The FDA's New Digital Health Program

Introduction to Scope, Evolving Regulatory Requirements & New Initiatives

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FDA Regulatory Outlook – Key Areas of Focus

- **FDA Digital Health Overview**
- **Software as a Medical Device (SaMD)**
- **Cures Act Analysis**
- **FDA Digital Health Innovation Action Plan**
- **Precision Medicine – *Anticipating New Rules for Compliance***

FDA Digital Health Overview—
FDA Goes Virtual !

- Scope is broader than "the Cloud" and Mobile Medical "Apps"

- **<u>Key FDA objective announced</u>:**

  - ***Creating an environment that enables:***
    - ✓***Innovation and regulatory efficiency***
    - ✓***While protecting patients and public health***

FDA Digital Health Scope

Digital Health Includes:

- ✓ Mobile Health
- ✓ Health Information Technology
- ✓ Wearable Devices
- ✓ Telehealth & Telemedicine
- ✓ Personalized Medicine

KEY TOPICS

- Software as a Medical Device (SaMD)
- Next Generation Sequencing (NGS) Technologies
- LDT/IVD Companion + Complementary Dx
- Gene Therapies
- Cloud-based Clinical Laboratory Tools/Test Components
- Mobile Medical "Apps"
- Clinical Decision Support (CDS)
- Medical Device Data Systems
- General Wellness
- Cybersecurity

Digital Health FDA Regulatory Landscape

Key Areas:

1. **Federal Food Drug and Cosmetic Act (FDCA), section 201(h)**
   - Defines what is a FDA regulated "medical device"
   - Applicability to "software" (numerous overlapping FDA Regulations & Guidance)
2. **"Draft" FDA Guidance: Software as a Medical Device (SaMD)**
   - Establishes IMDRF as FDA intended model/definitions
3. **21st Century Cures Act (Cures Act)**
   - Enacted to aid in the acceleration of medical technology development to provide patients with faster access to new and emerging innovations in medicine
   - "Clarifies" FDA's regulation of medical software (exclusions, exemptions to exclusions)
4. **FDA's Digital Health Innovation Action Plan – Digital Health Initiative**
   - Finalize/issue new Draft Guidance to better explain FDA compliance for regulated software (Cures Act, SaMD definition/requirements, etc.)
   - Implement Pilot Program to develop a new method for streamlining regulatory process ("Pre Certification" of companies) & hire additional new FDA staff with software experience

What is a "Medical Device" (FFDCA §201(h))?

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - …***intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals***,…
- The definition ambiguous enough for historically wide latitude by FDA:
  - E.g., Software and Laboratory Developed Tests (LDTs) have long been considered regulated "medical devices" per FDA policy interpreting:
    - … "*contrivance*"… "*in vitro reagent*"… or other "*similar or related article,*" *including a component part, or accessory*…

FDA Digital Health /Precision Medicine "Medical Device "Products—*Regulatory Compliance*

Question:

Does FDA require companies to obtain FDA clearance/approval for ALL SaMD / Medical Devices?

Answer— *NO*.

- ✓ FDA uses a **"risk based approach" (e.g. device classification)**
- ✓ **However**, **FDA's view of "risk" of the product to human health can be very different from the company/developer's view of the risk**
- ✓ Limited precedent with novel products, but still applies to all products defined as medical devices (**based on the "Intended Use" of the product**)

Software as a Medical Device (SaMD)

Understanding "SaMD" & FDA Risk Classification in an Evolving "Digital Health" Product Regulatory Landscape

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What Makes Software SaMD?

