delivers the right functionality.

The vision for SIP is to enable a true working partnership across all stakeholders aligned with

a common goal, making it easier for the investigative site to conduct clinical trials. SIP fosters a community for support and mentoring, as well as the promotion of frequent and just-in-time communication for investigative sites and their staff.

It is critical that platforms designed to support more collaborative and communicative trials offer the scalability and open design required to integrate new technology developments. These very well may include the use of electronic medical records in the patient setting to identify potential trial participants.

SIP will continually evolve as technology advances to support the best, most efficient practices for streamlining clinical trials. The vision is that biopharma companies and investigative sites will reduce both time and cost on administrative tasks. At the same time, communication and collaboration between a sponsor and its sites, as well as data accuracy, should improve. SIP is driven by a shared vision for optimizing clinical trials to help the industry meet the demand for less expensive, more effective therapies, in a timely manner.

Note: TransCelerate selected Cognizant last year to develop a platform that will transform the way clinical sites collaborate with pharmaceuticals companies on clinical trials. Learn more [here](#).

About the Authors

Lorraine Marchand is a Senior Director within Cognizant Business Consulting, Life Sciences. Throughout her career, she has designed and developed strategies to increase drug development cycle time and commercialization. She has led operational improvements to study management, site performance, patient recruitment and quality and compliance. Lorraine has held executive roles in management, operations and business development for publicly and privately held companies, including pharmaceutical companies and CROs. She co-founded two life sciences companies and established a national education program at the National Institutes of Health. Lorraine received the 2014 Businesswoman Leadership Award from the Governor of Pennsylvania. She is faculty advisor for entrepreneurship at Princeton University. Lorraine holds M.B.A.s from Columbia University and the London Business School; a master's from The American University; and a bachelor's in science from the University of Maryland. She can be reached at Lorraine.Marchand@cognizant.com.

Beenu Kapoor is a Director in Cognizant Business Consulting with a focus on clinical operations and data management in the life sciences industry. Beenu has more than 20 years of experience in pharma, biotech and CROs. She has worked and consulted in transforming clinical trial management and operations. She has defined strategies and roadmaps, and implemented solutions (processes and tools) for clinical trials. She earned an Executive M.B.A. in finance from Rutgers Business School and a master's of science in computer application from Delhi University, India. Beenu can be reached at Beenu.Kapoor@cognizant.com.

About Cognizant's Healthcare and Life Sciences Practice

Cognizant's Healthcare and Life Sciences practice is committed to helping change millions of lives for the better by working with clients to build solutions to healthcare challenges, continually improve the way they do business, set the pace in clinical development, strengthen their regulatory infrastructure, and increase competitiveness. With over \$3 billion in annualized revenue, Cognizant's healthcare practice is consistently ranked among the top 10 on the Healthcare Informatics Top 100. Cognizant serves 28 of the top 30 global pharmaceutical companies, 16 of the top 20 health plans in the U.S., 4 of the top 5 pharmacy benefit management companies in the U.S., 9 of the top 10 biotech companies, and 12 of the top 15 medical device companies. With a large team of dedicated professionals – including doctors, pharmacologists, physicians, biomedical engineers, pharmacists, biostatisticians, medical writers, and GxP consultants – the practice provides domain-aligned consulting, IT, business process and analytics solutions globally.

About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world's leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 100 development and delivery centers worldwide and approximately 217,700 employees as of March 31, 2015, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.



Cognizant

World Headquarters

500 Frank W. Burr Blvd.
Teaneck, NJ 07666 USA
Phone: +1 201 801 0233
Fax: +1 201 801 0243
Toll Free: +1 888 937 3277
Email: inquiry@cognizant.com

European Headquarters

1 Kingdom Street
Paddington Central
London W2 6BD
Phone: +44 (0) 20 7297 7600
Fax: +44 (0) 20 7121 0102
Email: infouk@cognizant.com

India Operations Headquarters

#5/535, Old Mahabalipuram Road
Okkiyam Pettai, Thoraipakkam
Chennai, 600 096 India
Phone: +91 (0) 44 4209 6000
Fax: +91 (0) 44 4209 6060
Email: inquiryindia@cognizant.com