**The <NAME> for Digital Pathology – Collaborative Community**

***“<NAME>-CC”***

–Charter–

I: Preamble

**Section 1: Name**

The <NAME> for Digital Pathology – Collaborative Community (<NAME>-CC) is a regulatory science initiative with members from academia, industry, regulators, health care providers, and advocacy groups.

**Section 2: Preamble**

Several categories of documents will govern <NAME>-CC activities, duties, and responsibilities.

The <NAME>-CC documents may include but may not be limited to: (1) <NAME>-CC Charter (this document) and (2) Standard Operating Procedures (if applicable). If there is any perceived inconsistency between (1) and (2), this document governs.

**Section 3: Mission and Vision**

The Mission and Vision of the <NAME>-CC are:

**Mission:** To accelerate the development and delivery of regulatory science initiatives in the pre-competitive space that advance the field of digital pathology, including but not limited to machine-learning and artificial intelligence. This may be accomplished through collaborative initiatives using various health technologies, leveraging real-world data, and innovative research.

**Vision:** The central vision of the <NAME>-CC is to serve as the umbrella organization regarding regulatory science questions related to digital pathology. This umbrella organization will include organizations interested in regulatory issues pertaining to digital pathology, starting with academic medical centers (e.g. MGH, MSKCC, etc.), professional organizations (e.g., DPA, CAP), device consortia (e.g., MDIC), patient advocacy groups (e.g., FOCR), and the FDA. The key deliverable is a clinical, interoperable, modularized, integrated solution for digital pathology implementation, from tissue acquisition to diagnostic algorithm. All meetings will be open to the public. The <NAME>-CC encourages that applicable content, after confirmation with the author(s), will be made publicly-available on the digital pathology <NAME> website.

Article II: Steering Committee

**Section 1: Responsibilities of Membership**

The Steering Committee supports the successful establishment and maintenance of <NAME>-CC, and recommends strategic and operational goals via policies consistent with but not limited to individual projects or overarching aims and their specific requirements. Members of the Steering Committee will be responsible for representing and securing support from their larger communities on the direction of the <NAME> CC. The Steering Committee is also responsible for establishing new Subcommittees and/or working groups and approving working group leads and/or members. The intent is to ensure diverse and distributed leadership and to explore and support (non-financially) new opportunities. Steering committee members must attend 75% of the steering committee meetings.

**Section 2: Terms of Members**

Working group and Steering Committee members serve for up to a three-year term and may be reappointed. Reappointment decisions are made by the Steering Committee, excluding the re-elected member. Initial Steering Committee members shall have staggered terms of one, two, or three years as determined by drawing of lots. The Chair who is elected in 2020 will automatically be given a four-year second term. Subsequent Steering Committee members will serve standard three-year terms. Representatives from the government [e.g. the U.S. Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), National Institutes of Health, etc] and representatives from MDIC are exempt from term limits so long as they remain employed by and have the approval of their respective organizations.

**Section 3: Composition of Membership**

The Steering Committee is composed of up to 15 members representing a diverse range of stakeholders including, but not limited to, patients, clinicians, device manufacturers, regulators, health systems, and payers. Six seats must be filled by nominees from each of the following organizations:

1. Massachusetts General Hospital (MGH) or another academic medical center
2. Digital Pathology Association (DPA)
3. the Food and Drug Administration (FDA)
4. the Medical Device Innovation Consortium (MDIC)
5. Two seats are reserved for patient organizations. Whenever possible, one position should be from the Friends of Cancer Research (FOCR)
6. At least one representative from a pathologist organization (e.g. CAP, USCAP…)
7. The <NAME>-CC Treasurer

One seat will be reserved for a Collaborator representative from a non-pathology subspecialty. Industry representation on the <NAME>-CC Steering Committee must make up at least 10%.

**Section 4: Selection Process of Members**

The remaining seats on the Steering Committee will be filled through an open nomination process and review. The Steering Committee puts forward recommendations for Committee members for approval.

**Section 5: Regular Meetings**

Regular meetings of the Steering Committee 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.

**Section 6: Special Meetings**

Special meetings of the Steering Committee may be called at any time by the Steering Committee Chair. Notice of the time and place of each special meeting will be provided to each Steering Committee member at least three days in advance of the meeting.

