U.S. FOOD & DRUG ADMINISTRATION

Regulatory Considerations Psychiatric Devices

Clinical Design Considerations

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Disclosures None

Patients are at the Heart of What We Do

CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Developing a Psychiatric Device: Clinical Study Design Factors to Consider

- Type of Psychiatric disorder treated
  - Major Depressive Disorder (MDD)
  - Obsessive-compulsive Disorder (OCD)
  - Tourette Syndrome
  - Substance Use Disorder (SUDs)
  - Post-traumatic stress Disorder (PTSD)
- Adjunctive vs standalone treatment
- How will it be studied – i.e. randomized, blinded, control

Developing a Psychiatric Device: Clinical Study Design Factors to Consider

- Risk-Benefit Analysis
  - Other options
  - Medication issues
  - Risk analysis
  - Benefit assessment
  - Uncertainty
- Target Population
  - Age: Pediatric population/Adult population
  - Treatment resistant population
  - DSM-5 TR diagnosis
- Data leverage
  - Pivotal trial
  - Marketing submission

Developing a Psychiatric Device: Clinical Study Design Factors to Consider

- Safety
  - Parameters, adverse events, long-term plans
- Effectiveness
  - Pre-determined, Alignment with the indication for use
  - Time frames
  - Statistical Analysis Plan
  - Validation
- Monitoring
  - Assessment, informed consent forms, Case report forms
  - DSMBs/SMCs
  - Safety monitoring boundaries (aka stopping rules)
- Sample size
  - Safety outcomes
  - Effectiveness outcomes

Outcome measure selection

- Should highlight patient's ability to function fully in life
- Demonstration of how a patient feels, functions or survives
- Domains of physical function, occupational function, social and family function, cognitive, and emotional function
- Less potential for bias if verifiable
- DHTs could potentially be used to support this goal

Clinical Scale Challenges

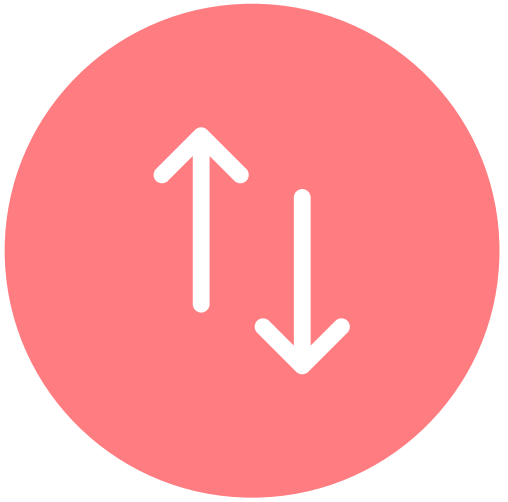
- Diagnose/Severity
- Signs and symptoms
- Don’t measure treatment effect

When using data from a DHT to inform an endpoint, treat the endpoint like you would any other endpoint

Definition

Justification

Type
(Safety, Effectiveness)



Positioning
(Primary, Secondary, etc.)

DHTs can Offer Many Unique Benefits When Used in a Clinical Investigation

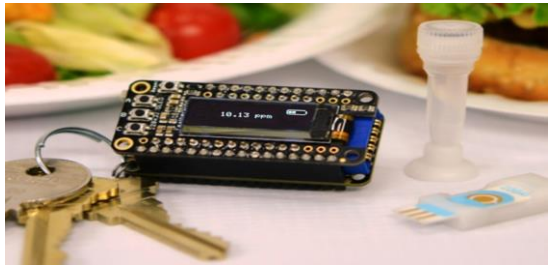
- Decentralized clinical investigations
- Improved participant recruitment and retention of participants
- Continuous or more frequent data collection compared to traditional methods
- Longitudinal monitoring of a patient's health status without requiring visits to study sites
- Improved study accessibility for participants
- Capture of real-world data (RWD) and patient-generated health data (PGHD)
- Transmit data directly from participant to study staff
- Potential to inform novel endpoints

Patient-Generated Health Data:
Harnessing Real World Evidence (RWE)

Real World Data (RWD) → RWE

- RWD – Patient health status, delivery of health care
- Insights – performance and clinical outcomes
- Examples: data from EHRs, claims/billing, product/disease registries, home-use settings, mobile devices
- See Guidance Document



Takeaways

There are key study design factors we consider when reviewing devices

Outcome measures should highlight a patient's functionality

DHT-derived data could be used in various ways

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Pathways Program at FDA

Further Questions or Feedback

www.fda.gov/medical-devices

For general questions about medical devices regulation, contact the Division of Industry and Consumer Education
dice@fda.hhs.gov

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