Regulation of Medical AI in the United States

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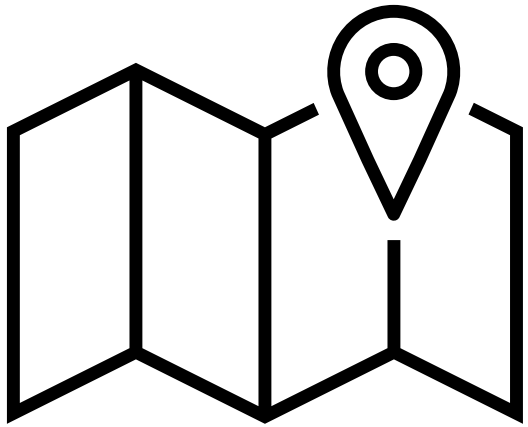
Declaration of interests:

No interests to declare

Roadmap



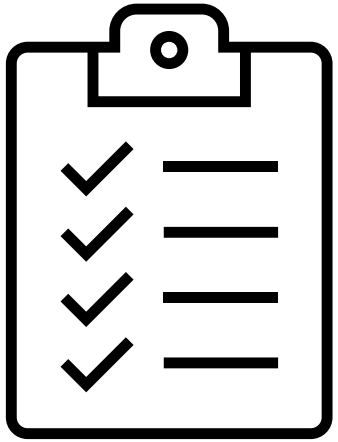
- The Role of FDA
  - Pre-Cert
  - Change plans
  - GMLP
- Limits of Centralized Governance
- Challenges of Distributed Governance

[Side note: roles for transformation]

- Pushing frontiers
- Democratizing expertise
- Automating drudgery
- Allocating resources

Why regulate?

- Limited studies
  - Retrospective
  - Geography
  - Demography
- Potential for harm
- Potential for bias

