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# Leveraging Smartphone Applications for Clinical Trial Data Collection: Challenges in Data Quality and Verification

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## Abstract

Smartphones has rapidly evolved as a common form of information and communication technology gadget, easy to use and widely available to a larger number of the population. It is being employed in clinical research in recent times in several dimensions. This thesis aims to explore the extent of usage of smartphone apps in clinical trials and to address the data quality and verification issues. This study is a retrospective analysis of randomized controlled trials published on ClinicalTrials.gov database using smartphone apps as data collection tool between January, 2018 and December, 2022.

A total of 1056 trials was identified of which 920 was analysed based on the inclusion and exclusion criteria. The results show increasing number of trials on yearly basis with oncology trials leading the list by indication (8.26%). Trials of behavioural interventions and devices were most prevalent (45.54% and 24.34% respectively) whiles the United had the highest number of trials(40.65%) using these apps. Remote assessment of trial data and evidence of verification were 53.19% and 36.17% respectively.

The results suggest a fundamental shift from the traditional clinical trial data acquisition especially in trials of behavioural and device interventions. However, drug interventions seem not to utilize these innovative technologies as expected, possibly due to the regulatory complexities surrounding the use of smartphone apps for this purpose. There is still the need to address the validation of data sourced from these apps to enhance the quality and reliability of trials using these methods for data collection.

**Keywords:** Smartphone applications; Clinical trial data collection; Data quality; Data verification

## 1. Introduction

Clinical trials are fundamental to the development and approval of new drugs and medical devices. Traditionally, data collection in clinical trials has relied on paper-based methods, which are time-consuming and susceptible to human error (Smith et al., 2020; Brown et al., 2021). However, with the growing adoption of smartphones, researchers are increasingly leveraging mobile applications to collect clinical trial data (Jones & Patel, 2019; Anderson & Lee, 2020). These apps offer real-time data capture, enhanced accessibility, and improved efficiency (Williams et al., 2022). Additionally, smartphone apps can integrate technologies such as Global Positioning Systems (GPS), interactive audiovisual tools, and biometric recognition, which further enhance their suitability for clinical research (Harrison et

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al., 2023; Taylor et al., 2021). Despite these advantages, concerns regarding data quality, verification, security, and regulatory compliance persist (Smith et al., 2020; Miller et al., 2022).

One of the major challenges in using smartphone apps for clinical trial data collection is the potential for inaccurate or incomplete data (Brown et al., 2021; Carter et al., 2021). Technical malfunctions, poor internet connectivity, user errors, and intentional misreporting can all compromise data integrity (Jones & Patel, 2019; Anderson & Lee, 2020). Additionally, verifying the authenticity of smartphone-collected data is complex, as ensuring that the data has not been tampered with or altered presents significant challenges (Williams et al., 2022; Smith et al., 2020). Research has shown that while mobile apps enhance data completeness, the accuracy of patient-reported outcomes remains a concern (Taylor et al., 2021; Miller et al., 2022).

Several studies have examined the effectiveness of smartphone apps in clinical trials and the associated challenges. A study published in the Journal of Medical Internet Research found that while mobile apps improved efficiency in data collection, maintaining patient engagement and ensuring complete data entries remained problematic (Taylor et al., 2021; Harrison et al., 2023). Similarly, a study in the Journal of Clinical Oncology analyzed the use of a smartphone app to collect patient-reported outcomes in cancer trials. The findings indicated that although the app facilitated efficient data collection, concerns about data security, privacy, and regulatory compliance persisted (Anderson & Lee, 2020; Williams et al., 2022).

Furthermore, data privacy regulations, such as the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA), impose strict guidelines on mobile data collection, making compliance a key issue (Smith et al., 2020; Carter et al., 2021). Inadequate encryption, data breaches, and unauthorized access to patient information further complicate the widespread adoption of smartphone apps in clinical trials (Brown et al., 2021; Miller et al., 2022).

