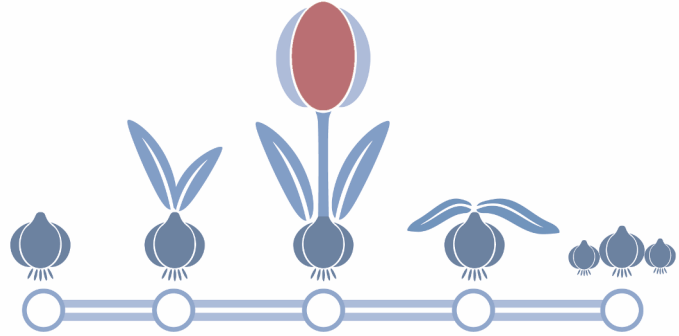


Alliance Proposal



A temporary alliance to move digital pathology and precision medicine forward

Joe Lennerz – MGH/HMS

Jlennerz@partners.org

Esther Abels – PathAI & DPA

esther.abels@pathai.com

Executive Summary

Market overview

- First WSI systems received FDA 510(k) Clearance 2017 and 2019
- Different offerings from archiving to full solutions including algorithms
- By 2025 Digital Market is \$887.7 million with 12% CAGR

Adoption challenges and opportunities

- Business case is a challenge as full integration is demanding while efficiency in workflow is not substantiated yet
- Full integration can improve efficiency by ~13%

Executive Summary

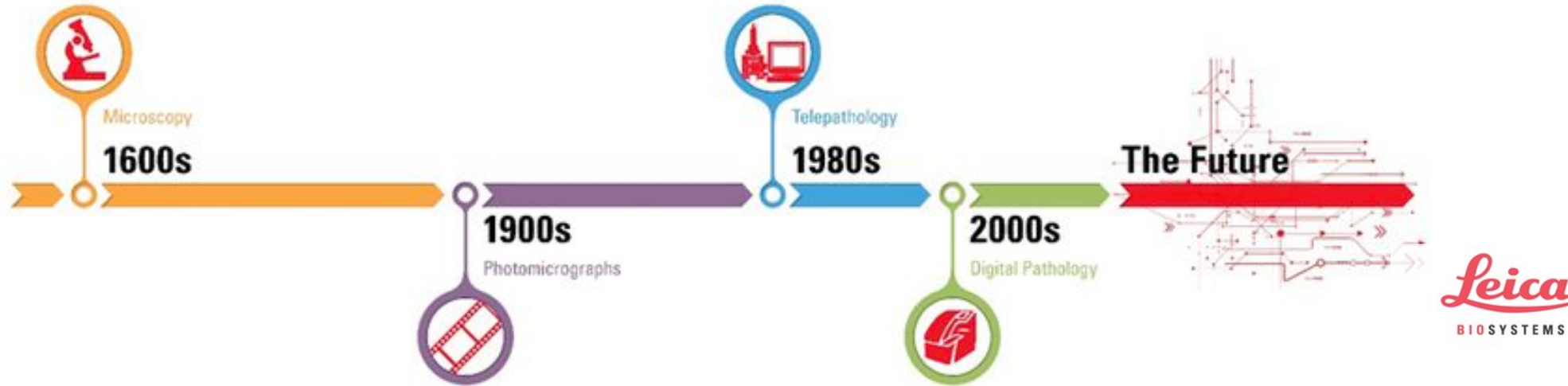
Stakeholders

- Users, government, insurance companies, patients, vendors
- Diverse groups with different focus and goal

Solution

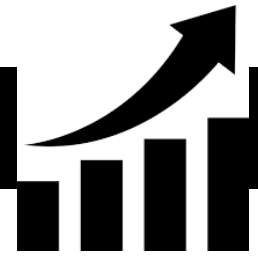
- Temporary framework to synergize and tackle larger scale projects
- Harmonize & standardize reference set to be used in end to end workflow by
 - Creating tools and datasets
 - Progressing and enabling market access
 - Creating clarity on regulatory pathways via mock submissions
 - Harmonizing efforts between various stakeholders to optimize interoperability, integration and implementation

Starting points



- The modern microscope is >300 years old
- Modern diagnostics continues to rely on microscopy
- Essentially all cancer diagnoses are rendered using light microscopy
- Whole slide imaging (WSI) has been around for decades
- In 2017 and 2019 the first WSI systems have received FDA 510(k) Clearance

