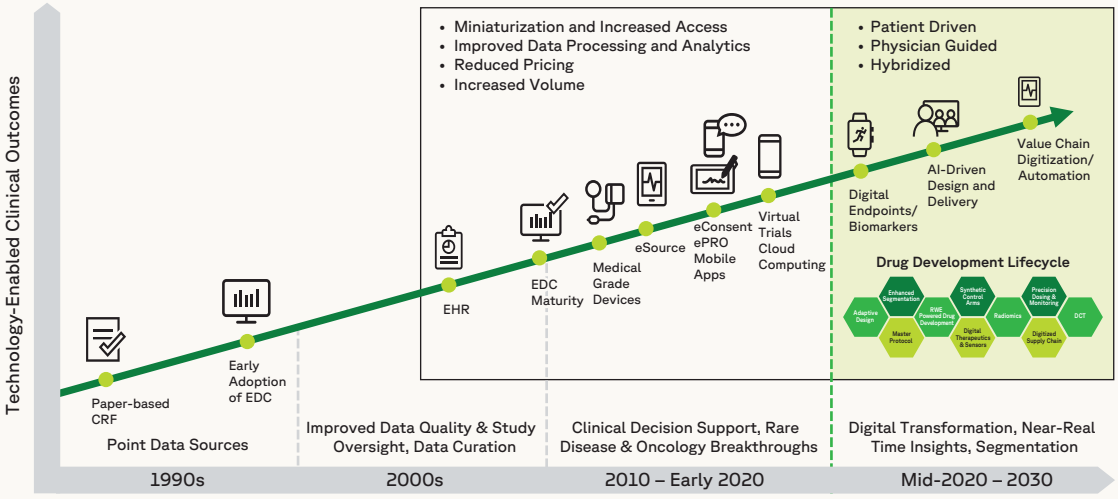
Fortrea

Recognizing the “new normal” of patient-centric clinical studies

The environment today

While today the Drug Development Industry remains somewhat frustrated and concerned about the slow uptake of new technologies, such as eCo nsent, ePRO and Mobile Apps, the strides being made far outpace the many years it took for Electronic Data Capture (EDC) to replace paper Clinical Report Forms. As technology has continued to expand its reach, opportunities to fundamentally impact the overall approach to how drugs are developed and brought to market abound.

Figure 1: Trajectory of drug development technology: accelerating transformational shifts

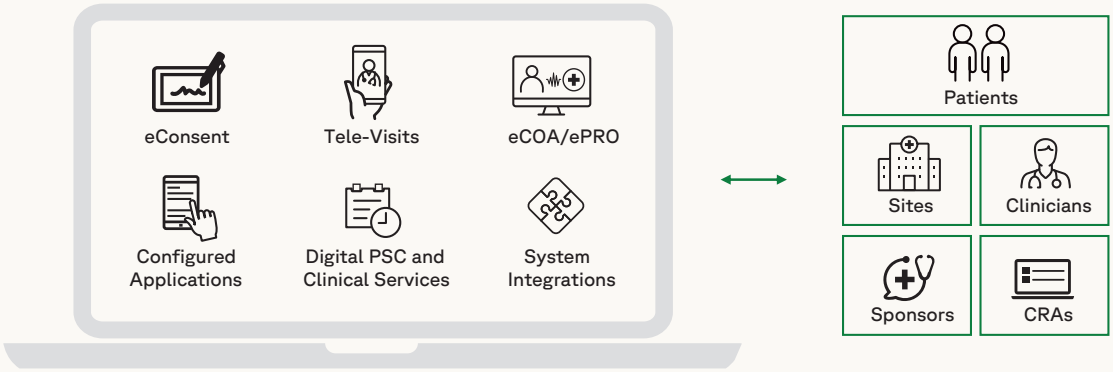


Building for tomorrow

The Fortrea goal is to create an environment where innovation and disruption thrive. By following such a model we are building a platform to “digitize” drug development starting with a patient-first point of view. This mindset has shaped the way we’ve helped drug development sponsors reimagine their clinical trials and create stronger connections with their patients. We must carefully balance the needs of multiple stakeholders—patients, investigators, study teams and sponsors—and recognize that there is no standard formula for success for clinical research. Each study is shaped by both strategic and practical considerations within the science, process, technology and tools that aim to provide a better experience for all participants.

Technology use to improve experience

Figure 2: Clinical trials with high-tech and high-touch



High-Touch—Patient Centricity, Connectivity and Engagement

For several years now the industry has been exploring the possibility of using technology to improve not just back-end systems, but rather the experience the patient will have when participating in a clinical trial. This exploration has led to the Decentralized Clinical Trial (DCT). While not a new concept, the COVID-19 pandemic served as a catalyst to highlight the fragility of the traditional model, as well as the benefits to be found in using modern tools and approaches. Trials had to quickly pivot to avoid the risks associated with patients traveling, congregating at sites or performing site visits. The pandemic also presented additional evidence that patients remain interested in using DCT technologies in studies. We observed that data completeness and continuity was possible when combined with certain high-touch aspects, such as in-home visits.