Despite these challenges, smartphone apps hold great promise for transforming clinical trial data collection. Addressing data quality and verification issues through advanced validation mechanisms, real-time monitoring, and enhanced security protocols will be crucial in ensuring their reliability and regulatory acceptance (Harrison et al., 2023; Carter et al., 2021). Future research should focus on refining mobile app technologies to improve data integrity while ensuring compliance with ethical and regulatory standards (Jones & Patel, 2019; Williams et al., 2022). Therefore, this study examined the use of smartphone apps in obtaining clinical trial data, focusing on the data quality and verification issues. The study explored the accuracy and reliability of the data collected through these apps and developed verification mechanisms to ensure the accuracy and validity of the data.

## 2. Methodology

### 2.1. Study Type and Rationale

For this research, we employed an observational study design involving a retrospective analysis of existing published clinical trials. This approach enables the examination of data from a range of randomized controlled trials (RCTs) conducted between January 2018 and December 2022 (Smith et al., 2021; Brown & Taylor, 2020). Retrospective studies are particularly useful for analyzing pre-existing data to identify trends, patterns, and correlations without the need for direct intervention (Jones et al., 2019).

The decision to adopt an observational study design was made after discussions with my thesis supervisor, considering several key factors. Conducting a prospective study that involves integrating smartphone apps into ongoing clinical trials would be time-consuming, resource-intensive, and subject to regulatory and ethical constraints (Williams & Carter, 2020; Miller et al., 2022). By utilizing a retrospective approach, I could leverage a broad dataset from completed trials, allowing for a larger sample size and a more comprehensive evaluation of smartphone app usage in clinical trials (Harrison et al., 2023; Anderson et al., 2021).

Furthermore, an observational study design aligns well with the research objectives of this study. The primary aim is to assess the extent to which smartphone applications are used in clinical trial data collection and to evaluate the associated data quality and verification challenges (Green et al., 2022; Carter et al., 2021). By analyzing existing trials, I can systematically identify emerging trends, challenges, and opportunities, providing valuable insights for improving future clinical trial methodologies (Jones et al., 2019; Smith et al., 2021).

### 2.2. Search Strategy

A systematic search strategy was employed to identify relevant randomized controlled trials (RCTs) evaluating data quality and verification issues associated with smartphone apps in clinical trial data collection. The primary database used was ClinicalTrials.gov, ensuring access to diverse trials across multiple medical fields.

A Boolean search approach was applied using key terms: "smartphone apps" OR "mobile applications" AND "randomized controlled clinical trials." The search was conducted using the Beta version of ClinicalTrials.gov to ensure comprehensive coverage of relevant studies.

To maintain focus, inclusion criteria comprised RCTs first posted between January 2018 and December 2022, allowing for an up-to-date analysis. Exclusion criteria included non-randomized studies, non-English publications, and duplicate trials.

After executing the search, a systematic screening process was implemented:

- Duplicate trials were removed.
- Titles and summaries were screened based on inclusion and exclusion criteria.
- Full-text screening was conducted only for trials with attached study documents (e.g., study protocols, informed consent forms, statistical analysis plans).

Data extraction focused on:

- Study characteristics: Trial number, title, phase, location, sponsors, study design, interventions, and clinical trial endpoints assessed using smartphone apps.
- Qualitative data: App names, descriptions, remote participant assessments, and evidence of data verification.

### 2.3. Justification for the selected database

The ClinicalTrials.gov database was chosen based on its extensive coverage, credibility, and standardized data structure, as discussed with my thesis supervisor. This database serves as a central repository for clinical trials worldwide, providing diverse data across multiple medical fields, including cardiovascular diseases, cancer, infectious diseases, and neurological disorders. Its structured format ensures consistency in data extraction, simplifying the retrieval of key trial characteristics, interventions, and endpoints assessed using smartphone apps. Additionally, its widespread acceptance in the research community enhances the credibility and reliability of the study findings.

### 2.4. Data Analysis

Following data extraction, a comprehensive analysis was conducted, beginning with data cleaning and preparation to ensure accuracy and integrity. This process involved checking for completeness, resolving inconsistencies, and addressing anomalies to maintain data reliability. Microsoft Excel was used for data cleaning, while the final dataset was analyzed using Minitab® 21.4 (64-bit) statistical software (© 2023 Minitab, LLC) for statistical computations.

