ANNUAL REPORT 2020

INTERNATIONAL CONSORTIUM for INNOVATION & QUALITY in PHARMACEUTICAL DEVELOPMENT

ANNUAL REPORT 2020

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LETTER FROM THE CONSORTIUM CHAIR

MARGARET M. FAUL

AMGEN
IQ CONSORTIUM CHAIR

In reflecting on the past 18 months, I am grateful for and proud of all that the IQ community accomplished in 2020 and in these initial months of 2021. In the face of the COVID-19 pandemic, our industry, in collaboration with global regulatory agencies, rallied behind a shared goal: combatting an unprecedented global pandemic. We are now witnessing the extraordinary – the rapid development of safe and effective vaccines and a massive effort underway to bring these vaccines to people all over the world.

Every IQ member company embraced the challenges of the past 18 months with generosity and resilience. Some developed vaccines. Others collaborated to help with vaccine manufacturing or to work together in other ways. Notwithstanding the enormous uncertainties, including health risks and supply chain and operational disruptions, IQ members remained laser focused on bringing the best science and research to bear in the development and manufacturing of lifesaving drug products. In short, IQ never missed a beat!

During 2020, more than 2200 individual participants engaged in IQ initiatives—either through the consortium's 10 leadership groups or through one or more of the 100+ IQ working groups. IQ's membership continues to flourish and have great impact on the industry and the patient communities we serve. Several new IQ initiatives were launched last year. We launched initiatives in response to COVID-19, including three new working groups and held a consortium-wide webinar on IQ initiatives related to COVID-19. We formed the Regulatory Advisory Committee (RAC) as a resource for furthering industry's collaborative relationships with global regulators. The RAC has led the development of a paper on IQ's COVID-19-related initiatives that discusses how these efforts may shape future practices in the pharmaceutical industry. Furthermore, the IQ Board of Directors eagerly endorsed the formation of a Diversity & Inclusion Committee to develop, communicate, and implement a formal D&I strategy and action plan for the Consortium. This strategy and action plan will be rooted in IQ's commitment to enhancing and sustaining diversity and inclusion within the consortium and beyond (see IQ's statement on page 5).

Finally, the IQ Consortium celebrated its 10th anniversary in 2020. We commemorated this milestone with a number of publications (see page 11). Over a decade ago, the founding member companies established the vision to be the leading science-based organization advancing innovative solutions to biomedical problems and enabling pharmaceutical companies to bring quality medicines to patients. IQ's past achievements and publication record demonstrate that innovation and quality are fundamental to the IQ Consortium's work, and that will continue to drive the consortium into the next decade.

I congratulate and thank all IQ member companies and the thousands of IQ participants for their dedication to science, unwavering service to patients, and active and generous collaboration and engagement in IQ. Best wishes for good health and safety!

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 research and development (R&D) community.

STRATEGIC OBJECTIVES

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.

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

Proactively engage global regulators on issues and opportunities to advance science-based regulations in pharmaceutical development.

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

Ensure the continued value of IQ through committed leadership, focused and clear priority-setting, productive cross-disciplinary collaborations and active engagement by a diverse talent pool to plan for leadership succession.

IQ CONSORTIUM'S COMMITMENT TO DIVERSITY AND INCLUSION

Diverse thinking and experience drive enhanced innovation. The IQ Consortium is committed to providing an environment of inclusion and equity where all individuals feel welcome and valued and have the opportunity to deliver our vision to bring quality medicines to patients.

THE POWER OF COLLABORATION

With nearly 40 member companies — including the world's leading pharmaceutical and biotechnology companies — and over 100 scientifically driven working groups, IQ provides a science-focused forum for facilitating drug research and development. Our collaborative structure and culture foster powerful benefits.

SHARED TECHNICAL EXPERTISE

Members draw on the intellectual capital of more than 2,200 participating scientists in a pre-competitive space. Member company representatives engage collaboratively in a range of initiatives addressing timely and critical drug-development issues.

SHARED RESEARCH

IQ members leverage a unique database and data-sharing framework. Data is contributed voluntarily, and members analyze data to collaboratively formulate scientific positions, conclusions, and recommendations. Survey results, white papers, conference proceedings, and other materials are shared consortium-wide.

BENCHMARKING & ANALYTICS

IQ employs careful analysis of R&D data to assess performance, examine industry trends, answer critical business questions, establish best practices, and identify opportunities for innovation and scientific development.

EXTERNAL PARTNERSHIPS

IQ focuses on constructive scientific exchange through publications, conferences, workshops, and roundtables. Working groups frequently include representatives from government and academia, eliciting valuable and ongoing feedback from key opinion influencers and thought leaders.

PROFESSIONAL DEVELOPMENT

Members enter into project pilots and other work streams that might not be available through their individual companies. Industry leaders can harness the potential of IQ to build professional networks and hone "softer" team-building, emotional intelligence, and communications skills.

MANAGED RISK

Consortium members frequently sponsor cooperative research projects. This approach, even when it does not result in discovery, often provides data and insights that inform better decisions and further mitigate risk.

COST EFFICIENCIES

Members enjoy substantial economies of scale. Annual fees are reasonable, administrative costs are well-controlled, resource redundancy is minimized, and costly "dead ends" are often avoided.