**Section 7: Quorum**

The Steering Committee, Subcommittees, and Working Groups will seek to reach decisions collaboratively and through consensus. A quorum is generally achieved if greater than 50% of members are present. If the Steering Committee is voting to change the Charter, elect a new Chair, Vice Chair, or Treasurer, or approve the addition of a new Steering Committee member, more than two-thirds of Steering Committee members must be present to meet the quorum threshold for such votes. When a vote is taken, a simple majority is required to approve an action unless specified otherwise.

**Section 8: Actions of the Steering Committee**

Until such time, if at all, that the <NAME>-CC becomes a separate legal entity, the Steering Committee serves in an advisory capacity to its members. The Steering Committee’s actions will be consistent with the mission and vision of the <NAME>-CC (i.e., to advance regulatory science).

The Steering Committee will review, consider, and approve the <NAME>-CC Charter and the <NAME>-CC Strategic and Operational Plan on an annual basis. In addition, the Steering Committee will be responsible for sustainable planning and prioritization.

**Section 9: Resignations**

Steering Committee members may resign at any time by providing written notice to the Governing Committee Chair.

**Section 10: Vacancies**

Vacancies will be filled using the same selection process noted above. Steering Committee members who fill a vacant seat will serve out the remainder of that term and will then be eligible to serve one additional term.

**Section 11: Conflict of Interest**

All Steering Committee members will comply with a Conflict of Interest Policy (<https://mdic.org/about/history/>) and the <NAME>-CC’s Code of Conduct ([https://digitalpathology<NAME>.org](https://digitalpathologyalliance.org)). Disclosure statements are to be completed by all Steering Committee members once a year and are to be made available on the <NAME>-CC public website. If a new conflict of interest arises during the time between annual disclosures, it is the obligation of the Steering Committee member to provide an update to their disclosure statement.

Article III: Committees and Working Groups

**Section 1: Steering Committee**

**Section 1.1: Composition**

The Steering Committee leadership is composed of the Committee Chair, Vice Chair, and Treasurer. The Steering Committee will be comprised of 15 representatives, including mandatory occupation of 6 seats by the6 different stakeholder groups, and will meet at least four times annually in addition to an ad hoc basis.

**Section 1.2: Responsibilities**

The responsibilities of the Committee are to:

• Review nominations for Chair, Vice Chair, and Treasurer

• Assess the composition of the Steering Committee and put forward recommendations for Steering Committee members who add diverse perspectives, knowledge, and skills, and make recommendations for filling additional seats and renewing terms.

• The steering committee’s primary role is to focus on sustained engagement from the members of the <NAME>-CC. Mechanisms of ensuring sustained engagement are: planning and conducting meetings, prioritization of projects, publicly available information and updates of policies and website content.

• Annually review policies to ensure that the <NAME>-CC members can perform their duties without conflict of interest, or the appearance of conflict of interest, that could arise while <NAME>-CC evaluates novel aims or technologies. In the event that such policies are not in place, the Committee Chair or Vice Chair will make recommendations to the steering committee and/or working groups to establish such policies

• The steering committee will provide an annual performance review of the <NAME>-CC.

**Section 1.3: Plan**

The steering committee is also responsible for developing and approving plans.

A plan is a defined deliverable as put forth by the steering committee or the working groups that tackles one core regulatory science question.

Plans are developed collaboratively, and resources are allocated as the membership, working groups, and steering committee see fit.

**Section 2: Working Groups**

Working Groups composed of experts representing diverse perspectives can be established by the Steering Committee on an ad hoc basis in furtherance of the <NAME>-CC’s approved plans. The purpose and composition of these groups is subject to approval by the Steering Committee. A list of the <NAME>-CC working groups and deliverables is included in Appendix 1. The format of the deliverables should be directly tied to the <NAME>-CC vision; whenever possible, the relevance for patient care should guide the decision process to implement new workgroups.

• Term lengths for internal and external working groups will be determined by the Steering Committee

• In general, Working Groups will have a time-limited engagement. The Steering Committee has the authority to redistribute, redirect, or dissolve working groups and their deliverables.