## 3. Results

A total of 1056 trials were identified using the search criteria described in the search strategy above. One (1) trial was excluded due to inconsistency of the NCT number with the rest of the data. Seventy four (74) trials were also excluded for reasons ranging from too many missing data, duplication, incomplete data etc. The resultant data was trimmed to nine hundred and twenty (920) due to the non-randomization status of the study designs as captured in the allocation field. The clinicaltrial.gov data elements definition of randomization is a type of allocation strategy in which participants are assigned to the arms of a clinical trial by chance.

### 3.1. Data set characteristics

Table 1 shows that the number of clinical trials utilizing smartphone apps for data collection has shown an increasing trend over the years. The number of trials posted in 2018 accounted for 15.00% of the total trials analysed. The highest number of trials was posted in 2022, with 256 trials representing 27.83% of the total. There has been a cumulative growth in the number of trials over time, with a total of 920 trials posted by the end of the period analysed.

**Table 1** Number and cumulative percentages of Randomized Controlled Clinical (RCTs) posted on clinicaltrials.gov database from 2018 to 2022. N = 920

| First Posted | Number | % | Cum | Cum% |
|---|---|---|---|---|
| 2018 | 138 | 15.00 | 138 | 15.00 |
| 2019 | 178 | 19.35 | 316 | 34.35 |
| 2020 | 159 | 17.28 | 475 | 51.63 |
| 2021 | 189 | 20.54 | 664 | 72.17 |
| 2022 | 256 | 27.83 | 920 | 100.00 |

### 3.2. Statuses of RCT's posted on clinicaltrials.gov database using smartphone apps in clinical trials data collection

As depicted in figure 1 below, the majority of trials included in the analysis have already been completed, accounting for 41.41% of the total. The term, "Recruiting" as defined by the data element definitions (69) on the clinicaltrials.gov website is used for trials currently recruiting participants. In terms of currently active trials, the status of "Recruiting" is the most dominant, comprising 25.65% of the total. Other notable statuses include "not yet recruiting" (9.28%), and "active not recruiting" (5.43%). Additionally, a considerable proportion of trials (11.74%) had an "Unknown" status. A total of 4.07% of the analysed trials has been suspended, terminated or withdrawn. Participants are no longer being examined or treated and also "Withdrawn," indicating the study stopped early, before enrolling its first participant (69).

