Current Research Led By FDA

High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides

- Partnership with academia, clinicians, and industry through Medical Device Innovation Consortium (MDIC)
- Focus on truth by pathologists, the microscope and TILs in breast cancer
- Status: Creating project structure, workgroups and leadership

- Key Deliverables:
  1. FDA qualified dataset for algorithm validation
  2. MDDT or mock 510(k) submission for
     - WSI viewer
     - TILs in breast cancer algorithm

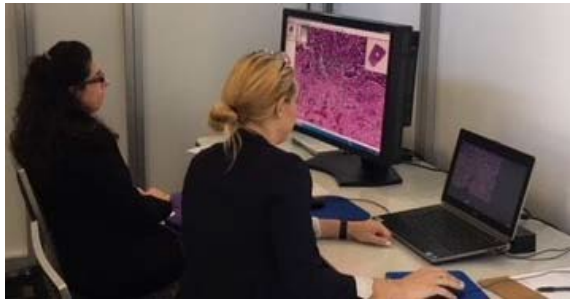
Work to be done in the public domain.

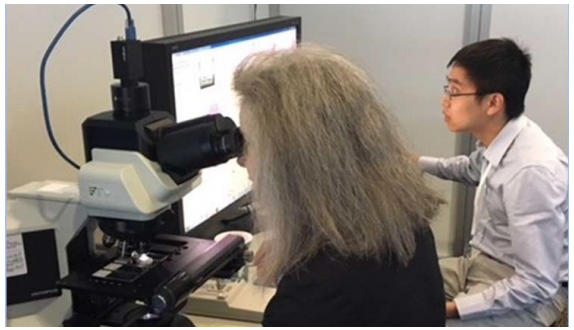
MDDT:
Medical Device Development Tool
https://www.fda.gov/medicaldevices/scienceandresearch/medicaldevicedevelopmenttoolsmddt/

510(k):
Premarket submission for Class II medical devices
https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm

High Throughput Truthing for AI Validation

1. **FDA qualified dataset for algorithm validation**
   - Collect slide annotation data at pathology conferences and other high-volume settings
   - Use microscope and system that records evaluation locations
     - Scanner agnostic: map annotations to any digital scan of the slides
   - Also collect annotations from WSI's to support viewer and algorithm deliverables
   - Multiple readers per slide/ROI (5 to 15, not 2+1)
   - Dataset as a Medical Device Development Tool (MDDT)
   - Available to developers (in a controlled way) to use in FDA submissions
2. **MDDT or mock 510(k) submission for WSI viewer**
   - The WSI viewer is an enabling technology that has been developed by many groups.
   - Goal: Demonstrate regulatory pathway to allow innovation enabled by different viewers.
   - Use MDDT data (deliverable 1). Share process publicly. Community follows the example.
3. **MDDT or mock 510(k) submission for TILs in breast cancer algorithm**
   - Create an algorithm use case (= FDA Indications for Use).
   - Validate algorithm with MDDT data (deliverable 1).
   - Share process publicly. Community follows the example.





Data Collection At ASCP 2018

Why is the FDA doing this?

"help encourage more developers to translate advances into clinically actionable tools to benefit patients"
Scott Gottlieb, Commissioner FDA, "Transforming FDA's Approach to Digital Health."

MDDT

Medical Device Development Tool

New pathway. New mechanism.

- Reduce burden to sponsors
  - Use MDDT data in the submission
  - Replace 40 pages of a submission with, "Using the MDDT dataset, our algorithm performance is …"
- Reduce burden to FDA
  - Approve data once to support multiple sponsors

New stakeholders.

- Not just industry
- Pathologists, Academia, Health Providers
- Associations, Societies, Colleges (CAP, USCAP, ASCP)

Create an example for stakeholders to follow.

Impact

Build consensus. Build tools. Disseminate.

- High-throughput data-collection tools and protocols
- Standardize annotation formats for humans and algorithms
- Statistical methods and software for algorithm performance evaluation

→ Improve submissions. Enable interoperability.

Give pathologists ownership and confidence.

- What the algorithms should do
- The validation process

→ Improve clinical practice

Shift effort to community.

→ Reduce FDA workload

High-Throughput Truthing for AI Validation

How can your team get updates or get involved ?

Info and Updates

- Browse this wiki page: https://nciphub.org/groups/eedapstudies/wiki/HighthroughputTruthingYear2
- Join this group: https://nciphub.org/groups/eedapstudies

Use Case Development

- Outline use cases appropriate for novel AI algorithms, provide clinical guidance for industry R&D

Conference Logistics

- Logistics and operations knowledge of pathology conferences, a primary source of pathologist recruitment

Pathologist Recruitment, Management, and Training

- Use-case training, biotechnology informatics