

International Quality Network for Pathology, Association sans but lucratif, IQN Path a.s.b.l.

Registered Office, 3A Sentier de l'Espérance L-1474 Luxembourg, Grand-Duchy of Luxembourg R.C.S

In the year two thousand and fifteen, on the 20th of November

Preamble

IQN Path would like to give particular thanks to the following founding members: ESP (supported by the European Society of Pathology and Leuven University), Gen&Tiss (supported by AFAQAP and GFCO), AIOM, DGP (in association with QUIP), Mogens Vyberg (Director of NordiQC) and UK NEQAS - in particular the UK NEQAS Molecular Genetics and ICC&ISH schemes, for their vision and commitment in initiating and shaping IQN Path and Vivactiv for bringing the concept to fruition

Article 1 - Name

The name of the Association is "***International Quality Network for Pathology, Association sans but lucratif***" and its and its acronym is "***IQN Path a.s.b.l.***".

Article 2 – Registered office – Official languages

- 2.1 The registered office of the Association is located within the Grand-Duchy of Luxembourg, in the city of Luxembourg at the following address: 3A Sentier de l'EspéranceL-1474, Luxembourg, Grand-Duchy of Luxembourg.
2. The address of the registered office may be transferred within the Grand-Duchy of Luxembourg by decision of the Executive Board.
3. The official language of the Association is English. Within activities and working groups, the Executive Board and the General Meetings, English shall be the working language.

Article 3 - Nature of the Association

The Association is an international forum of External Quality Assessment (EQA)/Proficiency Testing (PT) providers and Scientific Societies/Organisations with interest in the quality of tissue and liquid biopsy-based diagnostic, predictive and prognostic biomarker assessment.

The association is a no -profit association and has not commercial scope.

The association cannot distribute funds to its members and cannot provide economical advantage to its members or administrators.

Article 4 - Object

- 4.1 The object of the Association is to:

- Improve and promote quality in the diagnostic process and clinical implementation of tissue and liquid biopsy-based biomarkers in the field of precision medicine;
- Support quality assurance in implementation of biomarkers in the clinic, in particular, through the participation of laboratories in high quality EQA/PT schemes as an important mechanism for implementing biomarkers in precision medicine that leads to better patient care;
- Exchange expertise and pool resources regarding quality in pathology including EQA/PT, the diagnostic testing process and laboratory management in order to establish, implement and coordinate education, training, best practice professional standards, research and innovation, and support high quality provision of EQA/PT in the field;
- Act as a forum and coordinating body for discussion and workshops to enable interaction of key opinion leaders and other EQA/PT stakeholders; and pursue all other ancillary activities in order to realise the objectives here above mentioned.

4.2 The Association shall pursue its missions through, among others, the following measures:

- Establish recommendations for new biomarker adoption and provide bench marks and best practice in EQA/PT;
- Coordinate interactions between international experts in EQA/PT, labs and other key stakeholders and organisations;
- Share benefits from a coordinated approach to develop and promote high quality EQA, develop and run educational training activities for laboratories, individuals and professionals in the field and/or EQA/PT providers, develop, verify or validate innovative tools that assist in implementing EQA/PT and promote the use of EQA/PT in the field;
- Develop methods, training, certification, products and data resources that appropriately support EQA/PT providers and labs to improve quality;
- Promote the use of EQA/PT, for example by creating compelling evidence to inform and lead policy development for EQA/PT, identifying trends and emerging needs and through conducting research in quality related matters in the field.

4.3 The association can receive all material and economical contributions to pursue its mission. Funds and materials must be used only to pursue the purpose of the association.

Article 5 – Duration

The Association is created for an undetermined duration and shall only be dissolved by a decision taken by the Extraordinary General Meeting in accordance with Article 27 of the present statutes.

Article 6 – Main principles of the Association

1. The Association is run as a non-profit entity and shall not have any commercial scope.
2. The Association will govern itself in accordance with principles of openness, fairness, transparency and accountability to its Members and seek to ensure its long-term viability.
3. The Members of the Association (hereafter the “Members”) will seek to work in a collaborative spirit, promote diversity of expertise within the Association and agree to actively participate in and promote the activities of the Association.

The Members shall interact with other relevant stakeholders and associations on behalf of the Association where needed in order to achieve the mission and objectives of the Association

Article 7 – Membership

The Association is open to organisations interested/involved in EQA/PT that fit the membership criteria below and that subscribe to the professional standards and internal policies of the Association.

