ePROmetric

A mobile application for patient driven drug development

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Introduction

- Many healthcare organizations consistently measure
  - Mortality rates
  - Readmissions
  - Lab values

- Issues impacting patients’ quality of life often overlooked

- Need to prioritize patient-reported outcomes → clinical decision support tool

- Digital health interventions
FDA Research Priority Areas

- Develop methods and tools to streamline clinical and postmarket evaluation of FDA-regulated products
  - Scientifically valid approaches to incorporating **patient input** (e.g., patient preference, patient reported outcomes) into regulatory decision-making
  - Approaches to leveraging complex data to inform regulatory decision-making, including use of **real world data** sources and mobile technologies
ePROmetric

- Proactive patient health monitoring app
- Wearable tech-enabled
- Patient interface relays data to physicians
  - Efficient vitals and symptoms collection
  - Predictive analytics for personalization
  - Secure transmission
Wearable Technology
Product Overview

- Mini Form
- Scale: On a scale of 1 to 10, what is your mood?
  - Mood: 8.725
- Basic Information:
  - Blood Type: O Negative
  - Date of Birth: 01/01/2000
  - Weight: 70 kg
- Do you have a headache?
  - Yes

Selection Survey:
- How did you feel last night?
- Which symptoms do you have?
  - Cough
  - Fever
  - Headaches
  - None of the above
Enrollment and Consent
Predictive Analytics

- Anticipating and reducing risk based on current and historical patient data
- TF-IDF (term frequency -inverse document frequency)
  - finding patients’ similarity in observational studies
  - discovering disease correlations
  - finding sequential patterns in databases
## Competitors

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<th></th>
<th>Collect vitals and symptoms</th>
<th>Predictive analytics</th>
<th>Wearable tech enabled</th>
<th>Secure data transmission to FDA</th>
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Summary

- Secure and complex patient symptoms ➔ real-world data
- Standardized mobile application for clinical trials
- Integrates physical, mental, and emotional symptoms
- Comprehensive clinical measure
References

- https://www.fda.gov/media/138258/download
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789421/
- https://clinicaltrials.gov/ct2/show/NCT02917954
THANK YOU!
QUESTIONS?

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Appendix: Secure Storage Environment