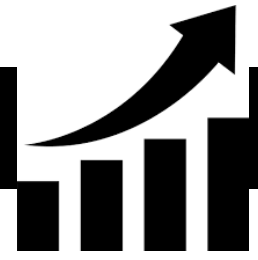
Market analysis



EXCLUSIVE DISTRIBUTOR OF

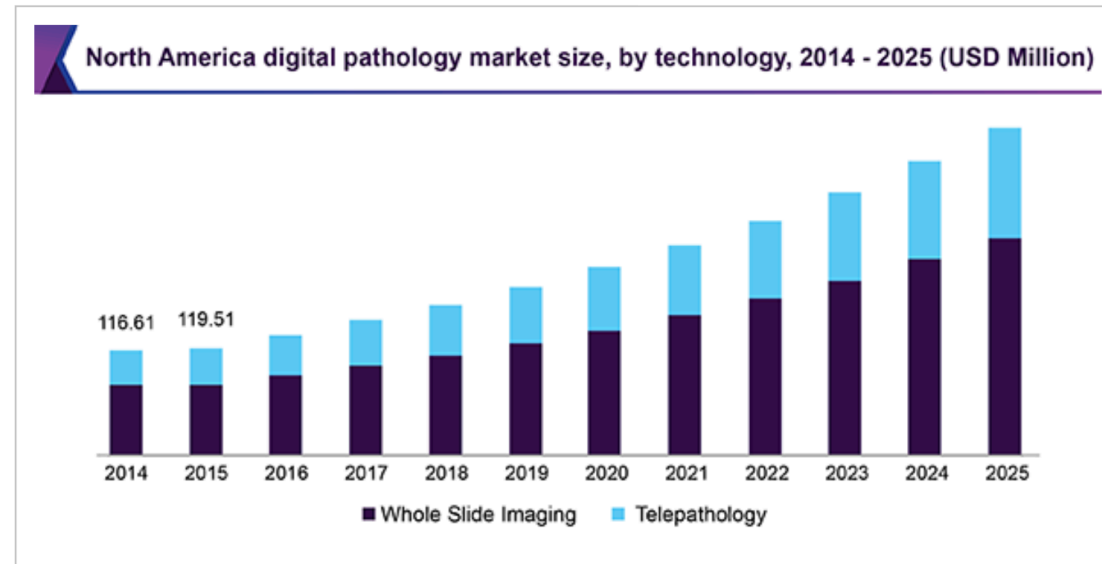


Market outlook



Industry Outlook

The global digital pathology market size was valued at USD 321.7 million in 2016. It is expected to witness a CAGR of 12.0% during the forecast period. Increasing focus on improving workflow efficiency and implementing faster diagnostic tools for chronic diseases, such as cancer, is one of the key trends triggering market growth.



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Home » Press Room » Digital Pathology Market Worth \$887.7 Million By 2025 | CAGR: 12.0%

Digital Pathology Market Worth \$887.7 Million By 2025 | CAGR: 12.0%

June 2018 | Report Format: Electronic (PDF)

The global [digital pathology market](#) size is expected to reach USD 887.7 million by 2025, according to a new report by Grand View Research, Inc., exhibiting a CAGR of 12.0% during the forecast period. Growing prevalence of chronic

