IQ Strategic Objectives for 2015-2017

Vision:

The vision of the International Consortium for Innovation and Quality in Pharmaceutical Development ("IQ Consortium" or "IQ") is to be the leading science-based organization advancing innovative solutions to biomedical problems and enabling pharmaceutical companies to bring quality medicines to patients.

Mission:

As a technically-focused organization of pharmaceutical and biotechnology companies, IQ advances science and technology to augment the capability of member companies to bring transformational solutions that benefit patients, regulators and the broader R&D community.

Objectives for 2015-2017

To advance IQ's mission, IQ's strategic objectives for 2015-2017 are to:

I. Collaborate across IQ member companies to create cross-functional data sets, scientific positions and conclusions with greater scope and impact than possible by any member company alone

A key asset of IQ is its ability to leverage the collective knowledge and expertise of member companies through appropriate collaboration. It is the expectation that scientific positions, conclusions and recommendations developed by the Consortium will be data-driven. To facilitate this, the Consortium is establishing a flexible database to collect and store voluntarily shared member company data and experiences and is standardizing data sharing processes. While other data collection activities (e.g. surveys) may be used, Leadership Groups (LGs) and Working Groups (WGs) will be encouraged to utilize this Consortium database capability whenever appropriate. Further, the Secretariat is committed to meeting the timelines for database administration and utilization.

To maximize the scope and impact of the Consortium's positions, it is anticipated that the Consortium's members will support and contribute to these collaborations.

Metrics: Evidence that IQ database collaborations are impacting scientific and/or regulatory directions within and/or external to IQ members, comprising (but not limited to):

1. Industry 'best practices' and regulatory guidance influenced by IQ collaborations
2. External collaborations (e.g. NCATS, PhRMA, academic institutions) initiated by or contributed to IQ collaborations or capabilities.
3. Increases (year to year) in percentage participation by IQ members having data to share in IQ database collaborations
4. Evidence gathered thru surveys of member companies indicating incorporation of new or revision/modification of existing practices, based in part on an IQ database collaboration.

II. Advance relationships with global professional organizations, other consortia, academics and government research institutes to ensure scientific excellence and harmonization

Engagement of other scientific organizations ensures that the best possible expertise may be leveraged, allows for transparency, prevents duplication of effort, and avoids contradictory positions. Each LG should engage relevant external organizations within their discipline on a regular basis. WGs should be chartered with a consideration to include experts from IQ member companies, global professional organizations, academia, other industries, and government/regulatory organizations. Consideration should be given to engage other LGs as appropriate.

The Board of Directors ("the Board") should continue to engage other groups (such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) on matters of mutual interest.

Metrics: Evidence that IQ relationships with external organizations collaborations are advancing scientific excellence and harmonization across the biopharmaceutical community, comprising (but not limited to):

1. Industry 'best practices' and regulatory guidance influenced by IQ/external collaborations
2. Collaborations (e.g. NCATS, PhRMA, GRAs, academic institutions) initiated by the external party, (presumably, because they have identified IQ Consortium as a potential/optimal partner)

3. Increases (year to year) in percentage participation by IQ members in collaborations with external organizations
4. Increases in non-IQ member participants in IQ WG (indicating growing participation of non-member organizations in IQ projects)

III. Proactively build consensus with global regulators on issues and opportunities to advance innovation and quality in pharmaceutical development

Two-way communication with global regulatory authorities is essential to IQ's mission. It is vitally important for LGs/WGs to consider the regulatory impact of all technical positions that they develop, and mechanisms for engagement with regulatory agencies. This could be accomplished by engaging regulatory agencies directly, in collaboration with other external groups, or leveraging existing joint meetings (e.g., Preclinical Safety Leadership Group – Food and Drug Administration (FDA) Annual Joint Meeting, Clinical Pharmacology and Drug Metabolism Leadership Groups/FDA Joint Meeting, Chemistry, Manufacturing, and Controls (CMC) Topic-Driven Meetings with FDA). As appropriate, proactive engagement of global regulatory authorities (e.g. European Medicines Agency (EMA), Health Canada and the Pharmaceuticals and Medical Devices Agency (PMDA) is strongly encouraged, either directly, or with partner organizations.

