



IPMPC

International Pharmaceutical &  
Medical Device Privacy Consortium

2021

YEAR IN REVIEW



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## **DEAR MEMBERS AND PROSPECTIVE MEMBERS OF THE IPMPC,**

In reflecting on the past year, I am grateful for and proud of the IPMPC's impressive growth and accomplishments. As we navigate these uncertain times in a mostly virtual environment, I want to sincerely thank all IPMPC members for their generous collaboration on global data privacy issues impacting the life sciences industry. The ability to compare programs and progress with peer companies is extremely beneficial, and the IPMPC continues to create opportunities for members to learn from each other. This year the IPMPC focused on the pressing issue of international data transfers and held regular strategic meetings to develop pragmatic resources and share invaluable benchmarking perspectives. We also addressed privacy developments across the globe, including data protection reform in the United Kingdom, the implementation of China's Personal Information Protection Law, and changes in U.S. privacy with the passing of new state privacy laws.

In the face of evolving regulatory requirements, increasing restrictions on data transfers and use, and new privacy risks and challenges, the IPMPC is committed to promoting ethical data protection standards to support crucial innovation in healthcare and health delivery. I am confident IPMPC members will continue to help one another navigate the complex data protection landscape to support business initiatives in 2022 and I look forward to the organization's growth over the next year.

**XAVIER JEAN**

**CHAIR OF IPMPC, GLAXOSMITHKLINE**



IPMPC member companies share a common goal: protecting the personal information of patients, healthcare practitioners, and employees, while maximizing the insights from personal information to improve medical research and to provide better treatments.

# OUR MISSION



Provide a forum to ensure that the global life sciences industry speaks with one, coherent voice on data privacy issues



Augment member companies' data protection capabilities through the development and sharing of industry best practices



Educate internal and external stakeholders on data protection in the industry and the importance of data innovation



Anticipate and respond to new challenges affecting the protection of health information



Advance the protection of individual privacy

## PRIVILEGES OF MEMBERSHIP

- Access to extensive privacy-compliance resources tailored to the needs of the pharmaceutical and medical device industry.
- Timely analyses of new privacy laws, court decisions, and pharmaceutical and medical device enforcement actions impacting business operations.
- Updates on global privacy developments and informative, practical discussions with local counsel from around the world.
- Opportunities to interact with key regulators.
- Expert insight into how evolving business models could be impacted by privacy laws.
- Cost-sharing to efficiently leverage budget resources.
- Regular interaction and benchmarking with industry colleagues facing similar challenges.
- The legal, project management, and logistics support of the IPMPC Secretariat.



**“The IPMPC has been the most helpful organization that we have been a part of from a privacy perspective. From the numerous benchmarking opportunities to the relationships with peers to the immediate reactions of the IPMPC lawyers and staff in response to new legislation and developments, participation in the IPMPC has been invaluable.”**

