COLLABORATIVE COMMUNITIES TOWN HALL

Panel 1: Lessons Learned in Establishing a Collaborative Community

FDA

MedTech Color Collaborative Community

- Representative: Nada Hanafi, MS, MPH & Ariana Albiar, MS
- FDA Liaison: Michelle Tarver, MD, PhD

Digital Health Measurement Collaborative Community (DATAcc)

- Representatives: Jeanne Chung, MBA & Jennifer Goldsack, Mchem, MA, MBA, OLY
- FDA Liaison: Annie Saha

Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community

- Representative: Ben Brown
- FDA Liaison: Brittany Schuck, PhD

Wound Care Collaborative Community (WCCC)

- Representative: Vickie Driver, DPM, MS, FACFAS
- FDA Liaison: Cynthia Chang, PhD

Heart Valve Collaboratory (HVC)

- Representative: Martin Leon, MD & Michael Mack, MD
- FDA Liaison: Changfu Wu, PhD

RESCUE (REducing SuiCide Rates Amongst IndividUals with DiabEtes) Collaborative Community

- Representative: Katharine Barnard-Kelly, PhD
- FDA Liaison: Yiduo Wu, PhD

MedTech Color Collaborative Community on Diversity and Inclusion in Medical Device Product Development and Clinical Research

Our Mission:
The MedTech Color Collaborative Community is a forum where healthcare providers, regulators, industry, patients and other stakeholders collaborate to advance diversity and inclusion in medical device product development and clinical research.

DATAcc

Q1: Why did you choose the collaborative community approach as to another mechanism to partner with others?
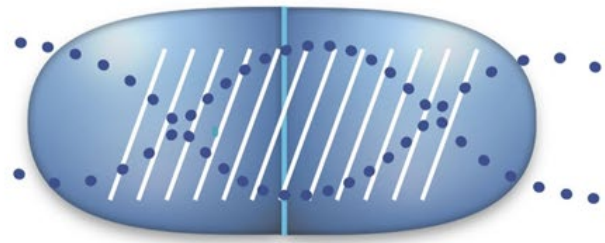
DATAcc, hosted by DiMe, convenes the broad and inclusive range of stakeholders necessary to modernize the way we measure and define health and disease using digital approaches and technologies.

Founded in 2019, the Digital Medicine Society (DiMe) is the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. Together, we drive scientific progress and broad acceptance of digital medicine to enhance public health.

Members also include FeetMe Devices, HHS-HC3, Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality, National Cancer Institute, National Digital Inclusion Alliance, OptumLabs, US Dept. of Veterans Affairs, and Verily

(Updated 10/18/21)

Collaborative Community Town Hall

October 21, 2021

Q: How Did WCCC Select Stakeholders

We invited key influencers that represent the expanded wound care community in the U.S., to include:

- Industry (Manufacturers, Distributors, and Biotech)
- Payors/Insurers/Health System Providers
- Health Data Registry Experts
- Clinicians (Urban and Rural)
- Researchers/Academia
- Government Agencies (VA, DOD, CMS, FDA)
- Multidisciplinary Practitioners
- Society and Association National and Global Recognized Leaders
- Patient Advocacy Groups

How Reducing Suicide Rates Amongst Individuals with Diabetes (RESCUE) Stakeholders Were Identified

- ► It was crucial, if we were to succeed, that key stakeholders across the whole spectrum of involvement in diabetes were involved

- ► To this end, I took a very broad-brush, transparent and inclusive approach

- ► I was mindful of the sensitivities, challenges and potentially legal issues industry in particular might face and have been very clear to express this and work with our stakeholders to avoid any anxiety or mistrust

www.rescuediabetes.com

BARNARD HEALTH
HEALTH PSYCHOLOGY RESEARCH

Early Wins & Roadblocks

- Two fast publications setting scene and highlighting extent of ISI / Suicide

- Rapid initiation of small-scale but impactful research projects to demonstrate outputs and maintain interest eg HCP and PWD surveys

