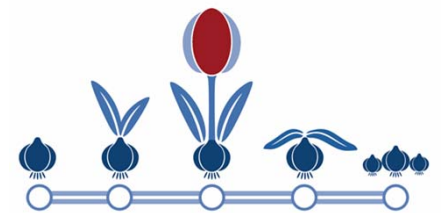




Alliance Progress & Update

Joe Lennerz & Esther Abels



Why are we here?

Self-actualization

desire to become the most that one can be

Esteem

respect, self-esteem, status, recognition, strength, freedom

Love and belonging

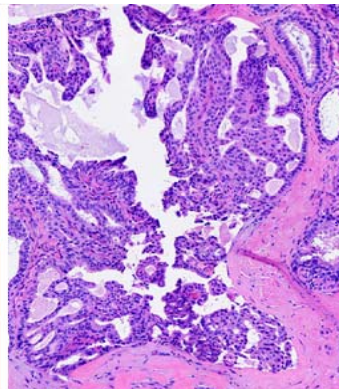
friendship, intimacy, family, sense of connection

Safety needs

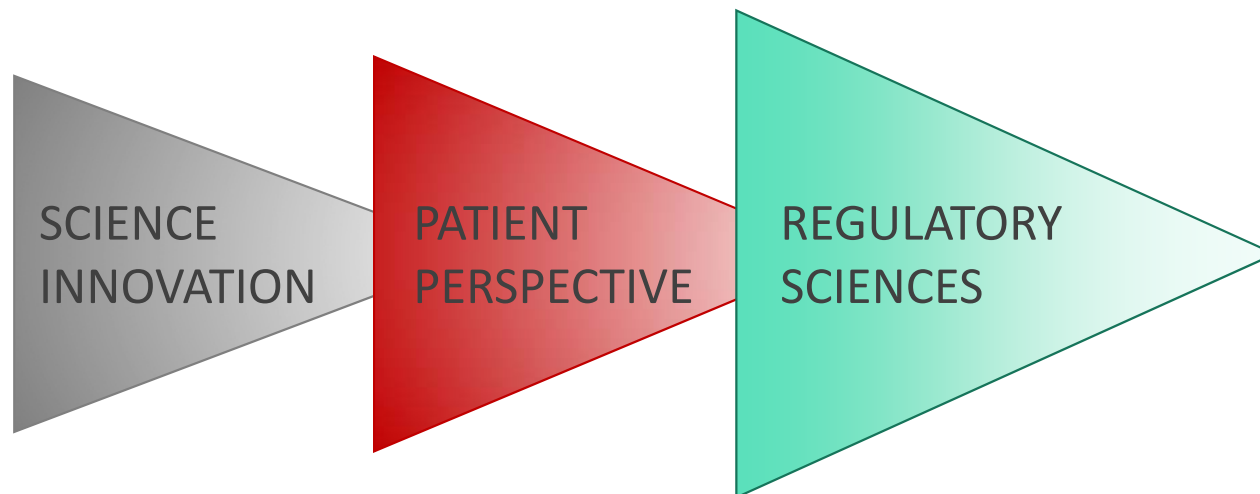
personal security, employment, resources, health, property

Physiological needs

air, water, food, shelter, sleep, clothing, reproduction

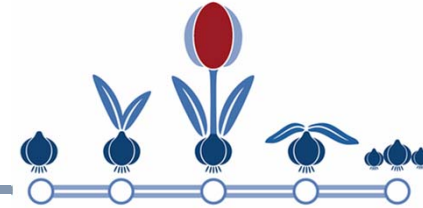


A regulatory science initiative to harmonize and standardize digital pathology processes to speed up innovation to patients.

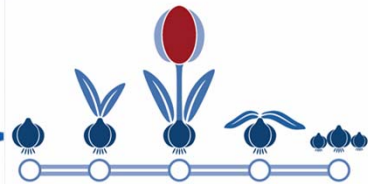


The Alliance for Digital Pathology is a collaborative and voluntary group interested in the evolution of regulatory science as it applies to digital pathology. We seek participation from all stakeholders (industry, vendors, academic medical centers, patient advocates, regulatory bodies, associations etc.) to come together and identify key elements necessary to move the field of digital pathology forward.

The purpose of the Alliance is to accomplish *concrete practical deliverables* and *relevant strategic aims* in order to sustain and expand the existing collaborative infrastructure.



