# The role of remote data capture, wearables, and digital biomarkers in decentralized clinical trials

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## Abstract

Decentralized clinical trials (DCTs) are gaining momentum in clinical research as these studies can be executed remotely through telemedicine and mobile/local health-care providers. The COVID-19 pandemic has further accelerated advances and adoption in this area. In the past few years, there has been significant development and growth in the use of remote data that are electronically transmitted from a clinical trial (CT) participant, from outside the clinical setting, to a data repository. Such data may include laboratory data, safety data, or outcome measures reported by the participant, the clinician or the observer. Similarly, wearable health monitoring devices are being increasingly used in health-care and CT settings. Digital biomarkers, which can support continuous measurement of physiologic parameters outside the physical confines of the clinical environment, are also creating new and improved opportunities for patient care and biomedical research, enabling remote monitoring and DCTs. There are several benefits to using remote data capture, wearables, and digital biomarkers in clinical health-care research; however, several questions and challenges still need to be addressed. In an effort to understand the adoption of these technologies in DCTs, and the challenges therein, the authors of this workstream conducted an online survey of clinical research stakeholders across India and reviewed 80 responses. The review article summarizes the key findings from this online survey.

**Keywords:** Decentralized clinical trials, digital biomarkers, remote data capture, wearables

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**Received:** 13-10-22, **Accepted:** 06-06-23, **Published:** 13-10-23.

## INTRODUCTION

The COVID-19 pandemic has severely impacted the conduct of clinical trials (CTs), with trial site closures, participant travel limitations and infection risk, investigational product supply chain interruptions, etc., being some of the challenges encountered. Given this scenario, regulatory authorities have acknowledged the need to modify and adapt ongoing CT protocols to address this. One such area of change is remote data capture (RDC) from trial participants with clinical investigator oversight.[1] This allows for different types of patient data collection such as outcome measures, including patient, clinician, and observer-reported outcomes.

As CTs incorporate more virtual and digital components, data generation and collection are evolving with the use of mobile phones and wearable devices, which can generate round-the-clock patient data.[2]

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|---|---|
| Quick Response Code: | Website: www.picronline.org |
| | DOI: 10.4103/picr.picr_219_22 |



**How to cite this article:** Chodankar D, Raval TK, Jeyaraj J. The role of remote data capture, wearables, and digital biomarkers in decentralized clinical trials. Perspect Clin Res 2024;15:38-41.

This type of technology produces large volumes of interrelated information that creates a real-world picture of how a patient is responding to a drug. For example, if a patient has been taking a drug during a 6-month CT, the clinical team can potentially have visibility to all the parameters of interest at any time during that period using RDC, instead of relying on information captured at certain points in time during office visits. In addition, since one has access to dynamic patient data, it is possible to identify safety events as they occur during the trial, instead of retrospectively depending on the trial participant for such information. RDC also offers the benefit of less missing data and allows for increased flexibility in terms of analyzing this data at any point during the trial.[3]

Wearable devices are also helping to address the critical challenge of patient participation and retention in CTs by eliminating or greatly reducing what patients often identify as the most inconvenient part of CTs- the need to come to the clinic.

To better understand how clinical research stakeholders across India have either already implemented or plan to implement remote data collection into their CTs, the authors of this workstream conducted an online survey and evaluated 80 survey responses.[4] The survey findings are categorized in the following groups:

## EXPERIENCE WITH DECENTRALIZED CLINICAL TRIALS, REMOTE DATA CAPTURE, WEARABLES, AND BIOMARKERS

About 67% of survey respondents reported that <25% of their CTs were decentralized; none said that 100% of their trials were decentralized.

Concerning prior experience with RDC, wearables, and biomarkers, only 50% of the respondents reported some prior experience, mainly with implementation of RDC in their CTs, and 40% reported implementation of RDC in their observational studies.