1. The number of Members is not limited but cannot be less than three (3).
2. The Association is composed by the following categories of Members:
 - Founding Members;
 - Full Members;
 - Aggregate Organisation Members;
 - Corporate Sponsor Members;
 - Other membership categories created by the General Meeting.

Article 8 – Main provisions regarding membership

- 8.1 Membership is only valid if membership dues have been paid.
2. All Members have to pay their membership dues in a timely fashion.
- 8.3 All Members agree that they abide and are bound by the present statutes, internal policies of the Association, internal rulings, confidentiality agreements, and the decisions of the Executive Board.

Article 9 – Founding Members

- 9.1 Founding Members must fulfil the criteria of Full Membership as set in Article 10 of the present statutes. Founding Members originally conceived, supported and shaped the formation of the Association.
2. Founding Members will be EQA/PT providers registered in a European Union country.
3. Founding Members are subject to the same rules and rights as Full Members.

Article 10 – Full Members

Full membership is available to EQA/PT providers and Scientific Societies/Organisations that meet the following criteria:

- i. Have a defined and sustainable organisational structure;
- ii. Have in place appropriate governance processes to avoid conflict of interest with commercial entities;
- iii. Are from European Union or non-European Union countries;
- iv. Are providers with demonstrated experience in the organization of EQA/PT (at least five years) or organizations with demonstrated experience in the clinical implementation of biomarkers for precision medicine (at least ten years of support to EQA schemes, guidelines/recommendations in molecular pathology and/or precision medicine, etc). This may be Academic, Regulative bodies, non-governmental or other non-professional organisation;
- v. Operate/support schemes that are profession-based and that do not have a commercial emphasis;
- vi. Play a relevant role in the implementation of biomarker based precision medicine, e.g. are non-profit or academic in philosophy. These may be associated with an academic professional association, academic institute or national, public, body.

Article 11 – Aggregate Organisation Members

- 11.1 Scientific societies/Organisation involved in local/regional implementation of high quality biomarker testing for precision medicine.
- 11.2 Aggregate Organisation Members shall have no commercial scope
- 11.3 Aggregate Organisation Members shall have no voting rights and may attend sessions and meetings that are designated as open to Aggregate Organisation Members.

Article 12 – Corporate Sponsor Members

- 12.1 Corporate Sponsor membership is open to companies that wish to support the activities of the Association
- 12.2 Corporate Sponsor Members shall have no voting rights and may only attend open sessions and open meetings of the Association.

Article 13 – Other membership categories

- 13.1 The General Meeting may at any time decide to create additional membership or subscriber categories.

In the event that new categories are created, the General Meeting shall specify the privileges, admission and membership withdrawal criteria as well as duties of such membership.

Article 14 – Admission of new Members

To become a Member, an applicant must:

- a. Apply in writing to the Executive Board and provide any additional requested information; and
- b. The General Meeting shall be responsible for approving new membership applications.

Article 15 – Resignation

- 15.1 Members are free to resign at any time by addressing their request to the Executive Board by registered letter with an acknowledgment of receipt.
- 15.2 A Member is deemed to be resigning in the following cases:
- 15.2.1 The Member organisation is winding-up;
 - 15.2.2 The Member failed to fulfil the admission or membership criteria;
 - 15.2.3 The Member failed to pay the membership dues following the reception of a warning letter and did not react within the sixty (60) days following the date on which the warning letter was sent;
 - 15.2.4 If the member is a Founding Member, Full Member or Aggregate Member Organisation; in the event that the Member changes its legal status and/or organisational

form, in this case the Founding, Full or Aggregate Member is deemed to be automatically resigning and its membership will be re-evaluated. A different membership category may be offered or if the Founding, Full or Aggregate Member is no longer in compliance with these statutes, membership may be terminated.

15.3 The General Meeting will take notice that one of the above conditions is fulfilled, after advice of the Executive Board.

Article 16 – Exclusion

16.1 A Member can be excluded from the Association, on proposition of the Executive Board or one-fifth (1/5) of the Members and after decision of the General Meeting, in the following cases:

- Failure to abide by to the present statutes, the policies, internal rules or decisions taken by the Executive Board or the General Meeting of the Association;
- A Member who impedes the aims of the Association.

2. The General Meeting shall take the final decision by a two-third majority vote of the present or represented Members.

3. Any Member assessed for exclusion as according to Article 17 shall have the right to represent itself and to be heard before the Executive Board and the General Meeting, except in the case where Members are subject to the condition of 16.2.4.

16.4 Processes for exclusion from the Executive Board shall be handled by the Independent Executive Board Nomination Committee and detailed in the bylaws of the Association, except in the circumstances outlined in 16.2.4 where termination will be immediate and can occur without final decision or vote by the General Meeting as provided for in Article 17.2.