MDIC
MEDICAL DEVICE
INNOVATION CONSORTIUM



01

We Are Subject Matter Experts

With a strong interest in moving the field of digital pathology, ML/AI forward

02

Focus on Regulatory Sciences

We try to establish a framework for larger scale projects that require interdisciplinary collaboration

03

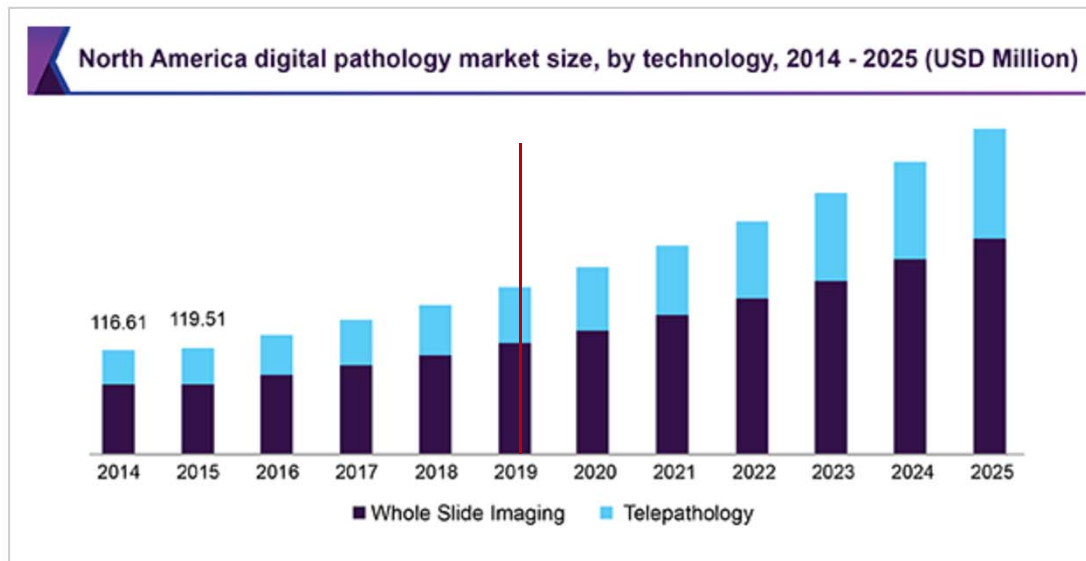
Independent and transparent

We are not a legal entity and not part of a larger group

Executive Summary

- 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

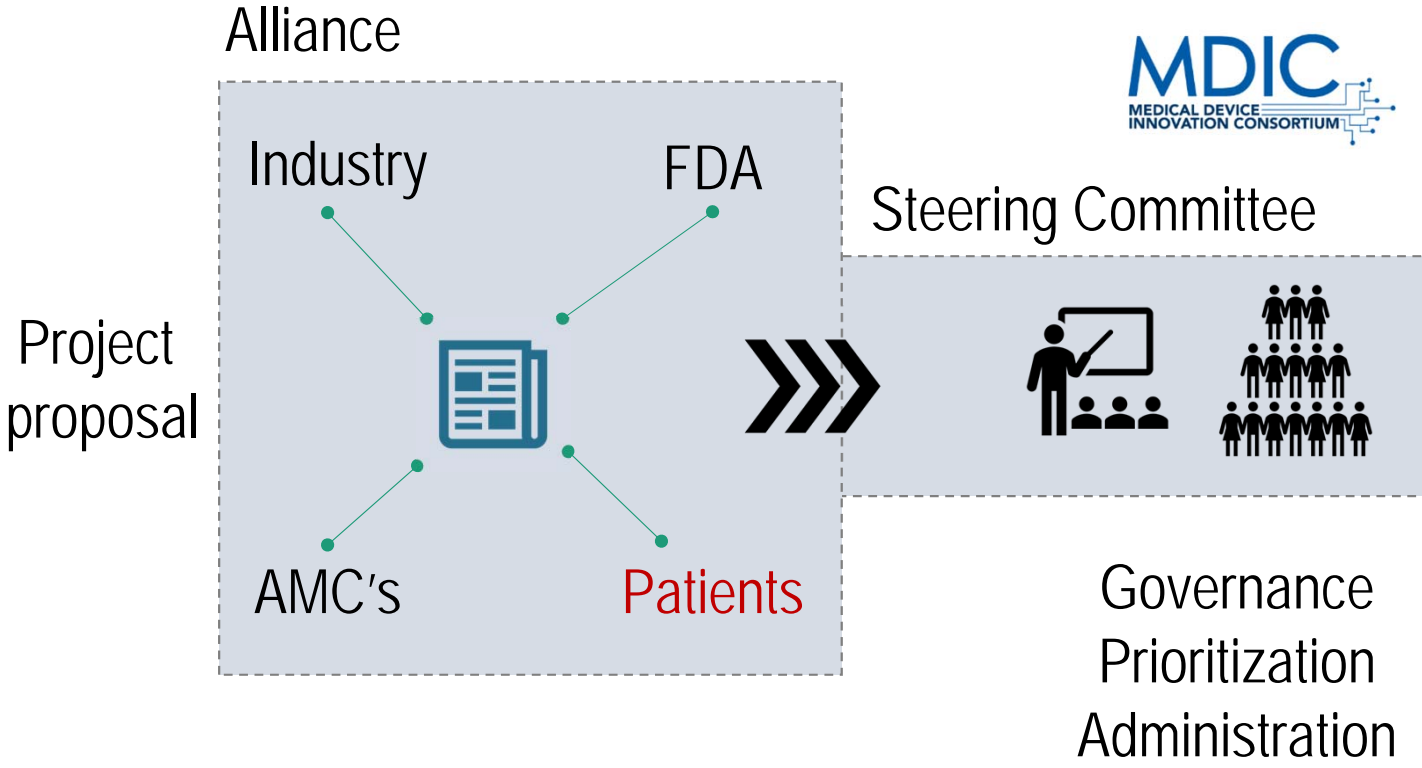
We are re-defining a market



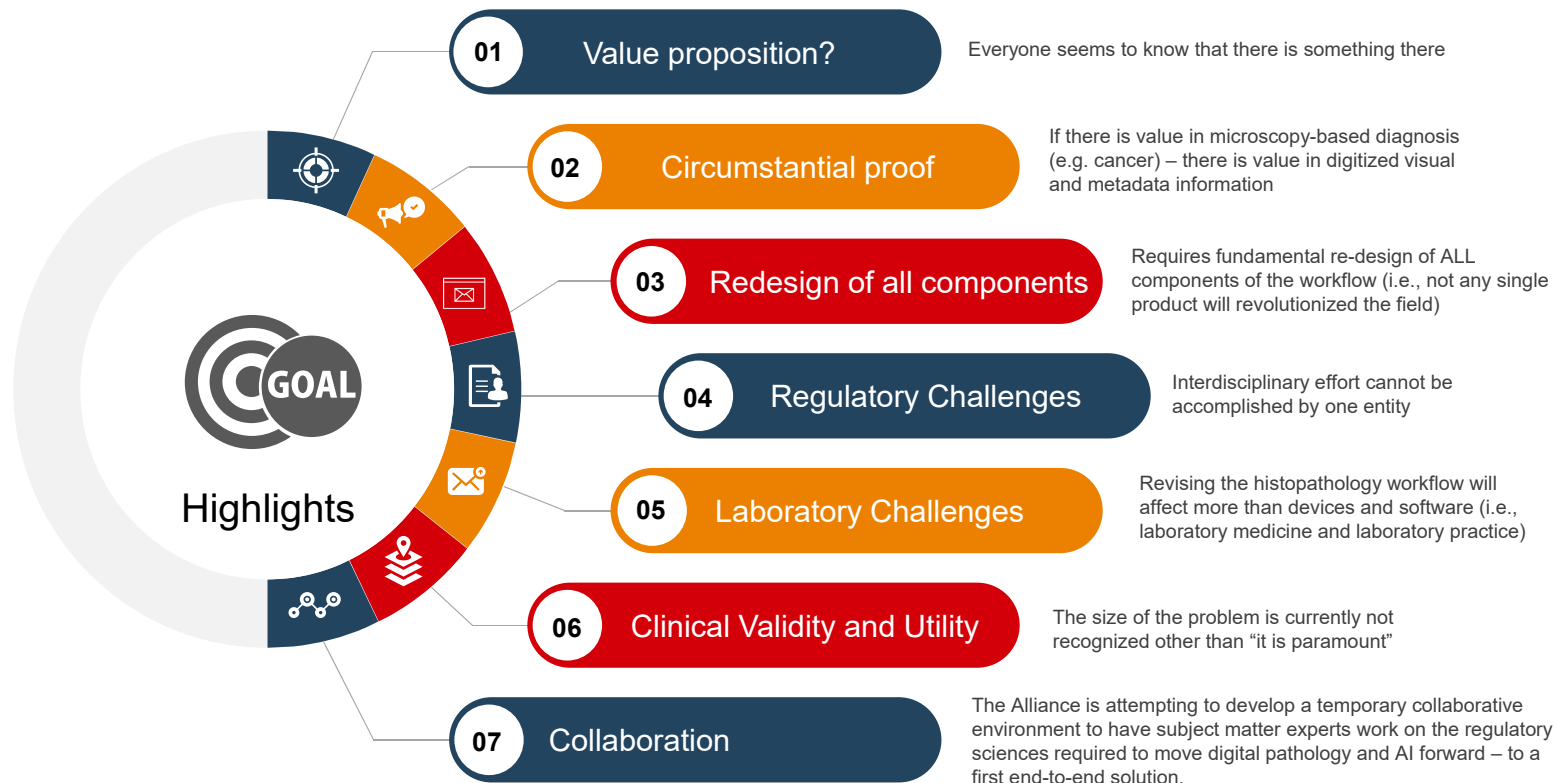
Source:



