Regulating Reality:

A Guide for Entrepreneurs and Innovators

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Regulating Reality: A Guide for Entrepreneurs & Innovators

- **Introduction**
- **Regulatory Involvement in Digital Therapeutics**
  - FDA's mandate and purpose
  - What about the FTC?
  - Current view of digital therapeutics and XR
  - Application of regulation: treat, cure, or prevent
- **Influence of regulation on product development or business model**
  - Are you in scope?
  - FDA vs FTC
  - Capital and cost implications: do your investors and developers understand?
- **Influence of regulation on product pitch: sellers and buyers**
  - What are you selling? What are you buying?
  - Not all health products are FDA regulated or evaluated
  - Consumer (and buyer) approval are not the same as regulatory approval
  - Financial sponsor of care might or might not value regulatory approval
- **Conclusion and recommendations**

Introduction: definitions and examples

- **Digital Therapeutics**
  - Are evidence-based therapeutic interventions
  - Delivered by high quality software programs
    - prevent, manage, or treat medical disorder or disease
  - Used independently or in concert with medications, devices, or other therapies

- **Best Practices**
  - Design
  - Clinical validation
  - Usability
  - Data security

- **Role of regulatory bodies**
  - Review claims: risk, efficacy, intended us
  - Clear and approve

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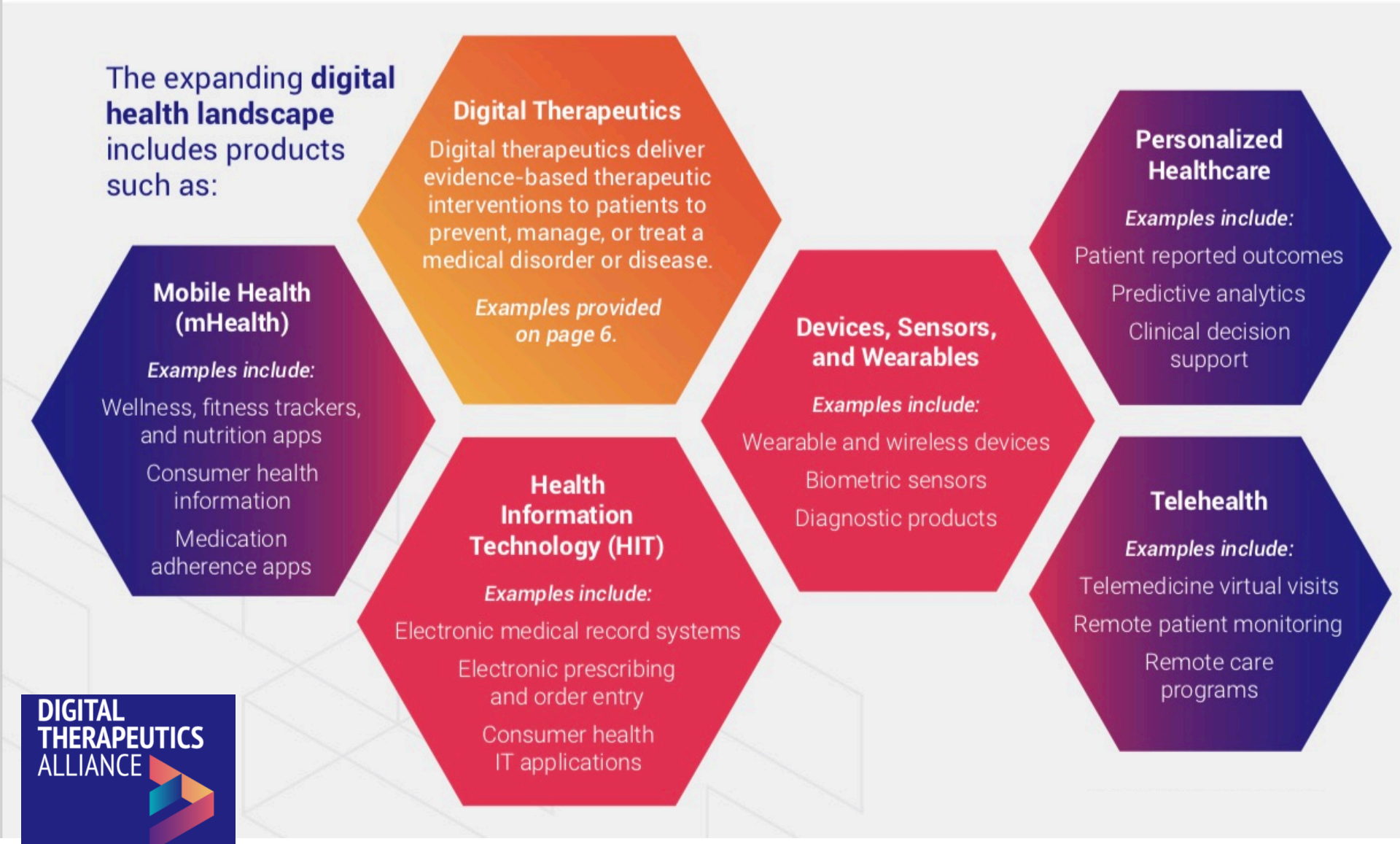