Article 17 – Resignation – exclusion

17.1 The membership fees for the current financial year are still due by any Member who is resigning or is excluded.

2. The Member who is resigning, is excluded, is winding-up, or has declared bankruptcy shall have no right or claim to any assets of the Association.

Article 18 – Members' register

1. A Members' register shall be kept at the registered address of the Association.

18.2 The Members' register shall mention, in alphabetic order, the name and surnames, nationality and address of the physical Members. If a Member is a legal entity, the Members' register shall mention the corporate name, the legal form and the registered office of said Member.

2. This Members' register is lodged every year with the Luxembourg Trade and Companies Register (Registre de Commerce et des Sociétés, R.C.S.). Every year, this Members' register is updated by indicating, in alphabetical order, all the changes that concern the Members.

4. The Members' register may be accessed by third parties without charge.

Art. 19. Contributions

All Members must pay a contribution fixed by the Board under art. 23.10 of this Statute.

This contribution shall not be reimbursed in case of exclusion or resignation of the Member.

Article 20 – Representation of Members

Each Member that is an organisation shall designate one person as its permanent representative and may designate alternative representatives, who shall act in the representative's absence, regarding the Association's matters, including but not limited to participating and voting at meetings if applicable. Each Member shall be entitled to replace said representative or alternate at its sole discretion by notifying the Association in advance.

Article 21 – Legal bodies of the Association

The legal bodies of the Association are:

- The General Meeting;
- The Executive Board; and
- The Independent Executive Board Nomination Committee (IBNC).

Article 22 – General Meeting

22.1 The General Meeting is the supreme governing body of the Association and shall hold a meeting at least once per year at the Annual General Meeting (AGM).

2. The General Meeting shall be composed of all the Members of the Association and shall be chaired by the President of the Executive Board.
3. Each Founding Member and Full Member shall have one vote.
4. Members of the Association may be represented by a proxy, who must also be a Member of the Association. All proxy instruments shall be presented to the meeting chair before the opening of the meeting. No Member may represent more than three (3) votes.
5. Only Members who have paid all their due amounts owed to the Association, including membership dues, may attend or vote at meetings.
6. The General Meeting has the power to:
 - Amend and change the present statutes;
 - Appoint and remove members of the Executive Board of the Association;
 - Approve admissions and exclusions of Members;
 - Approve the overall strategy and mission of the Association;
 - Approve the annual budgets and accounts of the Association; and
 - Dissolve and liquidate the Association.
7. Annual General Meetings shall be convened by the President of the Executive Board or at the request of one-fifth (1/5) of the Members. Meetings shall be called by convening notice addressed by ordinary letter or e-mail to the Members at least twenty-one (21) days prior to the date of the Meeting.
8. Extraordinary meetings of the General Meeting shall also be convened upon written request of one-

quarter (1/4) of the Members of the Association or by the majority of the Executive Board. Meetings shall be called by convening notice addressed by ordinary letter or e-mail addressed to the Members at least twenty-one (21) days prior to the date of the Meeting.

9. General Meeting decisions shall be taken by a majority vote of the present or represented Members. In the case of equality of voting, the President of the meeting (who shall be the present or outgoing President of the Executive Board) shall have a second or casting vote.
10. Decisions of the General Meeting to amend the statutes shall only be validly adopted if the object of the amendments is expressly specified in the convening notice of the General Meeting. Any decision of the General Meeting to amend the statutes shall only be validly adopted if at least two-third (2/3) of the Members are present or represented and shall only be validly adopted by a two-third (2/3) majority vote of the present or represented voting Members.
11. Null or white votes shall not be taken into consideration for the calculation of the majority.
12. Members may participate in the Annual General Meetings and in the Extraordinary General Meetings electronically via video or teleconferencing in accordance with the policies and bylaws of the Association.
13. All decisions of the General Meeting shall be documented in minutes and distributed to Members and third parties.

Article 23 – Executive Board

1. The Executive Board members shall be elected by the General Meeting.
2. Executive Board members are up for election every three (3) years.
- 23.3 Past Board members are always re-eligible. The Board members continue their mandate after the expiry until the new Board members are elected.
4. The Executive Board shall be composed of representatives of Founding Members or Full Members. The Executive Board must be composed of at least three (3) people and maximum five (5) people and wherever possible should be representative the membership and always as odd number.

