# Medical Therapies Commission Regulatory Affairs Task Force

Annual Report 2023

#### MEMBERS

Stéphane Auvin (France), co-chair Dennis Dlugos (USA), co-chair Jackie French (USA) Alexis Arzimanoglou (France) Lieven Lagae (Belgium) Kelly Knupp (USA) Eugen Trinka (Austria) Emilio Perucca (Australia)

## HIGHLIGHTS

- Meeting with EMEA people during the 35<sup>th</sup> International Epilepsy Congress (IEC 2023) in Dublin, Ireland, September 2023
- Preparation of the comments and meeting on draft EMEA guidelines on epileptic disorders
- Publication to unify the use of the ILAE terminology in the regulatory

## MEETINGS

We had six meetings over the year (four Zoom meetings, one meeting during IEC 2023 in Dublin, Ireland, and one meeting during the American Epilepsy Society Annual Meeting in Orlando, USA, December 2023.

# ACTIVITIES

- Discussion around clinical trials design for IGE
- Discussion about draft guidelines of the EMEA guidelines on epileptic disorders

# ACCOMPLISHMENTS

We closely worked with the EMEA in the prospective of the amendment of the EMEA guidelines. The draft was issued at the end of 2023 with a public meeting that was at the end of January 2024 with the involvement of the ILAE Task Force members during the public meeting.

#### **RESEARCH & ARTICLES PUBLISHED**

Auvin S, Arzimanoglou A, Brambilla I, French J, Knupp KG, Lagae L, Perucca E, Trinka E, Dlugos D. <u>Call for the use of the ILAE terminology for seizures and epilepsies by health care professionals</u> <u>and regulatory agencies to benefit patients and caregivers</u>. *Epilepsia*. 2023 Dec 17. doi:10.1111/epi.17868. Epub ahead of print. PMID: 38105624

Report submitted by Stéphane Auvin