Leveraging Consumer-Grade Wearables in Clinical Trials: Insights from Digital Primary Endpoints

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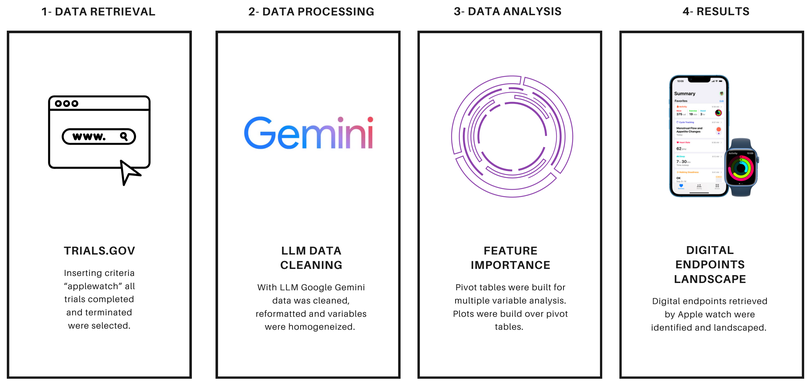

Figure 1. Schematic representation of the automated report generation process. *The Python-developed Guiding Multiple Choice and Field Completing System (MCFCS) is depicted, showing a segment of the generated report (*).*

01. Introduction

The landscape of clinical research is continually evolving, with a growing emphasis on leveraging digital technologies to enhance efficiency and data quality. Among these innovations, wearable devices, particularly smartwatches like the Apple Watch, have emerged as promising tools for continuous and remote patient monitoring (1,2). This study delves into the current application of smartwatches in clinical trials, specifically focusing on their role in capturing digital primary endpoints across a spectrum of therapeutic areas. By examining a comprehensive dataset of completed and terminated trials utilizing these devices, this research aims to illuminate the current trends, identify key application areas, and discuss the potential and challenges associated with their wider adoption in clinical research.

02. Objective

This study evaluates the application of smartwatches, particularly the Apple Watch, in clinical trials for collecting digital primary endpoints, focusing on their potential to streamline trial processes across therapeutic areas.

References

1. Buendia, Ruben, et al. "Wearable sensors to monitor physical activity in heart failure clinical trials: State-of-the-art review." Journal of Cardiac Failure (2024).
2. Miyakoshi, Takashi, and Yoichi M. Ito. "Assessing the current utilization status of wearable devices in clinical research." Clinical Trials 21.4 (2024): 470-482.

03. Methods

A dataset comprising 87 studies was extracted from ClinicalTrials.gov, focusing exclusively on trials marked as completed or terminated. The Google Gemini language model facilitated data cleaning and variable homogenization to ensure data consistency. Subsequent analysis explored key characteristics, including therapeutic focus, endpoint types, geographic distribution, and study design. Following this initial analysis, automatic pivot tables were generated to visualize trends involving multiple variables. Finally, plots were directly created from these pivot tables to highlight prominent patterns within the data.

04. Results

Among the 87 studies analyzed, a high completion rate was observed, with 81 studies (93.1%) successfully finalized, while 6 (6.9%) were terminated prematurely. Cardiology emerged as the most represented therapeutic area, accounting for 25 studies (28.7%), followed by neurology with 19 studies (21.8%) and oncology with 10 (11.5%). The primary endpoints varied across disciplines, including ECG alterations (18.4% of studies), heart rate variability (12%), and oxygen saturation levels (10%). In emerging fields such as mental health and oncology, secondary endpoints like mood registration (5.7%) and sleep pattern analysis (3.4%) were also documented.

Interventional study designs dominated the research landscape, comprising 64% of trials, whereas observational studies were less common. Recruitment rates were notably high, surpassing 80% in the majority of cases. Geographically, North America led in trial execution (55%), with Europe following at 30%.

Finally, validation studies underscored the reliability of wearable devices, demonstrating strong diagnostic accuracy necessary for regulatory approval processes.

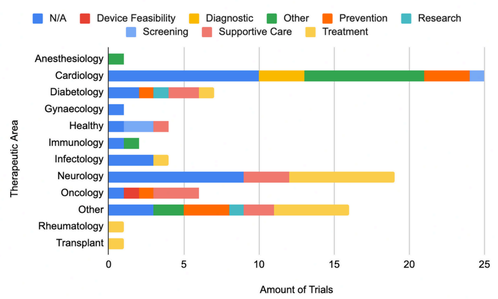

Figure 2. Distribution of Trials Utilizing Apple Smartwatch Technology by Therapeutic Area and Primary Endpoint Category. *This stacked bar chart illustrates the distribution of 87 trials that employed Apple smartwatch technology for collecting digital primary endpoints. The therapeutic areas are listed on the vertical axis, and the horizontal axis represents the number of trials. Each bar is segmented by the primary endpoint category, as indicated by the color-coded legend.*

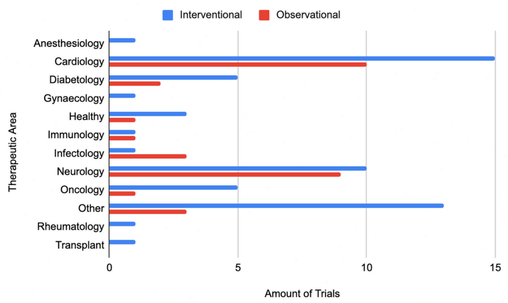

Figure 3. Study Design of Smartwatch-Based Clinical Trials Across Therapeutic Areas. *This grouped bar chart displays the distribution of interventional and observational study designs within the 87 Apple smartwatch-based clinical trials analyzed. The therapeutic areas are listed on the vertical axis, and the horizontal axis represents the number of trials. For each therapeutic area, two bars are shown: one blue bar representing the number of interventional trials and one red bar representing the number of observational trials.*

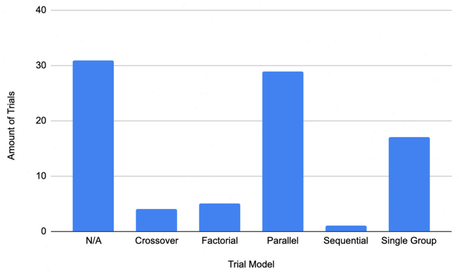

Figure 4. Distribution of Trial Models in Apple Smartwatch-Based Clinical Studies. *This bar chart illustrates the distribution of different trial models utilized within the analyzed set of 87 Apple smartwatch-based clinical studies. The horizontal axis displays the various trial models while the vertical axis represents the number of trials employing each model.*

05. Conclusion

The increasing adoption of wearables in clinical trials highlights their potential to enhance patient engagement, reduce costs, and improve scalability. However, challenges such as technical reliability and adherence must be addressed. Further research should explore their integration into value-based healthcare and global trial frameworks.

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