The Pathology Innovation Collaborative Community (PIcc)
also known as the Alliance* for Digital Pathology

Effective Date: 11/24/2020

The Pathology Innovation Collaborative Community (PIcc) is a temporary 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 collaborative community (PIcc) 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. We aim to develop key performance indicators to monitor and communicate progress on how pre-competitive regulatory science can drive innovation in pathology.

Vision: The central vision of the collaborative community is to serve as an inclusive organization for all stakeholders regarding pre-competitive regulatory science questions related to pathology innovation. The key deliverable is a clear path for regulation of pathology innovation through regulatory science. The collaborative community 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 collaborative community 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 collaborative community are supported democratically through a simple majority vote

* During the drafting sessions, it was felt that the information gleaned from the name *Alliance* was insufficient. We agreed that *Pathology Innovation Collaborative Community (PIcc)* better reflects what we are passionate about.

(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: 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 requested by signatories 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, documents, whitepapers, or other educational material on regulatory science that could support policy
- 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 collaborative community is open to all those working in the field who wish to join. Whenever possible the collaborative community strives to have at least one patient advocacy group among its members. 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 collaborative community at any time. All members will comply with our 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.

The collaborative community includes representatives from:

Massachusetts General Hospital
Digital Pathology Association
Friends of Cancer Research
Medical Device Innovation Consortium
Visiopharm
Memorial Sloan Kettering Cancer
Roche
Washington University
Hamamatsu
GlaxoSmithKline
UCSF
College of American Pathologists
iRhythm Inc.
PixelMed
mTuitive
Case Western Reserve University
Leica Biosystems
mpathy LLC
Harvard Medical School
Yale University
National Cancer Institute
Proscia
NCI
NIH
Aiforia, Inc.
Merck & Co., Inc.
University of Wisconsin
Paige
ASIP
Dana-Farber Cancer Institute
University of Utah
NSF International
Tempus
Hospital Italiano
MD Anderson Cancer Center
pathologywatch
Talking Laboratories
Aignostics GmbH
Uniklinik RWTH Aachen
Medical Cytometrix
ContextVision
Mayo Clinic
Johns Hopkins University
Techcyte Inc.
Pathware
JAV Advisors Corp
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
Apollo
University of Virginia
Tehran University of Medical Sciences
Olympus Corp.

Charter review and amendments: This Charter will be reviewed and approved by the voting charter signatories 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.

Project framework: PIcc projects and workgroups strive 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 collaborative community will make materials publicly available and share links to each organization to help all stakeholders. The collaborative community 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 may be utilized in continued regulatory research.

Goals: The collaborative community will strive 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.

How we measure efficacy of the collaborative community? The group strives to assess effectiveness and benefits of the initiative. An evaluation method will be developed to assess and monitor that the group:

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

We will adjust our framework as needed to better drive successful innovation.

The collaborative community would eventually like to identify and develop regulatory science tools and provide input into regulatory pathways that streamline innovation in

pathology. We hope to enable the development of a clinical, interoperable, modularized, and integrated solutions for digital pathology from tissue acquisition to diagnostic algorithm. The group will dissolve once a clinical, interoperable, modularized integrated solution (from tissue acquisition to diagnostic report) has been implemented.

The collaborative community hopes to promote the use of these pathways to:

- allow for harmonized exchange of information
- provide input into regulatory decision making
- build the necessary level of scientific evidence

to enable informed decision-making to speed up clinical innovation to patients.

Charter Signatories

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Additional Signatories

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