

## ***Good off-label use practices: Where are we? What next?***

Members Salon, European Parliament

Date: 14 November 2023

8h00/9h30

### **PROGRAMME**

	<b>Good off-label use practices: Where are we? What next?</b>	
07:30-08:00	Welcome & entrance to the European Parliament (Meeting point: Spinelli Simone Veil entrance)	
08:00-8:10	Opening remarks	<b>Stelios Kypouropoulos</b> , MEP – EPP/Greece <b>Nicolas Casares</b> , MEP – S&D/Spain (TBC)
08:10-8:15	<b>Introduction</b> to the topic and goal of the event	<b>Frédéric Destrebecq</b> , European Brain Council, Executive Director
08:15-08:25	<b>Patient perspective</b>	<b>François Houyez</b> , EURORDIS, Information & Access to Therapies Director & Health Policy Advisor (TBC)
08:25-08:35	<b>Clinician representative</b> <i>Concrete example (hurdles, achievements)</i>	<b>Mike Isle</b> , European Alliance for Access to Safe Medicines (EAASM), Chair and Executive Director (TBC)
08:35-08:45	<b>Implementing the GOLUP Declaration</b> <i>What do we need to do next ?</i>	<b>Marc Doms</b> Pharmacist, University Hospitals, Leuven, BE, Senior Orphan Drug

08:45-08:55	<b>Policy response</b> <ul style="list-style-type: none"> <li>▪ European Commission</li> <li>▪ EMA <i>EMA's repurposing project</i></li> <li>▪ Spanish Agency of Medicine and Health Products <i>Spanish EU Presidency event on the 'Repurposing and better use of Clinical Data'</i></li> </ul>	<p><b>Fabio D'Atri</b>, Policy Officer, Deputy Head of Unit B5 Directorate General for Health and Food Safety, European Commission, Belgium (TBC)</p> <p><b>Christelle Bouygues</b>, EMA, Human Medicines Division (TBC)</p> <p><b>Yoana Nuevo</b>, Spanish Agency of Medicines and Medical Devices (AEMPS), Department of Medicines for Human Use, Responsible of the Innovation Office and National Scientific Advice Unit</p>
08:55-09:05	<b>Q&amp;A session</b>	<b>Frédéric Destrebecq</b> , European Brain Council, Executive Director
09:05-09:20	<b>Next steps</b>	<p><b>Frédéric Destrebecq</b>, European Brain Council, Executive Director</p> <p><b>Biomedical Alliance in Europe representative</b> (TBC)</p>
09:20-09:30	<b>Closing remarks</b>	<p><b>Stelios Kypouropoulos</b>, MEP – EPP/Greece</p> <p><b>Nicolas Casares</b>, MEP – S&amp;D/Spain (TBC)</p>