Metrics: Evidence of IQ relationships with global regulatory authorities (GRAs) are advancing innovation and quality across the biopharmaceutical community, comprising (but not limited to):

1. Evidence suggesting IQ/GRA collaborations impact scientific and/or regulatory directions (e.g. adoption/inclusion of concepts, innovations, etc. developed/supported/championed by IQ in regulation, guidance, practices, and co-authored manuscripts and white papers.)
2. Collaborations/symposia/workshops/whitepapers, etc. initiated by GRAs/staff (presumably, because they have identified IQ Consortium as a potential/optimal partner)
3. Increases (year to year) in percentage participation by IQ members in collaborations/activities with GRAs (including peer-to-peer meetings)
4. Increases in GRA participation in IQ WG (indicating growing participation of GRAs in IQ projects)

IV. Share the results of IQ's initiatives with international scientific and regulatory communities

Prompt dissemination of IQ technical positions is an essential part of its mission and is beneficial to scientific and regulatory communities. LGs and WGs should publish their work in the peer-reviewed or trade literature so as to provide validity to IQ's positions, promote the visibility of IQ, and establish scientific precedent. The choice of a journal should be strategic in nature, taking into the account the intended audience. The use of webinars as enduring multimedia outlets is strongly encouraged. For particularly important topics, a thematic symposium or workshop may be considered.

Metrics: Evidence of maximization of internal and/or external impact IQ sponsored initiatives, comprising (but not limited to):

1. Evidence suggesting IQ/GRA collaborations impact scientific and/or regulatory directions (e.g. adoption/inclusion of concepts, innovations, etc. developed/supported/championed by IQ in regulation, guidance, practices, and co-authored manuscripts and white papers.)
2. Evidence of IQ sponsored initiatives to impact scientific and/or regulatory directions (e.g., citation statistics for published papers, numbers and diversity of participants at IQ sponsors/co-sponsored workshops and webinars).
3. Numbers (annually) of peer-reviewed publications, other publications, work-shops, and webinars, and confidential internal reports resulting from IQ sponsored initiatives.
4. Dissemination of internal IQ reports and acceptances for publication of manuscripts within 3-months (or another aggressive cycle-time, as agreed at commencement of project.

V. Ensure the continued value of IQ through active leadership, focused and clear priority-setting, and effective cross-disciplinary collaborations

To be recognized as the leading science-based industry association, IQ needs to consistently deliver recommendations and solutions to the most urgent and impactful opportunities and problems facing the pharmaceutical and biotechnology industry. Thus, at regular intervals, LGs and the Board should scan the horizon for emerging issues and opportunities with tangible deliverables, prioritize IQ's project portfolio accordingly, and adjust strategies to ensure optimal value of IQ. It is the responsibility of the Board and LGs to ensure that IQ has sufficient resources to support its project portfolio.

In developing these strategies, LGs should consider internal cross-disciplinary collaboration opportunities as well as external engagements and alignments to capitalize on synergies and avoid redundancies (also see Objective II).

Metrics: Evidence of active/effective IQ Leadership (LGs and BoD), comprising (but not limited to):

1. Evidence that IQ LGs and BoD anticipate or are amongst the first to identify significant issues (e.g. non-trivial) with tangible deliverables in pharmaceutical development and engage prospectively (e.g., collaborations, initiatives, workshops, peer-to-peer discussions) to identify/disseminate/champion IQ consensus solutions (contrasted with solely reacting to the proposed/imposed solutions developed by others)
2. Leverage of resources across the IQ organization (and external organizations) for new significant issues (e.g. cross-disciplinary collaborations), as appropriate, to insure early capture of diversity of perspectives within, and potential for alignment across the biopharmaceutical community
3. Numbers (annually) of new and ongoing cross-disciplinary collaborations and external alignments.