2021

YEAR IN REVIEW

IPAC-RS

International Pharmaceutical Aerosol Consortium on Regulation & Science

Contents

A Message from the IPAC-RS Chair

Carla Vozone

In reflecting on 2021, I am grateful for IPAC-RS' work and proud of the consortium's impact and accomplishments. As we continue to navigate the global pandemic and unprecedented disruption, the IPAC-RS community has remained strong and steady, staying abreast of global regulatory developments and leveraging a range of tools and platforms to stay meaningfully engaged in the current virtual environment. The collaboration and generosity of IPAC-RS members were manifest through a new series of public roundtables on digital health and connected devices, benchmarking and thought leadership shared widely, and numerous scientific and technical projects focused on orally inhaled and nasal drug products (OINDPs). The consortium's 20 plus year commitment to advance the science and regulation of OINDPs has been unwavering. Further, IPAC-RS' reach is now, without question, global. The consortium has undertaken initiatives in the US, EU, Asia and South America and its engagement extends to many global regulatory agencies. An effort to become more inclusive led to a broadening of the Associate Membership category. This will ensure that OINDP component manufacturers, smaller and innovative OINDP companies, and OINDP service providers can work closely with IPAC-RS Full Members and further enhance the active, diverse, and vibrant IPAC-RS community. As we enter 2022, we look forward to continuing collaboration with regulatory authorities and all OINDP stakeholders to advance a shared goal: to develop OINDPs that support health and transform the lives of patients for the better.

Thank you to all in the IPAC-RS community. It is a privilege to serve as Chair of this important and vibrant consortium. I am looking forward to a productive and hopeful 2022!

Thank you

Martin Oliver

Martin Oliver, Vice-Chair of the IPAC-RS Board of Directors, retired in October 2021. Martin had a long career in inhaled drug development, and was a long-time member of IPAC-RS, generously contributing his expertise and leadership. Along with current IPAC-RS Chair, Carla Vozone, Martin helped IPAC-RS navigate the challenging COVID times, provided invaluable support and insights to expand IPAC-RS's international outreach, and ensured that the Consortium remained strong.

With Martin's departure, IPAC-RS held an election and selected two new Co Vice-Chairs. Mike Needham, Global Respiratory Product Development Manager at Kindeva Drug Delivery, will serve as a Co Vice-Chair through the end of May 2022, and then will become IPAC-RS Chair beginning on June 1, 2022. Jennifer Wylie, Director, Analytical Research and Development at Merck Research Labs, will serve as IPAC-RS Vice Chair through May 31, 2024 and then as IPAC-RS Chair through May 31, 2026.

New Co-Chairs

Mike Needham, Global Respiratory Product Development Manager at Kindeva Drug Delivery

Jennifer Wylie, Director, Analytical Research and Development at Merck Research Labs

Welcome to New Members and Associate Members

In 2021, the IPAC-RS family welcomed these Members and Associate Members:

- **PPD**
- **Nemera**
- **Genentech**

We are proud of the growing strength and breadth of our membership!

New in 2021

"IPAC-RS and the Roundtables it organizes are uncommon. IPAC-RS creates a meaningful space for stakeholders to discuss complex issues collaboratively and in greater depth than is possible in most meetings."

Robert Berlin, *JD, M.P.H., Head of US Regulatory Policy, GlaxoSmithKline, IPAC-RS Digital-Devices Roundtable Organizing Committee*

IPAC-RS now has its own video channel!
Please visit to watch recordings of IPAC-RS webinars and other resources.

IPAC-RS launched its company page on LinkedIn. Follow IPAC-RS here.