From project proposal to workstream



TOWARDS A CONCISE PROBLEM STATEMENT – Complete Re-Design



File Edit View History Bookmarks Tools Help

The Alliance for Digital Pathology X

https://digitalpathologyalliance.org 110%


Email Alliance NCIhub Code Projects IntlMeeting quick music dict library maps MS tips FDA Save to Ideabook

HOME INFORMATION NEWS
PROJECTS

THE ALLIANCE FOR DIGITAL PATHOLOGY

[DONATE](#)

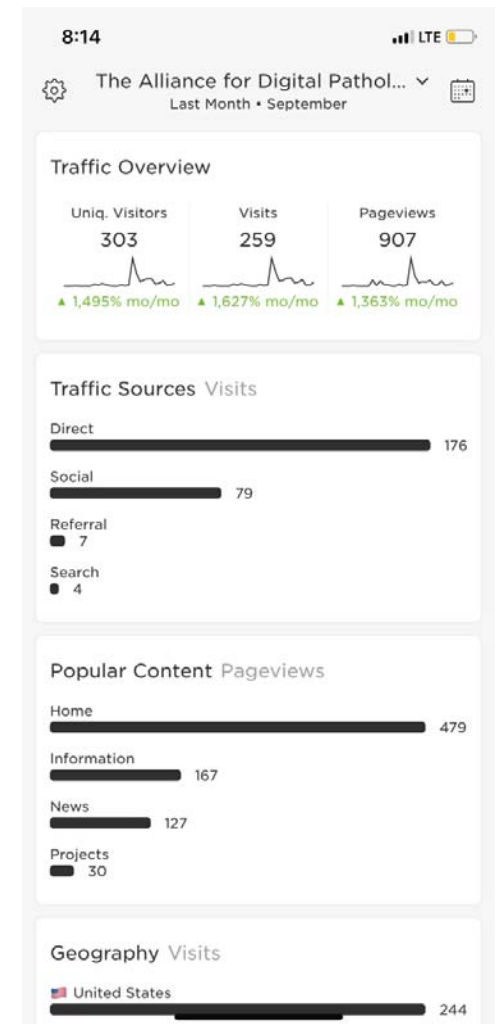
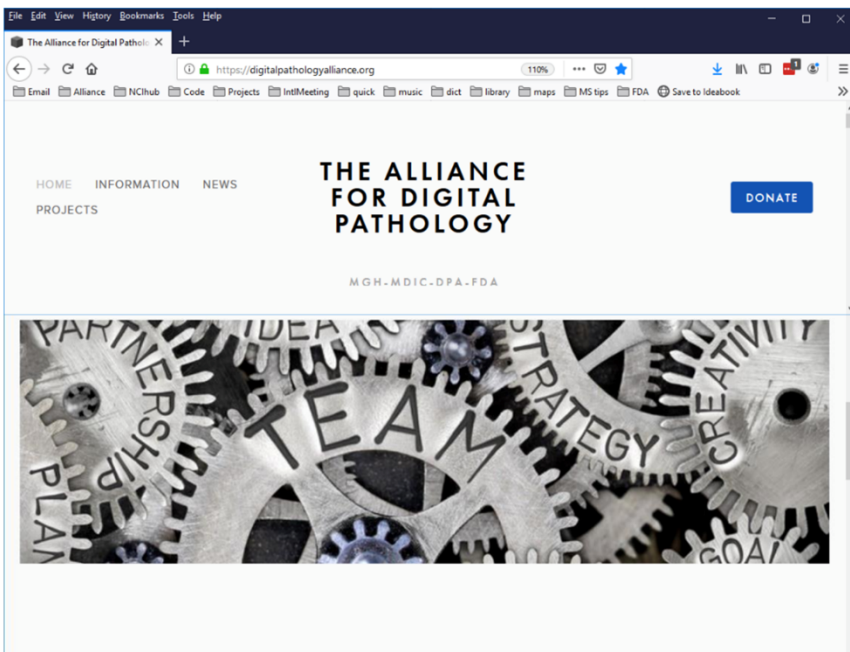
MGH-MDIC-DPA-FDA