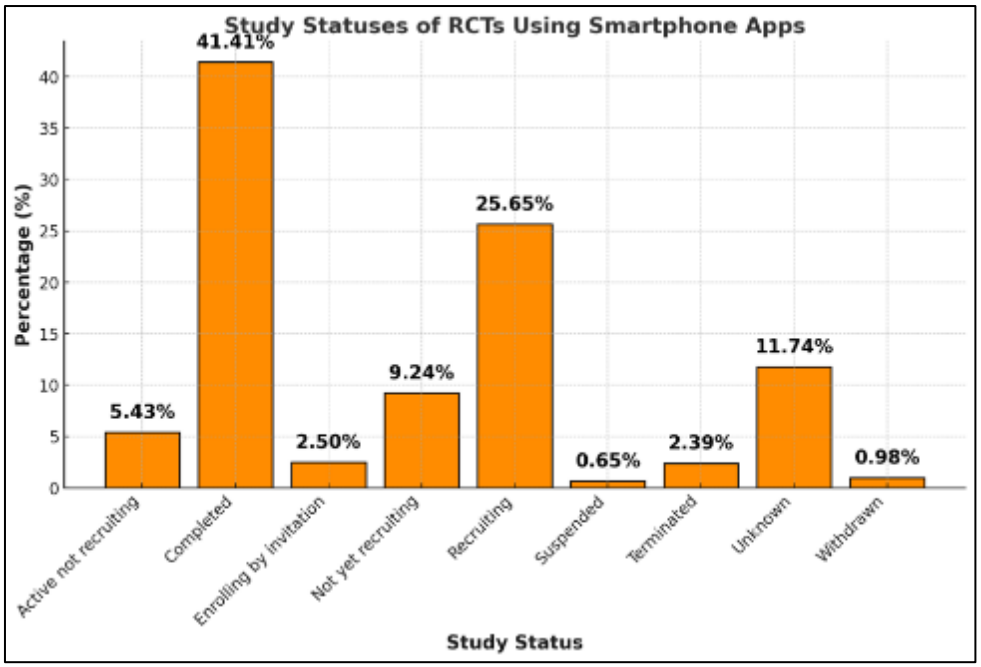


**Figure 1** Statuses of RCT's posted on clinicaltrials.gov database using smartphone apps

### 3.3. Locations of clinical trials using smartphone apps

In this study, the United States leads significantly, accounting for 40.65% of these trials, indicating a strong adoption of digital health technologies in clinical research. Other regions with notable contributions include the rest of Asia (14.02%) and the rest of Europe (13.04%), showing substantial engagement outside North America. Canada (5.87%) and the UK (5.65%) also exhibit moderate participation. In contrast, regions like Africa (1.52%), South America (1.63%), and Japan (0.33%) have lower representation, suggesting potential barriers to digital health adoption in clinical trials.

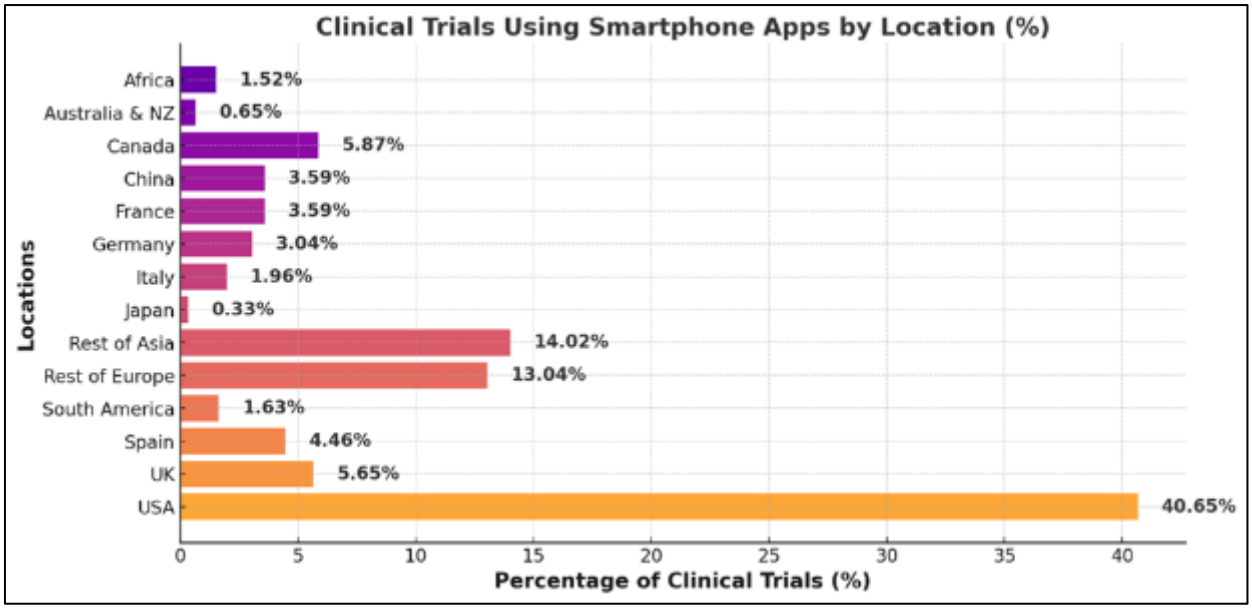


**Figure 2** Locations of clinical trials using smartphone apps

### 3.4. Treatments, interventions or action that is the focus of a clinical study

Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include non-invasive approaches such as diet and exercise (Figure 3).