LEGAL & ADMINISTRATIVE RESOURCES

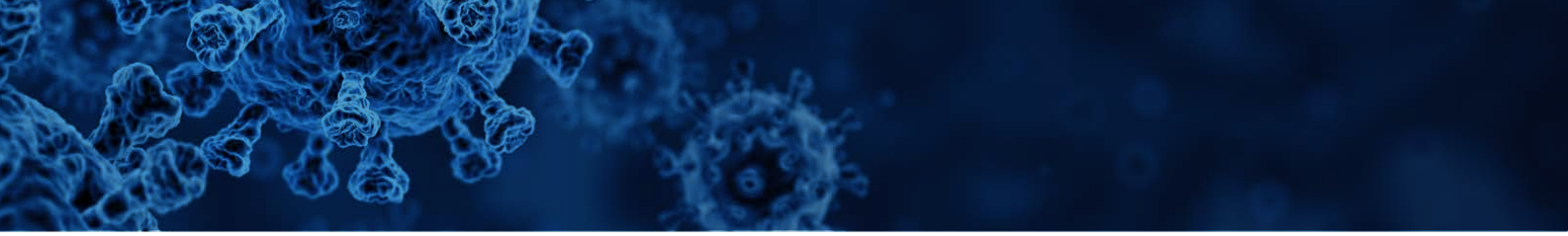
The Consortium's Secretariat provides legal, compliance and technical support for IQ's activities, fostering compliance with antitrust laws and assisting with the combination of data sets across companies for use in defined research projects. The Secretariat also handles various administrative tasks, allowing IQ participants to maintain a scientific focus.

REGULATORY ENGAGEMENT

Consortium members enjoy a valuable platform from which they can engage with the FDA and with regulators in North America, Europe, Asia, and South America.

AFFILIATED GROUPS

As needs arise and members' interests warrant, IQ serves as an ideal forum to explore distinct pharmaceutical and biotechnological issues that are often launched into an affiliate initiative. These efforts seek to reduce redundancies and generate potential cost savings. Currently, scientists representing a cross-section of companies are focused on two IQ affiliates: the IQ Drug-Induced Liver Injury Initiative (IQ DILI) and the IQ Microphysiological Systems Affiliate (IQ MPS).



2020 IN REVIEW

- **2231** Participants
- **37** Member Companies
- **10** Leadership Groups
- **104** Working Groups
- **30** Publications
- **11** Comments on Regulatory Guidances & Standards
- **29** Conference Presentations & Posters
- **11** Webinars
- **6** Data Sharing Projects
- **58** Surveys

COVID-19 PANDEMIC

The COVID-19 pandemic has impacted every aspect of our lives. Within the IQ framework, our members quickly pivoted to mobilize groups and continued to deliver risk-based and evidence-driven knowledge to the industry and the patient communities we serve. We launched several initiatives in response to COVID-19. Three new working groups (WGs) formed: the COVID-19 and Clinical Trials WG (CPLG), COVID-19 Pandemic Animal Research Program Experiences and Responses WG (3Rs TPS LG), and the Nonclinical Safety Strategies and Practices for COVID-19 WG (DruSafe).

In November 2020, the Symposium Organizing Committee presented a webinar, "Progress Amidst the Pandemic: IQ's Response to COVID-19." This webinar featured IQ groups that are exploring approaches to facilitate efficiencies during the development and lifecycle management of drugs in the age of COVID-19 and beyond: the Stability WG (ALG), Control Strategy Global Harmonization WG (QLG), ICH Q12 WG (QLG), COVID-19 and Clinical Trials WG (CPLG), Nonclinical Safety Strategies and Practices for COVID-19 WG (DruSafe), COVID-19 Pandemic Animal Research Programs WG (3Rs TPS LG), Patient Centric Sampling WG (TALG), and the Accelerated Drug Product Development Group (DPLG). This webinar allowed us to take a holistic look at the IQ portfolio and explore opportunities for accelerating drug development.

REGULATORY ADVISORY COMMITTEE

The Regulatory Advisory Committee (RAC) launched in March 2020 with the mission of advising IQ membership on strategies for engaging with regulators and supporting leadership groups and working groups in the planning and execution of interactions with health authorities on behalf of IQ. The RAC has developed a white paper focusing on what can be learned from current COVID-19 related efforts in the IQ portfolio and how those lessons can be applied in the future using science and risk-based methodologies. The RAC aims to continue to strengthen industry collaboration and to provide opportunities to shape the external environment, including encouragement of continued regulatory harmonization and mutual recognition.

DIVERSITY & INCLUSION COMMITTEE

IQ is committed to enhancing and sustaining diversity and inclusion within the consortium. In 2020, the IQ Board of Directors endorsed the formation of the Diversity & Inclusion Committee to develop, communicate, and implement a formal D&I strategy and action plan for the IQ Consortium. This strategy and plan provide an opportunity to strengthen IQ's position to generate value and maximize the voice and contributions of the best talent. The IQ D&I Committee led the establishment of IQ's statement on diversity and inclusion (see page 5) and is facilitating ongoing dialogue with consortium members to develop purposeful activities that will embed a culture of diversity, equity, and inclusion throughout the organization.

IQ CONSORTIUM'S 10TH ANNIVERSARY

To commemorate the 10th anniversary of the IQ Consortium, a small group of Board members led the development and publication of articles about IQ in *Pharmaceutical Technology*. The first article was published in *Pharmaceutical Technology Regulatory Sourcebook eBook* in October 2020 and provides a brief history of IQ and its impact over the last decade. This article was followed up by a series of articles published in *Pharmaceutical Technology Regulatory Sourcebook eBook* in March 2021. The collection of articles in the eBook was developed by selected Working Groups and Leadership Groups and focuses on key areas of interest, including nitrosamine impurities, biologics CMC challenges, physiologically-based pharmacokinetic modeling, pediatric therapeutic development, and data integrity challenges. A list of the publications commemorating IQ's 10th anniversary is below.