A collage of interlocking gears with various business and organizational terms engraved on them, including 'PARTNERSHIP', 'TEAM', 'STRATEGY', 'CREATIVITY', 'IDEAS', 'PLAN', and 'GOALS'.

www.digitalpathologyalliance.org

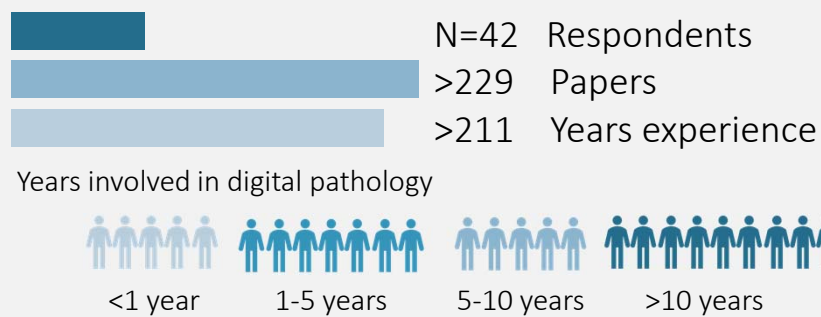
We will post all meeting materials, including presentations there soon.



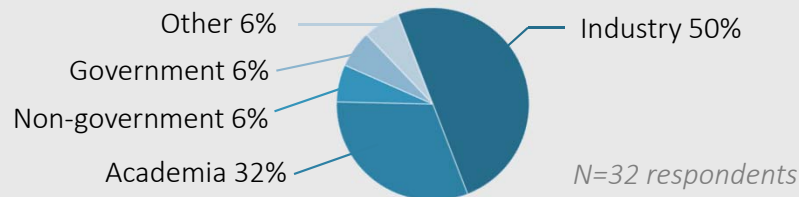
Alliance Survey Results Overview

Marble, Dudgeon, Huang, et al., unpublished

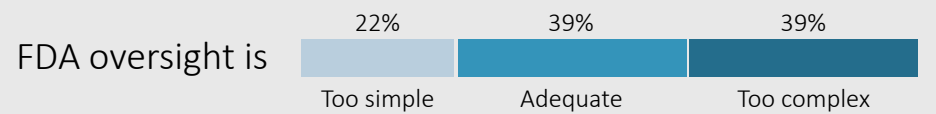
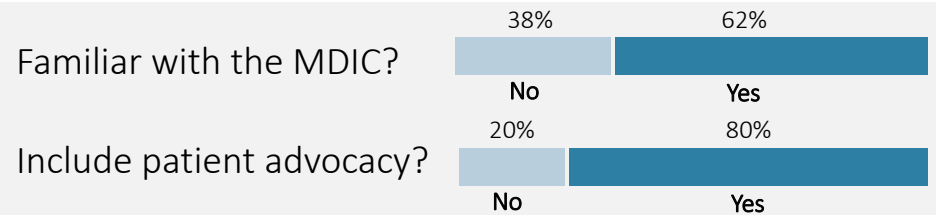
DEMOGRAPHICS