DIGITAL THERAPEUTICS ALLIANCE

www.dtxalliance.org

Source: Digital Therapeutics Alliance DTx Industry Foundations report, October 2018

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Examples of digital therapeutics on the market or under development include:

- Combined software and hardware program to improve asthma and COPD control and optimize healthcare utilization
- Digital therapeutic utilizing adaptive sensory stimulus software for the treatment of ADHD delivered through an engaging video game experience
- Digital therapeutic used as an adjunct to standard, outpatient treatment for Substance Use Disorder (SUD)
- Digital sleep improvement program featuring Cognitive Behavioral Therapy (CBT) techniques
- Digital therapeutic engaging individuals with Type 2 diabetes, hypertension, and obesity, and their providers, to improve self-management and outcomes
- AI-based digital diagnostics and personalized therapeutics for pediatric behavioral healthcare
- Neurologic Music Therapy to address motor, speech, and cognitive dysfunction caused by neurologic disease or injury
- Digital delivery of physical exercises, behavioral therapy, and education for chronic back pain patients
- Personalized digital program to help people prevent the onset of diabetes and other chronic diseases
- Basal insulin dose calculator for adults with Type 2 diabetes
- Intervention tool to train cognition in concussion patients

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FDA: Brief Primer

- **Agency within US Dept Health and Human Services**
  - Focus on public health
- **Original mission was primarily safety**
  - Evolved to effectiveness
- **Five main activities**
  - Review new products (no product development or testing)
  - Conduct surveillance
  - Create standards and regulations
  - Conduct research (to support standards and regulations)
  - Enforce regulations

FDA: Digital Health and Therapeutics

- **Center for Devices and Radiological Health**
  - Digital Health Program
- **Stated goal is to protect and promote public health**
  - Foster collaboration
  - Develop and implement regulatory strategies
  - Support timely patient access to high-quality, safe, and effective medical technology
- **In-scope technology (mobile medical apps)**
  - Diagnose
  - Treat
  - Cure
  - Prevent

FTC: Federal Trade Commission

- **Independent Agency**
  - Consumer protection
- **In-scope technology: mobile health apps that**
  - Collect,
  - Create, or
  - Share consumer information
- **Useful tool:**
  - https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

Federal Food, Drug, and Cosmetic Act (FD&C Act)

The FDA enforces the FD&C Act, which regulates the safety and effectiveness of medical devices, including certain mobile medical apps. The FDA focuses its regulatory oversight on a small subset of health apps that pose a higher risk if they don't work as intended.

Federal Trade Commission Act (FTC Act)

The FTC enforces the FTC Act, which prohibits deceptive or unfair acts or practices in or affecting commerce, including those relating to privacy and data security, and those involving false or misleading claims about apps' safety or performance.

5. Is your app intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease?

YES

Your app is a medical device subject to the **FD&C Act**.

GO TO QUESTION 6 to see if the FDA intends to apply its regulatory oversight for your type of app.

NO

The FD&C Act does not apply. Your app is not considered a medical device and is outside of FDA purview. For examples of mobile apps that are not medical devices, *see* Appendix A of the FDA's Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff [PDF].

GO TO QUESTION 8 to see if the FTC Act applies.

Current regulatory view of extended reality

- **For mobile medical apps, FDA will use same risk-based approach to ensure safety and effectiveness for other medical devices**
  - Meet the definition of a medical device
    - diagnose, cure, mitigate, treat, prevent disease
    - affect the structure or any function of the human body
    - BUT see Software as a Medical Device (SaMD)

- **Virtual reality may be considered "novel digital health"**
  - new, unfamiliar, unseen digital health technology
  - BUT - it depends on the intention - (D, T, C, P)

- **Regulatory review will depend on claims made**
  - Efforts underway to standardize this and guide inventors