In all, 59% of the respondents indicated wearables/devices as the most common methods used for RDC, and almost all these respondents also mentioned the type of wearables they had worked with in the past; wrist-worn wearables being the most commonly used. Over 50% of the respondents indicated the type of digital biomarkers they had used in the past; biosensors and wearables being the most commonly used ones.

### Standards for connected medical devices, internet of things sensor-based devices, and interoperability

About 60% of responders skipped the question about the standards being followed for RDC, and among those who answered it, 78% indicated 21 Code of Federal Regulations (CFR) Part 11 to be the most common standard.

Of the 32% of participants who answered the question about the standards being followed for connected medical devices, Internet of Thing (IoT) sensor-based devices, and interoperability, 69% chose the option "IS/ISO/IEEE 11,073 for India/IEEE 11,073 health informatics standards and related ISO standards."

### Regulatory guidance in India

While 50% of the respondents did not answer the survey question regarding clarity concerning the current regulatory guidance surrounding decentralized CTs (DCTs) and data capture in India, 45% of respondents, felt it was clear, whereas 5% felt it was not.

Of the 48% of respondents who answered the question about difficulties experienced in complying with regulatory guidance, 60% reported "training, monitoring, and ensuring compliance with regard to new data capture methods implemented" as the most common difficulty, 82% reported lack of a process to fast track the approval for the use of existing and new medical devices/wearables at home by participants of DCTs in India, and 56% were unsure about the possibility of softening the stringent rules and duties around the import of medical devices into the country.

The Government of India has formulated a Draft IoTs Policy structure for appropriate governance of IoT activities and its implementation.[5] The existing framework for data protection in India includes the following:[6]

- Information Technology Act, 2000
- Personal Data Protection Bill, 2019
- National Digital Health Blueprint, National Digital Health Mission (NDHM) Health Data Management Policy, and NDHM strategy overview
- Report by the committee of experts on Nonpersonal Data Governance Framework.

### Ease of use and benefits

Almost 40% of the respondents did not answer the question asking them to rate the ease of use of existing medical devices and wearables by patients participating in DCTs, and the weighted average score of the respondents who did answer was 2.96 (on a scale of 1–5, one being very low, and five being very high).

Over 90% of the respondents found access to real-time data and insights as one of the key benefits of wearables and RDC technology. The participants also reported that it saved time and was convenient for the site staff (69%), the patients (60%), and the sponsors (55%).

### Key concerns and challenges

Over 69% of the respondents stated that the main disadvantages included expensive implementation, device choice, and logistical considerations. Seventy-one percent of respondents felt the most common key concerns regarding RDC and use of wearables were operational challenges. Fifty-nine percentage of respondents indicated "Semantics – lack of standardization" as the most commonly reported concern in leveraging digital biomarkers.

When asked about any ethics committee (EC) related challenges in implementing RDC, wearables, and digital biomarkers, 54% of those surveyed did not answer, 41% reported no challenges, and 5% said they had EC related challenges.

Unclear regulatory acceptance (64%), the need to deal with different technologies, each with a separate portal and login credentials and the complex integration required (57%), and lack of data integration (40%) were the most commonly reported technology-related challenges.

Less than half the survey participants reported challenges in setting up the data infrastructure, processing, analysis, and interpretation; the most commonly reported challenges were related to data ownership, privacy, and security (58%).

### The way forward

Survey participants were asked to rate the probability of their use of RDC capabilities in DCTs in India in the next 6 months to 1 year, on a scale of 1–5 (1 being very low and 5 being very high). Fifty-six percentage of the participants did not answer the question, and the weighted average score of those who responded was 2.83.

When asked about the impact of the adoption of DCTs in their technology requirements/current environment, 58% of the survey participants skipped the question, and of those who answered, the most frequent responses were "Must have the ability to integrate with other platforms" (74%), "Must ensure compliance" (71%), and "Must have the ability to reconcile inconsistent data formats" (65%).