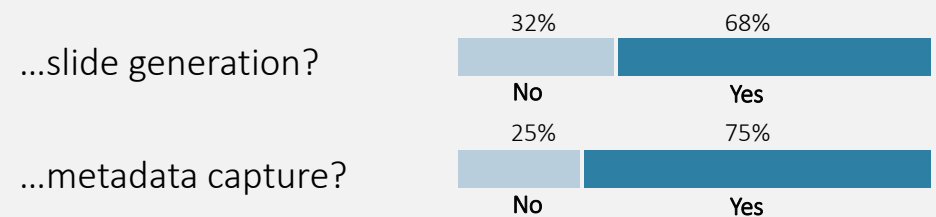
Self-assigned sector



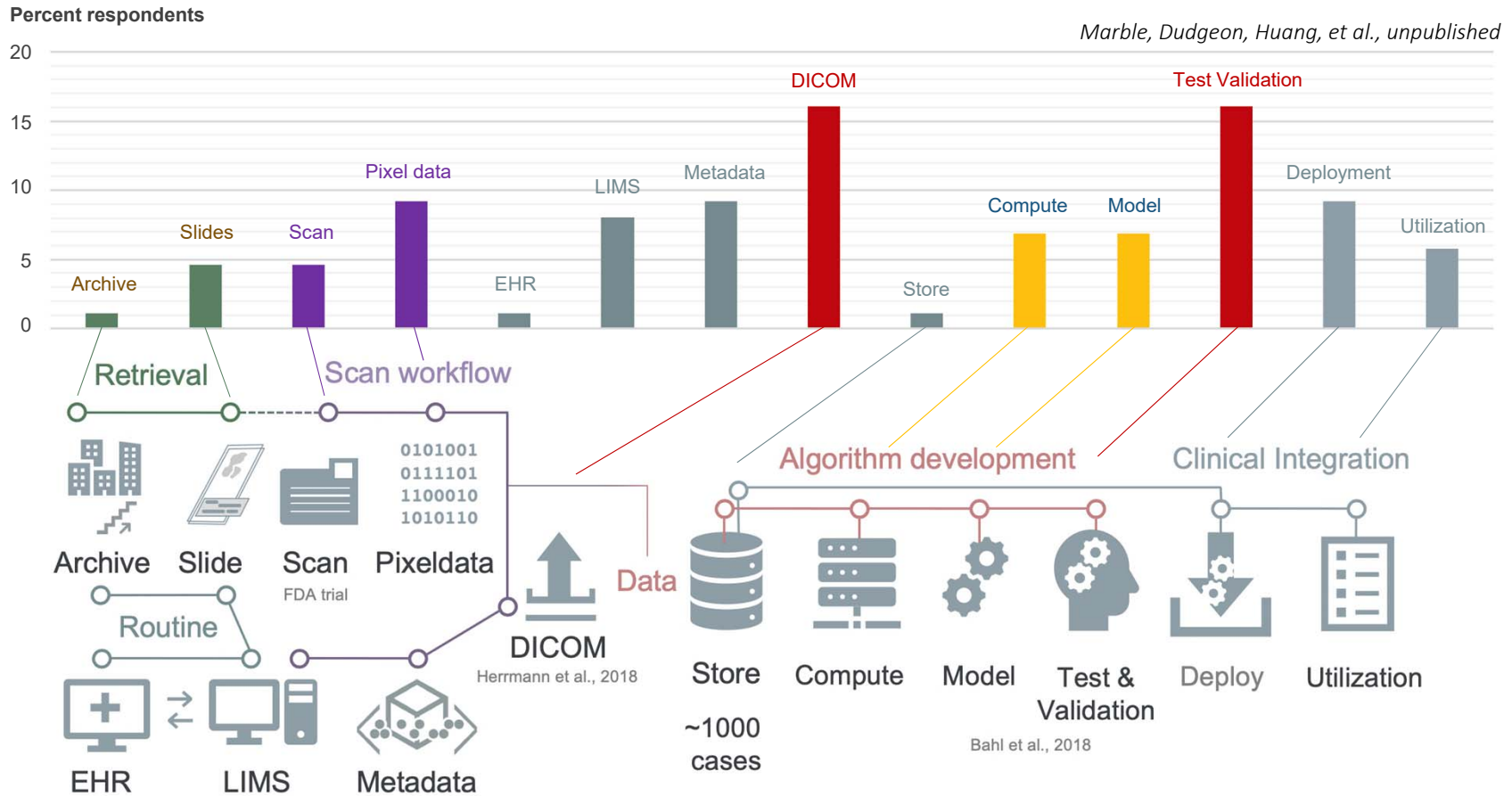
SELECTED RESPONSES



The Alliance focus should include....



