

23 March 2017  
EMA/83359/2017

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

23<sup>rd</sup> March 2017, 15:00 – 16:30 GMT, Meeting room 02-C

Chair: Noël Wathion, Deputy Executive Director, EMA

Item	Topic	Name	Time
1.	<b>Welcome and introductions</b>	N. Wathion	10 mins
2.	<b>EMA update on the guidance and related initiatives:</b> <ul style="list-style-type: none"> <li>• Currents status and upcoming submissions</li> <li>• Follow up from previous webinar: <ul style="list-style-type: none"> <li>◦ Cross-referred studies</li> <li>◦ Out of scope sections</li> </ul> </li> <li>• New 'toolkit': <ul style="list-style-type: none"> <li>◦ External validation checklist</li> <li>◦ Additional Anonymisation report template</li> <li>◦ Q&amp;A</li> </ul> </li> </ul>	A-S. Henry-Eude          J. F. Ferreira	30 mins
3.	<b>Discussion</b>	All	20 mins
4.	<b>EMA technical group on anonymisation set up in the context of the publication of clinical data</b> <ul style="list-style-type: none"> <li>• Public call for experts in anonymisation of clinical data and mandate of the Technical Anonymisation Group (TAG)</li> </ul>	M. Dias	10 mins

5.	<b>Industry proposal on eCTD life cycle management of Policy 70 submissions - Exploring the way forward to ensure consistency</b>	A. Nixon, EFPIA (GSK)	10 mins
6.	<b>Next steps and close of meeting</b>	N. Wathion	10 mins