Learning and implementing new technology is often viewed as the biggest challenge to executing virtual approaches. Therefore, barriers to adoption in the areas of people, process, and mindset at the investigator/site level must be considered for the success of decentralized approaches.[7]

Incorporating virtual components into clinical protocols from the inception will facilitate smoother implementation at clinical sites. As CTs incorporate more virtual components, CT data will no longer be limited to traditional formats. To ensure that the entire data flow is optimized, effects on data quality, health-care professional workflow, patient compliance, and feasibility of conducting trials in multiple locations must be considered.[8] Cumulatively, these offer a critical opportunity for improvement and advancement.

## WHAT ARE INSTITUTIONS/PHARMACEUTICAL COMPANIES/CONTRACT RESEARCH ORGANIZATIONS DOING IN THIS AREA?

Institutions and Pharmaceutical companies are creating dedicated teams to manage their remote data from devices.[9,10] They are identifying the devices and/or contract research organizations (CROs) with whom they can partner to implement hybrid DCTs. They are also evaluating the amount and nature of remote data needed to support their objectives.

CROs are creating similar teams; however, the differences are in the therapeutic areas supported by them, the investments made to promote device-agnostic solutions, and in the end-to-end services provided for the use of wearables and RDC in DCTs. CROs are also building strategic partnerships with Pharma companies and device manufacturers to be the single point of contact and offer comprehensive services for study teams.[9,10]

## FACILITATING PATIENTS' USE OF WEARABLES AND DEVICES USED FOR DECENTRALIZED CLINICAL TRIALS

Educating and making the target population comfortable with using the technologies required for RDC for DCTs is critical and should be given due importance. Technology reach and advancement throughout the country, including in remote areas, should be strengthened simultaneously.[7]

To better acquaint end users on how to use devices or wearables, educational videos or pictorial reference guides demonstrating correct usage, using the device for the first time under provider supervision, and providing training to the user are recommended.

## DECENTRALIZED CLINICAL TRIALS IN THE INDIAN CONTEXT

India's recent growth has been impressive, making it one of the fastest-growing global economies. Government initiatives such as Digital India, Ayushman Bharat,[11] and Make in India, as well as increasing foreign direct investment limits, are also generating promising opportunities.

A slew of new sensors and remote devices which measure various biological or behavioral events, with minimal effort on the part of the patient, allow for the collection of real-time data outside of limited windows of time when patients are in the clinic. This real-world data provide investigators with valuable new patient insights and can answer sponsors' scientific questions even faster.

Some key benefits of DCTs are an expanded trial participant pool, increased participant retention, improved participant convenience, and access to a wide variety of real-time patient data. In additions, DCTs offer a solution to:

- Site staff inconvenience
- Not receiving primary endpoints at the time of occurrence
- Maintaining required patient safety monitoring
- Second-hand data sources
- Need to run additional trial to validate digital efficacy endpoints.

The working group's recommendations for DCTs in India are as follows:

1. Create awareness about RDC and its application in DCTs, specifically pertaining to legal and operational challenges
2. Dialog with pertinent stakeholders on ethics, data privacy, and security
3. Create India-specific guidelines/adopt industry-wide standards for:
    - RDC in DCTs and how to overcome commonly faced challenges
    - Medical device approvals and use in CTs for RDC
    - Data security and privacy.
4. Adopt device-agnostic technology by focusing on data aggregation and standardization.

## Acknowledgment

We acknowledge the medical writing support provided by Utpala Daftary in revising and finalizing this manuscript.

We thank Anushila Vaishali (MW Council Chair) and Dr. Hetal Shah (MW Council Member) for their efforts in the overall planning and execution of the publication activities for the DCT Position Paper initiative.

## Disclosure

The insights stated in this article are author's personal opinion and does not reflect those of the current and previous employers.

## Financial support and sponsorship

The insights stated in this article are author's personal opinion and does not reflect those of the current and previous employers.

## Conflicts of interest

Deepa Chodankar is an employee of Sanofi India and might be shareholders of Sanofi.

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