- Symposia acceptance on big national and international conference programs

- Website

- Failed RO1 grant application

- Committee members not having enough time to commit alongside their other roles

- Huge project, so we set up sub-groups to address different aspects ie:

  - education,

  - key messaging

  - ID/coding

BARNARD HEALTH
HEALTH PSYCHOLOGY RESEARCH

Panel 2: Settling for the Long Run: Wins and Opportunities in Operating and Maintaining a Collaborative Community

FDA

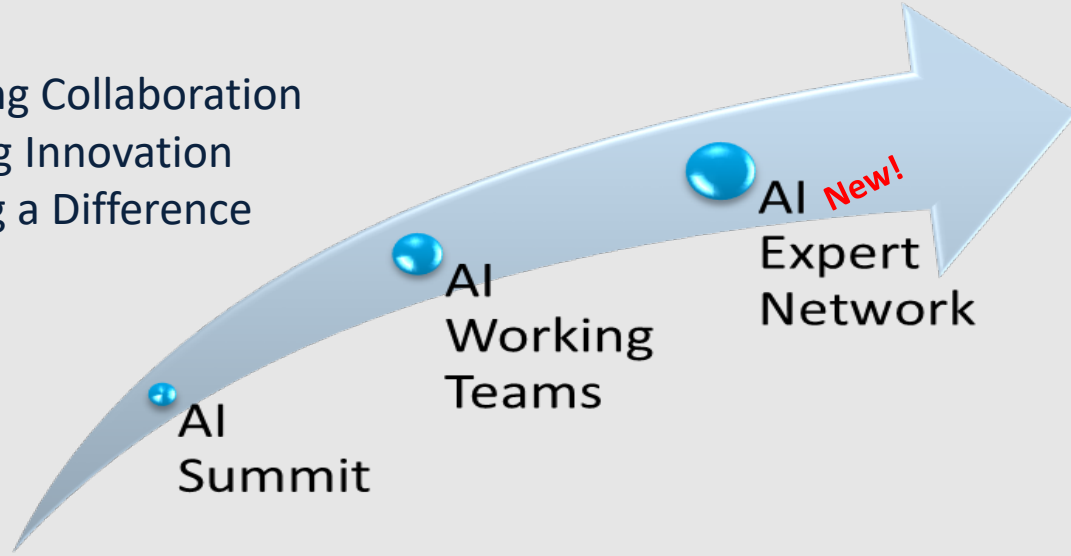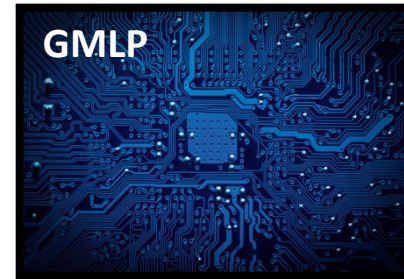|		
Xavier Artificial Intelligence (AI) World Consortium • Representative: Marla Phillips, PhD • FDA Liaison: Matthew Diamond, MD, PhD	**International Liquid Biopsy Standardization Alliance (ILSA)** • Representative: Dana Connors, MSc • FDA Liaison: Zivana Tezak, PhD	**Pathology Innovation Collaborative Community (PICC)** • Representative: Jithesh Veetil, PhD, Jochen Lennerz, MD, PhD • FDA Liaison: Brandon Gallas, PhD
National System for health Technology Coordinating Center (NESTcc) Collaborative Community • Representative: Flora Sandra Siami, MPH • FDA Liaison: Daniel Canos, PhD, MPH	**Case for Quality Collaborative Community (CfQ CC)** • Representative: Joseph Sapiente • FDA Liaison: Francisco Vicenty	**Collaborative Community on Ophthalmic Imaging (CC-OI)** • Representative: Mark Blumenkranz, MD, MMS • FDA Liaison: Malvina Eydelman, MD

