**The Pathology Innovation Collaborative Community (PIcc)**

(the Alliance for Digital Pathology)

Effective (date to be determined)

**The Pathology Innovation Collaborative Community (PIcc)** is a regulatory science initiative that aims to facilitate innovations in pathology as well as advance safety and effectiveness evaluation, and to harmonize approaches to speed delivery to patients using collaborative, pre-competitive approaches. The group is open to all stakeholders, **public or private**, including, but not limited to, academia, industry, health care providers, patients and advocacy groups.

**Mission:** The Pathology Innovation Collaborative Community (PIcc) brings together a broad range of stakeholders to accelerate the development and delivery of regulatory science initiatives in the pre-competitive space that modernize the clinical practice of pathology. Specifically, this will include digital pathology and its major enabling fields of machine-learning and artificial intelligence, imaging informatics, engineering, and computational and data sciences. The mission may be accomplished through collaborative initiatives building and evaluating various health technologies/platforms, leveraging real-world data, and enabling innovative research. ~~The group consists of multiple stakeholders representing the~~ **~~public and private sectors~~**~~.(keep or delete)~~

**Vision:** The central vision of the group is to serve as the umbrella organization for all stakeholders regarding regulatory science questions related to pathology innovation. The key deliverable is a clear path for regulation of pathology innovation through regulatory science. The group will educate each other, seek approvals through various submission programs, and tackle relevant questions by using applicable regulatory science tools.

**Meetings:** All membership meetings will be open to the public. The group encourages applicable content, after confirmation from the author(s), be made publicly available. Membership meetings are intended to provide updates on recent activities and to coordinate the scope of collective efforts. All decisions made by the group are supported democratically through a simple majority vote (provided that a quorum >50% of voting charter signatories) with dispute adjudication exercised before the full community. Minutes are taken and will be made publicly available.

Regular Meetings: Regular meetings shall be held at least four times per calendar year, in-person or remotely. At least one annual meeting, open to the public and for the entire membership, shall be held in-person or remotely. Notice of regular meetings will be provided at least fourteen days in advance of the meeting.

Special Meetings: Special meetings may be called at any time; notice of the time and place of each special meeting will be provided at least three days in advance of the meeting.

**Workgroups:** To accomplish advancements and innovation in pathology, the collaborative community believes in spreading tasks across workgroups. The workgroups will disseminate project information and updates through educational outreach, scientific presentations, and making all resources broadly and publicly available. These workgroups address topics that include but are not limited to:

* pre-analytical variables,
* a framework for slide scanning,
* (qualified) reference materials, samples, standards
* image format, data exchange, and interoperability,
* best-practices, standards for data collection, guidance documents, whitepapers, or other educational material,
* software tools and statistical packages,
* peer-reviewed studies, protocols, and/or trials,
* machine-learning and AI-algorithms,
* identification of practical use cases,
* submissions to pre-competitive programs (e.g. mock submissions, MDDT program submissions)
* surveys, forums, seminars, regulatory science education, training programs, bootcamps
* payor interactions, reimbursement, and financial sustainability

**Membership:** The PIcc and the Alliance for Digital Pathology are open to all those working in the field who wish to join. Members are expected to join teleconferences and in-person meetings and to provide input and feedback to inquiries from their colleagues. Members are free to leave the group at any time. All members will comply with the group’s Code of Conduct (<https://digitalpathologyalliance.org/code-of-conduct>).

MDIC serves as the Convener for the PIcc and is responsible for:

* providing general oversight of the PIcc;
* administrative and operational support;
* financial oversight of MDIC-funded aspects of the PIcc;
* overseeing compliance of PIcc activities with respect to MDIC’s charitable mission.

Note: there is **no requirement** for members of PIcc to be a member of MDIC.

**Present membership includes representatives from:**

Massachusetts General Hospital

Harvard Medical School

Yale University

FDA CDRH

National Cancer Institute

Proscia

College of American Pathologists

NCI

NIH

WHO

IARC

IC3R

Medical Device Innovation Consortium

Aiforia, Inc.

Leica Biosystems

Merck & Co., Inc.

University of Wisconsin

Proscia

Paige

ASIP

University of Utah

NSF International

Huron Digital Pathology

Memorial Sloan Kettering Cancer Center

Dana-Farber Cancer Institute

Tempus

Visiopharm

GlaxoSmithKline

Hospital Italiano

MD Anderson Cancer Center

pathologywatch

Digital Pathology Association

Talking Laboratories

Aignostics GmbH

Uniklinik RWTH Aachen

Medical Cytometrix

ContextVision

Johns Hopkins University

Techcyte Inc.

Case Western Reserve University

Pathware

JAV Advisors Corp

Friends of Cancer Research

EIZO Inc.

Barco

ClearView Healthcare Partners

Matsuyama City Hospital

Fundación Jiménez Díaz Quirón Salud

Royal Free Hospital

INEN

Lund University

Universidad Mayor

GZA-ZNA

Starpath

CorePlus Servicios Clínicos y Patológicos, LLC

Montefiore Medical Center

mpathy llc

PixelMed

Apollo

University of Virginia

Tehran University of Medical Sciences

Mayo Clinic

Olympus Corp.

mTuitive

iRhythm

**Charter review and amendments:** This Charter will be reviewed and approved by the voting members on no less than an annual basis. Changes to the charter can be proposed at least 7 business day prior to the main annual meeting and amendments will be approved by a simple majority.

**Objectives:** The collaborative community strives to:

* account for the patient perspective by including patient advocacy;
* investigate and develop methods and tools for the evaluation of effectiveness, safety, and quality to specify risks and benefits in the precompetitive phase;
* help delineate and strategize the sequence of clinically meaningful deliverables;
* encourage and streamline the development of ground‑truth data sets;
* clarify regulatory pathways by investigating relevant regulatory science questions.

The group will make materials publicly available and share links to each organization to help all stakeholders. The group will initially focus on the regulatory environment in the US setting. Development of a repository includes white papers that highlight best practices, relevant policies for different countries and regions (including improving pathology in developing countries), and eventually de-identified data sets from studies that be utilized in continued regulatory research.

**Goals:** The group would like to achieve three things:

* to unlock the potential of digital pathology using regulatory science approaches to help as many patients as possible;
* to train and educate each other in an interdisciplinary fashion with a focus on pre-competitive regulatory science;
* to create an environment that motivates and encourages all stakeholders to move the field of pathology forward.

One key deliverable is a clinical, interoperable, modularized, and integrated solution for digital pathology from tissue acquisition to diagnostic algorithm.

The group strives to assess effectiveness and benefits of the initiative. An evaluation method will be developed to assess and monitor that the group:

* consists of diverse stakeholders that make up the collaborative community;
* evaluates output in terms of educational material, guidelines, and meetings;
* proactively publicizes challenges.

The collaborative community would eventually like to identify and develop regulatory science tools and provide input into regulatory pathways that enable and streamline innovation in pathology. The group hopes to promote the use of these pathways to allow for harmonized exchange of information, provide input into regulatory decision making, and build the necessary level of scientific evidence to enable informed decision making, thereby speeding up clinical innovation to patients.

**Charter Signatories**

1. Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Organization   
2. Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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3. Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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10. Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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11. Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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