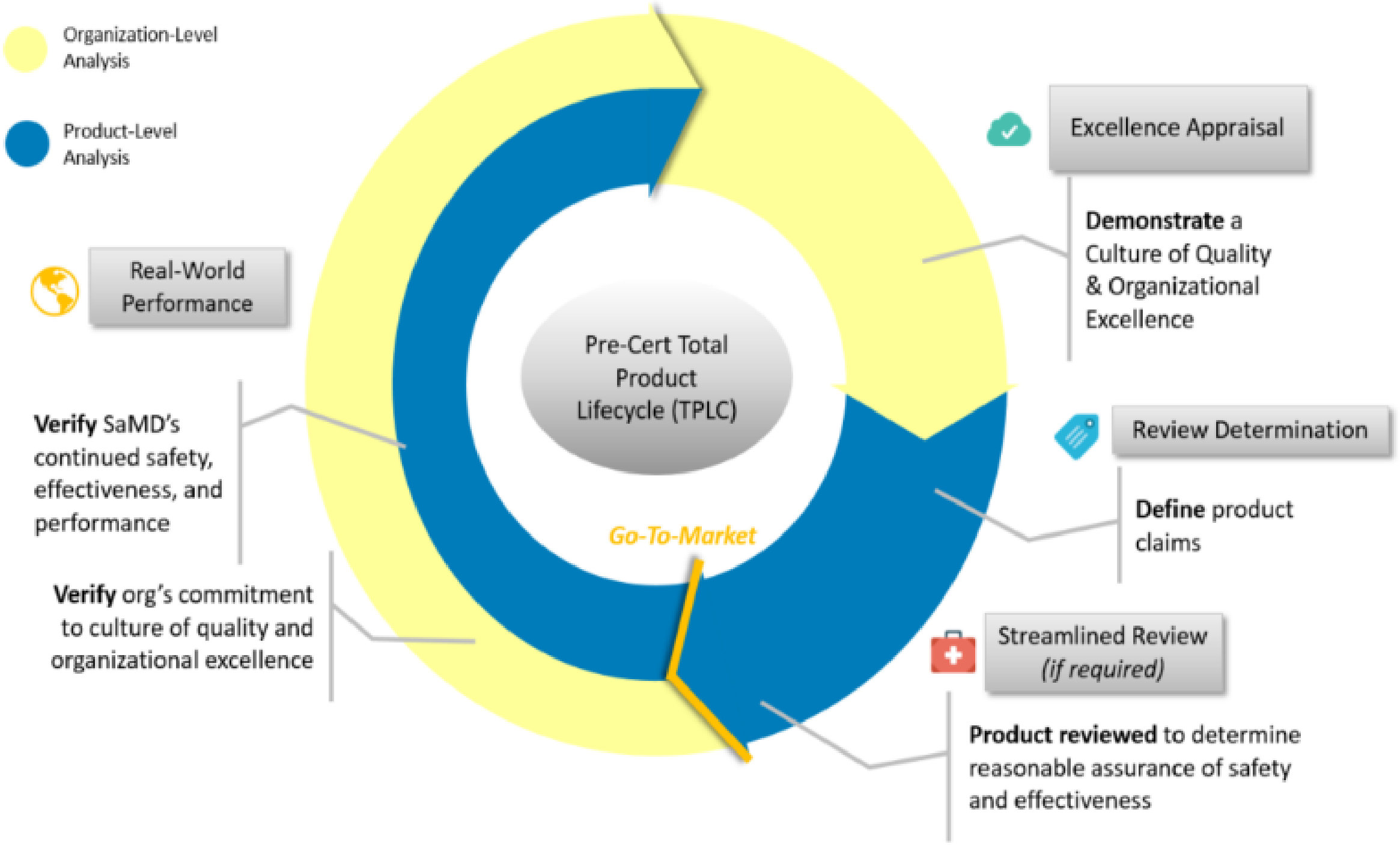


U.S. Food & Drug Admin.

- Software as a Medical Device (SaMD)
  - Class I, II, or III
- Clearance (510(k)) or de novo
- Hundreds of devices cleared!
- But…one by one; all locked

Pre-Cert Pilot (Aug. 2017)

- Products→companies
  - Culture of excellence
- Premarket→postmarket
  - Streamlined review
  - More surveillance


Organization-Level Analysis
Product-Level Analysis
Pre-Cert Total Product Lifecycle (TPLC)
Go-To-Market
Excellence Appraisal
Demonstrate a Culture of Quality & Organizational Excellence
Review Determination
Define product claims
Streamlined Review (if required)
Product reviewed to determine reasonable assurance of safety and effectiveness
Real-World Performance
Verify SaMD's continued safety, effectiveness, and performance
Verify org's commitment to culture of quality and organizational excellence

Dimensions of excellence

1. patient safety
2. product quality
3. clinical responsibility
4. cybersecurity responsibility
5. proactive culture

Predetermined Change Control Plan

- Real-world learning
- SaMD Pre-Specifications
  - What learning might change
- Algorithm Change Protocol
  - How the algorithm learns & changes
- Guidance expected

Good Machine Learning Practices

1. Multi-disciplinary Expertise TPLC
2. Engineering, Security
3. Representative data
4. Independent training, test datasets
5. Methodologically sound reference data
6. Model reflects available data, intended use
7. Focus on human/AI performance
8. Clinically relevant performance
9. Clear info to users
10. Performance/change monitoring

Broad picture

- Working on it!
- Proactive
- Collaborating with industry

BUT

Limits of FDA's reach

- Clinical decision support
- Not a medical device if (not IVD) AND intended for
  - "displaying, analyzing, or printing medical information about a patient or other medical information ...;"
  - "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition;" and
  - "enabling such health care professional to independently review the basis for such recommendations that such software presents"

So…what's not covered?

- LOTS
- EHR-embedded AI
- In-house systems
  - (LDT exception?)
- Much outside FDA's reach

More limits of centralized governance

- Different populations
- Different clinical care pathways
- Different EHR/IT infrastructure
- Different workflow integration
- Different monitoring
- . . . sometimes

Challenges of distributed governance

- Today: *tons* of work
- Requires continuing evaluation
- Lots of resources

- But…democratizing expertise

Enabling distributed governance

- Building infrastructure
  - Knowledge, technical, data, legal
- Outsourcing
  - OCHIN, others
  - FDA

Take-home points

- Regulatory environment in flux
- Commercially distributed AI→FDA
- FDA is proactively developing rules
- Broad ~unregulated space
- Excitement, but lots to do!

Thanks!