

Digital Tools for Postregistration Surveillance: What Matters to Clinicians?

The Role Of Digital Health Technologies in Drug Development
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Important Clinical Factors



- Effectiveness
- Tolerability
- Adherence

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Important Clinical Factors: Effectiveness



Questions:

- Does this drug work in “my” population?
 - Older, sicker, more diverse, comorbidities

- Is this drug better than current standard of care?
 - True comparative effectiveness

Important Clinical Factors: Effectiveness



Opportunities for Digital tools

- Endpoint monitoring
 - Activity tracking
 - Physiologic measurements (HR, BP, pulse ox, etc.)
 - Remote monitoring (ex: blood glucose)
- Survey (symptom improvement, quality of life, etc.)
 - App, SMS, voice
- Example: New intervention for arthritis
 - Use combination of activity tracker plus voice-administered SF 12 (QOL survey)

Important Clinical Factors



- Effectiveness
- **Tolerability**
- Adherence

Important Clinical Factors: Tolerability



Questions:

- Are there difficult to manage or previously understated toxicities?
 - Are toxicities more pronounced in special populations?
- Are side effects impairing quality of life?
 - Should the risk/benefit ratio be reconsidered?
 - Are the incremental gains over standard of care worth managing the new side effect profile?

Important Clinical Factors: Tolerability



Opportunities for Digital tools

- Survey (side effects, quality of life)
 - App, SMS, voice
- Side effect endpoints
 - Activity tracking
 - Physiologic measurements (HR, BP, etc.)
 - Remote monitoring (blood glucose)
- Example: Neuro effects of immunotherapy
 - Delirium screen leveraging voice/survey
 - Gamification-> mobile/online

Important Clinical Factors



- Effectiveness
- Tolerability
- **Adherence**

Important Clinical Factors: Adherence



Questions:

- Are patients able to adhere to the prescribed regimen consistently and on schedule?
 - Does this differ by special population?
- Can digital tools improve adherence?
 - Was this tested in the original drug development process?

Important Clinical Factors: Adherence



Opportunities for Digital tools

- Adherence tracking
 - Wearables, connected med dispensers
- Reminders and digital engagement
 - Apps and wearables
 - Gamification
- Example: Adherence for high risk medications
 - “Digital pill” with adherence monitoring plus digital reminders plus gamification