FDA Draft Guidance on SaMD adopts the IMDRF* definition:

- "Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."
- …software is a medical device ***if it informs or drives clinical decisions***, **<u>but</u> not if it is limited to retrieving information, organizing data, and/or optimizing processes, or is used in closed loop interventions.**

IMDRF = International Medical Device Regulators Forum

FDA's Current Working Definition—*Software as a Medical Device (SaMD)*

- ***SaMD***
  - *Software intended for one or more medical uses that may run on different operating systems or in virtual environments*
- ***Sometimes SaMD***
  - *Software run on a hardware medical device is a SaMD* ***when not part of the intended use of the hardware medical device***
- ***Not SaMD***
  - *Software is not SaMD if it drives or controls the hardware medical device*

"Cures Act" Analysis

Is your Digital Health Software Product Still a FDA Regulated "Medical Device"?

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21st Century Cures Act 2016
Is Your Digital Health Product a Medical Device?

Your Product is a Medical Device
New Analysis: **Cures Act § 3060** **Does it meet an "Exception to the Exclusions"**
The Cures Act maintains the FDA's authority to regulate products: • Intended to interpret or analyze patient records • Intended to interpret or analyze clinical laboratory test or other device data, results, and findings; and/or • Intended to acquire, process, or analyze a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system

Your Product is *NOT* a Medical Device	
Traditional View **Does not meet definition in FD&C Act § 201(h)**	***New Analysis:*** **Meets an "exclusion" from 201(h) listed in Cures Act § 3060(a)** **AND** **is *not included an "exception"* from such § 3060 exclusions.**
Example: **Microsoft Word**	Example: General wellness devices designed to maintain or encourage a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition

Only Software "Excluded" by Cures, but NOT then Exempted from such Exclusion, Requires FDA Fed. Reg. Notice to Regain Regulatory Authority

Changes Required by the Cures Act

- **FDA's current position on SaMD has to be reconciled with requirements under the Cures Act**
- **The Cures Act specifically identifies types of software that cannot be defined as medical devices** under the Federal Food, Drug, and Cosmetic Act §201(h)
  - "Excluded" software types no longer fall under FDA's jurisdiction, i.e., **they are "out"…*unless*…**
- **However, the Cures Act includes <u>*exceptions*</u> to the exclusions**
  - "*Exceptions to the exclusions*" still defined as medical devices and remain under FDA's jurisdiction, i.e., **they are "in"**

"In" vs "Out" Under the *Cures Act*

Not a Medical Device = Excluded = "OUT"	Medical Device Exception to Exclusion = "IN"
Administrative support/billing for health care facilities that maintain records that contain financial or health information	N/A
For maintaining or encouraging a healthy lifestyle	UNLESS it is related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
Transferring, storing, converting formats, or displaying clinical laboratory test or other device data results, findings by a health care professional with respect to such data and results, general information about such findings and general background information about such laboratory test or other device	UNLESS the software is intended to interpret or analyze clinical laboratory test or other device data, results, and findings
Display, analyze, or print medical information about a patient or other medical information and support or provide recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and enable a health care professional to independently review the basis for such recommendations that the software presents so that it is not the intent that the health care professional relies primarily on the recommendations to make a clinical diagnosis or treatment decision regarding an individual patient	UNLESS the software is intended to acquire, process, or analyze a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system

FDA Digital Health Innovation Action Plan

Overview of Initiatives and Implications

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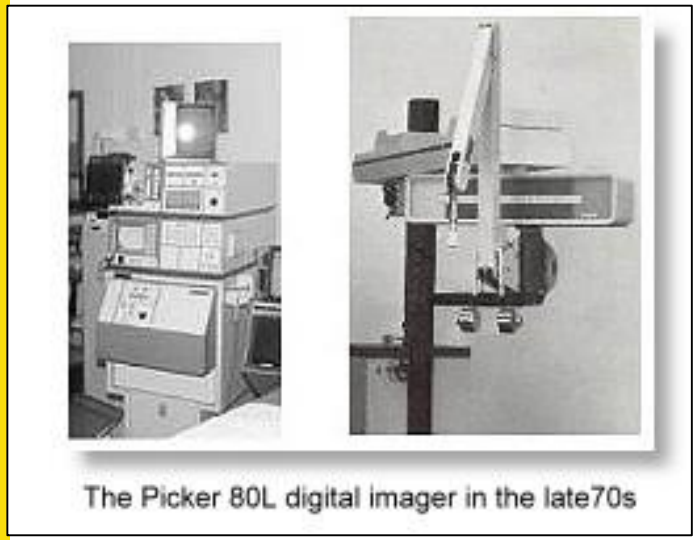
2017— FDA Moves Regulatory Science Forward Faster!

