



Name of the session	Global patient engagement across regional regulatory boundaries
Date and time	November 5th - 15:00 - 16:30 CET/ 9:00 -10:30 AM US ET
How to join	Please follow this link to get the link to join the session: https://us02web.zoom.us/webinar/register/WN_gA1pgNkKSKmgObV0DQNhxg
Registered attendees	~35 % Patient community, ~40% pharmaceutical industry, ~5% from academia, ~2.5% from regulatory and policy makers and other stakeholders

This session focuses on shedding some light to the science of patient input and patient engagement from the regulatory perspective. Through a panel discussion, we will find answers to questions like

- How are the regulators across the regions enabling and increasing patient centricity in the medicines development and approval?
- How are patients involved in the design of the processes that ultimately aim to benefit them?
- How are patients' experiences being gathered and used in the regulatory decision-making processes?
- How can we better support decision making through robust patient experience data?
- Do local (cultural and historical) specificities exist in the acceptance of sharing and using patients' experience data?
- What are the local, regional and global culture differences that (can) hinder patient engagement?

In this session we also aim to learn about the differences and similarities in regulatory requirements as well as challenges and opportunities for increased patient engagement - not to mention how COVID-19 situation has affected the regulatory work and potential repercussions to be experienced by the patient community.

Join us to hear about the current patient engagement developments from the regulators' side, learn about the global regulatory dialogue and ask your questions to the panel.



Session speakers



Moderator
Nicholas Brooke

Executive Director Patient Focused Medicine Development (PFMD)

Nicholas Brooke is founder and Executive Director of The Synergist, an incubator that brings key players together in people-public-private partnerships with the express aim of solving significant societal problems through collective action.

Under Nicholas' leadership, The Synergist acts as a backbone, providing vision, strategy, stakeholder alignment and execution on multiple international, multi-stakeholder programmes. As Patient Focused Medicine Development (PFMD.org) Executive Director, Nicholas develops collaborative leadership to build collective patient engagement across the lifecycle of medicine.

Panelists



Juan Garcia Burgos
Head of Public and Stakeholders Engagement Department
European Medicines Agency (EMA)

Juan Garcia Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences.

In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.



Daisaku Sato

Ph.D., Chief Management Officer & Associate Centre Director for Regulatory Science, from The Pharmaceuticals and Medical Devices Agency in Japan (PMDA)

From June 2016 to July 2018, he was Director, Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, the Ministry of Health, Labour and Welfare (MHLW), Japan.

Before returning to MHLW, from 2013 to 2016, he was Director, Office of New Drug V for oncology drug review and Director, Office of Cellular and Tissue based Products at PMDA, respectively.

From 2011 to 2013 he was Director, Office of Compliance, Pharmaceutical and Food Safety Bureau, MHLW and involved in the quality assurance of medicines and global issues of spurious & falsified (SF) drugs.

Dr Sato worked for more than 25 years as a technical administrator at MHLW, Japan. He also experienced various drug regulatory responsibilities in pharmacovigilance, clinical research, health research funding, blood safety, food safety, international harmonisation (such as ICH) and normative activities at MHLW. During his service of the Ministry, he worked at the Division of Drug Management and Policy, WHO (Geneva) on secondment from 1994 to 1996.

He is a registered pharmacist and received a Ph.D. degree (pharmaceutical sciences) from the University of Tokyo. He has been a member of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations since 2014.



Lenita Lindström

ICH Assembly Chair and Senior Expert - DG Health and Food Safety (Medicines: policy, authorisation and monitoring)

Mrs Lindström-Gommers is the Chair of the ICH Assembly. She is working as a Senior Expert in the Directorate General for Health and Food Safety (DG SANTE) in the European Commission where she is in charge of international relations in the field of pharmaceuticals. Mrs Lindström-Gommers has over 20 years experience in the European Commission, including over 10 years in the field of pharmaceuticals. She holds a Master of Laws degree from the University of Helsinki, Finland.



Robyn Bent

Director of the Center for Drug Evaluation and Research (CDER)
Patient-Focused Drug Development (PFDD) Initiative, FDA

Robyn Bent joined the US FDA in 2019 as the director of the Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development (PFDD) Initiative, an effort to systematically obtain patient input and facilitate the incorporation of meaningful patient input into drug development and regulatory decision making. The PFDD initiative includes the CDER Standard Core Clinical Outcomes Assessments and Endpoints Pilot Grant Program which provides avenues to advance the use of patient input as an important part of drug development.

Prior to joining FDA, Robyn held several positions at the National Institutes of Health. Captain Bent has extensive experience in clinical trial design, conduct, and oversight. Robyn earned her Bachelor of Science in Nursing from The Catholic University of America and her Master of Science degree from the George Washington University.