White Paper for non-Drug Clinical Trial

Capturing the Real-World Experience: Leveraging mHealth for Patient-Generated Health Data (PGHD) in Non-Drug Clinical Trials

JANUARY 2025

JOURNAL my HEALTH

1.Introduction

The Rise of Non-Drug Trials and the PGHD Challenge

The landscape of clinical research is undergoing a significant shift. The non-drug trial market is experiencing substantial growth, exceeding $22 billion in the US alone. These trials are crucial in evaluating the effectiveness of behavioral interventions, rehabilitation programs, and digital health solutions. However, a critical hurdle exists in capturing real-time patient experiences, a vital component of non-drug research.

This white paper explores the challenges of collecting Patient-Generated Health Data (PGHD) in non-drug trials and proposes a solution leveraging mobile health (mHealth) technologies. By capturing rich and comprehensive PGHD data, we can unlock the full potential of non-drug interventions, ultimately leading to more effective healthcare solutions

2.

Limitations of Traditional PGHD Collection Methods

Researchers primarily rely on paper journals, surveys, and retrospective recall for PGHD collection in non-drug trials. These methods suffer from several limitations:

- Incompleteness: Patients often struggle to keep detailed records in paper journals or accurately recall experiences over time.
- Inaccuracy: Retrospective recall is prone to bias, as patients may forget or misremember details, impacting data reliability.
- Limited Insights: Traditional methods capture data at specific points, failing to capture the nuances of the ongoing patient experience.

These limitations significantly hamper the quality and generalizability of data collected in non-drug trials. Only complete and accurate data can lead to correct conclusions about the effectiveness of interventions, hindering progress in developing better non-drug healthcare solutions.

3.

The Impact on Data Quality and Generalizability

The limitations of traditional PGHD collection methods directly impact the quality and generalizability of data obtained in non-drug trials. Incomplete and inaccurate data sets lead to:

- Unreliable Results: Research findings based on flawed data may need to accurately represent the intervention's effectiveness.
- Limited Generalizability: Results may not apply to broader patient populations due to skewed data sets.
- Inefficient Development: Researchers may need help identifying trends and optimizing interventions based on unreliable data.

Ultimately, these issues can hinder the development and adopting of potentially life-changing non-drug healthcare solutions.

4.

Leveraging mHealth for Enhanced PGHD Collection

Mobile health (mHealth) technologies offer a powerful solution to overcome the challenges of traditional PGHD collection methods. By leveraging mHealth apps and wearables, researchers can capture real-time, comprehensive, and accurate patient data in non-drug trials.

Key Features of mHealth Solutions:

- Automated Data Capture: Wearables can automatically collect data on vital signs, activity levels, and sleep patterns, reducing reliance on patient recall.
- Real-Time Reporting: Patients can use apps to record experiences and symptoms as they occur, fostering more accurate data.
- Reminders and Gamification: mHealth solutions can prompt patients to record data consistently and include gamification elements to improve engagement.

These features can significantly improve data completeness, minimize recall bias, and give researchers a richer understanding of the ongoing patient experience.

5.

Addressing Data Security and Privacy Concerns

The security and privacy of patient data are paramount. mHealth apps and wearables employed for PGHD collection must comply with all relevant data privacy regulations. Here are crucial considerations:

- Data Encryption: All communication between devices and servers must be encrypted to safeguard sensitive information.
- Informed Consent: Patients must be fully informed about how their data will be used and can withdraw their consent at any time.
- Data Storage and Access Controls: Patient data should be stored securely on platforms with robust access controls to prevent unauthorized access.

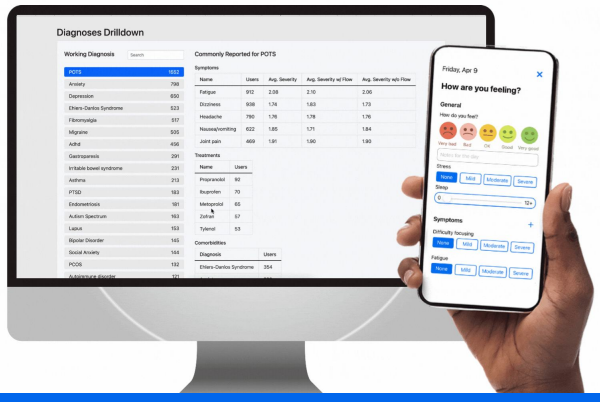
By prioritizing data security and privacy, researchers can build trust with patients and ensure the ethical conduct of non-drug trials leveraging mHealth technologies.

Conclusion

Unlocking the Full Potential of Non-Drug Interventions

The growing non-drug trial market presents a tremendous opportunity to improve healthcare outcomes. However, capturing real-time and accurate PGHD remains a critical challenge. mHealth solutions with features like automated data capture, real-time reporting, and reminders offer a promising path forward. By leveraging mHealth and prioritizing data security, we can collect high-quality PGHD data, leading to more effective non-drug interventions and improved patient care.

JOURNAL my HEALTH



Moving Forward:

This white paper has explored the challenges and opportunities of PGHD collection in non-drug trials. Continuous development and innovation in mHealth technologies hold immense potential for revolutionizing data collection methods. By embracing these advancements and prioritizing data security, researchers