1976

Medical Devices 201(h)



The Picker 80L digital imager in the late70s

2016

FDA/Int'l SAMD

IMDRF International Medical Device Regulators Forum

?????

FDA

2016

Congress "Cures" Act

2017

FDA Digital Health Initiative

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FDA Digital Health – Current Initiatives

Digital Health Innovation Action Plan

- Goal: Streamline Premarket Reviews
- Implements provisions written into 21st Century Cures Act
- Administered by FDA's Center for Devices and Radiological Health (CDRH)

Software as a Medical Device Precertification Program

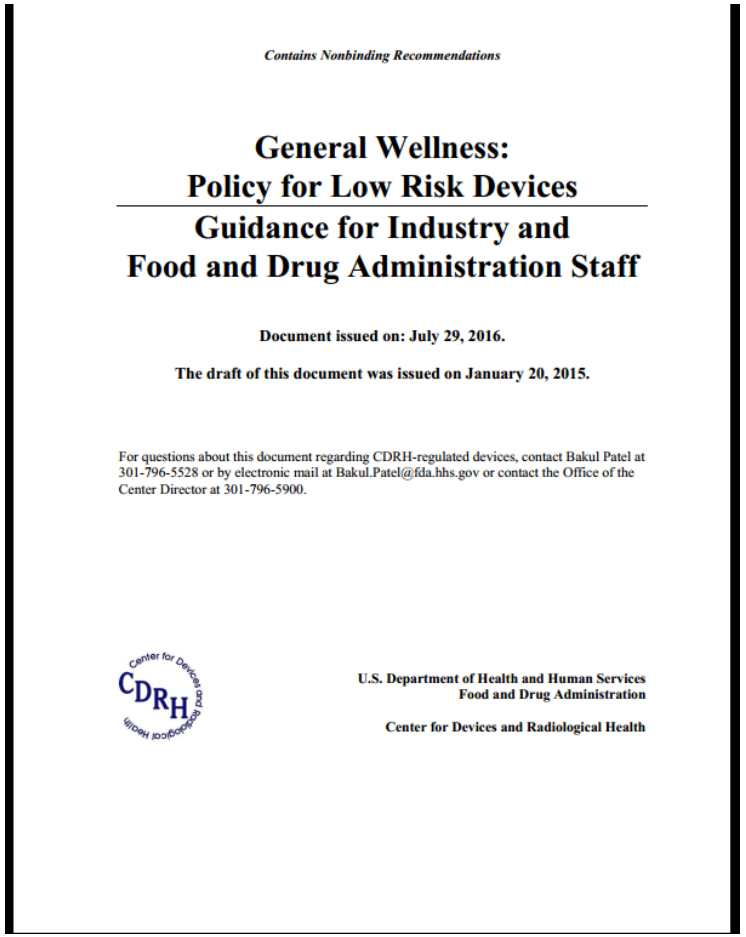
- A voluntary component of the Digital Health Innovation Action Plan
- SaMD developers may be eligible for faster premarket reviews if they meet certain requirements
- Available as a pilot program

Digital Health Innovation Action Plan

Why Now?

- **FDA realizing software evolves too rapidly for the existing paradigm for physical devices**
- **Initiative seeks to incorporate software development timelines, international regulations, and industry practices**
- **Not all proactive: Some changes mandated by 21st Century Cures Act**

Planned Guidance Documents



Contains Nonbinding Recommendations

General Wellness:
Policy for Low Risk Devices

Guidance for Industry and
Food and Drug Administration Staff

Document issued on: July 29, 2016.