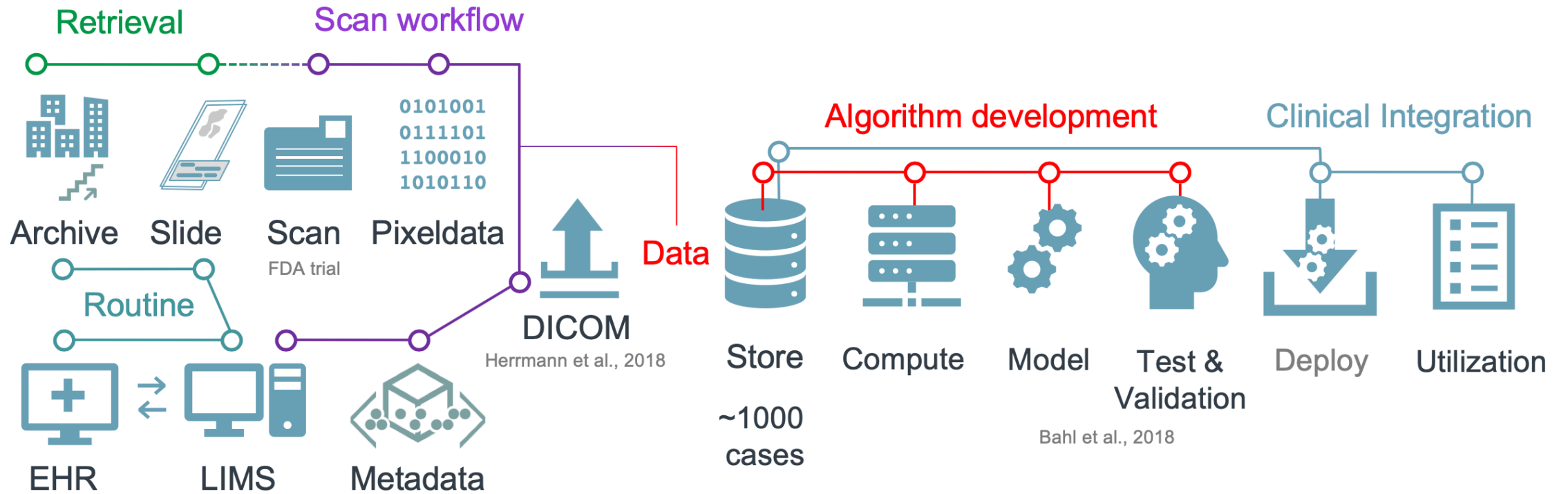
Why hasn't the digital revolution happened in pathology?

ROI of Digital Pathology Today is a Challenge

- 1) Technical performance **AND**
 - 2) Demonstrate a clear and definitive savings in time or money **OR**
 - 3) An improvement in the effectiveness of services
- Obvious and substantial impact on workflow.
 - IT and infrastructure needs
 - **Full digital integration needed to see overall benefits**
 - When implemented: digital Pathology can improve efficiency by ~13%

Ho J, Ahlers SM, Stratman C, et al. Can digital pathology result in cost savings? a financial projection for digital pathology implementation at a large integrated health care organization. *J Pathol Inform.* 2014;5(1):33;

What is needed ?



What groups could be involved

DIGITAL
PATHOLOGY

DPA

ASSOCIATION

search



MEMBER LOGIN

NON-MEMBER LOGIN

JOIN TODAY

MEMBERSHIP

PATHOLOGY VISIONS

RESOURCES



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MONTHLY BLOG POST

DICOM FOR DIGITAL PATHOLOGY INTEROPERABILITY

BY: DAN HOSSEINZADEH



2019 PATHOLOGY
VISIONS

CELEBRATING 10 YEARS OF THE DIGITAL PATHOLOGY ASSOCIATION

DIGITAL PATHOLOGY:
**EVOLUTION
& REVOLUTION**

OCTOBER 6 - 8
HYATT REGENCY ORLANDO | ORLANDO, FL

KEYNOTE PRESENTED

NEWS

Leica Biosystems Receives FDA 510(k) Clearance to Market a Digital Pathology System for Primary Diagnosis

May 29, 2019

Proscia updates pathology lab software May 22, 2019



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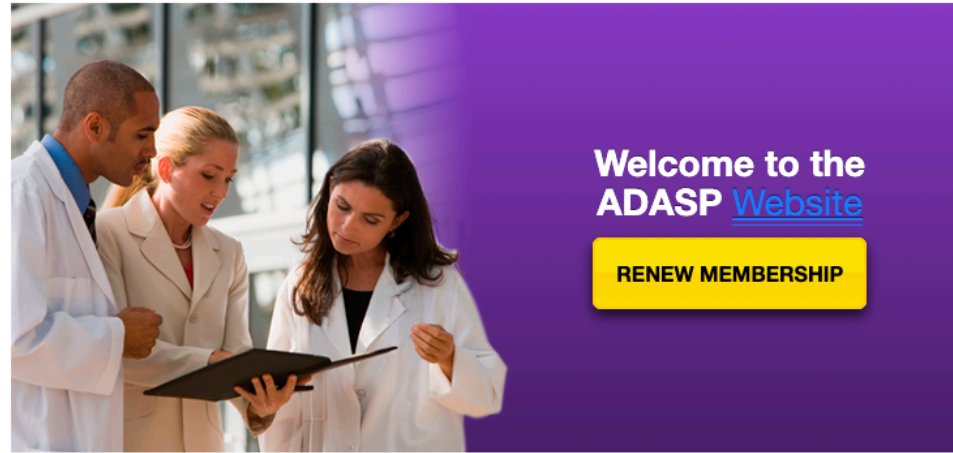
[Job Openings](#)