For patient outcome tools like ePRO or eCOA, patients have a more direct line of contact with investigators. If they are reporting their symptoms in near real-time instead of at their next site visit, the investigator can initiate contact with the patient or follow up with a telemedicine visit for a safety check. Even though the investigator and the patient may be physically apart, the technology can bring them closer.

The patient experience should also consider how to make data collection feel like a regular part of one's daily life. Examples include delivering medication to a patient's door, using a device as easy as a wristwatch and designing sensors without complex instructions. Designers should aim to achieve a level of seamless interaction that is similar to buying a new phone or requesting a ride on-demand from a ride-sharing program.

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Expanding access

It has been recognized that there are limitations to the populations/demographics with which clinical trials have historically been conducted. We need to reach more people outside of the large academic medical centers and within communities that have little to no knowledge of what is needed to bring a new drug to market. As access to technology expands, the diversity gaps that we urgently need to correct can be addressed. We can now limit the need for sometimes significant and regular travel through the use of telemedicine, home health nurses and data collection via wireless devices.

It is important to recognize that when incorporating a DCT element it doesn't create a new barrier for participation for the targeted population. Sponsors should not assume that everyone has access to the internet, for example, or can easily follow the instructions for using a data-collection device. Each element of the DCT must be evaluated to consider the unique needs of disparate populations to reduce potential burdens and rather improve the overall experience.

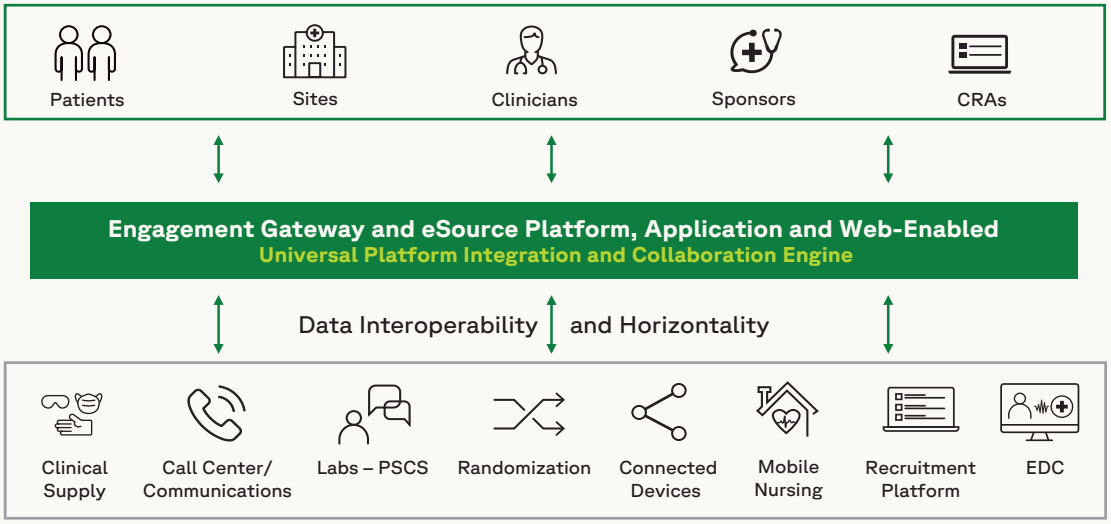
Related to the issue of improving diversity in clinical trials, technology can also enable a greater focus on trials that involve pediatric, adolescent or older adult populations as well as patients living with rare diseases.

Trials that include pediatric or adolescents often have to consider the needs of the patients' parents and caretakers as they are highly involved in the overall participation in a trial. Similarly, older adults may have to rely on the support and time of their caretaker to participate in a study. DCT tools like eConsent and portable data-collection devices can reduce the time needed to participate, minimize lost classroom time and even increase engagement with the participant. One example is a gamification approach in devices that can encourage adolescent participants to record their required study data. While this approach may increase the time needed for ethics approval or may require foresight to avoid a potential study bias, it could help with long-term patient engagement and timely collection of data.

The rare disease population is known for actively seeking out trials when few (or no other) approved treatments exist. The DCT model can work actively with this patient population to ensure the data collected is of interest to the patients also. For example, in a trial for a treatment that targeted a serious form of muscular dystrophy, the standard six-minute walk test was not always a viable option for potential participants as their disease progressed or if they had to travel a long distance to a site. The patients' caregivers appreciated a digital datapoint with remote actigraphy that they could collect; this datapoint was meaningful for the patients and their families but didn't compromise the study results as it wouldn't be used for the regulatory submission.