The draft of this document was issued on January 20, 2015.

For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

- Cures Act mandates FDA to refine its stance on digital health issues
- Several guidance documents planned to explain changes spurred by Cures Act
- Some will be “Draft Guidance", others will incorporate “Cures Act” changes into “Final Guidance”
- FDA provides estimated timeline for first set of Cures Act Guidance Documents

Aggressive FDA Guidance Publication Timeline

Draft Guidance
2017
✓ Cures Act effect on FDA's existing digital health policies
2018
✓ Clinical Decision Support Software, specifically delineating the clinical decision support software no longer under FDA's jurisdiction, because of the Cures Act
✓ Clarifying FDA oversight when software has functions that fall both in and out of agency jurisdiction

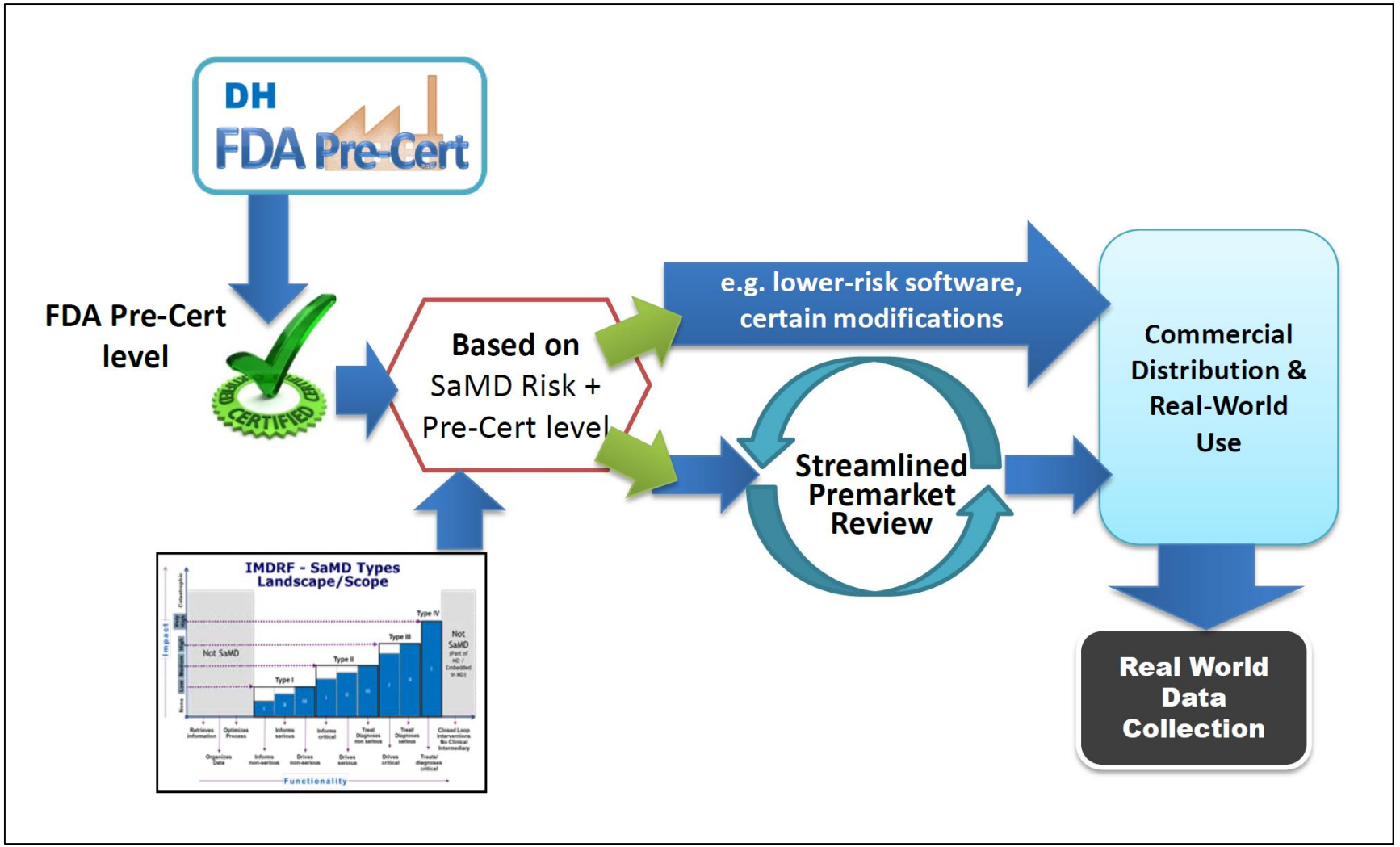
Final Guidance
2017
✓ Interoperable medical devices: factors to considers in product designs and premarket submission suggestions
✓ Software changes and deciding when to submit a 510(k) for a change to software for an existing device
✓ Formally incorporating IMDRF's suggested approach to clinical evaluation of SaMD into FDA guidance documents