PUBLICATIONS

- M. M. Faul et al., "Viewpoint: Precompetitive Collaboration Drives Pharma Industry Innovation," *Pharmaceutical Technology Regulatory Sourcebook eBook* (October 2020). This article provides an overview of the IQ Consortium's history and structure, describes its foundational principles and mission, and highlights its impressive impact on the life sciences industry over the past 10 years.
- T. Curran and J.P. Bercu, "Managing the Risk of Nitrosamine Impurities," *Pharmaceutical Technology Regulatory Sourcebook eBook* (March 2021). This article describes the activities occurring within the IQ Nitrosamine Working Group and Impurities Safety Working Group to improve the understanding of the nature of nitrosamines and inform industry, consumers, and regulators about important associated risks that nitrosamines pose to the pharma supply chain.
- S. Ramdas, B. Rellahan, et al., "Overcoming Challenges to Biopharmaceutical Development and Manufacture with Science- and Risk-Based Strategies," *Pharmaceutical Technology Regulatory Sourcebook eBook* (March 2021). The Biologics CMC Leadership Group's article highlights the findings from two Working Group studies conducted to identify emerging CMC challenges in accelerated product development, global harmonization, and data integrity.
- J. Sydor et al., "Enabling the Virtual Human Through Physiologically-based Pharmacokinetic Modeling," *Pharmaceutical Technology Regulatory Sourcebook eBook* (March 2021). This article by the Translational and ADME Sciences Leadership Group provides an overview of the basic principles of physiologically-based pharmacokinetic modeling and demonstrates its impact in streamlining the drug development process.
- S. Haertter et al., "Extrapolating Data from Adult Clinical Trials to Advance Pediatric Drug Development," *Pharmaceutical Technology Regulatory Sourcebook eBook* (March 2021). The CPLG Pediatric Working Group's article presents the findings from several new case studies which illustrate how the application of the extrapolation framework allows for optimization of pediatric programs. The paper also describes the Pediatric Working Group's critical role in fostering the implementation of the framework to accelerate children's access to effective and safe medicines.
- G. Mohan and C. Turner et al., "Collaborative Efforts Address Key Data Integrity Challenges," *Pharmaceutical Technology Regulatory Sourcebook eBook* (March 2021). The Quality Leadership Group's article describes the IQ Consortium's commitment to fostering collaboration and information sharing between quality disciplines to support innovative drug development approaches.

The accomplishments of IQ's first decade demonstrate the power of industry collaboration. Through open dialogue, a functional and agile structure, and a strong foundation of scientific excellence, the IQ Consortium has created a remarkable scientific community that is poised to continue to address industry-wide challenges well into the next decade.

IQ'S IMPACT ON PROFESSIONAL, SCIENTIFIC AND REGULATORY COMMUNITIES IN 2020

In 2020, IQ Consortium participants contributed to numerous deliverables through benchmarking activities, information exchanges, data-sharing and other joint initiatives pursued across our membership. Following is a list of select key deliverables developed by IQ Consortium participants last year.

PUBLICATIONS

1. Adamec, E., Babayan, Y., Catacchio, B., Coon, A., Dill, A., Fu, M., ... & Wannere, C. (2020). Lean stability case studies—Leveraging science- and risk-based approaches to enable meaningful phase specific pharmaceutical stability strategies. *Journal of Pharmaceutical Innovation*, 1-9. DOI: 10.1007/s12247-020-09463-z. • Analytical LG

2. Allian, A. D., Shah, N. P., Ferretti, A. C., Brown, D. B., Kolis, S. P., & Sperry, J. B. (2020). Process safety in the pharmaceutical industry—Part I: Thermal and reaction hazard evaluation processes and techniques. *Organic Process Research & Development, 24*(11), 2529-2548. DOI: 10.1021/acs.oprd.0c00226. • Drug Substance LG

3. Ashworth, I. W., Dirat, O., Teasdale, A., & Whiting, M. (2020). Potential for the formation of N-nitrosamines during the manufacture of active pharmaceutical ingredients: An assessment of the risk posed by trace nitrite in water. *Organic Process Research & Development, 24*(9), 1629-1646. DOI: 10.1021/acs.oprd.0c00224. • Drug Substance LG

4. Barrett, J. S., Bucci-Rechtweg, C., Cheung, S. A., Gamalo-Siebers, M., Haertter, S., Karres, J., ... & Yanoff, L. (2020). Pediatric extrapolation in type 2 diabetes: Future implications of a workshop. *Clinical Pharmacology & Therapeutics, 108*(1), 29-39. DOI: 10.1002/cpt1805. • Clinical Pharmacology LG

5. Bogdanffy, M. S., Lesniak, J., Mangipudy, R., Sistare, F. D., Colman, K., Garcia-Tapia, D., ... & Blanset, D. (2020). Tg.rasH2 mouse model for assessing carcinogenic potential of pharmaceuticals: Industry survey of current practices. *International Journal of Toxicology, 39*(3), 198-206. DOI: 10.1177/1091581820919896. • DruSafe LG

6. Bransford, P., Cook, J., Gupta, M., Haertter, S., He, H., Ju, R., Kanodia, J., Lennernas, H., Lindley, D., Polli, J. E., Wenning, L., Wu, Y. (2020). ICH M9 guideline in development on biopharmaceutics classification system-based biowaivers: An industrial perspective from the IQ Consortium. *Molecular Pharmaceutics, 17*(2), 361–372. DOI: 10.1021/acs.molpharmaceut.9b01062. • Clinical Pharmacology LG • Drug Product LG • Translational and ADME Sciences LG

7. DaSilva, J. K., Breidenbach, L., Deats, T., Li, D., Treinen, K., Dinklo, T., ... & Hempel, K. (2020). Nonclinical species sensitivity to convulsions: An IQ DruSafe consortium working group initiative. *Journal of Pharmacological and Toxicological Methods, 103*, 106683. DOI: 10.1016/j.vascn.2020.106683. • DruSafe LG

8. Demmon, S., Bhargava, S., Ciolek, D., Halley, J., Jaya, N., Joubert, M. K., ... & Tsai, P. (2020). A cross-industry forum on benchmarking critical quality attribute identification and linkage to process characterization studies. *Biologicals, 67*, 9-20. DOI: 10.1016/j.biologicals.2020.06.008. • Biologics CMC LG

9. Fabre, K., Berridge, B., Proctor, W. R., Ralston, S., Will, Y., Baran, S. W., ... & Van Vleet, T. R. (2020). Introduction to a manuscript series on the characterization and use of microphysiological systems (MPS) in pharmaceutical safety and ADME applications. *Lab on a Chip, 20*(6), 1049-1057. DOI: 10.1039/C9LC01168D. • MPS Affiliate