**Sara Berkson, Chief Privacy Officer & Global Head Privacy Counsel  
VERTEX PHARMACEUTICALS INCORPORATED**

## IPMPC 2021 MEMBER COMPANIES



3M

ABBOTT LABORATORIES

ABBVIE

ADAPTIVE BIOTECHNOLOGIES

AMGEN

ASTELLAS PHARMA

ASTRAZENECA

BAXTER

BECTON, DICKINSON AND COMPANY

BEIGENE

BRISTOL MYERS SQUIBB

COCHLEAR LIMITED

COOK MEDICAL

ELI LILLY AND COMPANY

FRESENIUS MEDICAL CARE

GENENTECH/ROCHE

GLAXOSMITHKLINE

JAZZ PHARMACEUTICALS

JOHNSON & JOHNSON

KYOWA KIRIN

NOVARTIS

NOVO NORDISK

ORGANON AND COMPANY

OTSUKA PHARMACEUTICAL COMPANY

PFIZER

PHILIPS HEALTHCARE

REGENERON PHARMACEUTICALS

SANOFI

SEAGEN

STRYKER

SUNOVION PHARMACEUTICALS

TAKEDA PHARMACEUTICAL COMPANY

VERTEX PHARMACEUTICALS

# 2021 BOARD OF DIRECTORS



Xavier Jean  
Chair of IPMPC  
GLAXOSMITHKLINE



Alejandro Gené  
Vice Chair of IPMPC  
BRISTOL MYERS SQUIBB

## 3M

Melia Arnett-Archie  
David Frazee

## ABBOTT LABORATORIES

Jacob Springer  
Patrick Zeller

## ABBVIE

Eric Berman  
Karen Sewell

## ADAPTIVE BIOTECHNOLOGIES

Doug Curwin  
Alea Garbagnati

## AMGEN

Charlie Blanchard  
Emily Mason

## ASTELLAS PHARMA

Theresa Niland  
Antonios Roussos

## ASTRAZENECA

Amy Papili  
Neil Wilson-Perkin

## BAXTER

Caroline Budde

## BECTON, DICKINSON AND COMPANY

Luca Nevano

## BEIGENE

João Barreiro

## BRISTOL MYERS SQUIBB

Luis Vilarin

## COOK MEDICAL

Megan Charlesworth

## ELI LILLY AND COMPANY

Jessica Mijares-Campo  
Audrey Mills

## FRESENIUS MEDICAL CARE

Abhishek Agarwal  
Sharon Frank

## GENENTECH/ROCHE

Kimberly Gold  
Florian Zabel

## GLAXOSMITHKLINE

Nicholas Accomando

## JAZZ PHARMACEUTICALS

Rachel Ralston  
Jessica Vialle

## JOHNSON & JOHNSON

Winston Khoo

## KYOWA KIRIN

Catherine Clemons  
Tara D'Orsi

## NOVARTIS

Ashley Bashore  
Maria Chiara-Atzori

## NOVO NORDISK

Anna Dolinsky

## ORGANON AND COMPANY

Ivelisse Clausell

## OTSUKA PHARMACEUTICAL COMPANY

Terry-Ann Cooper  
Agatha O'Malley

## PFIZER

Patrice Ettinger  
Joanna Levin

## PHILIPS HEALTHCARE

Joyce Musante

## REGENERON PHARMACEUTICALS

Anna Langhorne  
Ericka Watson

## SANOFI

Corey Dennis  
Lionel De-Souza

## SEAGEN

Elizabeth Smith  
Chad Taylor

## STRYKER

Gloria Greco

## SUNOVION PHARMACEUTICALS

Shannon Schultz

## TAKEDA PHARMACEUTICAL COMPANY

Rachel Chapman  
Nick Tyler

## VERTEX PHARMACEUTICALS

Sara Berkson

# 2021

## BY THE NUMBERS



**33**

MEMBER  
COMPANIES



**12**

ACTIVE WORK  
STREAMS



**100+**

TELECONFERENCES AND  
VIRTUAL MEETINGS

**50+**

TEMPLATES, SUMMARIES,  
AND ADDITIONAL  
RESOURCES DEVELOPED



**14**

COMPREHENSIVE AGGREGATED  
BENCHMARKING SURVEYS ADDRESSING  
A WIDE RANGE OF TOPICS SUBMITTED  
BY OVER 30 MEMBER COMPANIES



**10**

PRESENTATIONS FROM  
INVITED GUEST SPEAKERS



**5**

SUBMITTED RESPONSES ON  
REGULATORY GUIDANCE AND  
PROPOSED LEGISLATION



# THE VALUE OF INDUSTRY BENCHMARKING

In addition to the live benchmarking discussions and information-sharing between members during IPMPC meetings, the IPMPC also provides members with regular opportunities to submit benchmarking questions for circulation to all IPMPC member companies. In 2021, the IPMPC conducted monthly benchmarking surveys and created aggregated reports on over 30 different timely and critical topics submitted by members.



“The IPMPC provides a platform in which to address not only the legal requirements of new laws and regulations to be considered in building up a business process, but it also assists us in talking about the practicality of how we can translate that law into an actual implementation. The statistical value and actual data derived from peer benchmarking efforts distinguishes the IPMPC from other benchmarks available in the marketplace and gives us more confidence in our approaches to different issues. I’m a very proud member and it’s an honor to be a part of IPMPC and sit among the best minds in the industry”.