[CAP and ADASP Offer New
Guideline To Improve Lab
Testing](#)

[Active Surveillance: A Less
Harmful Treatment Option for
Patients with Low-Risk
Prostate Cancer](#)

[Two New Members Appointed
to ADASP Council](#)

[Pathology Leaders Convene in
DC to Address Workforce](#)



Founded in 1989, the Association of Directors of Anatomic and Surgical Pathology (ADASP) is an organization made up primarily of directors of anatomic and/or surgical pathology from academic institutions. The majority of members are from the United States. Individuals who are from outside the U.S. and who meet the membership criteria also are eligible to [apply for membership in ADASP](#).

The Association's objectives are to:

- Promote expertise, effective administration and productive education in the practice of administering anatomic pathology laboratories;



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September 11-13, 2019
Phoenix, AZ | Phoenix
Convention Center

Register today at
www.ascp.org/2019



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To learn more about the
Pathology Service
Coding Handbook
CLICK HERE



Digital Pathology Topic Center


CAP Resources

- [Digital Pathology Committee](#)
- [Digital Pathology Resource Guide](#)
- [US Food and Drug Administration Approval of Whole Slide Imaging for Primary Diagnosis: A Milestone Is Reached and New Questions Are Raised](#)
- [Implementation of Whole Slide Imaging for Clinical Purposes](#)
- [Validating Whole Slide Imaging for Diagnostic Purposes in Pathology](#) - Guideline from the [College of American Pathologists: Pathology and Laboratory Quality Center](#)
- [2018 Webinar - Whole Slide Imaging \(WSI\) For Primary Diagnosis: Is Your Practice Prepared for the Digital Future?](#)
- [Case of the Month](#)
- [DigitalScope whole slide image system](#) - CAP programs that contain WSI
- [Informatics Committee](#)
- [In vivo Microscopy \(IVM\) Committee](#)

HQIP Whole Slide Image Quality Improvement Program HQWSI


NEW

Procedure	Program Code	Challenges per Shipment	
		A	B
Endorectal resection	HQWSI	1	
Endometrial resection	HQWSI	1	
Endorectal needle core biopsy	HQWSI	1	
Endorectal needle core biopsy	HQWSI	1	
Endorectal resection	HQWSI		1
Endometrial resection	HQWSI		1
Endorectal biopsy	HQWSI		1
Endorectal punch biopsy	HQWSI		1



The International Academy of Pathology


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Welcome

to the International Academy of Pathology (IAP)

The IAP is dedicated to the advancement of Pathology through educational exchanges worldwide. Collectively, we provide a forum for the presentation and discussion of advances in the understanding of pathologic processes and for the presentation and critical evaluation of scientific, technological and methodological advances. Our goal, and a fundamental role of the IAP, is to provide [access](#) to the vast store of valid, currently authenticated and trusted knowledge for questioning minds.



Upcoming Events and Breaking News



[11th International Junior Academy Summer School](#)

August 8 – 10, 2019 in Riga / Latvia - see [link](#) above for bursary applications


Tweets by @IAPCentral

IAP Central Retweeted

Jo Martin @JoMartin_path
To all those celebrating, Eid Mubarak! @RCPath

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Education

Continuing Medical Education and Continuing Certification

USCAP has numerous CME and SAM activities that fulfill the CC Part II requirements for Lifelong Learning and Self-Assessment. Our formats appeal to the ways in which people learn at their own pace, in their own style.

Live Meetings

eLearning

What groups are involved - Summary



COLLEGE of AMERICAN
PATHOLOGISTS



Association of Directors of
Anatomic and Surgical Pathology



IHE
INTERNATIONAL

Integrating
the Healthcare
Enterprise



What is the current problem statement

Diverse professional societies
tackle different problems
conflict: progress vs. safety

Industry + Implementation
one-off solutions
conflict: effort vs. ROI

FDA
“Voice of Reason”
assess effectiveness and safety
focus
intended use

New pathways
MOCK submission
MDDT pathway
precertification
...