10. Faul, M. M., McMillian, C. L., Boulas, P., Saraceno, R. A., Devlin Capizzi, M. E., Cruz, M. T. (2020). Viewpoint: Precompetitive collaboration drives pharma industry innovation. *Pharmaceutical Technology Regulatory Sourcebook eBook, 3*(2020), 60-64. • IQ Board of Directors

11. Fowler, S., Chen, W. L. K., Duigan, D., Gupta, A., Hariparsad, N., Kenny, J., Lai, G., Liras, J., Phillips, J., Gan, J. (2020). Microphysiological systems for ADME-related applications: Current status and recommendations for system development and characterization. *Lab on Chip, 3*, 446-467. DOI: 10.1039/C9LC00857H. • MPS Affiliate

12. Hasselgren, C., Bercu, J., Cayley, A., Cross, K., Glowienke, S., Kruhlak, N., ... & Dobo, K. (2020). Management of pharmaceutical ICH M7 (Q)SAR predictions – The impact of model updates. *Regulatory Toxicology and Pharmacology, 118*, 104807. DOI:10.1016/j.yrtph.2020.104807. • DruSafe LG

13. Heimbach, T., Chen, Y., Chen, J., Dixit, V., Parrott, N., Peters, S. A., ... & Hall, S. (2020). Physiologically based pharmacokinetic modeling in renal and hepatic impairment populations: A pharmaceutical industry perspective. *Clinical Pharmacology & Therapeutics*, DOI: 10.1002/cpt.2125. • Translational and ADME Sciences LG

14. James, C. A., Barfield, M. D., Maass, K. F., Patel, S. R., & Anderson, M. D. (2020). Will patient-centric sampling become the norm for clinical trials after COVID-19? *Nature Medicine, 26*(12), 1810-1810. https://doi.org/10.1038/s41591-020-01144-1. • Translational and ADME Sciences LG • Clinical Pharmacology LG

15. Kaur, S., Bateman, K. P., Glick, J., Jairaj, M., Kellie, J.F., Sydor, J., & Zeng, J. (2020). IQ Consortium perspective: Complementary LBA and LC–MS in protein therapeutics bioanalysis and biotransformation assessment. *Bioanalysis, 12*(4), 257-270. DOI: 10.4155/bio-2019-0279. • Translational and ADME Sciences LG

16. Lam, Y. H., Abramov, Y., Ananthula, R. S., Elward, J. M., Hilden, L. R., Nilsson Lill, S. O., ... & Tanoury, G. J. (2020). Applications of quantum chemistry in pharmaceutical process development: Current state and opportunities. *Organic Process Research & Development, 24*(8), 1496-1507. DOI: 10.1021/acs.oprd.0c00222. • Drug Substance LG

17. Leach, M. W., Clarke, D. O., Dudal, S., Han, C., Li, C., Yang, Z., ... & Chemuturi, N. V. (2020). Strategies and recommendations for using a data-driven and risk-based approach in the selection of first-in-human starting dose: An International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) assessment. *Clinical Pharmacology & Therapeutics*, DOI: 10.1002/cpt.2009. • Clinical Pharmacology LG • DruSafe LG • Translational and ADME Sciences LG

18. Lippke, J., Mongillo, J., Cullen, T., Waller, C., Harasewych, K., Muhammad, Z., Bennett, J. (2020). Assessing data integrity risks in an R&D environment. *Pharmaceutical Technology, 44*(8) 51-53. • Quality LG

19. McMahon, M., Williams, H., Debie, E., Fu, M., Bujalski, R., Qiu, F., ... & Pulliam, D. (2020). Utilization of risk-based predictive stability within regulatory submissions; industry's experience. *AAPS Open, 6*(1), 1-11. DOI: 10.1186/s41120-020-00034-7. • Analytical LG

20. Peters, M. F., Choy, A. L., Pin, C., Leishman, D. J., Moisan, A., Ewart, L., ... & Kolaja, K. L. (2020). Developing in vitro assays to transform gastrointestinal safety assessment: Potential for microphysiological systems. *Lab on a Chip, 20*(7), 1177-1190. DOI: 10.1039/C9LC01107B. • MPS Affiliate

21. Phillips, J. A., Grandhi, T. S. P., Davis, M., Gautier, J. C., Hariparsad, N., Keller, D., ... & Van Vleet, T. R. (2020). A pharmaceutical industry perspective on microphysiological kidney systems for evaluation of safety for new therapies. *Lab on a Chip, 20*(3), 468-476. DOI: 10.1039/C9LC00925F. • MPS Affiliate

22. Pillutla, R., Gorovits, B., Gleason, C., Quiroz, J., Christopher, D., Braun, M., ... & Williams, L. (2020). Recommendations for singlet-based approach in ligand binding assays: An IQ Consortium perspective. *Bioanalysis, 12*(12), 823-834. DOI: 10.4155/bio-2020-0094.
• Translational and ADME Sciences LG
• Statistics LG

23. Regev, A., Avigan, M. I., Kiazand, A., Vierling, J. M., Lewis, J. H., Omokaro, S. O., ... & Uetrecht, J. P. (2020). Best practices for detection, assessment and management of suspected immune-mediated liver injury caused by immune checkpoint inhibitors during drug development. *Journal of Autoimmunity, 114*, 102514. DOI: 10.1016/j.jaut.2020.102514.
• DILI Initiative

24. Reynolds, V. L., Butler, P., Abernathy, M. M., Aschenbrenner, L., Best, D. D., Blank, J., ... & Hart, T. K. (2020). Nonclinical safety assessment of epigenetic modulatory drugs: Current status and industry perspective. *Regulatory Toxicology and Pharmacology, 117*, 104746. DOI: 10.1016/j.yrtph.2020.104746.
• DruSafe LG

25. Riedmaier, A. E., DeMent, K., Huckle, J., Bransford, P., Stillhart, C., Lloyd, R., ... & Parrott, N. (2020). Use of physiologically based pharmacokinetic (PBPK) modeling for predicting drug-food interactions: An industry perspective. *The AAPS Journal, 22*(6), 1-15. DOI: 10.1208/s12248-020-00508-2.
• Translational and ADME Sciences LG

