

26 January 2026  
EMA/19650/2026

## Agenda – HMA-EMA group focused on AI with industry stakeholders meeting

4 February 2025, 10.00-11.30, virtual

Co-Chairs: Joerg Zinserling (BfArM), Peter Arlett (EMA)

Item	Preliminary draft agenda	Initials	Time
1.	<b>Welcome and adoption of draft agenda</b>	Joerg Zinserling/Peter Arlett	5'
2.	<b>Guiding principles and terminology</b> <ul style="list-style-type: none"> <li>Update from the Network</li> <li>Discussion</li> </ul>	Joerg Zinserling, BfArM All	15'
3.	<b>Guidance development and Biotech Act</b> <ul style="list-style-type: none"> <li>Update from the Network (10')</li> <li>Industry's needs and priorities</li> <li>Discussion</li> </ul>	Peter Arlett, Luis Pinheiro, EMA Industry stakeholders All	40'
4.	<b>AI in pharmacovigilance</b> <ul style="list-style-type: none"> <li>Update from the Network</li> <li>Discussion</li> </ul>	Luis Pinheiro, EMA All	20'
5.	<b>Organisational matters</b> <ul style="list-style-type: none"> <li>Meeting topics coordination</li> <li>Future meeting dates</li> </ul>	Joerg Zinserling, BfArM	5'
6.	<b>AOB and close</b>	Peter Arlett, All	5'