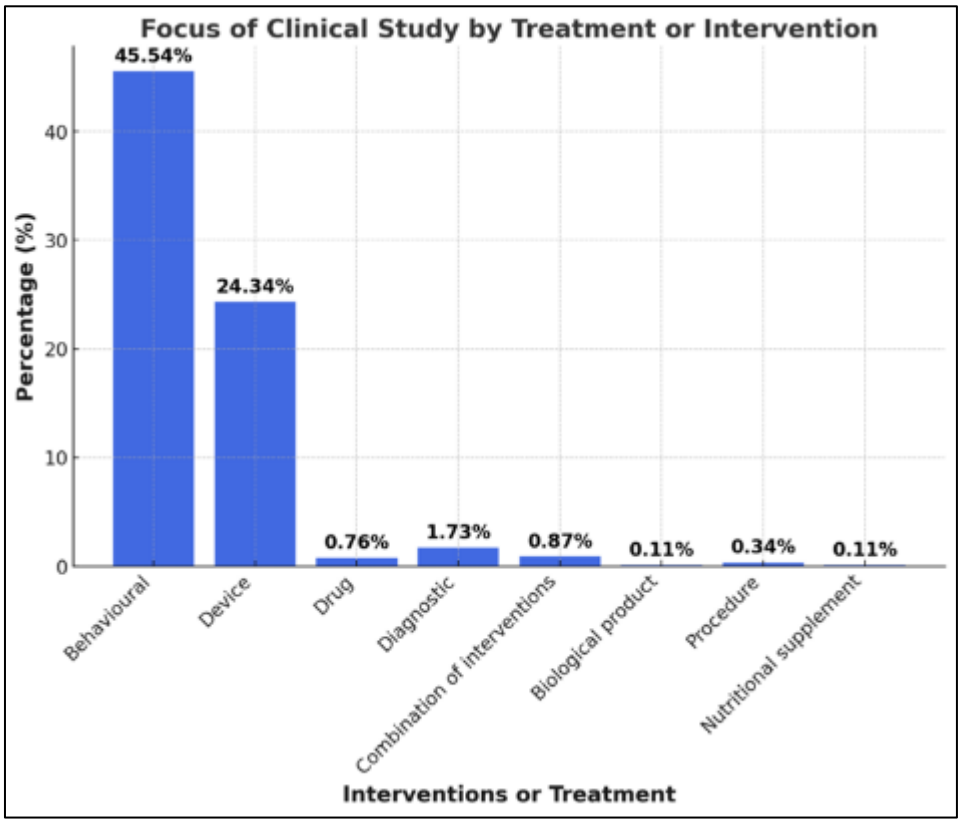


**Figure 3** Treatments, interventions or action that is the focus of a clinical study

### 3.5. Disease, disorder, syndrome, illness, or injury that is being studied

Table 2 presents data on the various diseases, disorders, syndromes, illnesses, or injuries being studied, categorized by condition and their respective frequencies and percentages. Among the 920 cases analyzed, oncology conditions were the most studied, accounting for 76 cases (8.26%), followed closely by mental health disorders at 72 cases (7.83%) and substance abuse at 63 cases (6.85%). Cardiovascular diseases (5.98%) and diabetes (5.87%) were also significant areas of focus. Depression (5.65%) and pain management (3.91%) were notable concerns, while infectious diseases such as HIV/AIDS (3.48%) and COVID-19 (1.41%) were also included. Other conditions, collectively making up the largest category, represented 40.65% of the total cases, indicating a broad range of additional health concerns beyond those explicitly listed.

**Table 2** Disease, disorder, syndrome, illness, or injury that is being studied

| Conditions | Number | % |
|---|---|---|
| Oncology | 76 | 8.26 |
| Mental health disorders | 72 | 7.83 |
| Substance abuse | 63 | 6.85 |
| Cardiovascular | 55 | 5.98 |
| Diabetes | 54 | 5.87 |
| Depression | 52 | 5.65 |
| Pain management | 36 | 3.91 |
| HIV/AIDS | 32 | 3.48 |
| Adherence to therapy | 27 | 2.93 |
| Weight loss/Obesity | 24 | 2.61 |
| Other Infectious disease | 17 | 1.85 |
| Anxiety | 15 | 1.63 |
| Covid - 19 | 13 | 1.41 |
| Kidney disease | 10 | 1.09 |
| Other condition | 374 | 40.65 |

### 3.6. App characteristics deduced from attached study documents

The bar chart illustrates the distribution of app characteristics based on study documents, comparing the presence ("Yes") and absence ("No") of specific features. The majority of studies (81.91%) provided the app name, while 18.09% did not. Similarly, 71.28% included a detailed app description, whereas 28.72% lacked this information. Regarding data assessment, 53.19% of studies enabled remote data assessment, but 46.81% did not. The lowest inclusion rate was seen in data verification, where only 36.17% provided evidence of data verification, while 63.83% lacked it.

