



3 December 2024
EMA/563348/2024

Draft agenda - European Commission/EMA meeting with stakeholders on Translarna (ataluren)

10 December, 11:00-12:00 (CET), Webex meeting

Co-Chairs: Olga Solomon (EC) and Juan Garcia Burgos (EMA)

Time	Preliminary draft agenda	Speaker
11:00	Welcome and introduction	Olga Solomon (EC) Juan Garcia Burgos (EMA)
11:05	Overview of the evaluation process, evidence considered, stakeholders involvement, scientific grounds for recommendations, and next steps	Steffen Thirstrup (EMA)
11:15	Q&A session	Steffen Thirstrup (EMA) Pavel Balabanov (EMA) Florian Schmidt (EC)
11:55	Conclusion and next steps	Juan Garcia Burgos (EMA) Olga Solomon (EC)

Participants:

- Olga Solomon, Head of DG Health and Food Safety Unit D1 - Medicines: policy, authorisation and monitoring, EC
- Juan Garcia Burgos, Head of Public and Stakeholders Engagement, EMA
- Steffen Thirstrup, Chief Medical Officer, EMA
- Pavel Balabanov, Head of Therapies for Neurological and Psychiatric Disorders, EMA
- Florian Schmidt, Deputy Head of DG Health and Food Safety Unit D1 - Medicines: policy, authorisation and monitoring, EC