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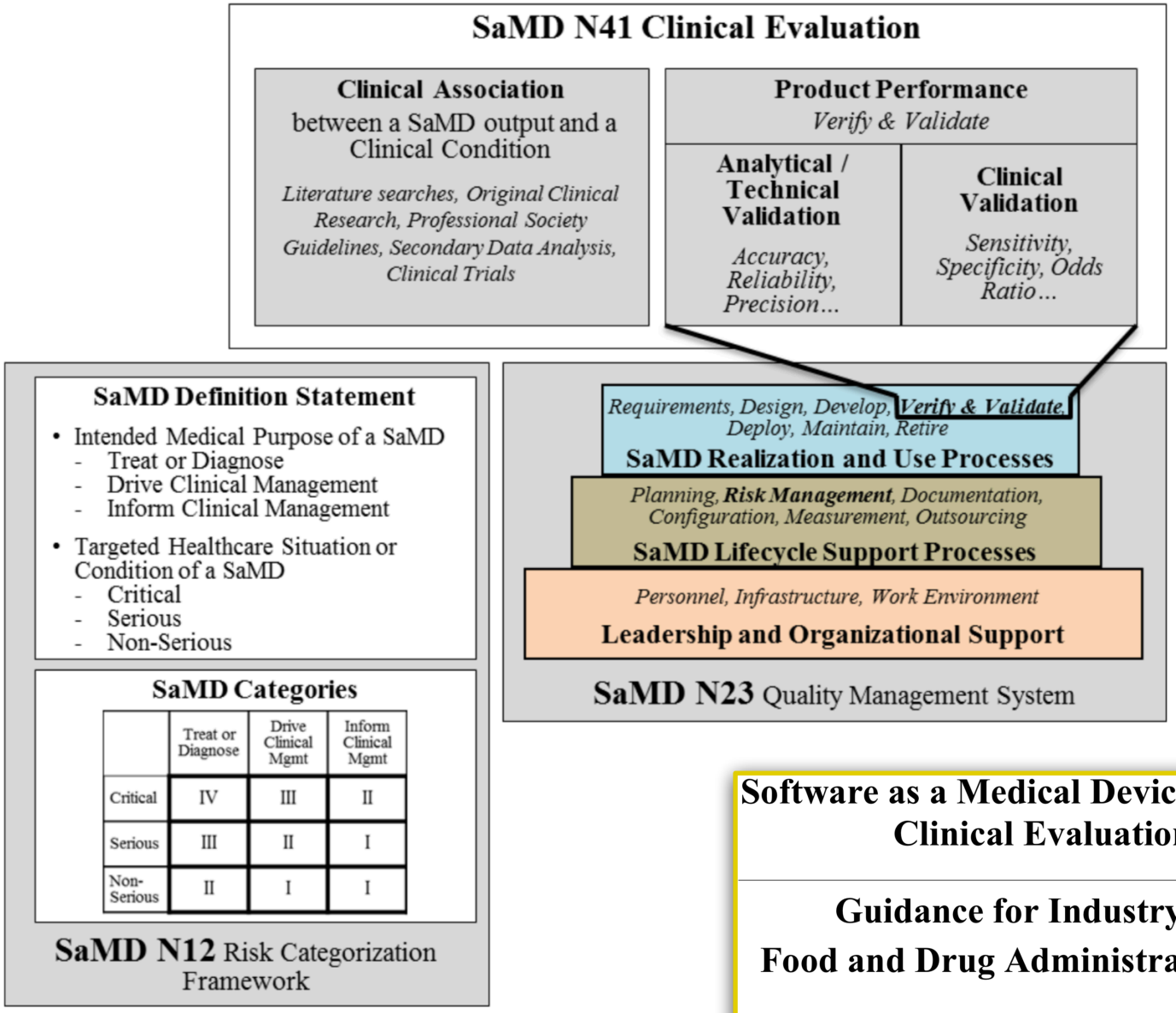


Software as a Medical Device (SAMD): Clinical Evaluation

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 8, 2017.

"Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[5]

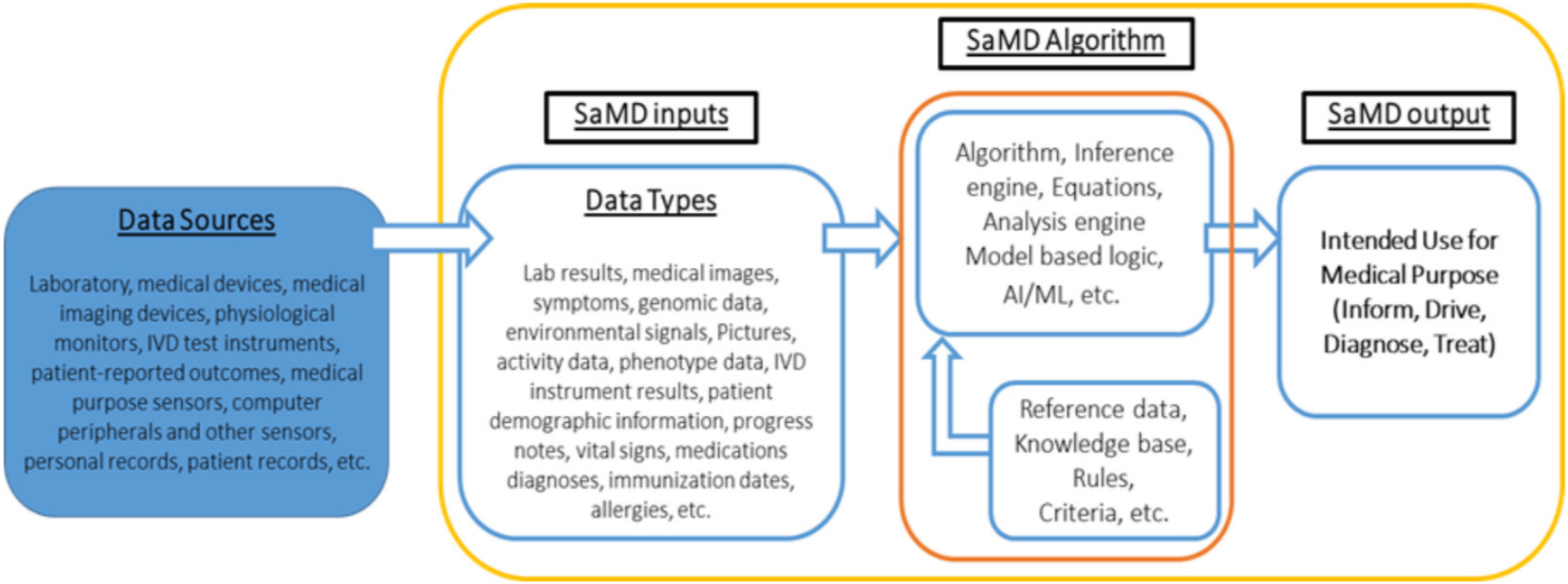


Figure 1. Description of SaMD, including possible data sources from which inputs are derived and that may be used for one or more medical purposes.

[5] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.docx

The sun is shining and the sky is blue

Regulatory Environment Embrace as Competitive Differentiator

- **Guides product development**
  - Building an evidence base
  - Clinical Association
  - Technical Validation
  - Clinical Validation

- **Supports the business model**
  - Differentiate your “digital medicine” from 300,000+ mobile health apps
  - Establish trust with providers, payers, consumers

VS

Reality is much stormier

Risks of Regulatory Embrace

- **Guides product development**
  - Stringent Quality Management Systems requirements
  - Multi-year, multi-million dollar investments
  - Impedes iteration and agility

- **Supports the business model**
  - FDA Registered, Cleared or Approved?
  - FDA approval means reimbursement, right?
  - Meet CMS - The Centers for Medicare & Medicaid Services
  - Ok, but payers just look at CMS benefit approvals and the FDA, right?