**Abhishek Agarwal**, Chief Information Security Officer  
FRESENIUS MEDICAL CARE NA

## 2021 BENCHMARKING

- International Transfers of Data
- Implementation of China’s Personal Information Protection Law
- Privacy Program Structure & Governance
- Data Protection Officer Role Structure and Responsibilities
- Environmental, Social & Governance Privacy Principles
- Privacy Stewardship and Privacy Champion Programs
- Data Protection Impact Assessment Process
- Managing Privacy Requirements with Third-Parties
- Negotiations with Next Generation Sequencing Vendors
- Requests from Ethics Committees
- Cookie Banner Management
- Market Research Activities
- Social Media Branded Marketing Campaigns
- Data Governance Process for Managing Personal Data Collected through Social Listening Activities
- COVID-19 Employee Vaccination & Return to Work Privacy Considerations
- Conducting Remote Clinical Trials
- Retention Schedules
- Collection of IT Systems in GDPR Article 30 Register
- Managing Records of Processing Activities and Data Subject Requests in Asia
- Privacy Program Compliance Considerations in Russia
- Clinical Trials in Russia
- Role of Data Controller
- HIPAA Business Associate Agreements
- US Clinical Trial Agreements
- Data Protection Representatives
- Data Subject Requests for Safety Database
- Patient Support Programs
- Legal Basis for Processing Adverse Events and Technical Complaints
- Accountability Principle of Cross-Border Protection Rules
- HCP Segmentation
- Sending Electronic Communications to HCPs in the European Union
- Privacy Notices to HCPs



## European Working Group

The European Working Group had a productive and busy year in 2021. In response to the Schrems II judgment, the group engaged in critical industry discussions with other life sciences privacy associations to promote the importance of transatlantic data flows in the life sciences industry. The group also continued to respond to concerns regarding differences in GDPR interpretation amongst member states. In 2022, the European Working Group will continue to promote industry coordination and focus on mitigating the consequences of barriers to life sciences data flows.



**Luca Nevano**  
European Working Group Co-Chair  
BECTON DICKINSON



**Efstathia Gkika**  
European Working Group Co-Chair  
BAXTER

## 2021 ACHIEVEMENTS

- Monitored privacy developments in Europe and provided summaries of key changes, including the EDPB's Guidelines on GDPR Territorial Scope and Cross-Border Data Transfer Restrictions, the European Commission's questionnaire on processing data for scientific purposes, supervisory authorities' guidance on international data transfers, the draft Artificial Intelligence Regulation, and the UK and EU Trade and Cooperation Agreement
- Submitted response to European Data Protection Board's Stakeholder Event survey on "application of the GDPR to the processing of personal data for scientific research purposes"
- Submitted comments on the Consultation on the UK Data Protection Regime
- Launched the Schrems II Roundtable and International Data Transfers Project Team

# United States Working Group

In 2021, the US Working Group monitored and responded to proposed privacy legislation and addressed increased activity and enforcement by the California Attorney General and the Federal Trade Commission. We expect state privacy activity to continue to increase in 2022 and will prioritize monitoring and responding to proposed legislation, developing new practical resources for compliance, and supporting collaborative privacy advocacy efforts with member companies' government affairs colleagues and other life sciences industry associations.



**Jennifer Chillas**  
U.S. Working Group Co-Chair  
BRISTOL MYERS SQUIBB



**Laura Donahue**  
U.S. Working Group Co-Chair  
ELI LILLY

## 2021 ACHIEVEMENTS

- Shared regular alerts and summaries about key privacy developments, including proposed privacy legislation at the state and federal levels, international data transfers, HIPAA Authorization & Marketing Consent, California Attorney General's CCPA Enforcement Review, US Supreme Court Decision on ATDS Subject to TCPA, and the Federal Trade Commission's increased activity
- Developed chart comparing California Consumer Privacy Act, California Privacy Rights Act, Virginia Consumer Data Protection Act, and Colorado Privacy Act
- Organized webinar on Virginia Consumer Data Protection Act
- Regularly circulated updated versions of the IPMPC State Privacy Legislation Tracker
- Submitted comments on HHS Notice of Proposed Rulemaking on Modifying Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule")
- Organized Presentation by National Advertising Division on health-related advertising claim substantiation and intersections with regulators
- Signed Florida Advocacy Letter to Representative McFarland and Senator Bradley regarding introduced privacy legislation
- Organized Roundtable session with TransCelerate about its DataCelerate Privacy Methodology
- Signed AdvaMed's Letter to the New York Governor on the proposed New York Data Accountability and Transparency Act