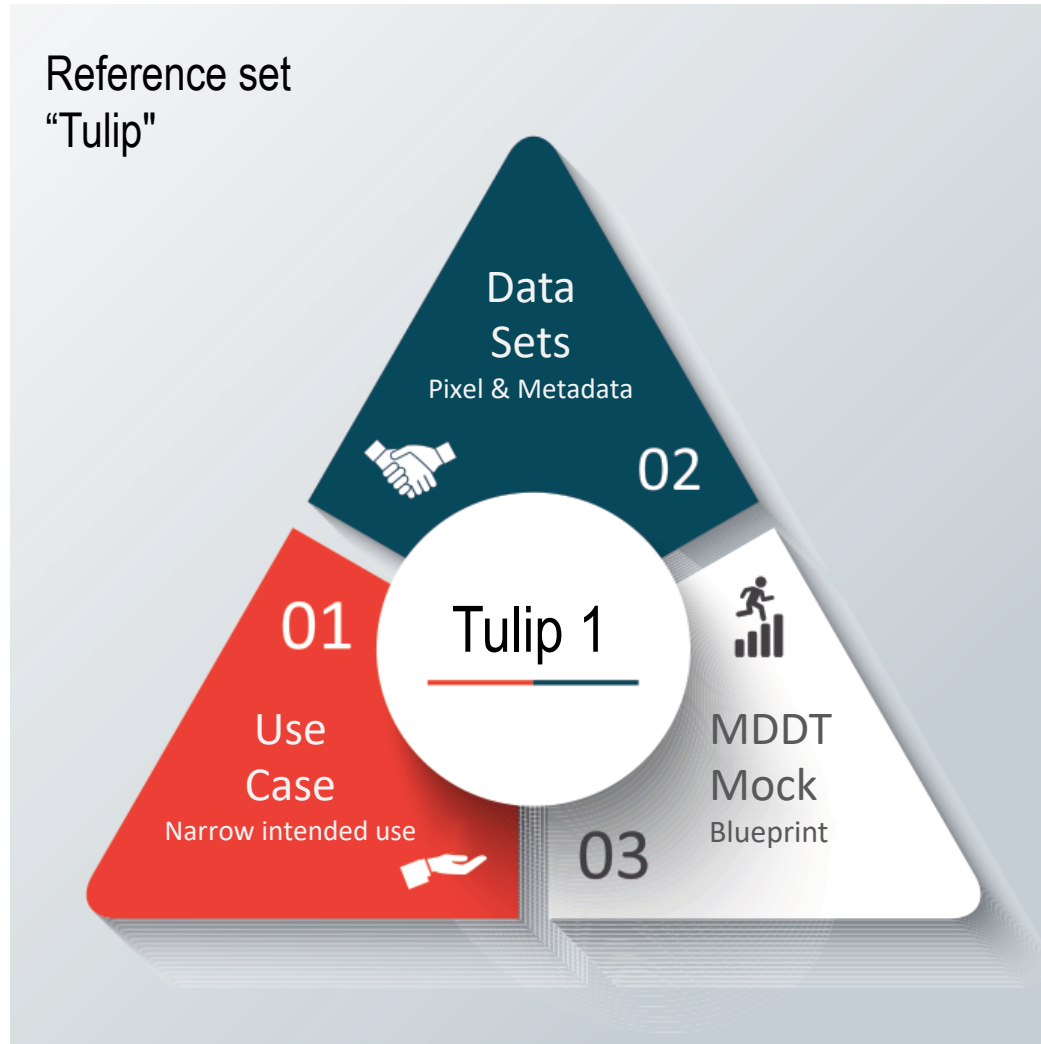
AI, Deep learning, ML
Substantial change
Software as a Medical Device