Single source

Figure 3: Improved operational model—consolidate, integrate and simplify enriching outcomes



In addition to improving the experience for patients and all trial participants (investigators, caregivers), a digital approach delivered with a platform of capabilities that is integrated, both via technology and operations, will lead to better data cleanliness and completeness. This will ultimately save time and eliminate non-value-add roles, such as those based primarily on ensuring that forms are filled out correctly, or harmonizing data definitions. The availability of de-identified data and significant processing power will enhance approaches and create more value-add roles for upskilled individuals.

A recent article from Deloitte Insights suggests that such an approach can:

- Accelerate recruitment 2 to 3 times—increase number of subjects, increase access
- Expand ability to contact patient digitally and expand catchment area
- RWE Enabled Drug Development: 21st Century Cures Act EU guidance on AI, HGRAC and Genetics

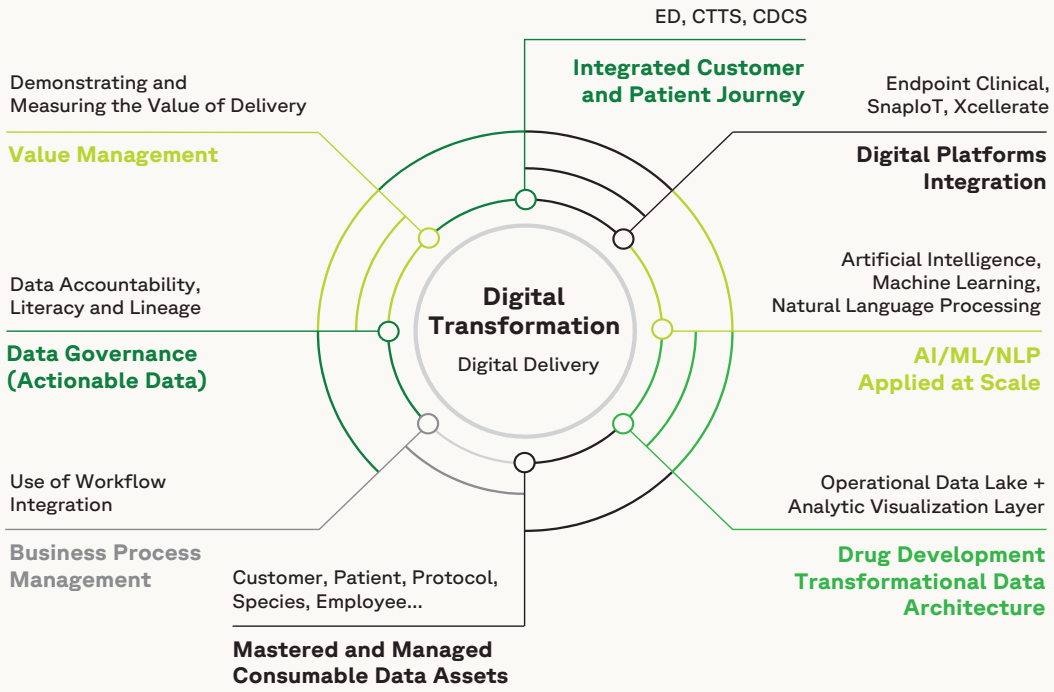
Figure 4: Digitization of clinical development—powering outcomes at scale

Source: Deloitte Insights

The Fortrea digital framework

By combining capabilities from across the enterprise with a focus on value delivery and an understanding of the journey taken by sponsor organizations and patients, a "digital framework" is being created.

Figure 5: Building a digital framework to improve outcomes for patients, investigators and customers



Developing digital biomarkers and enabling patient segmentation

As digital clinical technologies (encompassing sensors wearables, monitoring devices and others) gain increasing popularity and adoption through the full spectrum of the clinical trial process, the Fortrea Digital Framework is built to support the latest approaches, devices and protocols. The framework is designed to offer industry leading capabilities in the areas of:

- Turnkey scientific, operational and technical solutions to support new/exploratory end-point generation and drug approval or label extension
- Analytical expertise to support predictive and prognostic enrichment and improve return on drug development ROI
- The definition of novel biomarkers to drive therapeutic area differentiation in areas such as Neurology, Oncology, Cardiovascular and Rare Diseases

Our framework is built on the foundational principle that medical objectives for digital clinical measures drive the adoption of the appropriate technological features and operational capabilities.