The IPAC-RS Digital-Devices Roundtable Series launched in September 2021 and will continue in 2022. Recordings and presentations (PDFs) are available here. In 2021, five broad areas were discussed with IPAC-RS experts and invited guest presenters:

- During the inaugural event on September 10, 2021, presenters discussed digital biomarkers and clinical endpoints for products with digital components.
- On September 21, presenters spoke on beyond usability/human factors for digital healthcare, explaining the importance of moving away from risk and warnings towards encouragement and engagement when designing digital devices. This approach would support safety and enable efficacy, while providing an opportunity to go beyond treating illness and towards championing health.
- On September 29, manufacturing, CMC, and design considerations for digital-devices and drug-device combination products were discussed.
- On October 4, presenters discussed the business case for digital inhaler devices from a pharma company perspective and a platform provider's perspective.
- On November 22, regulatory challenges and considerations for digital-devices from EMA and FDA perspectives were discussed.

The first IPAC-RS Associate Member Roundtable was held on July 30, 2021. Participants discussed background and opportunities for Associate Members, ideas for future IPAC-RS projects, and proposals for increased engagement.

IPAC-RS rejoined the Product Quality Research Institute (PQRI) in July 2021. All IPAC-RS Members and Associate Members are now eligible to appoint delegates to the three PQRI Technical Committees (Biopharmaceutics, Development and Product Quality). PQRI is a unique forum created in 1999 by the U.S. FDA and industry leaders to provide a platform for product quality and joint research collaboration among pharmaceutical industry associations, FDA and other health regulatory bodies, and academia. PQRI work streams focus on addressing topics that have meaningful impact on regulatory science and provide valuable professional development opportunities for professionals who are employees at IPAC-RS Member and Associate Member companies.

IPAC-RS Board of Directors Discussion

Highlights

February 2021: IPAC-RS Board of Directors and guest presenter, Dr. Stavros Kassinos, reviewed the outcomes and future plans of the SimInhale initiative. (For more information see, short video and background.) The Board also reviewed outcomes of recent conversations with Members regarding the strategic direction of IPAC-RS, restructured the Devices Working Group into a Devices Knowledge Network, reviewed updates on the USP Prescription-Non-Prescription Stakeholder Forum, and endorsed the addition of a new membership level for smaller OINDP companies.

April 2021: The IPAC-RS Board of Directors and representatives of Associate Member companies reviewed the current IPAC-RS project portfolio and planned a new series of regulatory and digital-devices roundtables.

June 2021: PQRI representatives presented to the IPAC-RS Board an in-depth overview of the PQRI structure, benefits, priorities, and projects. FDA guests from CDER's Office of Policy for Pharmaceutical Quality (OPPQ) and Office of Lifecycle Drug Products (OLDP) provided an overview of the Agency's work addressing comments received on the 2018 draft CMC guidance for MDIs and DPIs. The Board also discussed the US EPA rule on HFC phasedown. Associate Member representatives were invited to join the Board meeting to hear from FDA.

September 2021: The Board, along with Associate Member representatives, heard updates on the consortium's portfolio from IPAC-RS Working Group Chairs, highlighting WG accomplishments and longer term plans.

October 2021: The Board considered proposals for new projects and a new strategic plan for 2022-2024. In coordination with the sister consortium IPAC (which focuses on regulatory environmental issues for pMDIs) updated IPAC-RS members on the ongoing active debates and legislation activities in Europe and the US, aimed at the HFC phasedown and other sustainability initiatives.

December 2021: The IPAC-RS Board of Directors finalized and endorsed the IPAC-RS Strategic Plan for 2022-2024. The Board and FDA guests from CDER's OPPQ, OLDP, Office of New Drug Products (ONDP), and Office of Medical Policy (OMP) discussed progress of the next draft CMC guidance for MDIs and DPIs, joint training and educational opportunities, the importance of coordination among FDA centers, and emerging topics such as alternate propellants. The FDA guests shared the Agency's efforts in combating COVID-related challenges while continuing to work on guidances, product reviews, research, and collaborations. Associate Member representatives were invited to join the Board meeting to hear from the FDA guests.

Highlights

Discussions

Materials WG and Devices KN reviewed USP chapters <1083> "Supplier Qualification" and <1229.20> "Decontamination and Sterilization."

