



TRANSFORMING TRIALS 2030

CTTI has developed a bold vision for how clinical trials should be done in 2030, one that all stakeholders can aspire to achieve together. We recognize that some aspects will likely happen sooner than others, particularly in some countries, special populations, therapeutic areas, types of trials, etc. However, we will use this vision to guide CTTI's priorities, encourage others to do the same, and collaborate with individuals and organizations to pursue these aims.

Although the vision is intended to apply to clinical trials broadly, CTTI's work will primarily focus on clinical trials as defined by the NIH—research studies in which one or more participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Our expectation, however, is that the results of our work may also apply to other clinical studies, such as those that do not use prospective assignment. Similarly, we recognize that clinical trials fall within the broader context of evidence generation and take this into account as we move toward a future vision.

By 2030:

1. Clinical trials are patient-centered and easily accessible.

- ▶ Patients and patient organizations are fully integrated in the design and governance of clinical trials, helping to ensure the relevance of the research questions and completeness of outcomes.
- ▶ When possible, individuals are involved in clinical trials without going to designated clinical sites to enroll or participate.
- ▶ Home trials, hybrid trials, and technologies are maximally used to allow all potential participants to take part regardless of geography and mobility and to maximize efficiency and minimize costs.
- ▶ Every potential participant is aware of clinical trials relevant to them.
- ▶ Enrolled clinical trial participants reflect the diversity of the population expected to use the medical product.



2. Clinical trials are fully integrated into health processes.¹

- ▶ Trials are integrated within learning health care systems—where science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.²
- ▶ Clinical trial data are collected via the electronic health record (EHR), with additional data collected only if unavailable in the EHR.
- ▶ Informed consent for clinical trial participation is integrated into the care process. Consent policies are directly tied to risk mitigation in a clinical study and are easily understood by trial participants.
- ▶ Health care systems and health plans are involved in planning studies and support the integration of trials into regular clinical practice in order to facilitate engagement of care providers, recruitment, data collection from EHRs, and uptake of trial results.

3. Clinical trials are designed with a quality approach.

- ▶ Clinical trials address clear and meaningful scientific questions that are determined with the input and consideration of those who will use the results, including care providers, regulators and payers.
- ▶ Clinical trials are fit for purpose—designed with study activities that are essential to ensure the safety of trial participants and the credibility of key study results and with nonessential activities eliminated in order to simplify conduct, improve trial efficiency, and target resources to most critical areas.
- ▶ A broad range of relevant stakeholders, internal and external to the sponsor organization (e.g. patients and study coordinators), are involved in protocol development and discussions around study quality of individual trials.
- ▶ Consideration is given to the validity and efficiency of clinical trials prior to their conduct, including the clarity and conciseness of the protocols and informed consent materials, the ease of adequate data collection that is not excessive, and the validity of analysis plans matched for the purposes of the trials.
- ▶ Innovative trial designs (e.g. statistical approaches) will continue to be developed and used to more efficiently and effectively conduct clinical trials.
- ▶ Where possible clinical trial infrastructure is reused.

¹ Health processes are interactions that involve or support the relationship between patients and care providers.

² Institute of Medicine. Roundtable on Value and Science-Driven Health Care: The Learning Health System and its Innovation Collaboratives: Update Report. Washington, DC: IOM; 2011.



4. Clinical trials maximally leverage available clinical and nonclinical data, including data collected via digital technologies, to minimize collection of necessary trial specific data.

- ▶ Clinical trials are enhanced by the integration of new types of data, such as consumer and digital data.
- ▶ Data are accessible, with appropriate governance and controls, to all researchers and sponsors.
- ▶ Use of EHR data and other relevant available data from trial participants is straightforward.
- ▶ Linkage with health plan claims data for trial participants is simple when beneficial for trial conduct.
- ▶ Data platforms support multiple clinical trials, rather than being built for individual trials.
- ▶ Choices of data sources and methodologies correspond to the level of evidence needed to answer the research question and considers how the study results will be used.
- ▶ Data standards and definitions are in place to support integration of data from various sources, and the systems are interoperable.
- ▶ Common standards exist to address privacy and security in an easily implementable and transparent manner.

5. Clinical trials contribute knowledge about how to prevent, diagnose, and treat disease, and clinical trials are one of many sources of information that can be acted upon to improve population health.

- ▶ New medical products are available to care providers and patients more quickly and efficiently than today.
- ▶ Results of trials are broadly shared with participants and care providers, so they can be considered as part of the totality of evidence and acted upon for the benefit of the public's health.
- ▶ With less expensive and more efficient clinical trials, more clinical trials and other types of research are done to answer the questions most important to patients.

As clinical trials continue to evolve, the language in this vision may be adapted as needed.