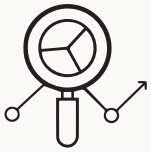
Figure 6: Improving patient segmentation and digital therapeutics

Recruitment

- Patient segmentation: personalized and digitized
- Enhancement of predictive and prognostic enrichment by selection of appropriate patient sub-segments

Digital Therapeutics

- Well-informed and accurate early futility analysis to inform critical go/no-go decisions
- New digital endpoints (secondary/exploratory)
- Predictive analytics: Early detection of compound efficacy and disease progression



Answers

- Real-world data collection and clinical experience for enhanced measurement of outcomes
- Granular insights and quantification of disease symptoms and progression

Process improvement enabled through the application of technology

Improving the processes that guide the conduct of a clinical trial will help us to move drug delivery into the future. Capturing data in a single system, audit trails that automatically detect issues with version control and the ability to mine existing patient data to identify patients that match inclusion/exclusion criteria and who have also consented to be contacted about opportunities to participate in clinical trials will eliminate weeks and/or months from the patient recruitment timelines. Single platform data capture can ensure Investigators are paid appropriately and promptly, enhancing their willingness to work with specific sponsor-guided studies. Trial resourcing, a challenge for all sponsor and CRO organizations, can have significant impact on the timelines of a clinical study. Technology applied through single platforms or via application of AI across platforms enables mining of existing de-identified patient data to facilitate Synthetic Control arms.

Figure 7: AI and NLP – architected to reduce the drug development lifecycle

Predict drug responses across a wide range of drug assets

UNDER CONSTRUCTION

Primate models to predict visits prior to disease manifestation

IN PROGRESS

Predicting investigators that will be successful in oncology clinical trials

UNDER CONSTRUCTION

Continued development of these tools and approaches should lead to reduction of timelines, trust in synthetic results, improved experiences for patients and investigators and ultimately drugs to market in significantly reduced timelines. Improvement in overall population health should follow closely.

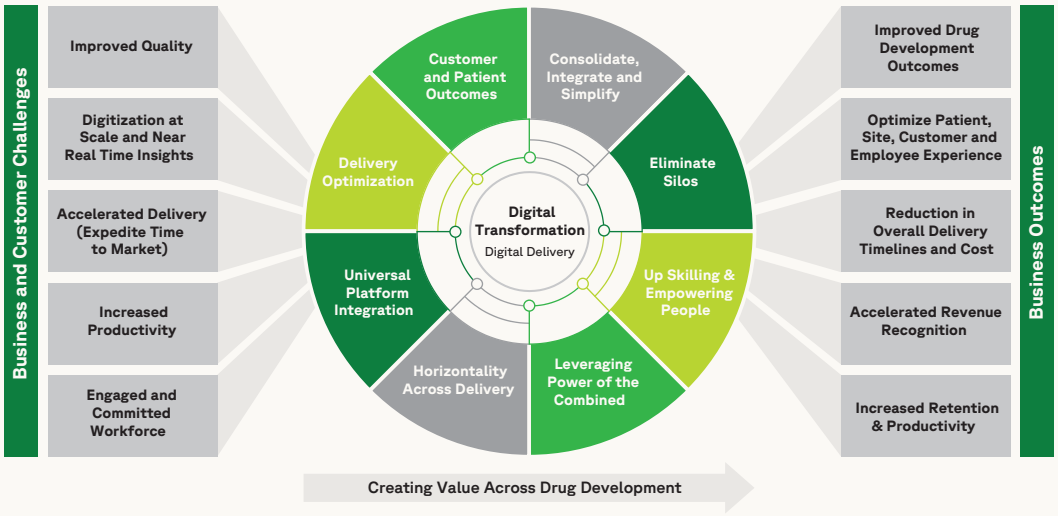
Conclusion

To win the future of drug development, Fortrea will continue to enhance our focus on how to develop, deliver and collaborate with all participants to deliver digitally enabled and improved outcomes. We will start with a DCT approach to all clinical study strategies, communicating the value these approaches will provide to all participants. Each strategy will reflect the needs of the patients, including those based on demographics, requirements that may be specific to an indication and its population, the schedule of events and the required endpoints as outlined in a protocol. As our industry has already shifted toward this model, we will continue to gather data to evaluate and quantify how DCTs inform better trial design, as well as improve data quality and cycle time for an overall study.

Regulatory changes will also help accelerate these changes and provide additional guidance for best practices. Sponsors will recognize that DCTs aren't just stopgap measures to address unexpected events like a pandemic, but a feasible and arguably better way to increase patient access to clinical trials through an improved and modernized trial infrastructure. We believe these trials will not only move personalized medicine forward at the most individual level but also bring us closer to solving some of today's biggest health challenges and improving population health on a global scale.

With this framework, Fortrea is digitizing at scale to create internal efficiencies, as well as to develop digital products—all with the purpose of improving outcomes. To this end, we have created a specialized business unit that focuses on the use of both internal and external data, coupled with AI, NLP and ML to produce analytics that drive horizontality and an integrated value chain across and within our businesses. Xcellerate® has enabled this for Fortrea, and customers, for more than a decade while continuing to build new capabilities and attack process problems with new approaches.

Figure 8: Digitizing at scale to improve outcomes



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