

29 January 2018 EMA/38307/2018 Stakeholders and Communication Division

Agenda – Update on the implementation of EMA policy on publication of clinical data (Policy 0070) – Industry Associations webinar

29 January 2018, 11:00hrs - 12:30 hrs

Chair: Melanie Carr, Head of Stakeholders and Communication Division, EMA

| Item | Topic | Name | Time |
|------|---|--------------------------------------|---------|
| 1. | Welcome and introductions | M. Carr (EMA) | 5 mins |
| 2. | EMA update on Clinical Data Publication: Current status and upcoming submissions Overview of 2017: CDP annual report Q&A | A-S. Henry-Eude (EMA) | 25 mins |
| 3. | EMA technical group on anonymisation (TAG) set up in the context of the publication of clinical data Feedback on the first TAG meeting Plans for 2018 Q&A | M. Dias (EMA) | 15 mins |
| 4. | Industry proposals on Policy 0070 Change management cycle Consistency between overlays and new cover letter table CCI redaction to final redacted package only | J. Holtzople / A. Cutting (EFPIA) | 20 mins |



| 5. | Discussion | AII | 20 mins |
|----|---------------------------------|---------------|---------|
| 6. | Next steps and close of meeting | M. Carr (EMA) | 5 mins |