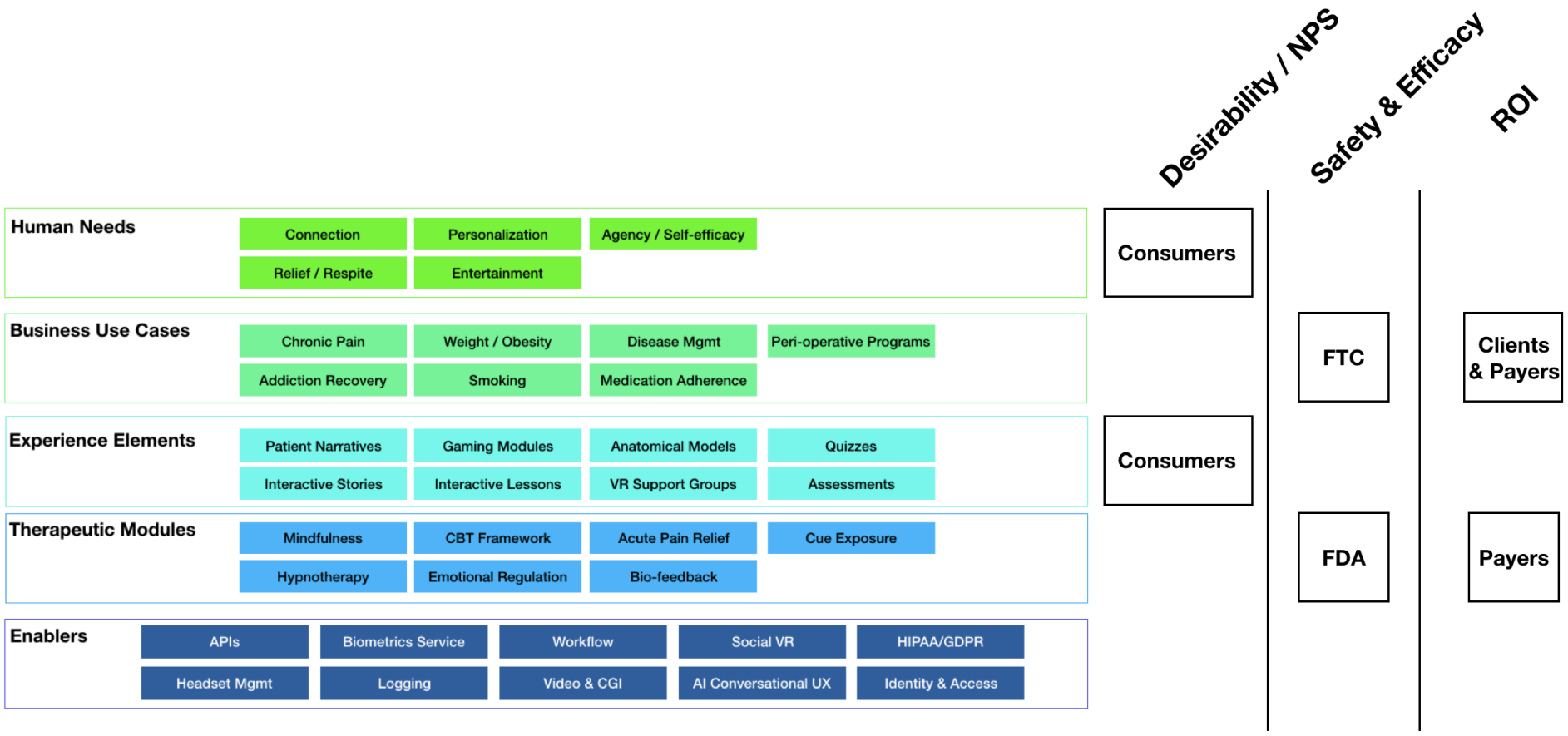
Medicare's Innovation Chief Wants To 'Blow Up' Model For Paying Primary Care Physicians

Adam Boehler wants to introduce a new model that focuses on quality of care. That new model will be the first major test of Boehler's efforts to accelerate the federal government's slow-moving shift to what's known as value-based care.

Source: Kaiser Health News, Feb 26, 2019

One Company's Example Roadmap

Different Measures For Different Stakeholders



Pitching and Catching: Payers

Payer Considerations

- Start small and be attractive
- Create a buzz and use social media to your advantage
- Focus early and often on how to monetize your solution

Payer Considerations (cont.)

- Consider shared savings in your pricing approach
- Tailor your business case for your audience
- Be disciplined and focused

Payer Considerations (cont.)

- Know who your competition is and how you differ
- Always have a demo ready to show

Pitching and Catching: Providers

Provider Considerations

- Provider systems have a different perspective than other sectors
- IT is a cost center and service provider, not a revenue generator or strategic asset
- Tech decision-makers are not the purchasers
- End-users are neither decision-makers nor purchasers

Pitching and Catching: Government

Government Considerations

- In Medicaid, the served population is dynamic, fast moving, and hard to engage
- For Medicaid, identifying and engaging the most complex cases is of high value
- Customer service can differentiate
- For Medicaid, resource and technology constraints are everything

Government Considerations (cont.)

- Focus on showing improved health outcomes
- Demonstrate promotion of independent living including reduced resource utilization (e.g., ER visits)
- Consider non-traditional health-related applications
  - GIS-based monitoring or guidance
  - Housing, transportation, food
  - Social determinants of health

Conclusions and Recommendations

- Prepare for complexity and iterate through it
- Create strong, foundational regulatory and IP strategies
  - Sometimes, that means saying “no” or “not yet”
- Start local with a global problem and solution
- Know who you are talking to
- Solve their problems, not yours
- Know when and how to move on

Contact us

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Questions now…and later