



26 October 2021  
EMA/582731/2021

## Agenda – CAT Interested Parties meeting with Industry

26 October 2021, 14:00-18:00, Virtual meeting

**Co-Chairs:** Martina Schuessler-Lenz and Ilona Reischl

Item	Agenda	Time
1.	<b>Welcome</b> <b>Agreement on the agenda</b> Martina Schuessler-Lenz (CAT), Ana Hidalgo-Simon (EMA)	14:00-14:10 <i>10 min</i>
2.	<b>CAT activities, ATMP lifecycle support and patient access</b> Martina Schuessler-Lenz (CAT) Q&A (All)	14:10-14:30 <i>20 min</i>
3.	<b>Comprehensiveness of clinical data in marketing authorisations</b> Maura O'Donovan (CAT) Q&A All	14:30-14:50 <i>20 mins</i>
4.	<b>GMO/ERA in Clinical Trials</b> Tomas Boran (CAT) <b>GMO/ERA in marketing authorisations</b> Patrick Celis (EMA) Q&A All	14:50-15:10 <i>15 mins</i>  <i>5 mins</i>

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5.	<b>EMA-FDA parallel advice</b> Anabela Marcal (EMA) Q&A (All)	15:10-15:30 <i>20 mins</i>
6.	<b>Industry feedback</b> <b>1) Challenges Randomised Clinical Trials for ATMPs</b> Nigel Yateman (EuropaBio) Maren von Fritschen (Eucope)  <b>2) Delays in ATMP marketing authorisations submissions 2021</b>  Ana Hidalgo-Simon (EMA) <i>Industry speaker</i>  Q&A (All)	15:30-15:50 <i>20 mins</i>
	<b>Coffee break</b>	15:50-16:10 <i>20 min</i>
7.	<b>The New HTA Regulation: key elements and next</b> Flora Giorgio (B6, DG SANTE, European Commission) Q&A All	16:10-16:30 <i>20 min</i>
8.	<b>Industry feedback</b> <b>Views, initiatives to ensure patient access to ATMPs</b>  <i>Industry speaker</i>	16:30-16:50 <i>20 min</i>
9.	<b>ATMPs and Real World Evidence</b>  <ul style="list-style-type: none"> <li>• <b>Update on Real World Evidence and DARWIN EU</b> Gianmario Candore (EMA)</li> <li>• <b>Real world evidence (data) in CAT decision making</b> Kieran Breen (CAT)</li> </ul>	16:50-17:30 <i>40 min</i>
10.	<b>Question and Answer</b> Discussion All	17:30-17:50 <i>20 min</i>
11.	<b>Conclusions and final remarks from chairs</b>	17:50-18:00 <i>10 min</i>

## List of Participants

### **ACRO**

Leanne Di Ronno  
Richard Dennett  
Venkat Reddy Sunkara  
Susana Pereira  
Carla Sterk

### **ARM**

Jill Morrell  
Michael Werner  
Paolo Morgese

### **EFPIA**

Jacquelyn Awigena-Cook  
Stuart Beattle  
Kowid Ho  
Emma Du Four  
Annelie Persson

### **EUCOPE**

Andrea Braun-Scherhag  
Andrea Patzner  
Maren von Fritschen  
David Uguen  
Anne Dupraz  
Nimi Chhin

### **EuropaBio**

Laura Liebers  
Miriam Fuchs  
Birgitta Sauer-Stoschek  
Christian Fulda  
Bettina Doepner  
Nagel Yateman

### **MPP**

Shayesteh Fürst-Ladani

### **CAT**

Martina Schuessler-Lenz  
Ilona Reischl  
Maura O'Donovan  
Tomas Boran  
Kieran Breen

Members and alternates of the CAT

### **European Commission**

Flora Giorgio  
Ioana-Raluca Siska  
Julia Schmitz  
Leslie Pibouleau  
Rocio Salvador-Roldan  
Daniela Marullo

**EMA**

Ana Hidalgo Simon  
Patrick Celis  
Gianmario Candore  
Victoria Palmi Reig  
Anabela Marcal  
Marie-Helene Pinheiro  
Michael Berntgen