Article IV: Officers

**Section 1: Steering Committee Officers**

The officers of the Steering Committee shall be the Chair, Vice Chair, and Treasurer. These will be appointed from within the ranks of the Steering Committee, not appointed as additional seats, and they will be voting members of the Steering Committee.

 **Section 2: Elections and Terms**

The Chair, Vice Chair, and Treasurer are selected through a nomination process that may include self-nominations. Nominations made by others will only be accepted if the individual nominated agrees in advance to serve if selected. Nominations are reviewed by the Steering Committee, which discusses and provides a slate for the Committee to approve. Individuals must have served on the Steering Committee for at least one year prior to being nominated for Chair, Vice Chair, or Treasurer. All three positions serve one, two-year term.

**Section 3: Resignations and Vacancies**

Resignations and vacancies of the Steering Committee leadership positions shall be handled with the same process outlined for the Steering Committee resignations and vacancies.

**Section 4: Chair**

The Chair is responsible for:

• Working collaboratively with the <NAME>-CC to set Steering Committee meeting agendas

• Engaging with key stakeholders to help ensure <NAME>-CC success in meeting key milestones

• Presiding over Steering Committee meetings

• Serving on and chairing the Steering Committee

**Section 5: Vice Chair**

The Vice Chair is responsible for:

• Engaging with key stakeholders to help ensure <NAME>-CC success in meeting key milestones

• Presiding over Steering Committee meetings in the absence of the Chair

• Becoming the Chair upon completion of a two-year term as Vice Chair or in the event of an unplanned vacancy of the Chair position

• Serving on the Steering Committee

**Section 6: Treasurer**

The Treasurer is responsible for:

• Providing in-depth feedback on the <NAME>-CC budget

• Serving as the Chair of the Payor/Financial Sustainability Working Group

• Serving on the Steering Committee

Article V: Structure

<NAME>-CC is a collaboration between many different stakeholders including industry, advocacy groups, academia, and regulators, among others. The <NAME>-CC organizational structure consists of a Steering Committee established by the <NAME>, the MDIC, the DPA, and the FOCR; Subcommittees, which may be established by <NAME>-CC Steering Committee; and a Senior Vice President supported by program staff.

**Section 1: MDIC**

MDIC acts as the convener of the <NAME>-CC. A representative of MDIC is responsible for:

* Providing financial and general oversight of the <NAME>-CC
* Overseeing compliance of the <NAME>-CC with activities of the MDIC’s charitable mission,
* Administering MDIC’s Conflict of Interest Policy and periodically reviewing and suggesting modifications, as needed

**Section 2: DPA/DPAF**

The DPA (and DPA Foundation) and at least one representative is responsible for:

* providing guidance
* serve as a sponsor for selected projects
* help with dissemination of information and educational goals

Be the primary destination of the work output when it comes to realizing the key deliverables

**Section 3: FDA**

The FDA will act as a federal partner and designate a sponsor and at least one liaison. The liaison will keep the sponsor informed about the activities of the collaborative community on an ongoing basis. Both the sponsor and liaison cannot hold official positions or direct the communities aims or operations.

**Section 4: Patient advocacy**

Given the relevance for cancer diagnostics, FOCR will act as the representative of the patient perspective.

**Section 5: Dispute Resolution**

In the event that the Steering Committee determines that communication between separate parties is necessary or appropriate with respect to a disputed issue, the Founders of the <NAME>-CC will hold a joint meeting to discuss the issue.

Article VI: Amendments

**Section 1. Charter Review**

This Charter will be reviewed and approved by the Steering Committee on no less than an annual basis.

**Section 2: Process for Amendment of the Collaborative Community Charter**Both ad hoc amendments to the charter independent of the annual charter review and amendments proposed during the formal, annual charter review will be reviewed and approved via a quorum-based, community voting method. The procedure for amending the charter is outlined below.

**Section 2.1: Amendment proposal**Proposed amendments to the charter must be submitted in writing for review at least 7 business days prior to the subsequent steering committee meeting. Amendment proposals should have the following sections in the document:

* Proposing authors, listed with their affiliations
* Date of submission
* Specification of whether the proposal is to amend an existing bylaw, or to propose an addition or new bylaw to the charter
* The proposed amendment, written in finalized language to be incorporated as is upon successful approval.