26. Schenck, L., Erdemir, D., Saunders Gorka, L., Merritt, J. M., Marziano, I., Ho, R., ... & Sun, C. C. (2020). Recent advances in co-processed APIs and proposals for enabling commercialization of these transformative technologies. *Molecular Pharmaceutics, 17*(7), 2232-2244. DOI: 10.1021/acs.molpharmaceut.0c00198.
• Drug Substance LG

27. Severin, T., Corriol-Rohou, S., Bucci-Rechtweg, C., An Haack, K., Fuerst-Recktenwald, S., Lepola, P., ... & Cheung, S. A. (2020). How is the pharmaceutical industry structured to optimize pediatric drug development? Existing pediatric structure models and proposed recommendations for structural enhancement. *Therapeutic Innovation & Regulatory Science, 54*(5), 1076-1084. DOI: 10.1007/s43441-020-00116-4. • Clinical Pharmacology LG

28. Sreedhara, A., Zamiri, C., Goswami, S., Weiser, S., Cram, M., Christian, T. R., & Jagannathan, B. (2020). Challenges of using closed system transfer devices with biological drug products: An industry perspective. *Journal of Pharmaceutical Sciences, 109*(1), 22-29. DOI: 10.1016/j.xphs.2019.10.042. • Biologics CMC LG

29. Treem, R. W., Palmer, M., Lonjon-Domanec, I., Seekins, D., Dimick-Santos, L., Avigan, M. I., ... & Chalasani, N. (2020). Consensus guidelines: Best practices for detention, assessment and management of suspected acute drug-induced liver injury during clinical trials in adults with chronic viral hepatitis and adults with cirrhosis secondary to hepatitis B, C and nonalcoholic steatophepatitis. *Drug Safety, 44*(2), 133-165(2021). • DILI Initiative

30. Zhu, T., Kayama, M., Girish, S., Sinha, V., Bello, A., Kawaguchi, A., Czerniak, R., Nagao, L. (2020). Collaborations between clinical pharmacologists in Japan and in the United States - Report from the IQ CPLG and JPMA CPTF meeting in Tokyo, Japan. *Clinical and Translational Science, 14*(1), 102-105. DOI:10.1111/cts.12853. • Clinical Pharmacology LG

COMMENTS ON REGULATORY GUIDANCES AND STANDARDS

1. IQ Analytical Quality by Design Working Group. (2020). IQ Consortium Comments on USP Chapter <1220> Draft Chapter, "The Analytical Procedure Lifecycle."

2. IQ CMC Statistics Forum. (2020). IQ Consortium Comments on USP Chapter <1010>, "Analytical Data Interpretation and Handling."

3. IQ Dissolution Working Group. (2020). IQ Consortium Comments on "Draft revision of WHO Dissolution Test for Solid Oral Dosage Forms: Dissolution Test for Solid Oral Dosage Forms Draft Proposal for Revision in the International Pharmacopoeia."

4. IQ Dissolution Working Group. (2020). IQ Consortium Comments on USP Chapter <1711>, " Oral Dosage Forms — Performance Tests."

5. IQ Dissolution Working Group. (2020). IQ Consortium Comments on WHO USP Proposed USP General Chapter <1001>, "In Vitro Release Test Methods for Parenteral Drug Preparations."

6. IQ Novel Excipients Working Group. (2020, February 3). IQ Consortium Comments on FDA-2019-N-5464, "Novel Excipient Review Program Proposal." ►

7. IQ Immunosafety Working Group. (2020, April 21). IQ Consortium Comments on FDA-2019-D-5607, "Revised Draft Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics Guidance." ►

8. IQ DruSafe Leadership Group. (2020, June 1). IQ Consortium Comments on FDA-2020-D-1136-0012, "COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products; Guidance for Industry and Investigators." ►

9. IQ Translational and ADME Sciences Leadership Group and Clinical Pharmacology Leadership Group. (2020, October 27). IQ Consortium Comments on FDA-2020-D-1480-0002, "Drug-Drug Interaction Assessment for Therapeutic Proteins; Draft Guidance for Industry." ►

10. IQ PBPK Food Effect Modeling Working Group. (2020, November 25). IQ Consortium Comments on FDA-2020-D-1517, "The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls; Draft Guidance for Industry." ►

11. IQ Clinical Pharmacology Leadership Group and Translational and ADME Sciences Leadership Group. (2020, December 3). IQ Consortium Comments on FDA-2010-D-0133, "Revised Draft Guidance for Industry on Pharmacokinetics in Patients with Impaired Renal Function — Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability." ►

PRESENTATIONS, POSTERS & WEBINARS

1. IQ MPS Affiliate. (2020). *IQ Microphysiological Systems (MPS) Affiliate 16th Tissue Chip Consortium Meeting* [Presentation]. National Center for Advancing Translational Sciences 16th Tissue Chip Conference (Online).

2. IQ MPS Affiliate. (2020). *IQ MPS Affiliate perspective on characteristics and requirements for new approach methodologies (NAMs)* [Presentation]. SBIR Town Hall meeting on Development of New Approach Methodologies to Reduce Animal Use in Toxicity Testing (Online).

3. IQ MPS Affiliate. (2020). *Proposed microphysiological (MPS) definitions and organ-on-a-chip definitions* [Presentation]. U.S. Food and Drug Administration Alternative Methods Working Group Meeting (Online).

4. IQ TALG and CPLG Antibody Drug Conjugates Working Group. (2020). *Bioanalysis of ADCs: Strategy and recent developments* [Presentation]. Pharmaceutical & BioScience Society Workshop (Online).

5. IQ TALG DDI-TP Guidance Commenting Group. (2020). *DDI-TP Guidance IQ Comments* [Presentation]. Drug Metabolism Discussion Group Congress (Online).

6. IQ TALG Organ Impairment Working Group. (2020). *PBPK modeling in renal and hepatic impairment populations: IQ PBPK organ impairment group* [Presentation]. G9 European Modeling & Simulation Group (Online).

