DIGITAL HEALTH: FDA ACTIVITIES

ONGOING REGULATORY CLARITY

MAY 3, 2018

Digitization Across the Health Care Continuum

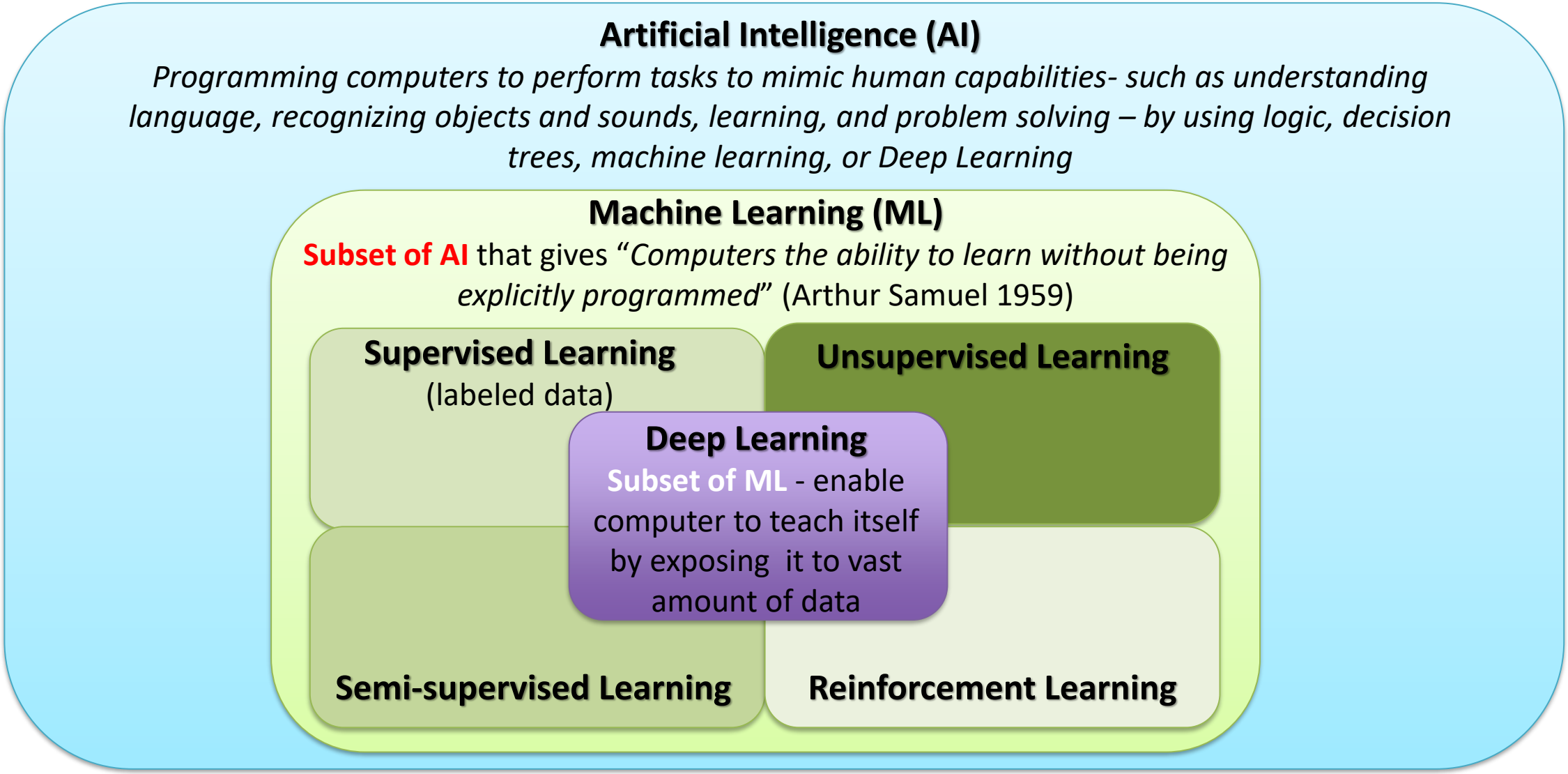
Moving health care from the clinic to the patient.

Understanding patient's behavior and physiology "*in the wild.*"

Focusing on prevention for early/smaller interventions.