**“NEED for a framework
to synergize and tackle
larger scale projects”**

Challenges
Time
Scope
Effort

Concrete pre-defined deliverables



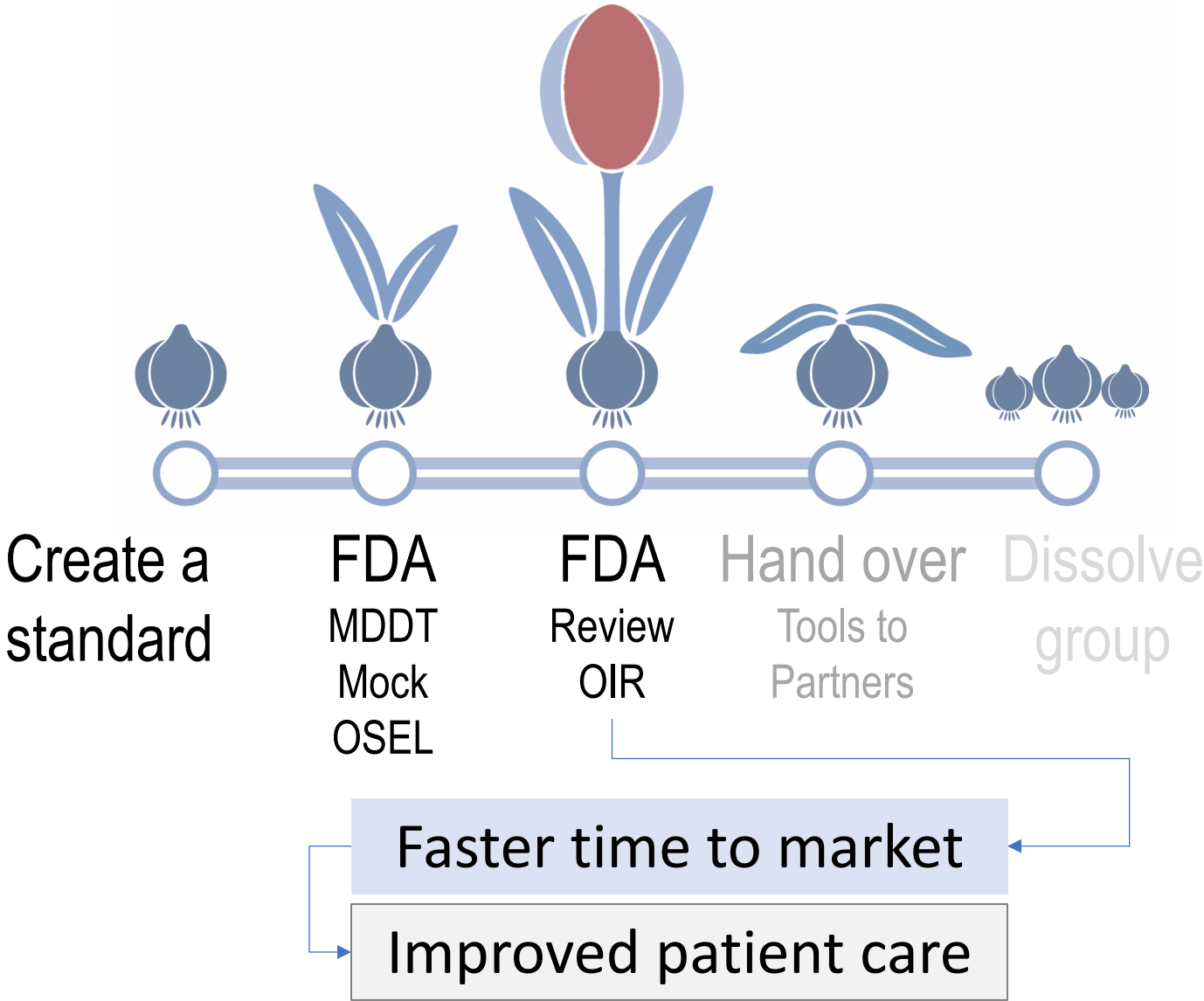
The **overall scope** of Project Tulip is:

Deliver reference sets for each workflow step

Use case from **scanning & metadata acquisition** to a fully clinically integrated diagnostic device