7. IQ BIO CMC LG Phase Appropriate Specifications Working Group. (2020, January 27-30). *Phase appropriate specifications: Patient-centric/commercial specification setting subteam* [Presentation]. CASSS CMC Strategy Forum and WCBP, Washington, DC.

8. IQ BIO CMC LG Subvisible Particles Working Group. (2020, January 27-30). *A multi-company assessment of submicron particles levels in biotechnology-derived protein products* [Presentation]. CASSS CMC Strategy Forum and WCBP, Washington, DC.

9. IQ BIO CMC LG Temperature Excursion Stability Working Group. (2020, January 27-30). *Global regulatory requirements for stability: It's not such a small world after all* [Presentation]. CASSS CMC Strategy Forum and WCBP, Washington, DC.

10. IQ DSLG Co-Processed API Working Group. (2020, February 18-19). *Co-Processed API: A proposed regulatory strategy to enable transformative capabilities in pharmaceutical manufacturing* [Presentation]. APV Continuous Manufacturing Conference, Freiburg, Germany.

11. IQ MPS Affiliate. (2020, February 19-20). *Organ on a chip: Can we finally replace animals in pharmaceutical research?* [Presentation]. 3D Cell Culture Conference, London, UK.

12. IQ DSLG Co-Processed API Working Group. (2020, February 23-26). *Co-Processed API: A proposed regulatory strategy to enable transformative capabilities in pharmaceutical manufacturing* [Presentation]. International Foundation Process Analytical Chemistry Meeting, Bethesda, MD.

13. IQ DILI Initiative. (2020, March 15–19). *Next-generation DILI biomarkers: Prioritization for qualification and best practices for biospecimens* [Poster]. Society of Toxicology 59th Annual Meeting (Online).

14. IQ DruSafe Predictivity of in vitro Teratogenicity Working Group. (2020, March 15-19). *Concordance between in vitro developmental toxicity assays and in vivo embryo-fetal development findings: The IQ DruSafe assessment* [Presentation]. Society of Toxicology 59th Annual Meeting (Online).

15. IQ TALG and CPLG Antibody Drug Conjugates Working Group. (2020, March 18-21). *Pharmacokinetic characterization of antibody-drug conjugates in clinical development: An IQ Consortium perspective* [Presentation]. American Society for Clinical Pharmacology & Therapeutics (Online).

16. IQ TALG Itraconazole Working Group. (2020, March 19). *Best Practice in Clinical Drug-Drug Interaction Study Design for Itraconazole: A PBPK Modelling and Simulation Approach* [Webinar]. ►

17. IQ Quality Leadership Group. (2020, March 30 – April 4). *Quality Leadership Group* [Poster]. Society of Quality Assurance Annual Meeting, National Harbor, MD.

18. IQ DPLG Pediatric Working Group. (2020, May 11-13). *Summary of pediatric formulation development: Challenges of today and strategies for tomorrow* [Presentation]. Excipient World Conference and Expo, Kissimmee, FL.

19. IQ DPLG Pediatric Working Group. (2020, May 28). *Pediatric Dosage Forms 'Out in the Wild' What Really Happens in Clinical Practice* [Webinar]. ►

20. IQ Quality Leadership Group. (2020, June 23). *Knock, Knock! It's FDA! — GLP Inspections* [Webinar]. ►

21. IQ DPLG Pediatric Working Group. (2020, June 25). *A Scientific and Risk Based Approach to Pediatric Formulations* [Webinar]. ►

22. IQ CPLG and TALG Patient Centric Sampling Working Group. (2020, July 8). *Clinical Trial Digital Innovation: Patient Centric Sampling* [Webinar].

23. IQ DSLG Co-processed APIs Working Group. (2020, July 9). *Recent Advances in Coprocessed APIs & Proposals for Enabling Commercialization of These Transformative Technologies* [Webinar]. ►

24. IQ DruSafe Leadership Group. (2020, July 31). *IQ Consortium Overview* [Presentation]. R&D-based Pharmaceutical Association Committee Meeting (Online).

25. IQ MPS Affiliate. (2020, August 14). *IQ Microphysiological Systems (MPS) Affiliate* [Presentation]. European Society of Toxicologic Pathology In Vitro Toxicology Model Working Group Meeting (Online).

26. IQ BCS Biowaivers/ICH M9 Working Group. (2020, September 3). *ICH M9: Harmonization of Biopharmaceutics Classification System Based Biowaivers* [Webinar]. ►

27. IQ DILI Initiative. (2020, September 4–5). *Drug- induced liver injury: Do we know what we don't know?* [Poster]. Gastro Update Europe Virtual Conference (Online).

28. IQ DPLG Pediatric Working Group. (2020, September 10). *Regulatory Considerations for Pediatric Drugs and Combination Products* [Webinar]. ►

29. IQ DruSafe Impurities Safety Working Group. (2020, September 14-15). *Some aspects of practical M7 implementation* [Presentation]. 4th Annual Impurities: Genotoxic and Beyond Summit (Online).

30. IQ DSLG Small Molecule Impurity Considerations for ADC Development Working Group. (2020, September 15-18). *Registered starting materials designation considerations for linker-payloads in antibody drug conjugates (ADCs)* [Presentation]. World ADC Conference (Online).

31. IQ MPS Affiliate. (2020, September 23). *IQ Microphysiological Systems (MPS) Affiliate update to NCATS* [Presentation]. National Center for Advancing Translational Sciences Tissue Chip Consortium Meeting (Online).

32. IQ MPS Affiliate. (2020, September 30). *IQ Microphysiological System (MPS) Affiliate: Organotypic manuscript series* [Presentation]. PREDiCT: 5th Annual 3D Oncology & Tissue Models Summit (Online).

33. IQ ALG Dissolution Working Group. (2020, October 5). *Challenges and Strategies for Dissolution Method Development for Amorphous Solid Dispersions* [Webinar].

34. IQ DSLG Co-Processed API Working Group. (2020, October 8). *Co-processing: An effective particle engineering approach for drug substance* [Presentation]. Pharmaceutical Crystallization Summit (Online).