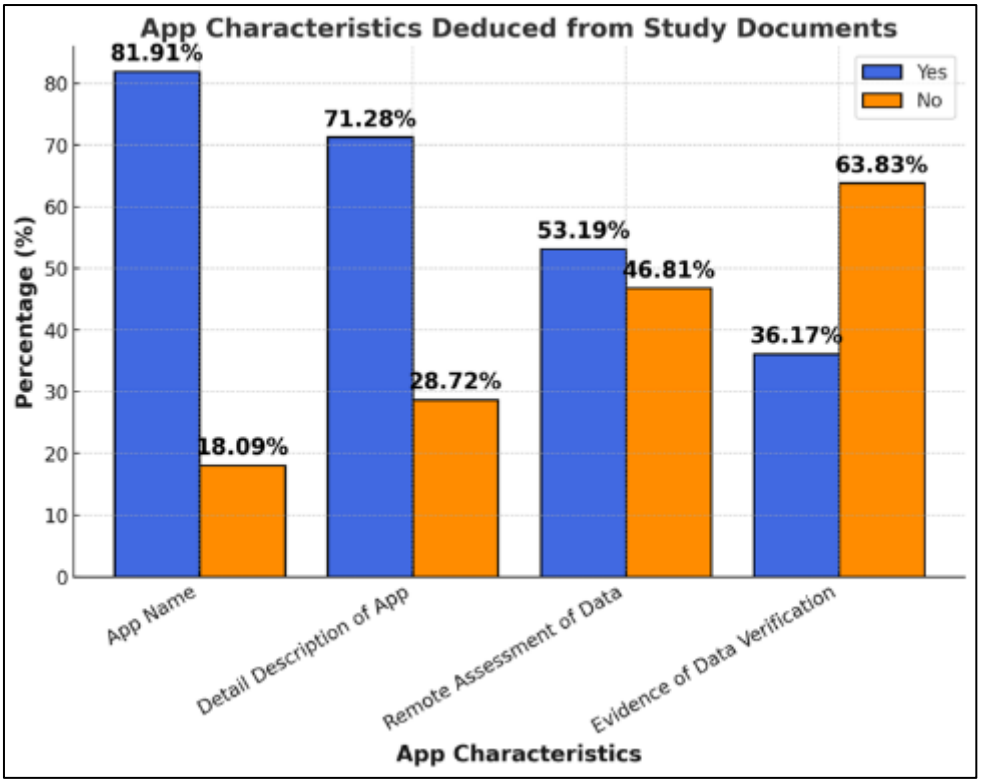


**Figure 4** App characteristics deduced from attached study documents

## 4. Discussion

The findings from this study highlight the increasing adoption of smartphone applications in randomized controlled clinical trials (RCTs), particularly in data collection and health interventions. The cumulative growth in the number of trials from 2018 to 2022 suggests a rising trend in integrating digital health solutions within clinical research. This aligns with prior studies indicating that mobile health (mHealth) technologies have gained significant traction in healthcare research due to their accessibility, ease of use, and ability to facilitate remote data collection (Zhao et al., 2020; Klasnja & Pratt, 2018).

The increase in smartphone app-based trials from 138 in 2018 to 256 in 2022, as shown in Table 1, underscores a growing reliance on digital health interventions. This trend is consistent with findings by Steinhubl et al. (2019), who reported that mobile technology adoption in clinical trials has been accelerating, driven by advancements in wearable technology, cloud-based platforms, and real-time data monitoring. Similarly, a review by Free et al. (2013) indicated that mHealth interventions could improve patient compliance and engagement, which may explain the increasing incorporation of smartphone apps in RCTs.

Despite this upward trajectory, challenges such as regulatory concerns, data privacy issues, and variability in smartphone accessibility persist, which may influence the adoption rates in different regions (Manta et al., 2021). The status of trials, as presented in Figure 1, further reflects these challenges. While 41.41% of trials have been completed, a substantial proportion (25.65%) remain in the recruiting phase, and 11.74% have an "Unknown" status. Previous studies have also noted delays in trial completion due to technical limitations, participant retention challenges, and ethical concerns related to digital interventions (Chan et al., 2015).