Materials WG and ELSIE consortium collaborated on a survey related to the China CDE requirements regarding a change management issue – specifically a lubricant change relevant to valves used in orally inhaled drug products.

GRRO Brazil hosted a special presentation on "Biosafe Cabin for Spirometry in Response to COVID-19 Restrictions," discussing research done by an IPAC-RS member company and use of the cabin in healthcare situations in Brazil.

Materials WG and Devices KN hosted a webinar (May 13) on 3D printed devices. A recording is available to IPAC-RS members on IPAC-RS Connect. *

GRRO Brazil conducted a survey to gauge companies' experiences with the therapeutic equivalence resolution (RDC 278) and normative instruction (IN 33), with respect to post approval changes. The group collaborated with Interfarma to circulate the survey within Brazil.

* *Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.*

Publications and Comments

Performance of Multiple-Batch Approaches to Pharmacokinetic Bioequivalence Testing for Orally Inhaled Drug Products with Batch-to-Batch Variability. AAPS PharmSciTech volume 22, Article number: 225 (August 2021). Read here.

Efficient Data Analysis (EDA): Size, Mass and Common Sense. Inhalation Magazine. (August 2021) Read here.

IPAC-RS Regulatory Roundtable Series: A conversation with the US FDA: Perspectives in the time of COVID-19 Inhalation Magazine (June 2021)

IPAC-RS comments on China CDE's draft guideline "Technical Requirements for Pharmaceutical Research on Chemical Inhalation Liquid Preparations" (July 2021)

IPAC-RS Comments to FDA on ICH Q12: Implementation Considerations for FDA-Regulated Products (July 2021)

IPAC-RS Comments to USP on Pharmacopoeial Forum Chapter <1031> The Biocompatibility of Materials Used in Drug Containers, Medical Devices, and Implants (September 2021)

IPAC-RS Comments to USP on Pharmacopoeial Forum Chapter <88> Biological Reactivity Tests, In Vivo (September 2021)

IPAC-RS Comments to USP on Pharmacopoeial Forum Chapter <87> Biological Reactivity Tests, In Vitro (September 2021)

Regulatory Agencies, Standards Organizations, Other Stakeholders

Meetings

IPAC-RS Board of Directors met with FDA representatives in June and December 2021.

Cascade Impaction WG met with representatives of USP, as well as EDQM, to discuss harmonization of pharmacopeial approaches, Abbreviated Impactor Measurements (AIM), and Efficient Data Analysis (EDA).

IPAC-RS connected with the leaders of the Center for Research in Complex Generics (CRCG) established by FDA. The two organizations confirmed mutual interest in discussing and potentially collaborating on science-based regulatory approaches for OINDPs.

IPAC-RS held a "Summer Chat" roundtable on MDR implementation (July 29). Representatives from BSI and TÜV SÜD shared their experiences with the recent Q&A guideline and other MDR updates.

In February 2021 and throughout the year, GRRO-China held teleconferences with representatives of China's NIFDC, NMPA (international outreach office), ChP and CPIA to discuss plans for further IPAC-RS Regulatory Roundtables.

Monitoring, Communications and Networking

IPAC-RS tracked global regulatory developments and standards that are relevant for OINDPs, discussed key publications, and shared insights from webinars and conferences, with its members and summarized them in the Monthly newsletter, which is distributed to all IPAC-RS members and all interested employees of Member and Associate Member companies.

IPAC-RS engages actively in reviewing and commenting on regulatory developments around the world and works collaboratively with all stakeholders to improve science-based regulations affecting OINDPs. IPAC-RS prepared a summary of relevant global regulatory developments in 2020.

IPAC-RS maintains a public Pharmaceutical Aerosols Resource Center (PARC) webpage, which highlights the latest research, educational materials, and regulatory standards relevant for OINDPs.

The IPAC-RS Board, Planning Committee, WGs, and KNs continued to meet regularly, network, and advance IPAC-RS projects throughout 2021 using a variety of online tools.

