IPAC-RS Digital Devices Roundtable Series

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

What is a Digital Biomarker and Why is it Important?

September 10, 2021

www.ipacrs.org

Who We Are

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects.

Representing the global OINDP industry since 2000, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, technical journals, and discussions with a wide-range of regulatory bodies.

Our Members

- **IPAC-RS Members** - corporations that develop, manufacture or contract to manufacture OINDPs

AstraZeneca
Boehringer Ingelheim
Catalent
Chiesi
Genentech
GlaxoSmithKline
Hovione
Kindeva Drug Delivery
Lupin Pharmaceuticals, Inc.
Merck & Co., Inc.
Novartis
Sunovion
Teva
Vectura
Viatris

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

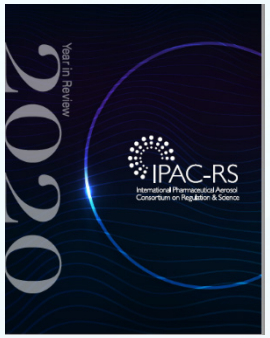
Amcor Flexibles
Aptar Pharma
Copley Scientific
H&T Presspart
Nemera
Oxford Lasers
PPD
Proveris Scientific Corporation
Team Consulting Ltd.

Recent IPAC-RS Successes

IPAC-RS continues to actively work on the goals outlined in its 2019-2021 Strategic Plan.

The Consortium:

1. Engaged with regulatory and standard setting authorities.
2. Provided up-to-date information to the members on relevant developments.
3. Identified and publicized OINDP industry's positions on key issues of regulatory science
4. Provided forum for members' discussions.
5. Actively participated in discussions in the wider stakeholder community.



See the IPAC-RS Year in Review 2020 for an overview of 2020 successes.

Top 5 Reasons to Join IPAC-RS

1. Stay ahead of emerging global regulatory and scientific challenges facing the OINDP industry.
2. Participate in joint industry discussions with, and guidance commenting to, regulators in North America, Europe, Asia, and South America.
3. Join industry thought leaders in providing feedback to standard-setting bodies and international pharmacopoeia.
4. Share knowledge, information and experiences with other industry leaders.
5. Stay abreast of pertinent development and also shape national and international trends and requirements.

IPAC-RS Roundtables

- In 2021, IPAC-RS developed a new Roundtable webinar series on digital devices for 2021. Presented by subject matter experts in the pharmaceutical sciences, this is a unique opportunity to learn about the latest research and regulatory trends focused on digital devices. See the IPAC-RS website for details and registration information.
  - Today's Webinar: ***What is a Digital Biomarker and Why Is It Important?***
  - ***Upcoming Webinars***
    - September 21, 2021 (10 AM – 12 PM US ET) ***Beyond Usability/Human Factors for Digital Healthcare***
    - September 29, 2021 (8:30 – 10 AM US ET) ***Digital Devices Manufacturing and Design Considerations***
    - October 4, 2021 (10 AM – 12 PM ET) ***Business Case for Digital Devices***

Today's Moderators

Marta Lombardini, Ph.D., Device Development Manager, Chiesi Group

Dr. Marta Lombardini is an Experienced Device Development Manager with a demonstrated history of working in the pharmaceuticals industry. Skilled in Device development processes, Agile Design, Human factors sciences, Product and process Validation, Documentation generation, Regulations and Product submissions. Enthusiastic professional with a Doctor of Philosophy (PhD) focused in Electronics and Biomedical/Medical Engineering from University of Bologna. Marta's aim is to develop products to improve quality of life. Since she firstly joined Chiesi in 2016 she has strongly contributed at spreading the Customer Centric design approach. She has experience in developing diverse type of device constituent part in combination products naming Syringes, Nebulizers and other electromechanics delivery systems. She is particularly interested in studying and collecting behavioral data that can be used to explain, influence, and predict health-related outcomes and she enjoys managing the diversity of the different projects which can include digital devices. Marta has always had a strong focus at standardizing the approach to get to the best outcome and performance of the systems we design. Prior to joining Chiesi she has been part of the Philips healthcare Respironics group and learned how to enhance medical products development using the human factors and risk based approach as a competitive advantage for achieving what is really needed in the market creating loyalty and ensuring it can be safely, efficaciously and pleasantly used by the final customers.

Lee Nagao, Ph.D., Senior Director, Science, Regulation & Policy, Faegre Drinker Biddle & Reath LLP, IPAC-RS Secretariat

Lee M. Nagao, Ph.D., is a Senior Director of Science, Regulation and Policy at the law firm of Faegre, Drinker, Biddle and Reath, LLP, and is a member of the Firm's Life Sciences Consortium Management and Regulatory Affairs Practice Group. The Group works extensively with pharmaceutical, biopharmaceutical and medical device companies on a range of scientific and regulatory collaborations and provides strategic and regulatory guidance to individual life sciences companies. Lee plays a lead role serving scientific and regulatory consortia including the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the Extractables and Leachables Safety Information Exchange (ELSIE), and the International Pharmaceutical Consortium on Innovation and Quality (IQ). Lee has extensively published and presented on many aspects of pharmaceutical development including supply chain, CMC, and translational sciences. She has represented various industry groups before regulatory and scientific agencies and organizations in the US, Europe and Asia, including the FDA, EMA, China NIFDC, Chinese Pharmacopoeia, ANVISA, Taiwan CDE, Japan PMDA, and USP.

