



1 November 2022
EMA/860813/2022

Agenda – Big Data Steering Group and industry stakeholders meeting

13.00-15.00 (CET) 3 November 2022, Webex

Co-Chairs: Peter Arlett (EMA) and Jesper Kjaer (DKMA)

Item	Preliminary draft agenda	Initials	Mins
1.	Welcome and opening remarks - Revised BDSG workplan 2022-2025	Peter Arlett (BDSG, EMA) Jesper Kjaer (BDSG, DKMA)	10 min 13.00-13.10
2.	Data discoverability - Good practice guide for the use of real-world metadata (under public consultation): <i>industry perspective</i> <i>Discussion</i>	Gianmario Candore (EFPIA) All	25 min 13.10-13.35
3.	Data quality & representativeness - Data quality framework (under public consultation) <i>Open discussion</i>	Ana Cochino (EMA) All	25 min 13.35-14.00
4.	DARWIN EU - DARWIN EU update including approach for consulting/informing industry on studies <i>Open discussion</i>	Andrej Segec (EMA) All	20 min 14.00-14.20
5.	EU network capability to analyse - Clinical Trials raw data pilot <i>Reflections from the Raw Data Pilot</i> <i>Industry Focus Group and discussion</i> <i>Discussion</i>	Almath Spooner (EFPIA) All	20 min 14.20-14.40
6.	Governance framework - EHDS pilot: <i>Industry perspective</i> <i>Discussion</i>	Inka Heikkinen (EuropaBio) All	15 min 14.40-14.55
7.	Wrap-up and conclusions	Peter Arlett	5 min 14.55-15.00