Xavier University AI Community

Mission:
- Inspiring Collaboration
- Leading Innovation
- Making a Difference

AI Summit → AI Working Teams → AI Expert Network **New!**

Types of Organizations in our Community

MERCK
AMA
gsk
Abbott
AMERICAN COLLEGE OF SURGEONS
aizon
PHILIPS
The Christ Hospital Health Network
MHRA Regulating Medicines and Medical Devices
AAD American Academy of Dermatology Association
FDA U.S. FOOD & DRUG ADMINISTRATION
AstraZeneca
Medtronic
Boston Scientific
SIEMENS
Health Canada
SANOFI
Honeywell
Sparta Systems

Xavier AI Working Teams

AI@POC — New!
AI at the Point of Care
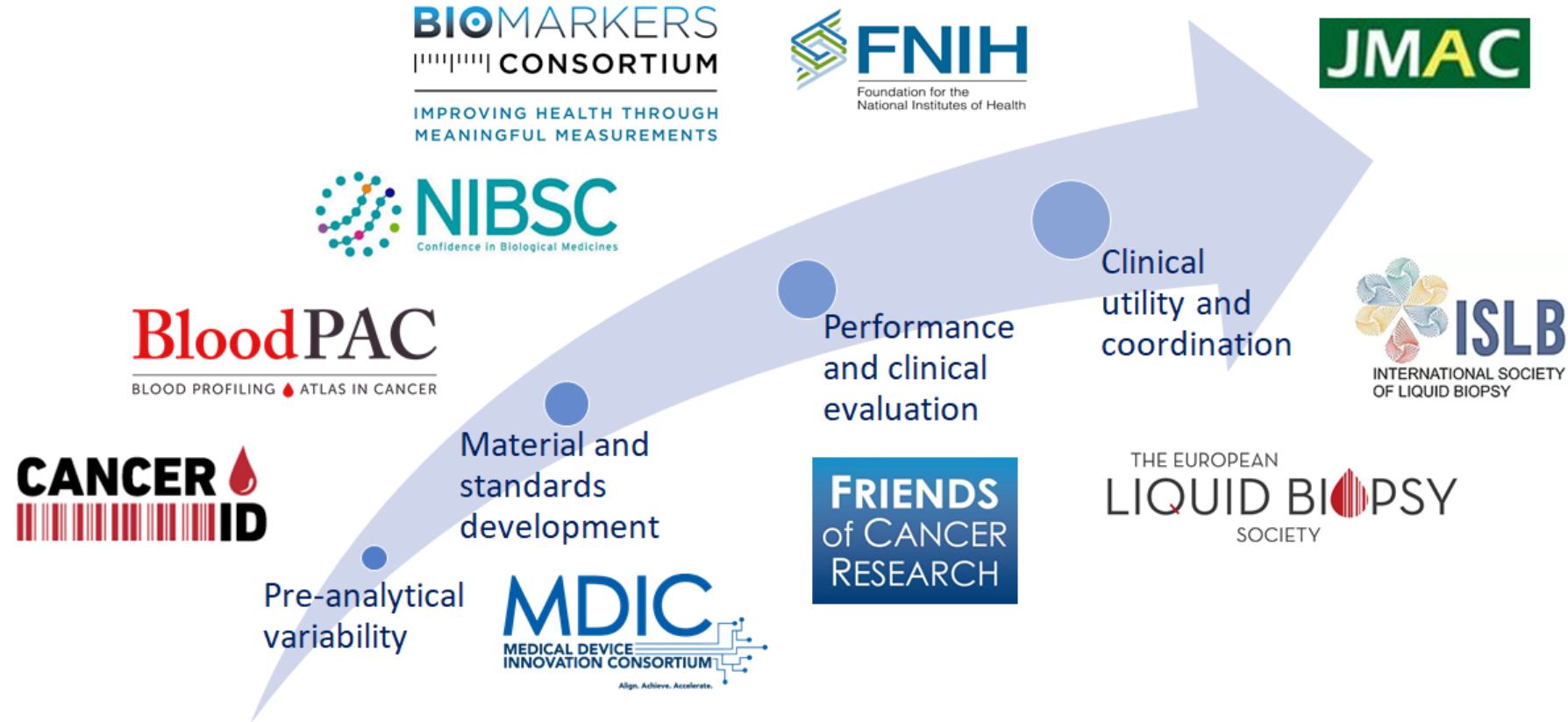
GMLP
Good Machine Learning Practices

