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Systems thinking: A new paradigm for clinical trial design and operations

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Sponsors and clinical researchers have been voicing a desire to [adopt patient-centric approaches to drug development](#) for more than a decade, but most clinical trials are still designed the same way they were before the industry began tentatively pursuing this model. If our industry is to truly enhance the patient experience and improve population health outcomes, we need to go beyond incremental efforts at innovation—such as inviting members of patient advocacy groups to provide input on clinical trial plans—and instead embark upon a full-scale paradigm shift.

No healthcare encounter ever takes place in a vacuum. To better address the social, environmental and cultural factors that prevent patients from achieving the best possible health outcomes, we need more collaboration across sectors and systems. Zooming out for a wider perspective on health ecosystems makes it easier for biopharmaceutical researchers to engage a broader, more diverse network of stakeholders. Sharing data, performance metrics and feedback enables these stakeholders to integrate their efforts to improve health equity.

Systems thinking spurs this sort of close and holistic collaboration.

Systems thinking in clinical trials

Systems thinking is [an approach to problem-solving](#) that emphasizes understanding how all components in a system are connected. Systems are dynamic and complex by nature; all

parts exist in ongoing relationships with one another and the system as a whole. Only by considering the interactions and feedback loops within these relationships can we begin to understand how they enable outcomes.

Applying a systems thinking framework to clinical trial design prompts purposeful and productive collaboration among stakeholders, with healthcare's "Quadruple Aim" as a shared vision that all can strive toward.

Now widely accepted as a way to expand health equity and improve health system performance, the Quadruple Aim includes the following four goals:

1. Improving population health
2. Enhancing the patient experience
3. Improving provider satisfaction
4. Reducing cost of care

When trials are designed with the shared goal of the Quadruple Aim in mind—and the needs, preferences and experiences of the patient at the center—it is possible to better engage all participants in the clinical trial ecosystem. An expanded group of stakeholders comes together to engender transformational change, not just in clinical research, but in the entire healthcare system's performance: patients, volunteers, regulators, investigators, physicians, nurses, clinical research associates, pharmacists and physicians—as well as churches, schools, employers and community organizations.

"Historically, clinical trials have been designed to generate specific data for regulators first and foremost," says Oren Cohen, President of Clinical Pharmacology and Chief Medical Officer at Fortrea. "These data are subsequently analyzed and interpreted by a wide array of stakeholders, yet the process is not optimized to produce the highest collective value for the system, and opportunities for learning are missed. If you're not thinking in terms of the system as a whole from the start, you won't consider *every* relationship—how best to engage with all stakeholders, how they influence and connect with one another, and how learning from all of them helps you adeptly redefine the research problem with greater empathy for the patient."

Rethinking clinical research from a human-centric perspective

Let's take a closer look at how systems thinking can transform clinical trial design. Achieving this vision requires trust among stakeholders, shared values and goals, and distributed leadership. It also requires the creation of transparent feedback loops. In this way, all

participants in the system have access to outcome measures focused on the patients, whose wellness is at the heart of the system.

Systems thinkers look for relationships instead of factors in isolation. They see wholes instead of parts, value connection over disconnection and strive for a circular (rather than linear) understanding of causality. In clinical trial design, this means asking some key questions, such as:

- *Where are the connections and interdependencies in this system?* The answer might allow us to strengthen the communication and alliances among CROs, sponsors and sites, for instance. It might encourage stakeholders to partner with retail pharmacists or local churches to better engage patients.
- *What's causing the friction in this system? Where are the bottlenecks?* Understanding these factors could make it possible to streamline the site startup and patient recruitment processes. Or it might reveal a need for technology-enabled data collection (such as wearables and sensors) to improve convenience, adherence and the patient experience.
- *How can we better integrate all parts of this system?* Data, analytics and communication technologies can play a major role here. Consider how retailers and hospitality businesses communicate with their customers through text messaging. What would it look like if sites did this too?
- *What kinds of evidence will demonstrate the real-world "system value" of this therapy?* Solving for shared value across a system requires integrated evidence planning. It may be possible to collect real-world data on a parallel track with a randomized controlled trial (RCT) to complement evidence generation, involving more stakeholders and enabling innovation crossover. Pragmatic clinical trials that randomize patients at baseline, as in a conventional RCT, but then incorporate additional observation methods to study larger and more diverse patient cohorts can produce findings with broader applications.

"While zooming out to view healthcare systems, we need to make sure we don't lose sight of the patient at the center of the system," Cohen says. "Creating a patient council—which pharmaceutical companies have historically done—is necessary but not sufficient. We need to zoom in to understand how patients live, what their interactions with healthcare providers are like, how they build relationships with investigators and nurses and sites. Then we need to measure—and be agile enough to iterate and improve—their experiences within the system."

Ultimately, bringing together this human-centric focus with a systems thinking perspective makes it possible to build a new, dynamic framework for clinical research. Within this systems-based framework, we can create and nimbly apply new models—for population health, payment and more equitable access to clinical trials and healthcare—that improve experiences and outcomes for us all.

Curious to learn more? [Contact John Doyle](#) to find out how he and Fortrea are using systems thinking—practically applied—to design and execute clinical trials that better address the Quadruple Aim.