General Wellness Tools for Clinical Trial Monitoring

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Disclosures

• Medical Director at Fossil Group, formerly at Misfit Inc.
• Advisory Boards Membership:
  – Consumer Technology Association
  – National Sleep Foundation
  – Center for Personalized Health Monitoring,
    Umass-Amherst Institute for Applied Life Sciences
  – Sohn Inc.
• New York University School of Medicine Physiatry Faculty
Patient Engagement Through Design

iBGStar®:
First glucometer children saved up their allowance to buy.
DEFINITION:

(1) Devices Intended to Promote a Healthy Lifestyle
   • Helps maintain or encourage a general state of health or a healthy activity;
   • Relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

(2) Pose a Low risk to User and Others
   • Invasive or implanted?
   • Involve an intervention or technology that may pose a risk to the safety of users and others if specific regulatory controls are not applied, e.g. lasers or radiation exposure?

General Wellness Tools (GWT)
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- Steps
- Calories
- Active Minutes
- Sleep
- Pulse
Traditional Methods in Clinical Trials

- **Surveys**
- **Direct Observation**
- **Research Monitors**
General Wellness Tools (GWT)

STRENGTHS

• Objective Data
• Continuous Real-Time Monitoring
• User Friendly Design
• Patient Engagement
• Seamless Data Integration
• Affordable
Tools for Data Integration
~300 Clinical Studies, including ~100 Validation Studies

GWT Function:
- Intervention Itself
- Measure Primary Outcomes
- Examine Confounders
- Evaluate Side Effects
- Engagement Tool/Accessory
• Misfit Shine is being used by physicians at the University of Pennsylvania to deliver a home-based cardiac rehab program.

• Randomized controlled trial for patients recovering from an acute myocardial infarction (heart attack).

• Researchers are using Misfit’s API integration to allow them to access data on their participants in an automated fashion.
Early Indication of Treatment Effects

Steps per day

Days

Next check-up
Better Understanding of Treatment Effect

![Graph showing weight changes over days with check-ups at 0 and 30 days.](image)
Endpoints that Matter for Value-Based Care

Cost

Meaningful Health Outcomes
Endpoints that Matter for Value-Based Care

Meaningful Health Outcomes are Functional Outcomes related to Activity, Lifestyle, Habits, Quality of Life that Wearables and other wellness tools uniquely provide.
CHALLENGES

- Validation/ Standardization
- Data Privacy/ Security
- Firmware and Software Updates
- Confounding Effects
- Adherence
Retention of Wearable Devices

Figure 2: Mean number of daily steps and percentage of Fitbit Zip wear, by study group.

Percentage of Fitbit wear indicates the percentage of participants who wore the Fitbit for at least 1 day in that week. Any day during which a participant logged 500 or more steps on the Fitbit was regarded as a valid day and constituted wearing the tracker for that day. The control group is not included in these graphs because control group participants did not receive the Fitbit activity tracker.

Improving Adherence:
Evolution of Wearables

1.0 TO 2.0

→ MORE FASHIONABLE

→ MORE FUNCTIONAL
Improving Adherence: Evolution of Wearables

ACTIVITY

SENSING

MEDICAL

SMARTWATCH

SAFETY

IDENTIFICATION

CONTROLS

WEARABLES 1.0

WEARABLES 2.0
Improving Adherence: Evolution of Wearables

**Activity Monitoring**
- Track Steps, Distance, and Calories
- Tag Different Activities
- Tap for LED Progress Display
- Automatically Monitor Sleep

**Vibration Notifications**
- Incoming Call and Text Alerts
- Smart Alarms
- Movement Reminders

**Smart Button IoT Integrations**
- Find Your Phone
- Take a Selfie
- Play and Pause Music
- Connect to Misfit Bolt
- Create Endless IFTTT Actions
Evolution of Wearables and the IoT
Evolution of Wearables: Incorporation into Our Lifestyles
Thank You

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