AIO
AI in Operations

International Liquid biopsy Standardization Alliance (ILSA)

Members / Stakeholders:

- Public and private sector - representing academia, industry, government, patients, end users
- International representation - US, EU, Japan

A number of non-profit efforts and consortia, dialogue with the FDA and EMA

Member organizations of the International Liquid biopsy Standardization Alliance perform synergistic functions from pre-analytical variables analysis to clinical utility activities to bring the promise of globally standardized and evaluable precision medicine to clinical practice.
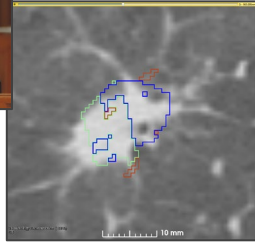
Pathology Innovation CC: Lessons learned

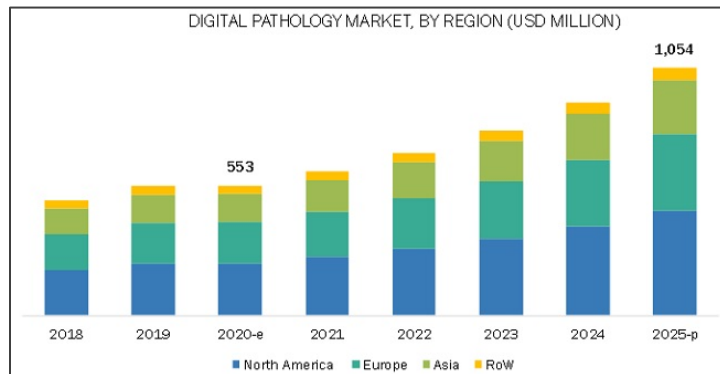## Overview of Public Health Issue

Wikipedia.org

It is 2021 and cancer is still diagnosed using the microscope

Cancerimagingarchive.net

Pathology is the ground truth for many applications

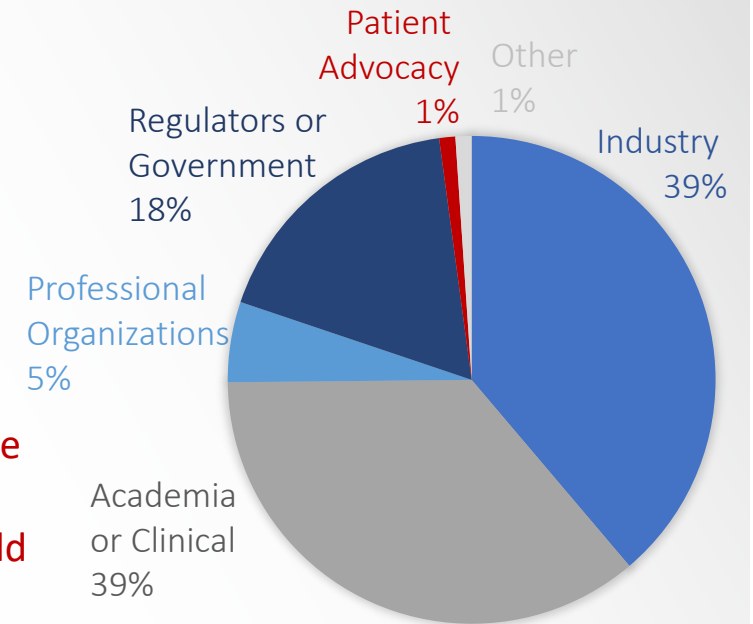DIGITAL PATHOLOGY MARKET, BY REGION (USD MILLION)

