

22 May 2024  
EMA/222258/2024

## Final agenda – biannual Big Data Steering Group and industry stakeholders meeting

09.00-11.00am (CET) 23 May 2024, virtual

Co-Chairs: Jeppe Larsen (DKMA) and Peter Arlett (EMA)

Item	Preliminary draft agenda	Initials	Mins
1.	<b>Welcome and opening remarks</b>	Jeppe Larsen (BDSG, DKMA), Peter Arlett (BDSG, EMA)	<b>20'</b>
2.	<b>Evidence generation</b>		<b>50'</b>
	<ul style="list-style-type: none"> <li>Industry feedback on early experience with DARWIN EU ® studies</li> </ul>	Álmath Spooner (EFPIA) Brian Bradbury (EUCOPE)	10' 10'
	<ul style="list-style-type: none"> <li>EMA update and next steps</li> </ul>	Patrice Verpillat (EMA)	10'
	<i>Open discussion</i>	All	20'
3.	<b>Data quality</b>		<b>20'</b>
	<ul style="list-style-type: none"> <li>Industry assessment of data quality tools/frameworks useful for implementing EMA's data quality framework and relevant to the future RWD quality chapter</li> </ul>	Jing Wang-Silvanto (EFPIA)	10'
	<i>Open discussion</i>	All	10'
4.	<b>BDSG and Accelerating Clinical Trials in the EU (ACT EU)</b>		
	Open discussion on potential synergies between BDSG and ACT EU	All	<b>20'</b>
5.	<b>Wrap-up and conclusions</b>	Peter Arlett (EMA)	10'

### List of events

- Joint HMA-EMA Big Data Steering Group workshop on RWE methods - 14 June 2024.
- DG-RTD/HMA/EMA Multi-stakeholder workshop on Pharmacogenomics – 24 September 2024.

For information on related past meetings and workshops, see [Big data | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/en/big-data)



## List of Industry participants

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<b>Alasdair Cook</b>	Association of Veterinary Consultants (AVC)
<b>Alexandra Schirmer</b>	COCIR
<b>Alexandre Malouvier</b>	ICON (EUCROF)
<b>Alison Hughes</b>	AESGP
<b>Álmath Spooner</b>	Abbvie (EFPIA)
<b>Angela Esposito</b>	Angelini pharma (EUCOPE)
<b>Antoinette Tolkamp</b>	Vet Online Consultancy (AVC)
<b>Béatrice Huret</b>	Sanofi (Vaccines Europe)
<b>Bernadette Dwan</b>	IQVIA (ACRO)
<b>Bettina Doepner</b>	CSL Behring (EuropaBio)
<b>Blanca Garcia-Ochoa</b>	MSD (Vaccines Europe)
<b>Brian Bradbury</b>	AMGEN (EUCOPE)
<b>Diana Teixeira</b>	AnimalhealthEurope
<b>Emma Hernandez-Sanabria</b>	Association of Veterinary Consultants (AVC)
<b>Francesca Cipolli</b>	BMS (EUCOPE)
<b>Gracy Crane</b>	Roche (EFPIA)
<b>Hanne van Ballegooijen</b>	IQVIA (ACRO)
<b>Inka Heikkinen</b>	Merck (EFPIA)
<b>Irina Güell</b>	HIPRA (Vaccines Europe)
<b>Jing Wang-Silvanto</b>	Astellas (EFPIA)
<b>Kun Shi-van Wielink</b>	Santen (EUCOPE)
<b>Leander Vranken</b>	EUCOPE
<b>Marcello Milano</b>	BioMarin (EUCOPE)
<b>Matt Herod</b>	PPD (ACRO)
<b>Michael Colmorgen</b>	Elanco Animal Health
<b>Mihai Ionita</b>	AESGP
<b>Monica Larsen</b>	LMI (EFPIA)
<b>Pamela Dobay</b>	Biogen (EFPIA)
<b>Philipp Goedecker</b>	COCIR
<b>Philip Bartle</b>	PPD (ACRO)
<b>Rick Clayton</b>	AnimalhealthEurope
<b>Rimma Ishimbaeva</b>	Association of Veterinary Consultants (AVC)

**Sinan B. Sarac**

Parexel (ACRO)

**Susanne Hartwig**

MSD (Vaccines Europe)