The IPAC-RS community stays connected and productive using the members-only IPAC-RS Connect portal,* and maintains high visibility through the IPAC-RS website and its new LinkedIn page.

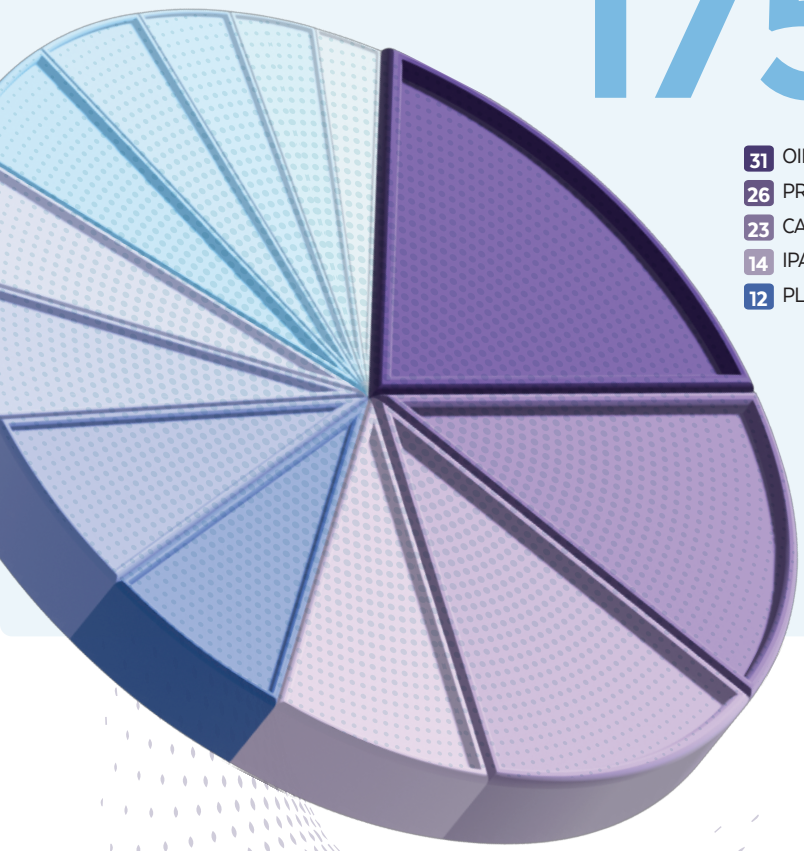
*Become an IPAC-RS member for full access to these materials. Contact the IPAC-RS Secretariat (info@ipacrs.org) for information.

By the Numbers

6 **Board Meetings**
The IPAC-RS Board met virtually in February, April, June, September, October, and December 2021, with both plenary and breakout sessions to brainstorm and work out specific issues, topics and proposals. More here.

5 **Digital-Devices Roundtables**
Read more here.

175 Webmeetings of IPAC-RS Working Groups, Knowledge Networks and subgroups, including:



- 31 OINDP MATERIALS, INCLUDING NITROSAMINES AND BIOCOMPATIBILITY SUBGROUPS
- 26 PRODUCT QUALITY DEMONSTRATION STRATEGY
- 23 CASCADE IMPACTION
- 14 IPAC-RS DIGITAL-DEVICES ROUNDTABLE ORGANIZING COMMITTEE
- 12 PLUME CHARACTERIZATION
- 12 GRRO- BRAZIL
- 11 GRRO- CHINA
- 11 GRRO - NORTH AMERICA
- 11 PLANNING COMMITTEE
- 9 PK BATCH-TO-BATCH VARIABILITY
- 7 GRRO - EUROPE
- 6 ANALYTICAL METHODS LIFECYCLE MANAGEMENT
- 2 MDR ANALYSIS

Looking Ahead

During 2021, IPAC-RS held several strategic discussions with Members and Associate Members to develop a Strategic Plan for 2022-2024. The new plan re-affirmed the key values and priorities overall and will add several new initiatives to the IPAC-RS portfolio, such as

