



WHITEPAPER

Conducting Research at the Point of Care

John Farah, PhD

Joe Vasey, PhD

Lee Kallenbach, PhD, MPH

Geoff Caplea, MD, MBA, FAAFP

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INTRODUCTION

Primary care and specialty physicians from Savannah to Seattle draw on evidence-based medicine—the best research evidence combined with clinical expertise and patient values¹—to deliver personalized, patient-centric, [value-based care](#). And yet, for some patients, the best possible outcomes at the lowest possible cost remain elusive.

For these patients, healthcare professionals might consider a change in clinical approach that has the potential to achieve outcomes that better align with goals outlined in patients' individualized care plans.

THE CURRENT CLINICAL RESEARCH MODEL: LIMITATIONS AND CHALLENGES

The randomized controlled trial (RCT)—the longstanding, interventional study design used to assess the safety and efficacy of new medical products—forms the basis of the current clinical research model. Findings from traditional RCTs are included among the highest levels of evidence in developing clinical practice guidelines produced by professional medical societies.

RCTs are internally valid with respect to determining whether a cause-and-effect relationship exists between the intervention being evaluated and pre-established clinical outcomes. However, the findings of RCTs may not apply to populations broadly encountered in routine clinical care.² Restrictive enrollment criteria meant to assure data quality and control variability may exclude patients with characteristics commonly found among those in daily practice. Thus, clinical guidance based on RCTs and their selected populations may not align with a patient's history, complaints, comorbidities, or concomitant therapies.

RCTs remain the basis of drug approval, yet a research process that relies on traditional clinical trials poses challenges, including high costs, extended time frames, and overall inefficiencies that often reflect difficulties in recruiting and retaining patients.^{3,4} Across various medical conditions, 5% to 10% of eligible adult patients participate in clinical research, with lower rates observed for women, minorities, and the elderly.⁴ Low engagement rates may relate to a patient's reluctance to temporarily leave the care of a trusted doctor, to accept services from unfamiliar healthcare professionals, or to navigate a complicated clinical trial system that is physically separate or geographically distant from their usual place of care.^{3,5}

Distinct challenges to participation in clinical research exist for doctors as well. Among these are time limitations due to the myriad responsibilities of busy practices and a lack of a supportive clinical research infrastructure, both administrative and financial.⁵

REAL-WORLD DATA AND ELECTRONIC HEALTH RECORDS: THE IMPORTANCE OF DIGITAL TRANSFORMATION

Having recognized the limitations and challenges associated with the current clinical research model, regulatory agencies and clinical trial sponsors are considering how best to leverage patient data routinely collected from real-world clinical practice as a complementary source of insight for regulatory and clinical decision-making and for new drug indications occurring post-approval. Real-world data (RWD) include the comprehensive health-related information captured in electronic health records (EHRs), medical and prescription claims, and clinical registries or other observational studies. RWD have been used to generate real-world evidence (RWE)—clinical evidence of the use and of the benefits or the risks of medical products.^{6,7}

The widespread adoption of EHRs and the expanded use and integration of other transformative, telemedicine-relevant digital technologies—among these, secure videoconferencing, wearable devices, patient apps, and electronic consent systems—are allowing healthcare stakeholders to reevaluate the traditional model for clinical research.³ Such digital transformation affords doctors and the patients they serve opportunities to participate in clinical research studies that are patient-centric and potentially less costly, more efficient, and administratively less burdensome than studies conducted using a more traditional research model.

THE DECENTRALIZED CLINICAL TRIAL: AN ADVANCE OVER THE TRADITIONAL CLINICAL TRIAL

With its emphasis on patient centricity, the decentralized clinical trial (DCT) represents in specific instances an advance over the traditional clinical trial.