Leveraging **computing power, sensors, connectivity,** ***and*** **software.**

World of SaMD and Artificial Intelligence



Challenges

Evaluation of safety and effectiveness:

Open questions:

- *Continuous learning while ensuring safety and effectiveness*
- *Availability for large and robust datasets with representable clinical variability*
- *Continuous Algorithm updates*
- *Interpretability and explain-ability of the "basis of the recommendation"*

The rapidly evolving nature of digital health is sparking a paradigm shift

Current Regulatory Paradigm	Digital Health Paradigm Shift
Premarket timeline suited for **hardware** based products	**Software** development timelines, software development practices + rapid iterations
Deterministic risks, known responsibilities, physical products	**Evolving issues**: cybersecurity; distributed responsibilities, non-physical products
Stable program volume: ~3,500 510(k) submissions / 2200 pre-submissions	Potential for **exponential** increase in volume of submissions

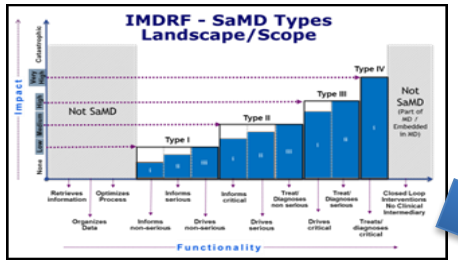
FDA Pre-Cert Program

An **organization-based** streamlined regulatory approach

for
Software as a Medical Device

that relies on a demonstrated
Culture of Quality and Organizational Excellence

Concept: A reimagined approach using FDA Pre-Cert



Based on
SaMD Risk +
Pre-Cert level

FDA Pre-Cert level

e.g. lower-risk software, certain modifications

Streamlined Premarket Review

Commercial Distribution & Real-World Use

Real World Data Collection

Regulatory Science
Real-World Evidence
Clinical Trials
Patient Preference
Outcomes research

DH
FEEDBACK

FDA Pre-Cert effectiveness feedback

Assessment effectiveness feedback

DH
FDA Pre-Cert

Program Update

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Developing a Software Precertification Program: *A Working Model*

(v0.1- April 2018)

Introduction

The Software Precertification Program is er
regulatory model more tailored than the cur
effectiveness of software technologies witho
The program is envisioned to provide a mor
software-based medical devices from manu
quality and organizational excellence (CQO
performance. The current vision for this reg
also sets out challenge questions for public

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Challenge Questions

Software Precertification Program

FDA proposes the following challenge questions for public input.

0.1 FDA recognizes stakeholder perspectives and priorities as important inputs into the development of the Precertification Program. How should anticipated stakeholder benefits in Table 1 in the program Working Model be revised, and what additional stakeholder perspectives should be included?

0.2 As a stakeholder, what would you want to know about the organizations that have been precertified and about the SaMD products that they manufacture?

Excellence Appraisal

FDA proposes the following challenge questions for public input. Although these questions are specific to excellence appraisal models and precertification status, they should be considered in

Software Precertification Pilot Program: Next Steps towards a Pre-Cert 1.0

The FDA anticipates public comment on the regular updates we issue.