Demonstrating Excellence In Quality

Precertification Pilot for SaMD Manufacturers

- Firms that demonstrate a "Culture of Quality and Organizational Excellence (CQOE)" **may** be able to forgo premarket reviews
- Program seeks to ensure quality control at the company level rather than at the product level. Low-risk software and updates may not need to be cleared by FDA if developer is pre-certified
- Voluntary program

FDAs Company Pre-Certification Concept



Source: fda.gov

Anticipating FDA Compliance

Navigating the Evolving Personalized Medicine/"Digital Health" Product Regulatory Landscape

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FDA's Evolving Regulatory Landscape

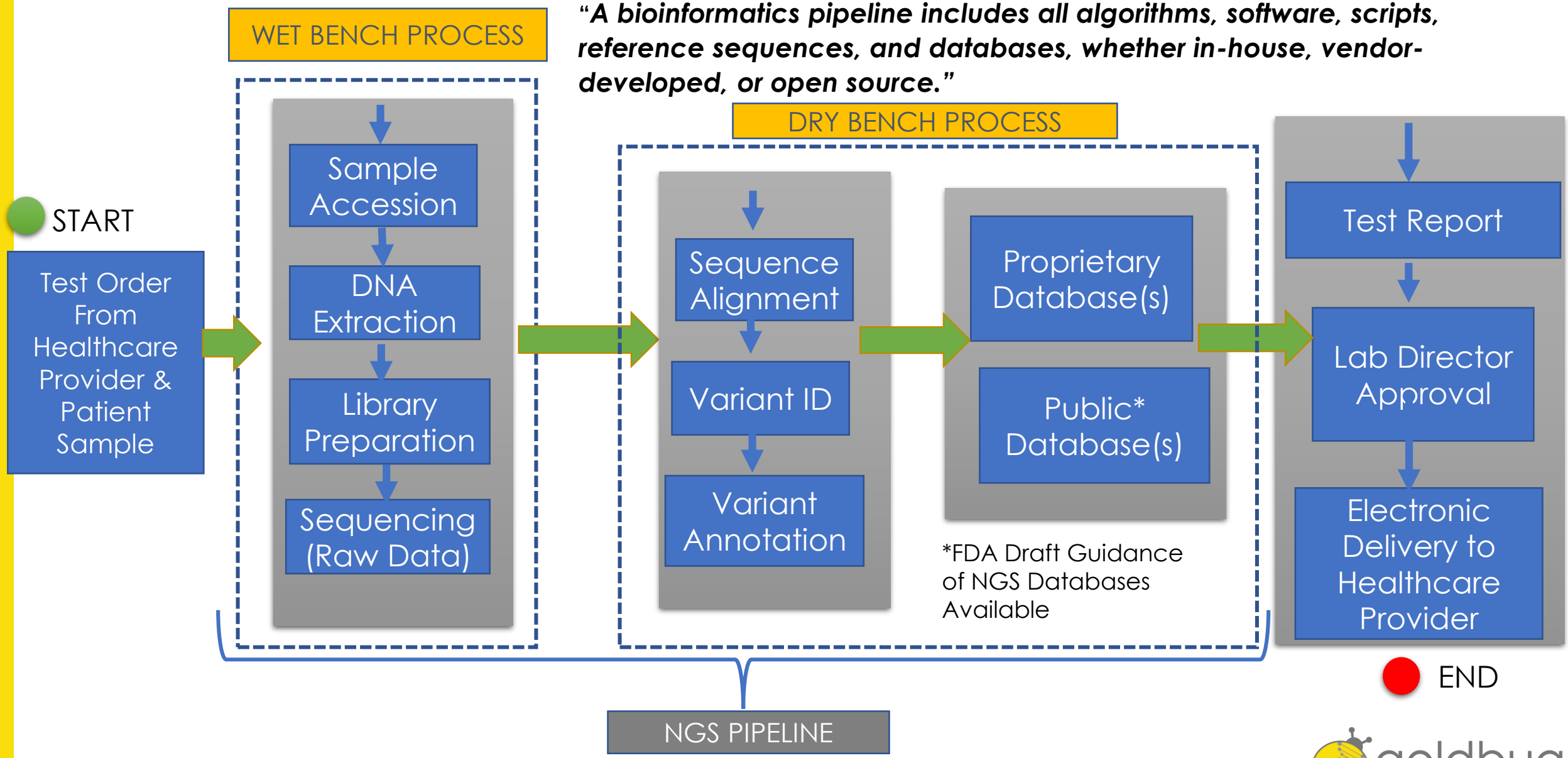
How do the evolving requirements affect innovative companies & investors developing and marketing precision medicine products?

