

Next Generation BBS Seminar on
Building Bridges: Communication Across
Academia,
Industry, and Regulators

TUE, 9th September 2025, 14h - 18h

**In-person only @ Biozentrum Room U1.191,
Spitalstrasse 41, Basel**



Effective communication is key for statisticians working across industry, academia, and regulatory bodies. With a focus on the needs of the NextGen community, this event will center on the topic of interactions with health authorities. We will explore how statisticians can increase their influence by stepping beyond technical discussions, building bridges with clinicians, and contributing meaningfully throughout the decision-making process.

This event is organized independently of the EFPSI Regulatory Workshop but is intentionally scheduled around the same time to encourage wider participation. We also aim to broaden our reach by engaging with individuals from different regions and European societies, exploring opportunities to expand the NextGen community beyond BBS.

The BBS Next Generation Committee organizes events focused on soft-skills, professional development, and networking. The in-person meetings are specifically dedicated to support the next generation of statisticians and quantitative scientists in the pharmaceutical industry to succeed in the future and to become influential.

Participation is free of charge. **Registration is closed.**

Please see the agenda outlined below.

Organizing committee: Antonella Mazzei (Bristol Myers Squibb), Burak Kuersad Guenhan (Merck KGaA), Hans Ulrich Burger (Roche), Joana Marques Barros (Idorsia), and Kristina Weber (Roche) on behalf of the BBS Next Generation Committee.

Agenda

Getting Started	
14:00	Icebreaker
14:30	Welcome
14:35	Introduction to the BBS NextGen
Session 1 - Perspectives across Regulators, Academia, and Industry	
14:55	<i>Some Thoughts on How to Interact with Regulators</i> Uli Burger (Roche)
15:10	Academia Perspective <ul style="list-style-type: none"> <i>Connecting Statisticians and Clinicians in Academia: Challenges and Opportunities for Effective Communication</i> Xiaofei Liu (Medical School Hannover and BfArM)
15:25	Industry Perspective <ul style="list-style-type: none"> <i>Statistical Perspectives on Global Regulatory Interactions in Early Oncology Trials</i> Christina Habermehl (Merck KGaA) <i>Regulatory Interactions and Challenges in a Phase 3 Confirmatory Trial: Observations and Key Learnings</i> Mouna Sassi-Sayadi (Viatris) <i>Beyond the P-Values: How Statisticians Shape Regulatory Interactions</i> Charlotte Vignal (Roche)
15:45	Regulatory Perspective <ul style="list-style-type: none"> <i>Information Asymmetry - Communication in the Regulatory Context</i> Florian Lasch (EMA) and Rafael Sauter (Swissmedic)
Networking and Coffee Break from 16:00 to 16:30	
Session 2 - Panel Discussion & Open Discussion	
16:30	Topics: <ul style="list-style-type: none"> Navigating professional boundaries. Comparing challenges in academia, regulatory and industry stats: Common issues, different contexts. Bridging communication gaps between statisticians and clinicians: Industry, academia and regulatory perspectives. The role of statisticians in regulatory agencies: When are we involved, and how can we be more present and influential? Specific challenges for NextGen statisticians in regulatory interactions The role of academic statisticians as independent advisors
17:40	Wrap up and event closing
Dinner @ KLARA (at own cost)	

Organizing committee: Antonella Mazzei (Bristol Myers Squibb), Burak Kuersad Guenhan (Merck KGaA), Hans Ulrich Burger (Roche), Joana Marques Barros (Idorsia), and Kristina Weber (Roche) on behalf of the BBS Next Generation Committee.