- **Inhaled biologics, including nebulized biologics.** This area has unique challenges from delivery mechanisms to analytics, formulation development, and regulations.
- **Nasally delivered biologics and large molecules,** including proteins, RNAs, nucleic acids, and vaccines. There are many gaps in the regulatory science behind these product types and IPAC-RS members are interested in building up knowledge base and consensus on best approaches.
- **Best cascade impaction** practices for aqueous formulations.
- **Better understanding of in-vitro** in-vivo correlations, clarification of specific approaches for generic OINDPs.
- **Best practices** for post approval changes and scale up for OINDPs.

In 2022, IPAC-RS will also continue work started in 2021

- **A joint session at** RDD 2022 to address Regulatory, Science and Technology Innovations Enabling Novel and Improved OINDP Design, Development and Manufacturing. The podium presentations will be supplemented with subsequent in-depth roundtables (delivered online after RDD 2022).
- **Materials WG's work** on strategies for ensuring materials quality with alternative propellants.
- **Plume Characterization WG** manuscript "Spray Pattern and Plume Geometry Testing and Methodology: An IPAC-RS Working Group Overview."
- **GRRO China's roundtable** with a focus on regulatory requirements in China. Proposed topics include combination products, digital components, new formulation types delivered by OINDPs, and international harmonization.
- **GRRO-NA's dialogue** with the FDA Office of Combination Products about the alignment of regulatory approaches and inter-center coordination.
- **The Nitrosamines and Biocompatibility** Subgroups of the Materials WG are both developing manuscripts.
- **The IPAC-RS Board** will meet virtually in March and June 2022, and will plan to meet in the Fall, in-person, in Washington DC.

What Our Members Are Saying

"I strongly believe that the digital health topics around which IPAC-RS has facilitated numerous roundtable discussions are critical. Digital technologies are revolutionizing the way we develop OINDPs and fostering innovation for the benefit of patients. I am grateful to IPAC-RS for facilitating opportunities to share our knowledge and experiences. IPAC-RS brings the industry together to focus on shared goals in furtherance of serving patients. IPAC-RS is more than an OINDP association – it is a community."

Marta Lombardini, *Ph.D., Device Development Manager, Chiesi Group, IPAC-RS Digital-Devices Roundtable Organizing Committee*

"IPAC-RS is one of the best OINDP industry associations in terms of membership, collaboration, and the quality and timeliness of substantive and well-organized discussions. The involved stakeholder community consistently offers diverse perspectives in a collaborative setting and interacts constructively with the FDA, EMA, Health Canada, Chinese FDA, and other regulatory agencies around the world. At its core, the IPAC-RS organization is a massive knowledge network that offers many benefits and opportunities to both members and the industry at large ."

Dino Farina, *M.S. E.M.E, CEO, Proveris Scientific Corporation, IPAC-RS Associate Member*

What Our Members Are Saying

"Through IPAC-RS [my company] has access to a great knowledge base and is able to leverage the breadth and depth of experience of the OINDP industry. At the same time, we receive a platform to share our perspectives and experiences and contribute to important conversations, interact and learn from others in the industry, have our input integrated into comments on regulatory guidance documents, and participate in dialogues with regulatory agencies. The global nature of IPAC-RS is very important to us as we have clients throughout the world. Finally, the new IPAC-RS Associate Membership structure enables companies like ours to engage actively in IPAC-RS and access many benefits as Associate Members at a reduced membership cost in comparison to large pharmaceutical companies engaged in development and manufacture of OINDPs."

Ian Carter, *Principal Scientist, PPD, part of Thermo Fisher Scientific, IPAC-RS Associate Member*

"There are tremendous benefits to being a member of IPAC-RS, including coordination with other industry organizations, access to government agencies, and speaking with a thoughtful and unified industry voice. I always viewed the cost of IPAC-RS membership in terms of the many resources and insights offered by the consortium; the return on the investment is strong and made the decision to be part of IPAC-RS easy. Further, navigating the evolving and challenging global OINDP regulatory environment without a broader industry group is not ideal and often leads to inefficiencies and missed opportunities."