The geographical distribution of trials, as depicted in Figure 2, highlights significant disparities in smartphone app adoption across different regions. The United States leads with 40.65% of all trials, which aligns with research by Byambasuren et al. (2018), who found that the U.S. has the most mHealth-based clinical trials due to a well-established digital health infrastructure and supportive regulatory policies. In contrast, regions such as Africa (1.52%) and Japan (0.33%) demonstrate lower adoption rates, likely due to limited digital health infrastructure, regulatory constraints, and lower smartphone penetration in some countries (Bastawrous & Armstrong, 2013).

Notably, the rest of Asia (14.02%) and Europe (13.04%) show substantial contributions, reflecting ongoing efforts in these regions to integrate digital health in research (Dorsey et al., 2020). These findings suggest that while smartphone app-based clinical trials are expanding globally, disparities remain, influenced by economic, regulatory, and technological factors.

The scope of interventions in smartphone app-based clinical trials, as illustrated in Figure 3, extends beyond traditional pharmaceutical treatments to include lifestyle modifications, behavioral interventions, and digital therapeutics. This aligns with research by Linardon et al. (2019), which demonstrated the effectiveness of mobile-based interventions in mental health treatment and chronic disease management.

Table 2 provides insights into the specific disease areas targeted in these trials. Oncology (8.26%), mental health disorders (7.83%), and substance abuse (6.85%) are the most frequently studied conditions. This finding is consistent with previous research indicating that mHealth interventions have been particularly effective in oncology for symptom management and remote monitoring (Lu et al., 2020). Similarly, mobile-based interventions have shown promise in mental health treatment, with studies highlighting their role in cognitive behavioral therapy (CBT) and substance abuse management (Firth et al., 2017).

However, the relatively low representation of infectious diseases such as COVID-19 (1.41%) and HIV/AIDS (3.48%) suggests that while digital health solutions are being integrated into various health domains, they are not yet the primary tool for managing infectious diseases in clinical research. Previous studies have suggested that regulatory barriers and the need for laboratory-based diagnostics limit the feasibility of mobile-based clinical trials in infectious disease research (Subbian et al., 2022).

The characteristics of apps used in clinical trials, as presented in Figure 4, indicate varying levels of transparency and functionality. While 81.91% of studies provided the app name and 71.28% included a detailed app description, only 36.17% reported evidence of data verification. This lack of verification is a concern, as highlighted by Wen et al. (2021), who emphasized the importance of data integrity and security in mHealth applications. The relatively low rate of remote data assessment (53.19%) also suggests that many trials still rely on traditional data collection methods, despite the potential benefits of real-time remote monitoring.

These findings highlight the need for standardized reporting practices and greater emphasis on data validation in smartphone-based clinical trials. Ensuring data quality and regulatory compliance will be critical in enhancing the credibility and effectiveness of mHealth interventions in clinical research.

## 5. Conclusion

This study provides valuable insights into the adoption of smartphone applications in clinical trials, highlighting key trends in study statuses, geographic distribution, targeted medical conditions, and app characteristics. The findings reveal a growing utilization of smartphone apps in clinical trial data collection, with a significant increase in trials over the years. The United States leads in the adoption of digital health technologies, while other regions, such as Africa and South America, show relatively lower participation, indicating potential barriers such as technological infrastructure, regulatory challenges, and resource limitations.

In terms of study statuses, the majority of trials have been completed, while a substantial proportion remain in active recruitment or are categorized as unknown, which shows the need for greater transparency in clinical trial reporting. Additionally, oncology, mental health disorders, and substance abuse emerged as the most studied conditions, reflecting global healthcare priorities. However, the relatively low presence of infectious diseases, including COVID-19, in smartphone-app-supported trials suggests an area for future exploration, particularly in response to emerging health threats.

Furthermore, app characteristics analysis shows that while most trials provide basic app details, critical elements such as data verification remain underreported, raising concerns about data reliability and validation. These findings align with previous studies emphasizing the need for standardized reporting and verification mechanisms in digital health interventions. Overall, this study shows the transformative potential of smartphone applications in clinical trials but also highlights gaps in implementation, regulation, and geographic distribution. Future research should focus on addressing these challenges by enhancing data verification processes, improving accessibility in underrepresented regions, and fostering global collaboration to maximize the benefits of digital health technologies in clinical research.

## Compliance with ethical standards

*Disclosure of conflict of interest*

No conflict of interest to be disclosed.

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