- DCTs are conducted through telemedicine and mobile healthcare providers or the patient's own physician.
- DCTs use procedures that differ from the traditional clinical trial model.⁸

The use of telemedicine became especially relevant owing to uncertainty surrounding coronavirus disease 2019 (COVID-19). Conducting clinical trials remotely using existing and emerging digital technologies, a key feature of DCTs, may ensure critical research continues while patients remain safely at home or visit their usual place of care (**Textbox 1**).⁹

1. THE COVID-19 PANDEMIC, CLINICAL RESEARCH, AND TELEMEDICINE

The COVID-19 pandemic created significant challenges to the conduct of clinical research. Within the first few months of the outbreak, hundreds of planned and in-progress US clinical trials critical to evaluating new interventions for the treatment of cancer, dementia, and other chronic diseases were interrupted or discontinued.¹⁰

In anticipating quarantines, study site closures, travel limitations, interruptions to supply chains, and other COVID-19-related disruptions would hinder adherence to protocol-specified visits and diagnostic and laboratory testing, the FDA issued and continues to update guidance on conducting clinical trials throughout the ongoing public health emergency.¹¹ Among considerations for clinical trials is ensuring the safety of participants, including the need to adjust patient monitoring, while keeping patients fully informed. The FDA continues to recommend the use of phone calls, virtual visits, and

alternative assessment locations when trial participants are unable to complete protocol-specified visits, with sponsors determining whether in-person visits are necessary, all to ensure safety.¹¹

In many cases, COVID-19 has accelerated adoption of new approaches to conducting clinical research. The number of trials disrupted by COVID-19 has declined and the number of resumed trials (over 900 worldwide¹²) has increased, suggesting successful modification of study strategies by contract service providers and trial sponsors.^{13,14} In a qualitative study that assessed the impact of the COVID-19 pandemic on clinical trial execution, nearly one-half of pharmaceutical and biotech stakeholders interviewed had implemented at least one approach to decentralizing ongoing trials,¹⁵ a finding that speaks to the growing importance of patient experience and engagement for clinical trial success.¹⁶

A decentralized approach may offer opportunities for more inclusive patient representation, expanded patient focus, and sustained patient engagement in the clinical trial enterprise. To facilitate adoption of DCTs, the Decentralized Trials and Research Alliance (DTRA), a coalition of life sciences and healthcare organizations, was recently established to spearhead policies, practices, and technologies that may remove barriers to clinical research.¹⁷

Among other aims, the collaboration intends to provide solutions for physicians and their patients, “improving access and convenience” rather than “creat[ing] complexity and additional burdens.”¹⁸

INTEGRATING CLINICAL RESEARCH WITH CLINICAL PRACTICE: RESEARCH AT THE POINT OF CARE

Integrating clinical research with routine clinical practice requires eliminating institutional and conceptual barriers.⁴ Once barriers are removed, the data captured during routine clinical care—wherever the patient is—may be used not only to answer research questions but also to remake healthcare services into “agile and adaptable” learning healthcare systems (**Textbox 2**).¹⁹

Patients and their doctors may benefit from an integrated research approach, with beneficial treatments identified for the former and medical insights and therapeutic guidance available for the latter.²¹ The integrated research model heralds a durable change in medical practice that holds the potential to enhance patient care and well-being.

With our participation in DTRA and launch of a technology-powered research platform that works within the current regulatory framework and makes it easier to prioritize and engage patients, Veradigm is enabling decentralized clinical studies with potential to support learning healthcare systems.

2. LEARNING HEALTHCARE SYSTEMS

According to the National Academy of Medicine (formerly the Institute of Medicine), a learning healthcare system “is designed to generate and apply the best evidence for the collaborative healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care.”²⁰

The learning healthcare system, which emphasizes shared decision-making when preparing personalized care plans, “focuses on exploring the potential of data collected in daily clinical practice as a source of up-to-date[,] minimally biased population-specific knowledge, which could be implemented into clinical practice in a more agile manner than randomized controlled trials.”¹⁹

As a member of DTRA with its mandate to advance policies, practices, and technologies to transform clinical research, Veradigm is working alongside other alliance members and regulatory agencies in evolving a patient-centric research environment supportive of all stakeholders.

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