# Asia-Pacific Roundtable

The Asia-Pacific Roundtable had a busy and productive year in 2021. Members met on a quarterly basis to discuss ongoing privacy developments in the Asia-Pacific region and engage in benchmarking discussions on topics specific to managing privacy programs and ensuring data protection compliance in the Asia-Pacific region. The IPMPC held multiple webinars, including sessions that welcomed privacy experts from jurisdictions in Asia, organized benchmarking surveys, and created detailed summaries. The Asia-Pacific Roundtable also focused on helping members understand and comply with the new privacy laws and guidance documents from the People's Republic of China. In 2022, the group will continue to monitor privacy updates in China and other priority countries in the Asia-Pacific region and develop new resources, including global privacy program management best practices, training materials for privacy professionals in Asia, and guidance documents for compliance with new regulations.



**Agatha O'Malley**  
Asia-Pacific Roundtable Co-Chair  
OTSUKA



**Viola Pan**  
Asia-Pacific Roundtable Co-Chair  
ORGANON

## 2021 ACHIEVEMENTS

- Held quarterly roundtable meetings
- Organized several presentations from local counsel to address privacy developments in China and Singapore
- Circulated alerts and summaries about key privacy developments, including the Chinese Draft Measures on Security Assessment of Cross-border Data Transfers and the EDPB's Opinion on the European Commission's Draft Adequacy Decision for the Republic of Korea
- Developed an overview slide deck on China's Personal Information Protection Law
- Shared updated Chart on Key Requirements of Asia Privacy Laws
- Created FAQ's on China's Human Genetics Resources Regulation
- Circulated benchmarking survey on China's Personal Information Protection Law

# Latin America Roundtable

The Latin America Roundtable was launched in early 2021 to provide an organized forum in which members can share information regarding privacy compliance implementation considerations, benchmark on industry best practices and lessons learned, and monitor privacy developments in Latin America. Members from many countries in Latin America have formed the core of this new Roundtable although it is open to all with an interest or responsibility in this important region. In 2022, the group will hold quarterly roundtable discussions, develop additional resources, and plan presentations on privacy developments in priority Latin American jurisdictions.



**Ivelisse Clausell**  
Latin America Roundtable  
Steering Committee  
ORGANON



**Sofia Cruz**  
Latin America Roundtable  
Steering Committee  
PFIZER



**Fernanda Carla de Lima Cordeiro**  
Latin America Roundtable  
Steering Committee  
NOVO NORDISK



**Fernanda Martins Rebelli**  
Latin America Roundtable  
Steering Committee  
PFIZER

## 2021 ACHIEVEMENTS

- Officially launched new roundtable with participants located in South America, Central America, the United States, and Europe
- Held several roundtable discussions
- Facilitated benchmarking survey on compliance with Brazil's LGPD
- Organized presentation from local Brazilian counsel about compliance considerations for Brazil's LGPD

# 2021 ADDRESSING EMERGING IMPORTANT TOPICS



The IPMPC launched six new timely initiatives in 2021, in addition to its existing roundtables. These roundtables and project teams allow IPMPC members to address pressing issues, engage in practical, detailed discussions about compliance approaches, and collaborate closely with peers to develop useful resources.

## The Artificial Intelligence Project Team

- Objective:** Facilitate members' learning about new AI initiatives and the use of AI in the life sciences industry and discussion of privacy implications
- Achievements:** Coordinated with MedTech Europe and EFPIA to organize a second Artificial Intelligence Seminar as a follow up to the joint presentation held in 2020

## The Genetic Sample Collection & Use Project Team

- Objective:** Promote a better understanding of privacy issues in genetic and genomic research
- Achievements:** Held 6 Project Team web-meetings, developed a glossary of important genetics terms, and discussed privacy implications of various life sciences use cases

## The Human Resources Privacy Roundtable

- Objective:** Create an opportunity for IPMPC members and their human resources colleagues to benchmark and discuss HR privacy issues identified by members
- Achievements:** Compiled benchmarking information on COVID-19 Employee Vaccinations & Return to Work and held roundtable discussion on the same

## The International Data Transfers Project Team

- Objective:** Create resources to assist members in implementing the European Commission's new standard contractual clauses and other necessary measures for compliance with EU cross-border data transfer requirements
- Achievements:** Organized weekly roundtable discussions and developed almost 30 different resources for members' use

“The resources, meetings, and support the IPMPC provided during the process of the implementation of the European Commission's new standard contractual clauses have been incredible assets and are reason enough to be an IPMPC member.”

