



Dear DIA Member,

On behalf of DIA's Board of Directors, I am writing to you today to request your support for a change to DIA's governance processes, requested by a substantial number of our members, where members ask our board to evolve and optimize itself. This change is fully consistent with current best practices for Boards of non-profit organizations like DIA.

As we considered this change, we consulted extensively with outside counsel, our Council of Regulators Leadership Committee, Regional Advisory Councils around the world, and our Fellows of DIA to ensure that we align our governance approach with best practices. **This proposed change requires your vote.**

Supporting Details

- **Low voter turnout.** DIA's bylaws require a minimum of 2% participation by members for changes, such as approval of a new slate of Directors, to be approved. Over the past many years, voter participation has been exceptionally low, ranging from 5-10%, with 2018's participation at 8.6%. There is no difference in participation levels if the Director slate is contested or comprised of a single candidate for each Board vacancy, and virtually 100% of members who vote do so in favor of the candidates presented. Benchmark data on Associations shows member participation in elections averages 34%, with an inverse relationship between association size and member participation. Very large associations, like DIA, share the same challenge, with very low member participation in governance matters. Many have made the change proposed.
- **Best practices.** The evolution to the proposed new model is in line with the governance model of many large, prominent membership Associations, where, like DIA, members want interactions with the Association to be enriching from a professional development perspective and not demanding with regard to governance matters. We feel a responsibility to ensure your engagement with DIA is welcomed, relevant, and enhancing to your professional development, rather than a "distraction" during your busy day.
- **Member support of DIA's mission and services.** The low voter participation in the selection of Board Directors is in stark contrast with DIA's overall experience, where we see large and increasing levels of participation in our meetings, learning events, virtual communities, publications, and membership. Thank you for the commitment you demonstrate to DIA's mission through this engagement level.
- **Demonstrated success of DIA strategy.** Over the past five years, the Board of Directors of DIA has undertaken a substantial body of work to refine DIA's strategic plan, and the results of that work have led us to where we are today. Our collective success can be measured in multiple ways, and we are especially proud of the impact we are having on the patients that we ultimately serve.
 - DIA's knowledge strategy is dynamic and valuable. Wherever we are around the world, through their direct feedback in surveys and focus groups, participants recognize the value of our expert volunteer program committees, advisory councils, and steering committees. These experts

choose to share their knowledge to advance our healthcare system, and this is the heart of DIA's mission and what has made the association successful for 55 years.

- Attendance and participation in DIA's annual and topical meetings reached record highs in 2018. Similarly we have seen substantial growth in participation in DIA's learning portfolio, particularly with the digital materials available in DIA Learning and on DIA NOW.
- Readership and downloads of DIA's publications is growing year-on-year. Our impact factor for our peer reviewed journal, *Therapeutic Innovation and Regulatory Science*, doubled over the past year.
- The Association today is strong, vibrant, and sustainable for decades to come. We have seen our role as Board as preparing DIA for the next generation of leaders who will continue to move our ecosystem forward to benefit patients.

To summarize:

- **Selection of Board Members.** For the sake of efficiency and based on member feedback, the Board from now on (if the changes are approved by DIA members) would have the responsibility to not only appoint and hold accountable the Global Chief Executive, but would also select future Board members based on its accumulated wisdom and knowledge of the needs of DIA and its members, on member nominations, and a well-designed, transparent governance process to evaluate those nominations. DIA works with the Center for Board Excellence (www.boardevaluations.com) to not only complete an annual board self-assessment for our own continuous improvement, and we also utilize their external guidance on composing the board of DIA against best practices related to director expertise, experience, and demographics.
- **Accountability of the Board.** The Board would remain fully accountable to DIA members for the quality of DIA content and services worldwide, fully acknowledging that membership is voluntary and is dependent on members' continued satisfaction with DIA.
- **Ownership.** Because voter turnout is and has historically been very low (less than 10%), the Board feels very deeply the responsibility to move DIA to a different governance model, in the best interests of DIA and its members, and of the continued viability and growth of the organization. The proposed changes are in line with these sentiments.

DIA's Board of Directors will hold an informational meeting of members on **Tuesday, December 11, 2018**, to review the proposed governance change. Please plan to join using the following link:

<https://diaglobal.zoom.us/j/130732507> .

Following the informational meeting, all voting members will receive a proxy ballot, requesting your approval to amend the DIA Articles of Incorporation -- specifically to amend section 7(a), which currently gives members the power to elect all DIA officer and Directors, and to reword it with a new provision permitting the DIA Board to elect Officers and Directors, and to make corresponding amendments to our Bylaws. The specific details of these changes are shown in the Appendix. Members will be sent a proxy ballot via email on **Monday, December 17, 2018**. The election will remain open until **Friday, January 18, 2019**. Members must vote during the election period for their vote to be counted, and we encourage everyone to participate.

A meeting of members will be held on **Monday, February 4, 2019**, from 8:00amCET – 8:15am CET, at the Meliá Vienna Hotel in Vienna, Austria, in advance of DIA's Europe Annual Meeting. All members will receive information on how to register for this meeting, also accessible by Webinar.