**Section 2.2: Steering committee review**The steering committee will acknowledge submission of the proposed amendment no later than 7 business days post receipt; at that time, the committee will assign a time during the next steering committee meeting to review the proposal. At least one proposing author must be present at the steering committee meeting during the designated time to present the proposal to the steering committee.

**Note:** if a proposal author is a member of the steering committee, that individual should (whenever possible) present the proposal before subsequent voting. If more than one steering committee member are authors on the proposal, said individuals must recuse themselves and appoint proxies from amongst the membership to vote on the amendment in their stead.

**2.3: Embargo period**After the proposal is presented to the steering committee, committee members will be provided with the written proposed amendment for their consideration. The steering committee will have until the following steering committee meeting to consider the proposal.

**2.4: Voting**At the steering committee meeting following the introduction of the proposed amendment, steering committee members will vote to either accept or reject the proposed amendment to the charter. At least 10 steering committee members have to be present and cast a vote. A successful approval will require a 2/3 majority vote. The following table shows the number of votes and fractions required for approval in relation to the number of steering committee members available for voting.

|  |  |  |
| --- | --- | --- |
| Steering committee members available and voting | Number of votes defining a 2/3 majority | Fraction |
| 15 | 10 | 0.667 |
| 14 | 10 | 0.714 |
| 13 | 9 | 0.692 |
| 12 | 8 | 0.667 |
| 11 | 8 | 0.727 |
| 10 | 7 | 0.700 |
| 9 or less | too few people | N/A |

If the proposal is rejected, the steering committee must provide concrete feedback to the proposal authors about why it was rejected.

**2.5 Resubmission**Upon rejection, proposal authors may revise and resubmit the amendment for review. Proposal authors are allowed no more than 3 resubmissions/appeals before the decision rendered by the steering committee is deemed final.

**2.6 Incorporation**Once the amendment has been approved, it will be incorporated into the charter and disseminated to the community membership within 7 business days. A note of charter approvals will be provided in a dedicated appendix 2 in this charter.

Appendix 1. Workgroups

The list of workgroups, team leads, and deliverables below is provided to enable an overview (status October 2020). Specific definitions, key elements, benefits for patient care, clinical utility, research and discovery and regulatory science are provided on the website: digitalpathology<NAME>.org

Will be revised by workgroup leaders

**Workgroup 1. Pre-analytics**

Current team lead: Amanda Lowe, Matt Leavitt

**Deliverables:** Pre-analytics guidelines

**Workgroup 2. Slide scanning**

Current team lead: Scott Blakely

**Deliverables:** Work on definitions; education campaign

**Workgroup 3. Truthing data sets**

Current team lead: Sarah Dudgeon, Hetal Marble, Brandon Gallas

**Deliverables:** Annotated images = truth/reference/validation data (HTT project: estimates of the density of tumor-infiltrating lymphocytes in breast cancer), an MDDT qualification plan for the validation data, statistical methods and software for assessing algorithm performance

**Workgroup 4. Continuous learning**

Current team lead: Esther Abels

**Deliverables:** Validation, verification, and interoperability guidance

**Workgroup 5. Standardization**

Current team lead: Markus Herrmann, Mike Isaacs

**Deliverables:** Database of standards; datasets as a resource/tool for algorithm development

**Workgroup 6. Practical use cases**

Current team lead: Matthew Hanna

**Deliverables:** digital pathology implementation toolkit with ROI calculator

**Workgroup 7. ML/AI – Model creation**

Current team lead: Ashish Sharma, Matthew Hanna

**Deliverables:** A white paper outlining “categorizations” of models

**Workgroup 8. Payor strategies**

Current team lead: Joe Lennerz, Esther Abels

**Deliverables:** Best practices on how to approach payors and clinical guideline development

Appendix 2. Charter Approvals

|  |  |  |
| --- | --- | --- |
| **Charter Approvals: Version**  | **Approver**  | **Date**  |
| Version 1  | <NAME> Steering Committee  | 10/22/2020  |