Agenda

I. Welcome and Introduction to IPAC-RS	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat
II. Overview of Webinar and Logistics	5 Minutes	Marta Lombardini Lee Nagao
III. The Progression of Digital Biomarkers in Clinical Trials and Beyond	30 Minutes	Joe Corrigan James Blakemore Cambridge Consultants
IV. Questions	5 Minutes	
V. Realizing the Vision of Digitally Enabled, Patient-Centric Clinical Trials	30 Minutes	Marissa Dockendorf Bryan Hansen Merck Research Laboratories
VI. Open Discussion and Q&A	45 Minutes	All Speakers
Total Time	2 hours	

Webex Housekeeping

- Panelists will be listed here.
- The Attendee list is only available to Panelists and Host. (You will only see your name listed.)
- The Chat function has been disabled for Attendees. You may receive chats from the Host, but you cannot reply.
- Type your question in the Q&A box or raise your hand to be unmuted.

All Attendees are muted.

The recording will be posted on the IPAC-RS website after the webinar.

Today's Presenters

James Blakemore, Ph.D.; Senior Consultant, Strategy Group, Medical Technology Division Cambridge Consultants

James is a Senior Consultant within Cambridge Consultants' Strategy & Definition group. He oversees portfolio development, market analysis and transaction support assignments on behalf of biopharmaceutical, medical device and investment companies. Project experience includes the application of digital strategies to add stakeholder value to pharmaceutical, drug delivery and diagnostic solutions. James has over 20 years' experience in medical markets, and previously worked in licensing roles for pharmaceutical and biotechnology companies towards the identification, validation and commercialisation of broad new therapies. He has a PhD in Molecular Neuroscience from King's College, University of London, and a BSc in Molecular Biology from Edinburgh University.

Joe Corrigan, CEng MIMechE, Head of Intelligent Healthcare, Global Medical Technology, Cambridge Consultants

Joe is Head of Intelligent Healthcare at Cambridge Consultants and has responsibility for developing digital services and connected medical devices that incorporate elements of advanced biosensing & biomarkers, machine learning & AI.

Currently Joe is working on a number of connected platforms including biomarker discovery and optimization for both connected pharmaceutical strategies and breakthrough innovations in minimally invasive surgical and nonsurgical procedures. Prior to joining Cambridge Consultants, Joe founded two startups in medical technology and machine learning and demonstrated methods for measuring spatially correlated vulnerable plaque biomarkers of cardiovascular disease in-vivo. Joe is a Chartered Engineer and holds a master's degree in mechanical engineering from UMIST with a specialism in thermofluids.

Short Q&A Session

- Type your question in the Q&A box or raise your hand to be unmuted.

Today's Presenters

Marissa Dockendorf, Ph.D., Director, Global Digital Analytics & Technologies, Merck Research Laboratories

Dr. Marissa Dockendorf is a Director in the Global Digital Analytics & Technologies group and has 15 years of experience in pharmaceutical R&D. Marissa provides strategic oversight for adoption of digital health approaches across Merck's portfolio and leads a team of scientists in evaluating emerging digital technologies, enabling their adoption in clinical trials, and in developing digital endpoints. She plays a critical role in Merck's digitally-enabled clinical trials initiative, which is focused on introduction of digital technologies and outpatient sampling approaches into clinical trials to reduce patient burden, collect higher quality data, enrich clinical trial data sets, and enable more rapid and informed drug development decisions. Since originally joining Merck in 2006, she's provided pharmacokinetic and pharmacometric expertise and scientific oversight for many programs across the discovery-development continuum and spanning multiple therapeutic areas. She's held roles of increasing responsibility, including disease and therapeutic area level scientific leadership positions in quantitative pharmacology & pharmacometrics for the areas of cardiovascular disease, neuroscience, and ophthalmology. Prior to rejoining Merck in 2011, she worked on ocular drug delivery research projects at Vistakon, a Division of Johnson & Johnson Vision Care. Marissa has a PhD in chemical engineering and a master's degree in biomedical engineering from the University of Florida and an undergraduate degree from the Illinois Institute of Technology.

Bryan J. Hansen, Ph.D., Associate Principal Scientist, Global Digital Analytics and Technologies, Merck Research Laboratories

Dr. Bryan J. Hansen is an Associate Principal Scientist in the Global Digital Analytics and Technologies team at Merck Research Laboratories, where his responsibilities include identifying clinically meaningful digital biomarkers from biosensors, smartphones, and different types of active and passive data streams. Currently, he is leading a diverse team of clinicians and researchers to identify novel digital biomarkers in a variety of neurodegenerative and neuropsychiatric diseases. Dr. Hansen is both a trained neuroscientist and exceptional at data analysis, effectively bridging the gap between biology and computation. His research has also been uniquely diverse, beginning in animal models, extending his findings to patients with epilepsy, and finally to digitally-enabled clinical trials. This work has been published and cited in many high-profile journals and presented internationally. Before joining Merck in 2015, Bryan was a post-doctoral fellow at the Salk Institute for Biological Studies in the Systems Neurobiology Laboratories, where his work focused on neural mechanisms underlying attention-related changes in brain state. Bryan received his doctorate in Biomedical Sciences from the University of Texas Health Science Center with a focus on systems/computational neuroscience and a Bachelor's in Neuroscience from Baylor University.

Thank you for attending the webinar!

- Type your question in the Q&A box or raise your hand to be unmuted.

Secretariat Contacts

For further information regarding membership or other questions about IPAC-RS, please contact a member of the Secretariat below. You can also learn more by visiting www.ipacrs.org.

Mary Devlin Capizzi
Mary.DevlinCapizzi@faegredinker.com

Dede Godstrey
Dede.Godstrey@faegredrinker.com

Lana Lyapustina
svetlana.lyapustina@faegredrinker.com

Lee Nagao
Lee.Nagao@faegredrinker.com