Finally, should participation in the voting process be lower than the supermajority (66.6%) required for passage of the amendments to the Articles of Incorporation and Bylaws, those members present at the meeting on **February 4, 2019**, will be asked to approve a second meeting of members to be held on **Sunday, June 23, 2019**, in advance of DIA's Global Annual Meeting, during which a second and final vote of members present and voting will be taken.

Please read the Additional Considerations attached to this letter.

DIA has maximized its relevancy over its 55 year history by evolving as it grows and as the needs of the healthcare product development ecosystem have changed. As we conclude DIA's most successful year in recent memory, we are compelled to continue that evolution. Thank you for your membership and commitment to DIA.

Sincerely,

Joseph Scheeren, PharmD
Chair, DIA Board of Directors

ADDITIONAL CONSIDERATIONS

In order to ensure a dynamic, open, diverse, and accountable Board, reflecting our membership, there are a few facts we want you to know:

- **Board term limits**, such as Director and Officer terms, as well as overall lifetime term limits, are written into our legal documents: the DIA Articles of Incorporation and Bylaws (<https://www.diaglobal.org/en/about-us/bylaws>). These rules are governed by the laws of the state of Maryland, USA.
- **Board responsibilities**, policies, and operating processes are documented in DIA's Governance Handbook. The Handbook is a set of guiding rules that DIA requires Directors to observe. These policies include our policy on *DIA's Commitment to Board Diversity and Inclusion*, requiring the Board to be reflective of the global constituencies that we represent from the perspective of expertise, national representation, and other demographic factors.
- **Nominations**. The Board will continue to request nominations for Directors from all members; we will review all nominations in relation to the needs of the association, as in the past, and develop a nominee slate; the Board will vote on the slate and communicate its decision and the rationale for such in our annual meeting of members, held at the DIA Global Annual Meeting.
- **Single change**. This proposed change relates to Board composition is the only change we propose to make. No other changes in DIA's governing documents can be made by the Board without member involvement. For changes to our governing documents, we require a supermajority (66.6%) vote in favor of the proposal.
- **Remediation mechanisms**. The Board has ensured that DIA has appropriate control mechanisms going into the future, should this proposed change be approved.
 - If there was significant dissatisfaction with the Board's leadership, members could propose amendments to the Bylaws to restore election of the Board by members.
 - It is legally possible for members to organize a Bylaws amendment process and turn out sufficient votes to meet the 2% quorum requirement and vote favorably for that amendment.
 - In addition, Maryland law allows the members of a nonstock corporation to bring a version of a shareholders' derivative action against the Board of Directors in the name of the corporation. This is one of the few U.S. States that allows this type of action.
 - The Board certainly hopes that these types of measures would never be necessary, and understands that they are linked to its performance and services provided to DIA members.
 - The Board is in very regular discussions with members through our Advisory Councils, Fellows, Program Committees, and Communities. Through these interactions, combined with the performance of the organization (e.g. membership, attendance, volunteerism, member satisfaction surveys), the Board receives leading indicators of emerging issues through our regular oversight mechanisms – and takes corrective action.

APPENDIX

Proposed Amendments to DIA Governance Documents

The proposed amendment to the DIA Articles of Incorporation is as follows:

Amend Article 7(a) as follows: “All Directors and officers of the Corporation shall be elected by the members of the Board of Directors in accordance with its Bylaws.~~Corporation at its annual meeting as defined by its By-Laws.~~”

The proposed amendments to the Bylaws are as follows:

Amend Bylaws Article IV, Section A.2 as follows: “Each active member shall be entitled to one vote for election of Directors and officers and changes in the Bylaws in accordance with procedures approved by the Board of Directors. Such votes shall be cast by proxy ballot, including electronic voting, in accordance with applicable law.”

Amend Bylaws Article V, Section A.8 as follows: “Officers and Directors shall be elected by members of the Board of Directors pursuant to proxy ballots sent to members entitled to vote for election at the annual business meeting of the Association in accordance with these Bylaws and the procedures adopted by the Board of Directors.”

Amend Bylaws Article V, Section A.9 as follows:

- a) The Executive Committee may recommend to the Board of Directors the names of persons to fill a vacancy of a director or officer that occurs for any reason ~~in accordance with ballots cast by the membership.~~ The Board of Directors may decide if the vacancy will be filled for the remainder of the term of the vacancy upon confirmation of a majority of the remaining Board members. This confirmation may occur by polling the remaining Board members or during a subsequent Board of Directors meeting. ~~Otherwise, vacancies may only be filled by vote of the members in accordance with these Bylaws and the procedures adopted by the Board of Directors.~~
- b) A director may be removed for cause or without cause by a ~~majority vote of the voting members who cast a ballot in accordance with procedures adopted by two-thirds vote of the Board of Directors present and voting~~ and with applicable law. An officer may be removed from such officer position for cause or without cause by a two-thirds vote of the Board of Directors present and voting. In the event of any removal action, the officer or director shall have the opportunity to receive notice of the reason for such removal and provide a written response to such notice.