In the event of the resignation (or termination from post for other reasons) of an Executive Committee Member, the Executive Board will co-opt other member/s to take his/her place. The other official Members of the Executive Board will pass a vote as to who will be co-opted during a Board meeting.
5. The Executive Board manages the day-to-day affairs of the Association and is responsible for actions taken in the name of the Association. The Executive Board is responsible for all acts that do not fall within the exclusive competence of the General Meeting.
6. The President or Treasurer have the power to sign documents and act on behalf of the Association including the signature of financial, employment, contractual or all other documents.
7. Executive Board members are accountable to the Members of the Association for the performance of their mandate.
8. The Executive Board members shall appoint among themselves a President and a Treasurer.
9. Each member of the Executive Board shall have one vote. Matters decided at any meeting of the Executive Board shall be decided by a simple majority of votes. In case of an equality of votes, the President shall ask for a re-vote. In the event of an equality of votes on the revote, the President shall have a casting vote.
10. The Executive Board has the power to:

- Develop and maintain the bylaws regulating its activities;
 - Determine the amount of the membership fees;
 - Develop detailed objectives, activities and strategy of the Association;
 - Establish and maintain sub-committees and working groups for different activities and may appoint technical panels to advise and assist it and may delegate matters to them. The composition of the working groups and sub-committees shall be approved by the Executive Board.
11. Under its own responsibility, the Executive Board appoints and delegates some of its powers and powers of signatory to an Executive Director. The Executive Director is not an Executive Board member but shall attend the General Meeting and Executive Board meetings. The Executive Director may sign and execute financial documents on behalf of the Association if previously authorised.
 12. The President shall chair the General Meetings, Executive Board meetings and Extraordinary General Meetings (except where the statutes or bylaws stipulate otherwise) and shall ensure proper progress of the Executive Board's activities.
 13. The Treasurer shall be responsible for managing finances, providing annual reports of the accounts and shall supervise fund raising.
 14. Meetings may also be held electronically via video or teleconferencing in accordance with the policies and bylaws of the Association. The participation in, or the holding of, a meeting by these means is equivalent to a participation in person.

Article 24 – Independent Executive Board Nomination Committee (IBNC)

- 24.1 An Independent Executive Board Nomination Committee shall oversee Executive Board membership, election and appointment and processes of removal of Executive Board members.
2. The Independent Executive Board Nomination Committee shall be composed of a minimum of three (3) people and at most five (5) and always in odd number people each appointed for three (3) years duration by the Annual General Meeting. The Committee can include Full Members, Aggregate Organisation Members, external invitees and where possible, one past Executive Board member, but cannot contain any current Executive Board members or candidates proposed for election to the Executive Board. Past IBNC members are always re-eligible.
3. The detailed responsibilities and processes of the Independent Executive Board Nomination Committee shall be in the bylaws, however, the Independent Executive Board Nomination Committee shall:
 - Observe the Executive Board election process and review all applications received for Executive Board positions in an anonymous fashion and has the right to not further a nomination
 - Anonymously evaluate any Member's concerns raised to them regarding the performance of any Executive Board member
 - May anonymously call on the participation of the Executive Director and shall take into account the viewpoint of the Executive Director
 - Has the right to call an Extraordinary General Meeting chaired by a member of the Independent Executive Board Nomination Committee.
 - Shall document all processes regarding appointment and removal of an Executive Board member and make this available to Members.

Article 25 – Finances

- 25.1 The maximum total yearly membership contribution of any Member shall not exceed nine hundred thousand euros (EUR 900.000,00).
2. The financial year shall be the calendar year.
3. Members shall pay an annual subscription proposed by the Executive Board.
4. The General Meeting shall approve the budget and accounts every year.
5. Members shall have no right or claim to any portion of the Association's assets.
6. The funds of the Organisation shall be deposited in bank accounts of a reputable local bank in the name of the Organisation and the authorised joint signatories for operating such accounts shall be the President and the Treasurer.

Article 26 – Publicity

The Association shall publish an annual report of its activities and maintain an updated list of Members.

Article 27 – Revision or Dissolution of the Association

- 27.1 Changes to the present statutes or proposals for dissolution of the Association shall be submitted to the General Meeting in writing. A quorum of two-thirds (2/3) of the General Meeting must be present for deliberation of dissolution of the Association.
2. In the event of dissolution, the remaining funds shall be donated to a non-profit cause designated by the General Meeting and in line with the Association's mission.

Article 28 – General Provisions

- 28.1 The law of April 21st 1928 on non-profit organizations and foundations (Loi du 21 Avril sur les associations et les fondations sans but lucratif), as amended, shall apply in so far as the present statutes do not provide for the contrary.
- 28.2 In case of divergences between the English and the French text, the English version will be prevailing.

