

Digital Health Technologies: A New FDA Regulatory Paradigm

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Panel

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Moderated by Kim Tyrrell-Knott, Member, Epstein Becker Green

Digital Therapeutics

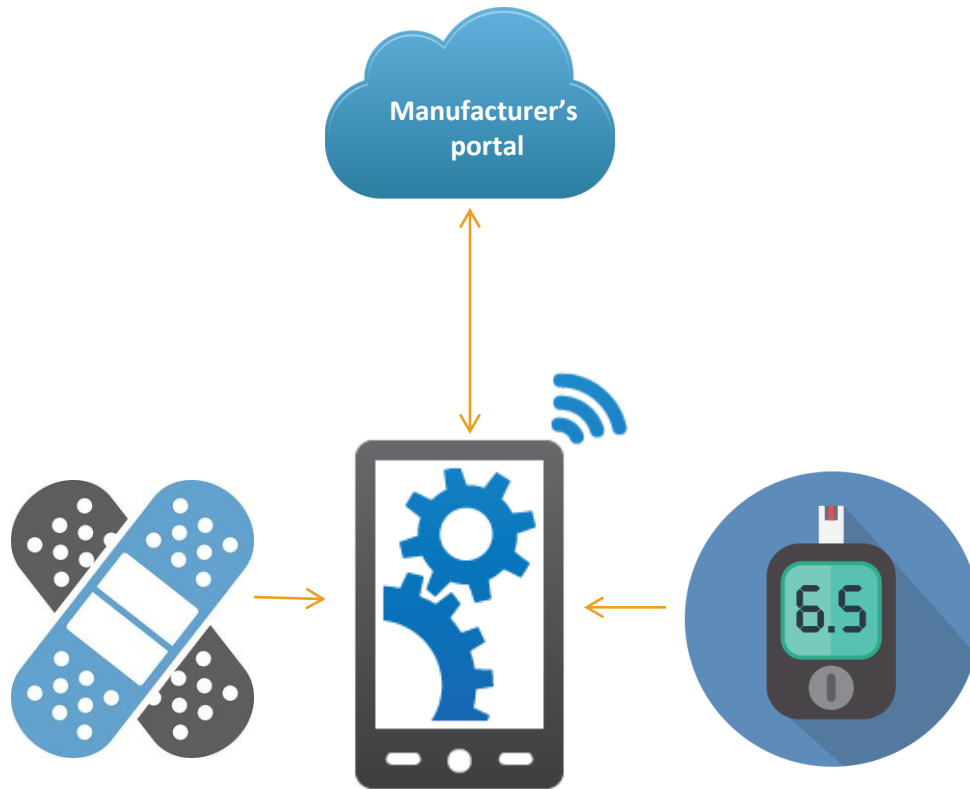
Case Study



- Digitizing behavioral and lifestyle medicine
- Engages and educates users on behavioral and lifestyle choices and helps maintain changes
- Enables health and wellbeing of users
- Prevents, arrests and reverses chronic conditions and some cancers
- Treats mental health conditions and substance use disorders through CBT
- Enhanced clinical outcomes weight loss, reduced A1C, reduced BP
- Shown to be more effective than leading drug in RCT
- Coach supported or fully automated

Digitally Enhanced Drug Delivery

Case Study



- Insulin patch that communicates to app and cloud based portal
- Delivery is done manually or programmed via the patch
- App tracks insulin dosages and readings from glucometer; provides medications reminders, and educational content
- Patient can record hypo-/hyper-events in the app and portal
- Improved clinical outcomes with digital enhancement than with drug alone
- Manufactured by...

Virtual Clinical Trial

Asthma Case Study



EPSTEIN
BECKER
GREEN

Questions?