35. IQ TALG Organ Impairment Working Group. (2020, October 8). *Physiologically based pharmacokinetic modeling to support dosing recommendations for patients with hepatic impairment: A readout from the IQ Consortium* [Presentation]. M-CERSI Workshop: Assessing Changes in Pharmacokinetics of Drugs in Liver Disease (Online).

36. IQ CRO Outreach Working Group. (2020, October 25–29). *Development of standardized assessment tools for evaluation of animal care and use programs at contract research organizations (CROs)* [Poster]. National AAALAS Meeting (Online).

37. IQ DPLG Pediatric Working Group. (2020, November 5). *Formulating Poorly Soluble Drugs for Pediatrics* [Webinar]. ►

38. IQ Consortium Mini-Symposium. (2020, November 17). *Progress Amidst the Pandemic: IQ's Response to COVID-19* [Webinar].

39. IQ TALG Patient Centric Sampling Working Group. (2020, November 17-20). *Patient centric sampling: How the COVID-19 pandemic is shifting the landscape* [Presentation]. European Bioanalysis Forum (Online).

40. IQ DruSafe In Vitro Secondary Pharmacology Profiling Working Group. (2020, December 14-18). *Evaluation of current secondary pharmacology practices in pharmaceutical R&D by the IQ DruSafe Consortium* [Presentation]. Annual Meeting of the British Pharmacology Society (Online).

IQ'S MEMBER COMPANIES

ABBVIE

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ALNYLAM PHARMACEUTICALS, INC.

AMGEN, INC.

ASTELLAS PHARMA INC.

ASTRAZENECA

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IQ'S BOARD OF DIRECTORS 2020-2021

The IQ Board of Directors provides strategic oversight of the consortium's project portfolio and ensures alignment with IQ's vision and mission. Our board members champion their companies' engagement in IQ and facilitate outreach between the consortium and regulatory authorities and other organizations.

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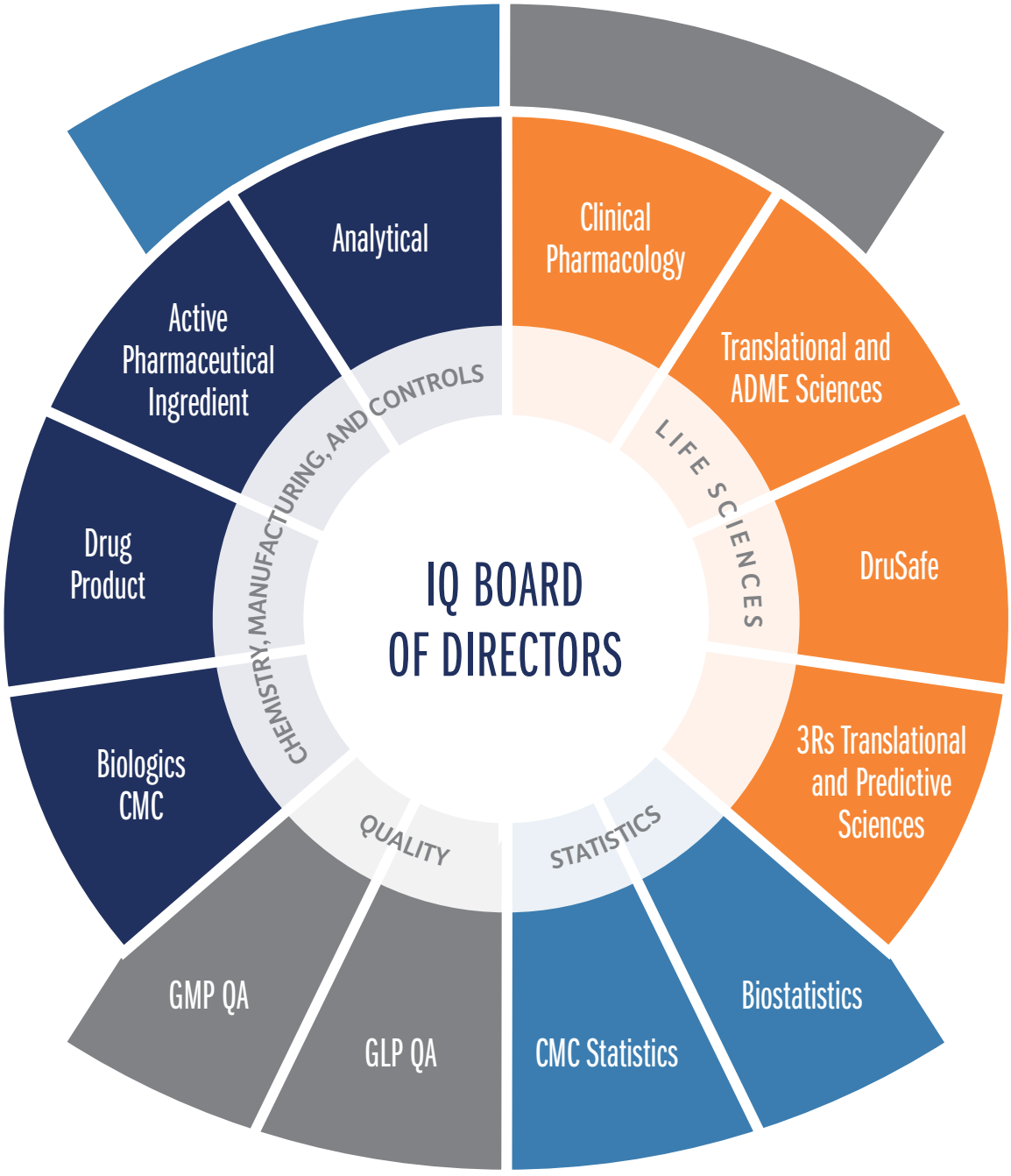
Brian Regler • Boehringer Ingelheim
Luzelena Caro • Merck
Sheetal Pai-Wechsung • Pfizer, Inc.
Alison Smith • GlaxoSmithKline
Islam Younis • Gilead
Tong Zhu • Astellas

IQ LEADERSHIP GROUPS

The IQ Consortium's Leadership Groups (LGs) are standing, technical area-specific forums for scientific exchange. Leadership groups comprise representatives of member companies with expertise and vested interest in the subject area. IQ has 10 Leadership Groups distributed across four disciplines: Chemistry, Manufacturing and Controls (CMC), Quality, Statistics and Life Sciences. The Quality and Statistics leadership groups are further divided into focus groups or forums



LEADERSHIP GROUP LEADS 2020-2021

IQ Leadership Group Leads provide guidance to Leadership Groups and Working Groups on their activities and initiatives. Leadership Group leads liaise with the Board of Directors to manage IQ's project portfolio and ensure that it aligns with the consortium's strategic objectives.