The content of FDA's upcoming Draft and Final Guidance documents can **change the Agency's oversight requirements** of digital health software products

- Expected to include SaMD that are already on the market and that are in development
- Though guidance is not legally binding, it explains FDA's current "thinking" on a topic and shapes the Agency's enforcement actions
- FDA is working toward 21st Century regulatory models that better accommodate products that depend on highly complex formulas and algorithms

NGS Implications: CAP Definition: NGS "Dry Bench":

"A bioinformatics pipeline includes all algorithms, software, scripts, reference sequences, and databases, whether in-house, vendor-developed, or open source."



Regulatory Implications—*Innovative Digital Health Developers & Investors*

Anticipating FDA Compliance—

- ✓ Companies required to obtain FDA clearance/approval for digital health products based on new law/policy are expected to know the compliance requirements
- ✓ If companies don't comply, the agency may "invite" you to do so: FDA "enforcement" letters - A few are public; many are not made public by the Agency
- ✓ **How?** FDA staff see your product advertised or hear about it at a medical conference or from one of your friendly helpful competitors
- ✓ ***Don't assume a competitor who is still marketing a similar product with similar claims has not received an FDA letter or is otherwise voluntarily interacting with FDA***

Strategies to Understand/Influence Regulatory Compliance Requirements

Informal Public Participation

- Share your company's thoughts and feedback with FDA through written comments
- Participate in any public workshops

Informal or Formal Confidential Interaction with FDA

- "Informational" Meetings on novel products
- "Pre-Submission" Meetings on specific product questions
- Be certain you are well-prepared to meet with FDA

Strategies to Mitigate Risk of FDA Enforcement Actions

- **Consider early interaction with FDA to discuss your specific product/company**
- **Evaluate current/anticipated level of company/product compliance with FDA's Quality System Regulations (QSR)**
- **Identify gaps between your approach and the software development lifecycle familiar to FDA (including upcoming guidance)**
- **Identify least burdensome options to demonstrate adequate compliance if FDA "notices" your company/product on the market without FDA clearance/approval**

Thank you. Questions?

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