Future value and challenges of treatment with e-connected medicine

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FDA set up digital health innovation action plan

Read our Digital Health Innovation Action Plan

The **Digital Health Innovation Action Plan** outlines our efforts to reimagine the FDA's approach to ensuring all Americans have timely access to high-quality, safe and effective digital health products. As part of this plan, we committed to several key goals, including **increasing the number and expertise of digital health staff** at the FDA, launching the **digital health software precertification pilot program** ("Pre-Cert") and **issuing guidance** to modernize our policies.

Commissioner's Statement: **Advancing new digital health policies to encourage innovation, bring efficiency and modernization to regulation**

The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

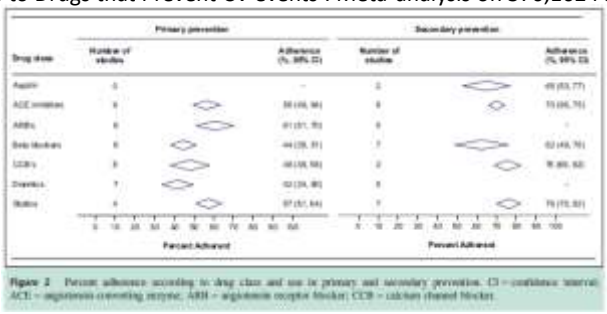
Providers and other stakeholders are using digital health in their efforts to:

- Reduce inefficiencies,
- Improve access,
- Reduce costs,
- Increase quality, and,
- Make medicine more personalized for patients.

https://www.fda.gov/medicaldevices/digitalhealth/

Adherence in prophylaxis use in long term care

Adherence to Drugs that Prevent CV events : Meta-analysis on 376,162 Patients[1)]



- 9% of CV events are caused by poor compliance[2)]
- Improved compliance would significantly reduce mortality in CV patients (up to 35% RRR)[3)]
- Stroke prevention in AF :
  20% improvement compliance →0.7% reduction,
  Improved persistence > 18 month→ 0.9% reduction

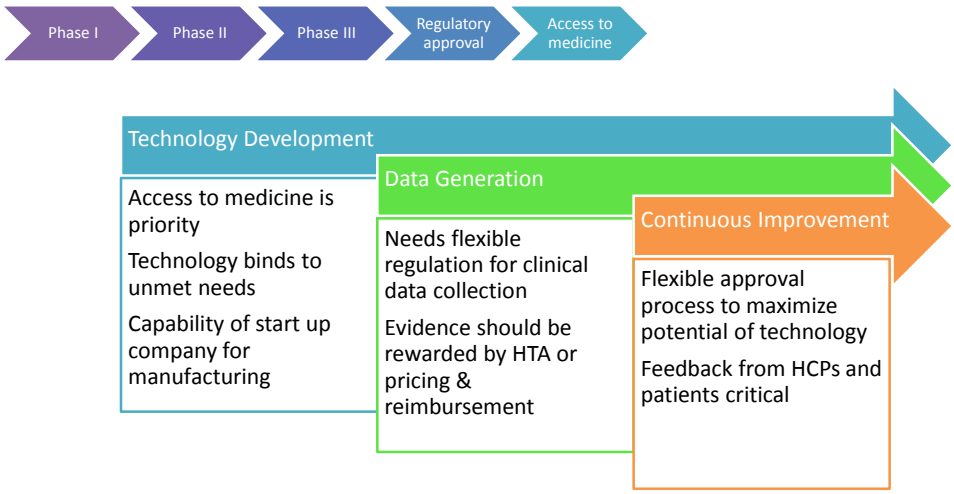
1) Sayed H. Naderi et al., The American Journal of Medicine, 2)Rajiv Chowdhury et al., EUR Heart Journal, 2013, 3) Michael Ho et al; Circulation, 2009

Pharmaceutical eco-system for patient disease management

Proteus
patients can easily monitor their medication-taking patterns on their mobile device. Physician have access to objective data that enables them to initiate, titrate, eliminate medication.
http://www.proteus.com/discover

Medical cost savings consisting of reductions in outpatient and inpatient services, monitoring, disease management, and medication costs were estimated to be $850-980 per patient per year (5-11% reduction in diabetes and CVD complications).
Kim YA et al. Value in Health 2015.

ZIO patch
Patient mails the patch to iRhythm after 2 weeks. The company downloads the readings, analyzes them with a machine learning algorithm, and sends them to the user's physician

Stick 2it program
Using data from participant questionnaires, the algorithm created a customized messaging and reminder program for each participant.
http://www.memotext.com

Continuous Improvement in market harmonizing HCPs and patients is critical