CMC

Analytical LG
Brian Regler • Boehringer Ingelheim
Anne Payne • Merck
Haiyan Grady • AbbVie

Drug Substance LG
John Traverse • Bristol Myers Squibb
Ayman Allian • Eli Lilly and Co.
Erin O'Brien • Biogen

Drug Product LG
Keith Horspool • Boehringer Ingelheim
Rubi Burlage • Merck
Greg Connelly • Vertex

Biologics CMC LG
Barbara Rellahan • Amgen, Inc.
Renata Varga • Teva

QUALITY

Quality Coordinating Committee
Chris Turner • Bristol Myers Squibb
Ganapathy Mohan • Merck

GMP QA Focus Group
Chris Grosso • Merck
Sunita Iyer • Merck
Andrea Pless • Teva

GLP QA Focus Group
Jeff Beebie • Pfizer, Inc.
Kerri Robles • Bristol Myers Squibb
Erin Johnson • Incyte

STATISTICS

CMC Forum
Phillip Yates • Bristol Myers Squibb
Erik Talens • Merck

Biostatistics Forum
J. David Christopher • Merck

LIFE SCIENCES

Clinical Pharmacology LG
Vikram Sinha • Takeda
Tong Zhu • Astellas Pharma Inc.
Chunze Li • Genentech, Inc.
Sandhya Girish • Gilead

Translational and ADME Sciences LG
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Tracy Williams • Eli Lilly and Co.
Nancy Agrawal • Merck

DruSafe
Mazin Derzi • Pfizer, Inc.
Joanne Birkebak • Gilead Sciences
Raja Mangipudy • Bristol Myers Squibb
Elisabeth Mortimer-Cassen • AstraZeneca
Thomas Monticello • Amgen, Inc.

3Rs Translational and Predictive Sciences LG
Natalie Bratcher • AbbVie
Sean Maguire • GlaxoSmithKline
Khary Adams • Incyte
Szczepan Baran • Novartis
Donna Lee • Genentech

IQ AFFILIATES

IQ affiliates provide a mechanism for member companies to take on next-level initiatives within the IQ framework, taking advantage of the benefits it provides. These include an established cross-pharma governance structure as well as data-sharing agreements and a shared database that can support collaborative work.

IQ affiliates address challenging pharma topics that require special focus to deliver the IQ mission of transformative solutions and innovation for drug development. The pharma industry is recognizing the potential of IQ affiliates to transform and expedite the drug discovery and development processes.

Current IQ affiliates are the IQ Consortium Drug Induced Liver Injury Initiative (IQ DILI), established in 2016, and the IQ Microphysiological Systems Affiliate (IQ MPS), created in 2018. Affiliates have an independent budget, distinct objectives and a steering committee that provides oversight of the affiliate.

IQ AFFILIATE BENEFITS

IQ Affiliates provide a mechanism for member companies to take on next-level initiatives within the IQ framework. Affiliates also:

- Provide a means for IQ members to take on different or larger projects that go beyond that of an IQ Working Group
- Provide opportunities to collaborate with other IQ Leadership Groups
- Receive scientific, project management, legal and administrative support from the Secretariat

IQ DILI INITIATIVE

Monitoring and diagnosing drug-induced liver injury (DILI) in clinical trials and new drugs presents a critical challenge to the pharmaceutical industry and patient care. Hepatotoxicity has been the most frequent single cause of drug marketing safety withdrawals for the past 50 years, and is the most common cause of aborted drug development. IQ DILI, established in 2016, is the first industry-led effort that is focused on clinical aspects of DILI not sufficiently covered by existing guidance.

iqdili.org ►

IQ MPS AFFILIATE

Microphysiological systems (MPS) are small microfluidic systems engineered to replicate the physiology of human organ systems. Also known as "organs-on-a-chip," MPS are potentially transformative tools for drug development and present alternatives to animal testing for the evaluation of drug safety, drug efficacy and disease modelling. The objectives of IQ MPS, an IQ affiliate established in 2018, include developing a framework for cross-organization testing and evaluation of human-relevant MPS platforms through either data-sharing or prospective collaboration.

iqmps.org ►

IQ SECRETARIAT SUPPORT

The law firm of Faegre Drinker Biddle & Reath, LLP (Faegre Drinker) serves as secretariat and legal counsel to the IQ Consortium.

Consisting of attorneys, scientists and project managers, Faegre Drinker's consortium management team executes central legal and administrative tasks. Team support includes:

- Facilitating member company decision-making processes to develop consensus positions on strategic initiatives and projects
- Ensuring antitrust compliance by providing training, oversight, and ad hoc legal counsel
- Providing broad scientific, project management, legal, and administrative support
- Providing the Board of Directors with robust strategic, operational, and planning support
- Supporting the exploration and scoping of various data-sharing initiatives
- Implementing and executing data-sharing projects through custom-designed databases and surveys
- Reviewing manuscripts under development to ensure antitrust compliance
- Facilitating external engagements with key stakeholders
- Managing internal and external communications
- Managing the public website and internal collaboration portal
- Providing venue and logistical support for in-person meetings

For more information about IQ membership, including related fees, please contact Mary Devlin Capizzi or Maureen Cruz at the IQ Secretariat.

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INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT
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