Barbara Falco, *President, Barbara Falco Pharma Consult LLC, IPAC-RS Science Advisor*

"OINDPs are complex, but that complexity leads inevitably to active engagement with the science. IPAC-RS enables this engagement and provides OINDP scientists from industry, academia, and regulatory agencies a unique forum for scientific thought leadership and collaboration."

Jennifer Wylie, *Ph.D., Director, Analytical Research and Development, Merck Research Labs; IPAC-RS Co-Vice Chair, Board of Directors*

Overview of IPAC-RS

Who We Are

IPAC-RS is an international association that seeks to advance the science of orally inhaled and nasal drug products (OINDP) by collecting and analyzing data. Representing the OINDP industry for two decades, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, webinars, technical journals, and discussions with regulatory bodies.

Vision

IPAC-RS is and will remain the leading technical resource and advocate of the global OINDP industry, with a focus on Chemistry, Manufacturing and Controls aspects.

Mission

The mission of IPAC-RS is to advance scientifically-driven approaches to enhancing product quality of OINDPs for the benefit of patients.

Purpose

- **Advance the science and regulation of inhalation products through discussion, research, and publication.** IPAC-RS identifies and addresses key questions for OINDP through key initiatives and develops and publishes best practices for OINDP.
- **Provide information and services to enable member companies to achieve their current and future product development and regulatory goals.** IPAC-RS serves as a resource for sound assessment of OINDP regulatory requirements and engages in initiatives to facilitate current and future OINDP product development processes.
- **Effectively collaborate with the broader OINDP industry, OINDP suppliers, regulatory authorities, and other stakeholders.** IPAC-RS seeks to expand relationships with decision-makers at worldwide regulatory agencies and standard-setting bodies. IPAC-RS provides educational opportunities and collaboration with the OINDP industry, suppliers, and regulators on current and emerging scientific and regulatory topics relevant to OINDP.
- **Be a well-respected and effective advocate for the OINDP industry. IPAC-RS actively comments on OINDP regulations and guidances and promotes clear and harmonized international regulatory expectations in the field.** IPAC-RS engages regulatory authorities in constructive discussion and sharing of ideas on OINDP best practices.

IPAC-RS Members and Associate Members

IPAC-RS is governed by a Board of Directors composed of Member company representatives. The IPAC-RS Board of Directors establishes the consortium's mission and objectives, forms working groups to achieve specific goals, oversees budget, and provides strategic guidance. Members and Associate Members participate in and drive Working Groups, which address current and emerging OINDP scientific and regulatory topics.

Members

(including Board members)
Chair: Carla Vozone **Vice Chair:** Martin Oliver

- **AstraZeneca**
  François Michelon
  Andy Rignall
- **Boehringer Ingelheim**
  Holger Memmesheimer
  Morgana Sebenello Wolf
- **Catalent**
  Craig Davies-Cutting
  David Wilcox
- **Chiesi**
  Francesca Usberti
  Monica Ferrari
- **Genentech**
  Negar Sadrzadeh
  Yoen-Ju Son
- **GlaxoSmithKline**
  Jeremy Clarke
  Susan Holmes
- **Hovione**
  Eunice Costa
  Marcio Temtem
- **Kindeva Drug Delivery**
  Ann Purrington
  Mike Needham, IPAC-RS Co-Vice Chair (as of 11/21)
- **Lupin Pharmaceuticals, Inc.**
  Mukul Dalvi
  Axel Perlwitz
- **Merck & Co., Inc.**
  Robert Berger
  Jennifer Wylie, IPAC-RS Co-Vice-Chair (as of 11/21)
- **Novartis**
  Jürgen Jauernig
  Hans Keegstra
- **Sunovion**
  Andrea Bauer
  James Conners
- **Teva**
  Julian Blair
  Prasad Peri
- **Vectura**
  Nicky Ellis
  Nikky Willis
- **Viatris**
  Andrew Cooper
  David Pole