Alliance Survey Results Overview



Digital Pathology Alliance

ROADMAP



AGENDA – 1

- 8.00-8.30 **Breakfast, Networking, & Arrival**
- 8.30-8.45 **MDIC Introduction and Welcome**
Pamela Goldberg
President & CEO, MDIC
- 8.45-8.55 **Introductions**
Joe Lennerz, MD, PhD
Medical Director, Center for Integrated Diagnostics
Associate Chief, Department of Pathology, Massachusetts General Hospital
Associate Professor, Harvard Medical School
Esther Abels, MS
VP Regulatory Affairs, Clinical Affairs, and Strategic Business Development
PathAI
Brandon Gallas, PhD
Senior Mathematician
Division of Imaging, Diagnostics, & Software Reliability, CDRH, OSEL, FDA
- 8.55-9.15 **Alliance Progress Update**
Joe Lennerz, MD, PhD
Esther Abels, MS
- 9.15-9.30 **Digital Pathology Association (DPA)**
Esther Abels, MS
Scott Blakely
Business Development Manager, Whole Slide Imaging & Digital Pathology
Hamamatsu Corporation
- 9.30-9.45 **Food and Drug Administration (FDA)**
Sara Brenner, MD, MPH
Associate Director for Medical Affairs,
Chief Medical Officer In Vitro Diagnostics, CDRH, FDA
Brandon Gallas, PhD

AGENDA – 2

- 9.45-10.00 **Break**
- 10.00-10.15 **Patient Centered Outcomes Research Institute (PCORI)**
Bill Lawrence, MD, MS
Senior Clinical Advisor
Office of the Chief Engagement and Dissemination Office
PCORI
- 10.15-10.30 **Friends of Cancer Research (FOCR)**
Laura Lasiter, PhD
Science Policy Analyst
FOCR
- 10.30-10.45 **American College of Radiology (ACR)**
Bibb Allen, MD, FACR
Chief Medical Officer
ACR Data Science Institute
- 10.45-11.00 **Healthcare Infrastructure**
Joe Lennerz, MD, PhD
- 11.00-11.50 **Overview of Projects**
for breakout sessions
- 11.50-12.00 **Explain Breakout Session Structure**
- 12.00-1.00 **Lunch**
(self-assignment for breakouts 1 & 2)

AIMS OF THE MEETING TODAY



Engage

Please help to establish a collaborative environment.
We are not on record
We also seek for continued participation (e.g. webex)