Charlie Blanchard, Head of Global Privacy & Data Protection  
AMGEN



## The Life Sciences Privacy Metrics & KPIs Project Team

- Objective:** Develop set of key privacy program metrics and KPIs for life sciences companies
- Achievements:** Held 5 team web-meetings, developed compiled list of useful metrics and key performance indicators, and created template chart for organizing the metrics by goal/purpose (e.g., program growth), audience (e.g., senior leadership), and key metrics that show privacy as a supporting function and business enabler

## The Medical Device Privacy Roundtable

- Objective:** Provide a forum for member companies to collaborate by leading discussions on topics that have particular importance to medical device manufacturers and companies focused on digital health
- Achievements:** Organized roundtable meetings on the following topics: *Issues Regarding Data Controllorship & Legal Basis for Cloud Storage of Device Data, Device Servicing, and Remote Monitoring in the EU; Data Privacy Issues in mHealth; Anonymization & De-Identification Challenges Specific to Medical Devices; Secondary Use of Data Obtained from Devices; The Evolution of Medical Technology from Simple Instruments to Smart Devices to SaMD*

“This year the Medical Device Roundtable held regular member-led sessions about key compliance considerations and challenges. The presentations and engaging discussions allowed members to share their real-life experiences, best practices, and lessons learned in the evolving field of medical devices as well as digital technologies and digital health, which have emerged as the new era in our industry.”

**Efstathia Gkika**, Associate General Counsel, Privacy, Cybersecurity & Digital & EU Data Protection Officer  
BAXTER HEALTHCARE SA



## The Schrems II Roundtable

- Objective:** Provide regular opportunities for member company benchmarking and open discussion on considerations related to the European Court of Justice’s Schrems II judgment
- Achievements:** Held 6 roundtable web-meetings from February to May 2021 and organized presentations from vendors on their approaches to compliance

## The Privacy Stewardship & Champion Programs Project Team

- Objective:** Discuss key challenges and potential solutions, and share best practices, in developing privacy stewardship programs and increasing awareness of privacy initiatives within the business
- Achievements:** Held bi-monthly web-meetings, conducted benchmarking effort to compile information on member companies’ approaches to Privacy Steward/Champion Programs, compiled suggested resources for Data Privacy Day, started a “living library” of privacy champion job descriptions and key responsibilities to facilitate member resource sharing, and provided a presentation on Privacy Steward/Champion Programs at May 2021 Board of Directors Meeting



“The IPMPC’s Privacy Stewardship and Privacy Champion Programs Project Team provides an invaluable opportunity for focused, practical, group discussions about implementing and maintaining privacy champion programs. This new initiative has fostered a generous community in which IPMPC members share resources, best practices, and new ideas to help highlight the importance of data protection within the business and secure support for privacy program efforts.”

**Amy Papili**, Associate Director, US Privacy  
ASTRAZENECA

# Secretariat

The law firm of Faegre Drinker Biddle & Reath LLP serves as Legal Counsel and Secretariat to the IPMPC. Composed of attorneys, scientists, and project managers, the Consortia Management Team forms and supports life sciences industry collaborations that help companies throughout the world address complex topics of mutual interest. For more than 25 years, the team's work with these collaborations has focused on issues impacting the pharmaceutical and medical device industries. For more information and to stay up to date on IPMPC activities, visit [www.ipmpc.org](http://www.ipmpc.org) and follow the IPMPC's [LinkedIn Page](#).

## IN SUPPORT OF THE IPMPC, THE SECRETARIAT:

- Prepares legal analyses and drafts compliance and training tools and materials
- Coordinates regular industry benchmarking
- Facilitates dialogue, consensus-building, and governance
- Manages outreach and legislative contacts
- Organizes teleconferences, meetings, and workshops
- Prepares meeting agendas, summaries, and presentations
- Serves as antitrust counsel

## IPMPC MEMBERSHIP INQUIRIES

Membership in the IPMPC is open to research-based medical device and pharmaceutical companies. Because membership is at the company level, members enjoy unlimited participation on IPMPC working groups and IPMPC educational webinars.

For questions about the IPMPC's priorities, progress, or membership, please email [info@ipmpc.org](mailto:info@ipmpc.org) or contact:



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