

## Workshop Interaction EMA and rare disease researchers on pre-licensing activities

Hotel Crowne Plaza  
Fira - Barcelona  
Av. de Rius i Taulet, 1-3  
Barcelona, Spain



9 of March 2016			
Plenary morning session			
09:00 - 09:10	Welcome word	Daria Julkowska Kristina Larsson	E-Rare EMA
09:10 - 09:40	Pre-licencing activities of EMA <ul style="list-style-type: none"> <li>• Services offered by EMA</li> <li>• Committees who work under the coordination of EMA for the member states</li> </ul>	Kristina Larsson	EMA
09:40 - 10:40	Presentation of relevant EMA services <ul style="list-style-type: none"> <li>• Goal and activities of different structures with focus on:               <ul style="list-style-type: none"> <li>○ Committee for Orphan and Medicinal Products</li> <li>○ Scientific Advice Working Party</li> <li>○ Paediatric Committee</li> <li>○ Committee for Advance Therapies</li> </ul> </li> </ul>	Segundo Mariz	EMA
11:00 - 11:15 Coffee break			
Orphan designation and protocol assistance			
11:00 - 11:30	<ul style="list-style-type: none"> <li>• Orphan designation and incentives for researchers               <ul style="list-style-type: none"> <li>○ How to submit for an OD? (regulation on orphan medicinal products/where can the researcher find the applications forms and other information)</li> <li>○ Application for an OD step by step (when to think and when to apply for an OD)</li> <li>○ What are the steps after obtaining an OD?</li> <li>○ OD versus patent</li> <li>○ Advantages/disadvantages to apply as researchers</li> <li>○ Relation researcher – pharmaceutical company</li> </ul> </li> </ul>	Stelios Tsigkos	EMA
11:30 - 12:00	Protocol assistance – how does it work?	Matthias Hofer	EMA
Lessons learned and success stories			
12:00 - 12:15	Vision-DMD project	Richard Head	Univ. of Newcastle, UK
12:15 - 12:30	IMPACTT PI project (TBC)		
12:30 - 13:00	Panel discussion with all speakers		
13:00 - 13:05	Closing remarks by the chair		
13:05 - 14:00 Lunch			
14:00 - 16:00	Face-to-face meetings with EMA officers		EMA