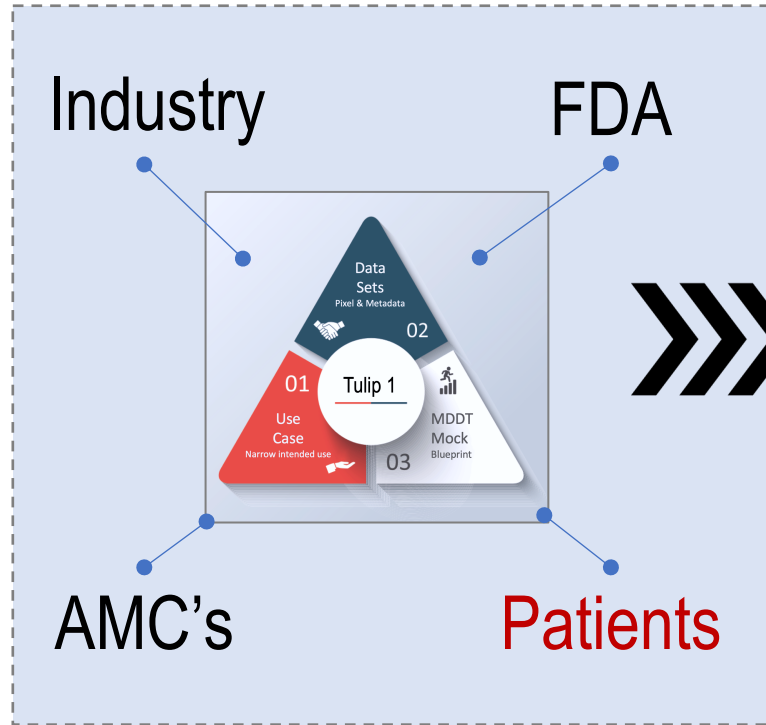
Primary endpoint: at least 1 reference set for the whole workflow

The Concept including a pre-determined Exit Strategy



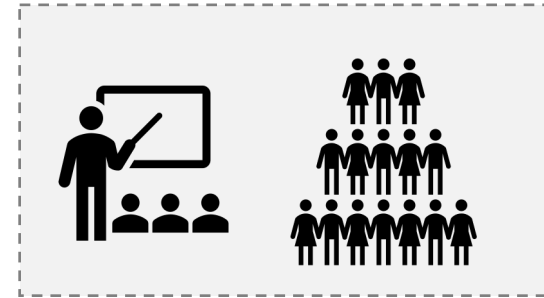
How can this be realized? A process proposal

HTT “wiki members”



“big ideas”

Steering Committee



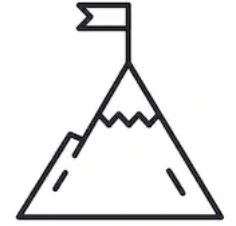
External ideas

A framework enabling progress - Advantages

- An additional opportunity to participate
- Voluntary => no harm by not
- Optional contribution from domain experts
- **Working group to create tools and datasets that enable progress**
- Emphasizes central role of the FDA
- Emphasizes interoperability
- Test drive mock submissions
- Create clarity about regulatory pathways
- Harmonize efforts from various stakeholders

“Be part of the change
instead of
being affected by it” 😊

A framework enabling progress - Challenges



- **Why yet another group/committee?**

FDA shouldn't be an invited guest but an active participant

Synergize with the FDA Office of Science and Engineering Laboratories (OSEL)

- Stakeholder buy-in?
- Operational challenges
- **Funding** – Incentivizing participation via data sharing?

All converge at “What is being accomplished?”

Splitting up the oversight - Challenges



- **MDIC:** industry experience and oversight to unify diverse interests
- **FDA:** regulatory oversight (OSEL)
- **DPA:** provide domain knowledge
- **API:** LIMS domain knowledge – integration + metadata
- **DICOM working group 26:** standards
- **CAP:** data-sets + proficiency testing + practicing pathologists
- **USCAP/IAP:** education – knowledge dissemination (academic medical centers)
- **ADASP:** administration of technology through laboratories
- **CMS:** Health economics input
- **Patient-Organization:** clinical impact and outcome

Deliverables- Functions?



- Develop the framework – functionalities
- HTT – [working group](#)
 - Review proposals and prioritize according to developed criteria
 - For example – initial submission prioritize open source distribution
 - Select project for steering committee review
 - Deployment
 - Intended use
- Implement the [steering committee](#) “chair = MDIC”
 - Monitor contributions
 - Help strategize
 - Review progress
 - Unify interests

Feedback and open discussion

- Options for working together
- Roles and responsibilities
- Steering vs. control
- Membership and governance
- Decision making
- Potential Needs for Agreements and Resources