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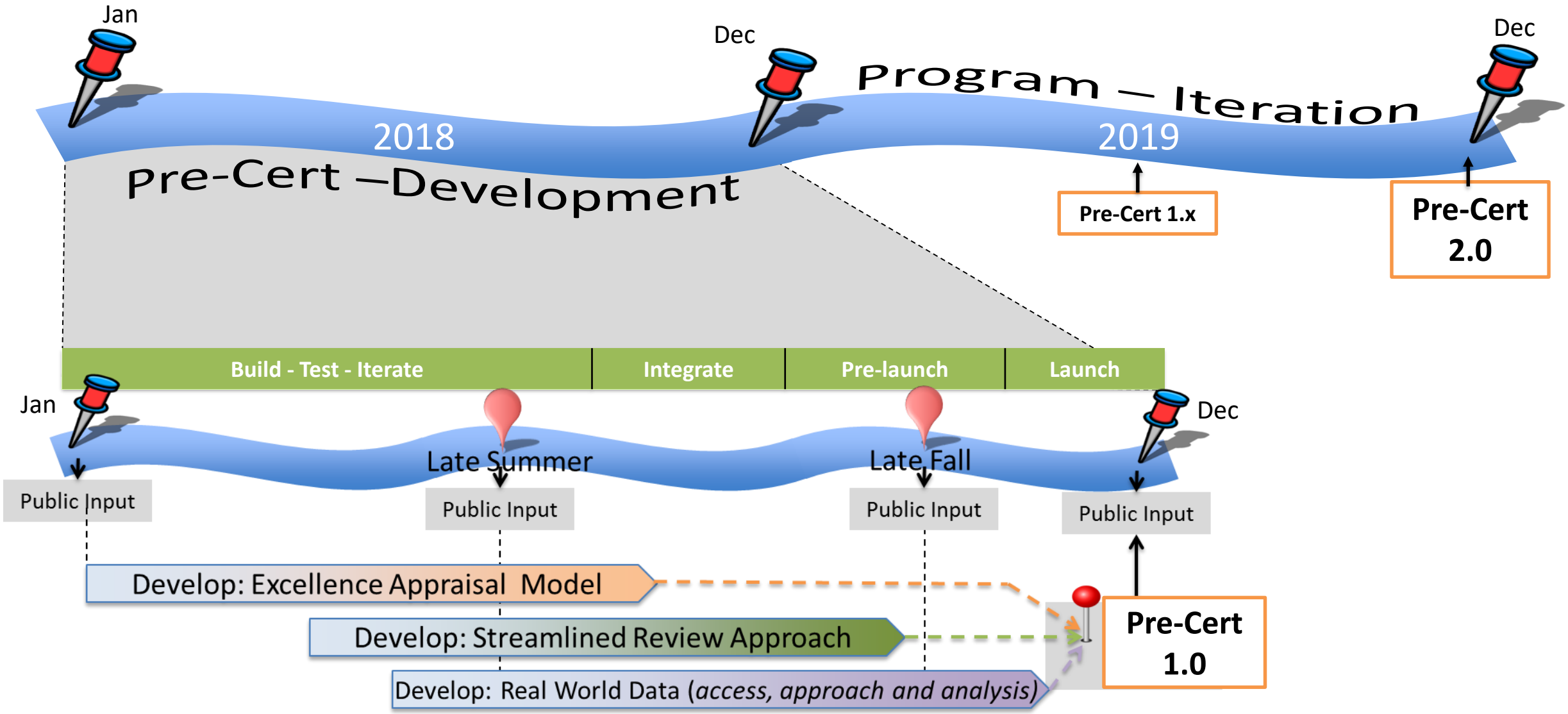
Build – Test – Iterate				Integrate – Simulate – Pre-launch			Launch
2018	Late April	Late May / Early June	Mid July	Mid August	Mid September	Mid October	December
Pre-Cert Components	Working model - Initial	Update	Update	Update	Update	Update	
Excellence Appraisal	• Excellence Principles – Objective indicators that demonstrate company-level commitment to creating safe and effective software as a medical device (SaMD) • Evaluation Method – How activities are evaluated for sufficiency • Success Criteria – How companies pass, fail, lose, and retain Pre-Cert status • Program Acceptance – How companies qualify for and initiate evaluation, including precertification levels						
Review Determination	• SaMD Risk Categorization – How the Pre-Cert program treats SaMD risk categories, including alignment to other frameworks such as IMDRF • Review Process – How FDA determines categorization, how categorization may change, triggers for re-evaluation, etc.						
	for receipt, evaluation, D products from Pre-Cert			• Scenario Testing: Reveal the degree to which program objectives are achieved, as well as lessons learned, in order to iteratively improve the components and the whole • Finalize Pre-Cert 1.0: Integrate stakeholder feedback, lessons learned, and other input, into a cohesive set of deliverables			• Pre-Cert 1.0 (First version of the program) • Program next steps for 2019
	handle product ety and efficacy of						
	elements to support clinical ness collected and made						
	world performance data						
	ers for modifications to						
	k for use of real world n						

evaluate the program model to inform how we establish the Precertification Program. Once we determine the elements ate mechanisms for establishing the program, including FDA's current statutory and regulatory authorities.

Pre-Cert Program Roadmap



#FDAPreCert

Engage

bit.ly/Precertupdates

Look for ongoing Program updates

FDAPre-CertPilot@fda.hhs.gov

Ask Questions about the Program

bit.ly/docketjan18

Provide ongoing input through the Public Docket