Associate Members

- Amcor Flexibles
- Aptar Pharma
- Copley Scientific
- H&T Presspart
- Nemera
- Oxford Lasers
- PPD
- Proveris Scientific Corporation
- Team Consulting Ltd

IPAC-RS Workstream Leadership

Working Group Chairs (2021)

- **Cascade Impaction**
  Adrian Goodey, Merck
- **GRRO (Global Regulatory Review and Outreach) Brazil**
  Leticia Grecchi, Chiesi
  Marcia Cavallin Silva, Boehringer Ingelheim
- **GRRO China**
  Mark Hindle, AstraZeneca
- **GRRO Europe**
  Franz-Josef Rehmann, AstraZeneca
  Sarah Bunyan, Vectura
- **GRRO North America**
  Susan Holmes, GlaxoSmithKline
- **MDR Analysis**
  Tim Chesworth, AstraZeneca
- **MDR Analysis Supplier Subgroup**
  Kristin Limouzin, Aptar
- **OINDP Materials**
  James Conners, Sunovion
- **Product Quality Demonstration Strategy**
  David Christopher, Merck
  Helen Strickland, GlaxoSmithKline
- **Plume Characterization**
  Sherryl Baxter, AstraZeneca
  Frank Chambers, Inhalytic Ltd

In addition to Working Groups,
IPAC-RS has the following Knowledge Networks, where members can discuss ongoing developments.

- Analytical Lifecycle Management
- Population Bioequivalence (PBE)
- Pharmacokinetics (PK) Batch-to-Batch Variability
- Devices

Membership Information

Full Membership in IPAC-RS is open to corporations that develop, manufacture, or contract to manufacture OINDPs.

Associate Membership is open to corporations that (1) develop or manufacture components and/or devices for OINDPs; (2) provide scientific or technical services relating to development and manufacture of OINDPs; or (3) are eligible for full membership but have revenues of less than seventy-five million US dollars.

IPAC-RS membership is at the company rather than individual participant level. Accordingly, Members and Associate Members can leverage IPAC-RS with unlimited participation from interested colleagues.

For questions about IPAC-RS' priorities, progress, or membership, please email info@ipacrs.org or contact a member of the IPAC-RS Secretariat.

Secretariat Support

Faegre Drinker Biddle & Reath's Pharmaceutical Consortia Management Team serves as Legal Counsel and Secretariat to IPAC-RS. Composed of attorneys, scientists, policy analysts, and project managers, and with offices in the US, Europe, and Asia, the Consortia Management Team forms and supports life sciences industry collaborations that help global companies address complex regulatory and compliance challenges, as well as other topics of mutual interest. For three decades, the Team has been dedicated to facilitating collaboration, joint research, and data sharing in the pharmaceutical, medical device, and supporting industries. The Secretariat provides a wide range of services, as requested by each consortium.
For example, the Secretariat:

- **Facilitates** decision-making processes to develop consensus positions on strategic initiatives and projects.
- **Ensures** antitrust compliance by providing training, oversight, and legal counsel.
- **Provides** broad scientific, project management, legal, and administrative support.
- **Provides** the Board of Directors with robust strategic, operational, and planning support.
- **Supports** the exploration and scoping of data-sharing initiatives.
- **Helps design,** develop, implement, execute, and curate custom-designed databases and surveys and other data-sharing projects.
- **Assists** with writing technical reports and papers, and contributes to, and reviews manuscripts under development, to ensure antitrust compliance.
- **Facilitates** external engagements with global regulatory agencies, standard setting organizations, industry associations, advocacy groups, and other stakeholders.
- **Manages** internal and external communications, including public websites and internal collaboration portals.
- **Provides** venues and logistical support for virtual and in-person meetings.

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IPAC-RS

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