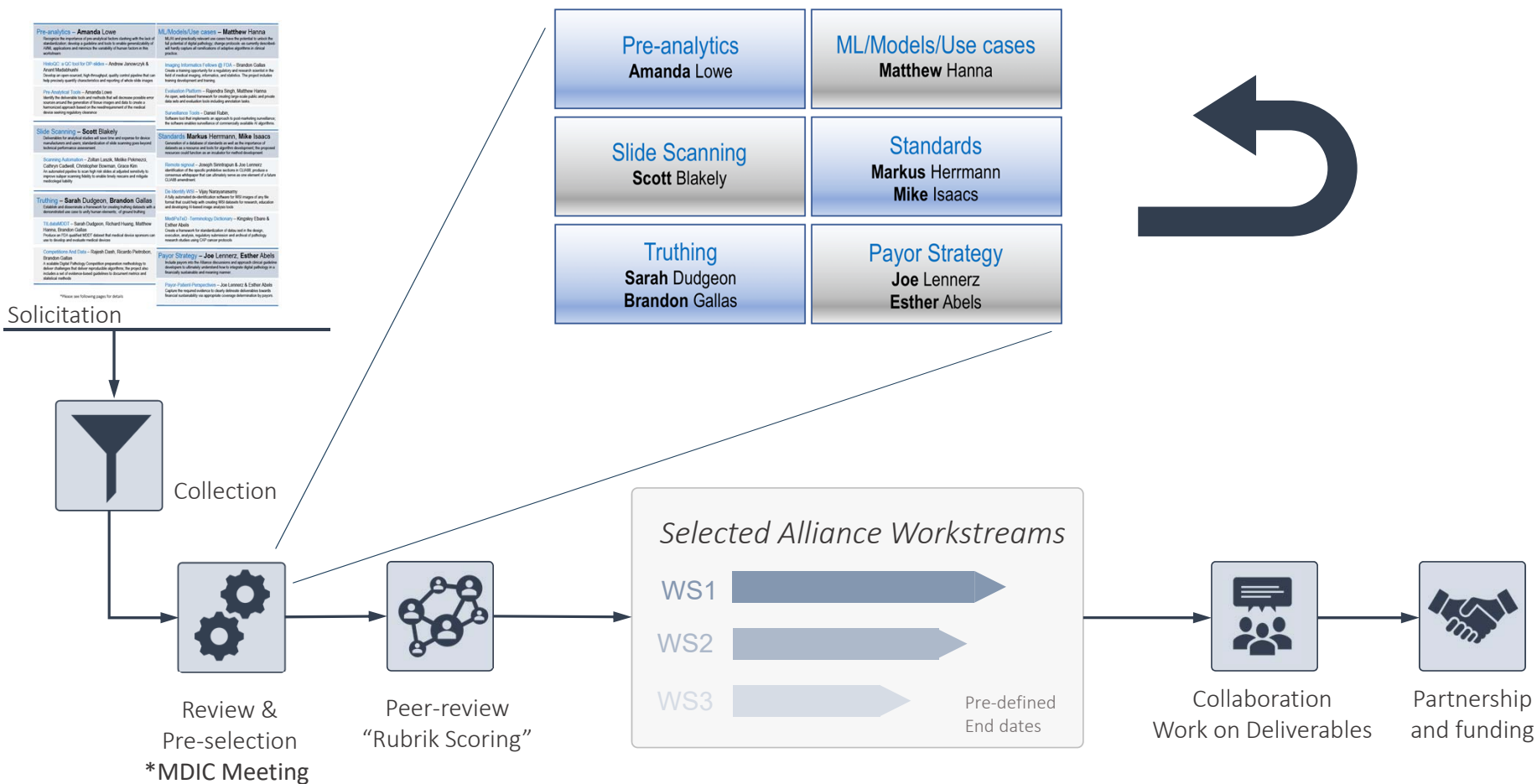
Collaborate

We try to get everyone's input.
Not only during the breakout session

Patient Perspective

Raise awareness of the patient perspective.
Try to bring this back to 'what does this mean for patient care'?

Process Diagram of Blueprint Solicitation, Review, Vetting and Workstream Prioritization



Alliance Workstream Scoring Rubrik

Significance



- Does the proposal address a major problem in the field?
- Does the proposal identify a novel problem?
- Does the proposal provide new information or solutions to the problem?
- Does the proposal address a critical barrier to progress?

Innovation



- Is the study proposing a new method, technology, or reasoning?
- If not, is it significantly improving/modifying an existing method, technology, or reasoning?
- Does the proposal advance understanding of the field or push into a novel area?
- Does the proposal impact other fields, or is it limited to pathology?

Approach



- Is the methodology clear and achievable given the state-of-the-art?
- Are appropriate controls included in the experimental design? E.g. “ground truths” for AI-ML algorithms, defined rates of negative and positive samples for sensitivity and specificity calculations, etc.
- Can the techniques/methods be easily used by others, or are they dependent on user expertise?
- Are the “aims” of the project interdependent, or can each aim stand alone should one or multiple aims fail?

Budget



- Is there funding available for the project from the investigator?
- How much funding is being asked for from the alliance or other entities?
- Does the budget factor in personnel costs and indirect costs along with the material costs of performing the study?
- Is there an appropriate budgetary breakdown by category for assessment?
- What is the timeline for the project?

Impact



- Does the project stand to change the standard of care or other gold standard in the field?
- Does the project address a known challenge in the field with a reasonable solution?
- How many potential publications are likely to result?

Alliance Workstream Scoring Rubrik

FDA

Pat.-Rep.

Ind./DPA

AMC

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