553   1,054

2018 2019 2020-e 2021 2022 2023 2024 2025-p

■ North America ■ Europe ■ Asia ■ RoW

Digitization and ML/AI is booming
1B$ market

MarketsAndMarkets Oct 2021

Lessons learned: Opportunity

1. The framework for evaluating digital pathology and AI/ML is still evolving

2. The community is hungry for relevant information

3. Sharing **a LOT of information** results in continued stakeholder engagement

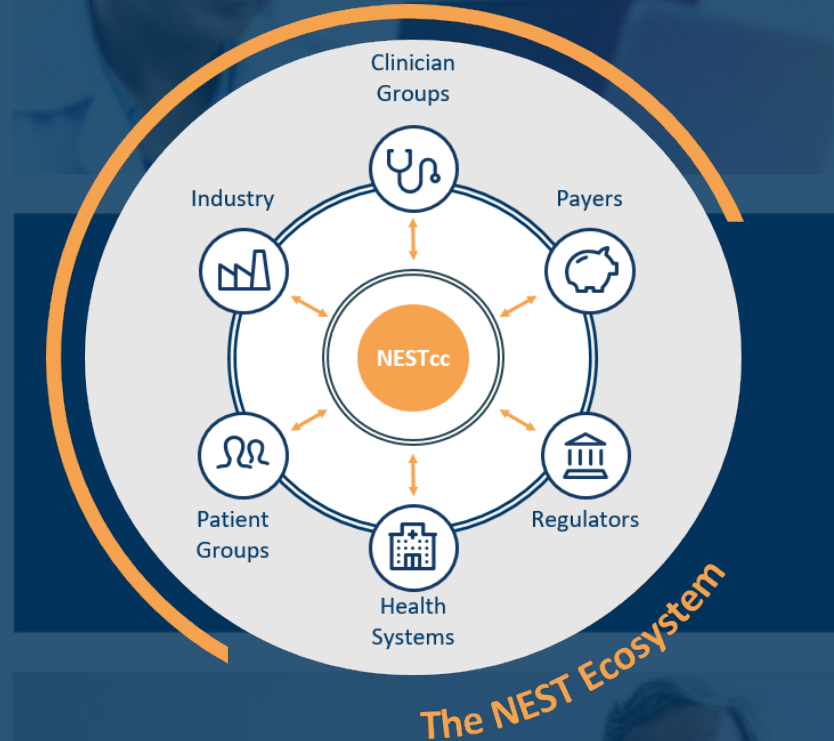**The message resonated with the field**

Now we collaboratively develop tools and data to solve regulatory hurdles in the community

Membership

514 Members + 31 meetings

Patient Advocacy 1%
Other 1%
Regulators or Government 18%
Industry 39%
Professional Organizations 5%
Academia or Clinical 39%

Oct 2021

MISSION AND VISION

Mission

The NEST community is passionately committed to transforming the way medical device technologies are tested, approved and monitored.
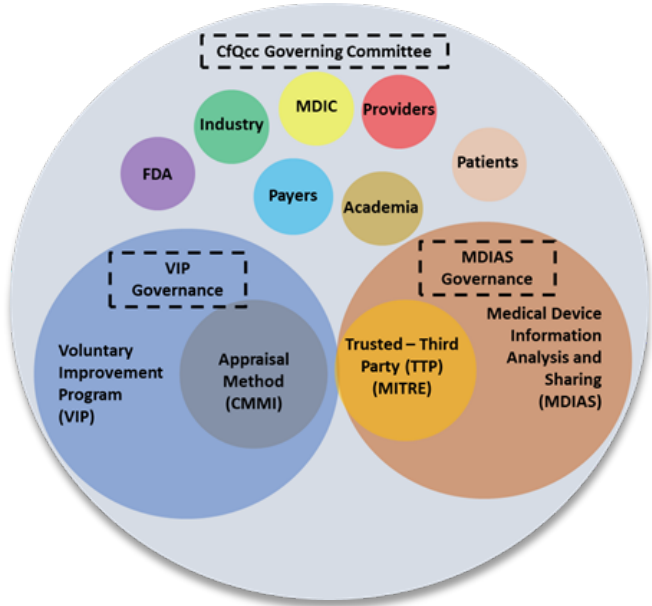

The NEST Ecosystem

Vision

We envision a world in which people are empowered to make informed medical choices that enable patients to live their lives to the fullest extent possible.

