

# Scientific Interest Group (SIG) Meeting

**05 March 2024**  
**13:00-14:30 CET**

**Basel, Switzerland &  
Online (*Teams*)**

## Navigating the Regulatory Landscape: from Global Influences to Local Engagement

Moderated by



Clément  
Robijns

EU Project Manager,  
BIOCOM Interrelations GmbH

Speakers:



Valeria  
Gigante

Team Lead AMR  
Division, World  
Health  
Organization

Agenda 1/2

**13:00** Welcome and introduction  
- Clément Robijns, BIOCOM Interrelations GmbH

**13:05** **SESSION 1: GLOBAL PERSPECTIVES**

WHO's instruments for AMR and TB drugs  
- Valeria Gigante, WHO  
Q&A with AMR Accelerator projects

**13:30** **SESSION 2: FORMAL AND INFORMAL ENGAGEMENT WITH REGULATORS  
& HTA AGENCIES**

Insights into EMA's Innovation Task Force for early-stage AMR/TB  
drug development guidance - Radu Botgros, Senior Scientific Officer,  
European Medicines Agency (*recorded speech*)



Nathalie  
Seigneuret

Scientific Project  
Manager,  
Innovative  
Health Initiative



Dalia  
Dawoud

Associate  
Director,  
Research, NICE

For additional information please contact Frederik Deroose: [frederik@connectingpharma.be](mailto:frederik@connectingpharma.be)

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**13:45** Guidance from IHI on when and how best to interact with regulators from a public-private partnership umbrella

- Nathalie Seigneuret, IHI

Q&A with AMR Accelerator projects

**13:55** Experiences from NICE participation in public-private partnerships

- Dalia Dawoud, NICE

**14:05** Q&A with AMR Accelerator projects & open discussion on:

- Balancing asset owners' formal engagement towards regulators and HTA bodies with projects' need for informal contacts
- Tactics to manage conflicts of interest, e.g.

- \*regulators and HTA bodies as members of research consortia or scientific advisory boards

- \*communication and dissemination of results from public-private partnership projects to regulators and HTA bodies

**14:25** Wrap-up and conclusion



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