Leveraging our unique position, we combine real world evidence with unparalleled expertise to accelerate patients' access to safe and effective medical technology

Case for Quality (CfQ) Collaborative Community Progression

November 2019
CfQ forum participants propose establishing a collaborative community for Case for Quality

March 2020
MDIC CfQ Steering Committee Launches working group to develop charter and proposal for the collaborative community

July 2020
Governing Committee for the Collaborative Community is nominated and established

September 2020
CfQ Collaborative Community Charter ratified and CfQcc is established

October 2020
FDA announces participation in the Case for Quality Collaborative Community

Collaboratively combining stakeholder engagement, continuous improvement, data, and analytics in advancing medical device quality and safety to achieve better patient outcomes.

Empowering stakeholders across the medical device ecosystem

Identification and visibility to projects aimed at fixing prioritized issues identified by the community.

Creating resources that depict changes needed to improve overall level of product quality which will benefit a broad group of stakeholders such as hospitals, payers, health care provides, and patients

GUIDING PRINCIPLES IN THE FORMATION OF THE COLLABORATIVE COMMUNITY IN OPHTHALMIC IMAGING (CCOI)

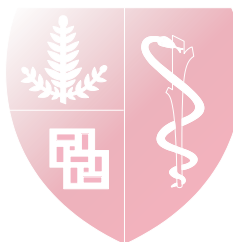It Seemed only fitting that we chose imaging which is the central mission of the eye

But we still needed to focus more tightly than imaging itself and we elected to tackle the looming challenges involved in moving imaging technology from the analog to the digital world

That gave us the ability to harness the power of computer aided image acquisition and processing within traditional optical hardware as well as newer laser based systems to create superior renderings of anatomy and physiology that were quickly available and transportable virtually

Additionally with the aid of machine learning and other artificial intelligence techniques, we could accelerate progress in enhanced interpretation of those images with or without the participation of highly skilled humans to improve efficiency, outcomes and cost.

We began to more narrowly focus on SaMD, the notion of software as a medical device

We Organized a First Workshop to Help Define the Opportunities and Challenges Involved in October 2017

Mark Blumenkranz, MD—Byers Eye Institute at Stanford University School of Medicine

Malvina Eydelman, MD—FDA - FDA/CDRH

Michael Abramoff, MD, PhD—University of Iowa School of Medicine

Emily Chew, MD—National Eye Institute

Michael Chiang, MD—Director, National Eye Institute

Aaron Lee, MD—University of Washington

David Myung, MD, PhD—Byers Eye Institute at Stanford University School of Medicine

Michael Repka, MD—Wilmer Eye Institute, Johns Hopkins University School of Medicine

Joel Schuman, MD—NYU Langone School of Medicine

Carol Shields, MD—Wills Eye Hospital at Thomas Jefferson University

Michelle Tarver, MD, PhD—FDA/CDRH

Collaborative Community on Ophthalmic Imaging

We needed to attract the best organizations and people

The same informal affinity group formed in 2017 that focused on digital tools then sponsored another well attended collaborative public workshop in early 2019 on Laser Based Imaging

On the basis of those meetings and the people organizing, speaking and contributing to the writing of the manuscripts, we were able to identify and recruit a very strong nucleus of interested and highly capable domain experts and thought leaders to help form and work with the CCOI.

Formal Organization of the CCOI began at the 2019 meeting and in the Fall of that year the FDA recognized us and agreed to participate

In 2021 the CCOI Foundation was incorporated as a 501 c3

CCOI Governance

Executive Committee[a]
Convener: Mark Blumenkranz

FPOAI[b]
Leader: Michael Abramoff

PII[c]
Leaders: Emily Chew and Joel Schuman

AMD[d]
Leader: Emily Chew

ROP[e]
Leader: Michael Chiang

Ocular Oncology[f]
Leader: Carol Shields

Glaucoma[g]
Leader: Joel Schuman