CME Session 13
Neuroimaging Committee
Wednesday, October 23, 2024, 08:00 - 09:30

Session Title
What is the Road Map to Install a New Neurological PET Tool?

Chairpersons
Donatienne Van Weehaeghe (Leuven, Belgium)
Matthias Brendel (Munich, Germany)

Programme

08:00 - 08:30 **Oliver Kiß** (Dresden, Germany): Use: Regulations in the application of neurological PET radiotracers in the EU

08:30 - 09:00 **Sofia Kapanadze** (Bonn, Germany): Approval: Marketing authorization of novel brain imaging biomarkers in the EU

09:00 - 09:30 **Matthias Brendel** (Munich, Germany): Reimbursement: How to get money for neurological PET in the EU

Educational Objectives

1. Understand the regulatory framework governing the use of neurological PET radiotracers in the European Union.
2. Identify the key regulatory bodies and their roles in the approval and monitoring of PET radiotracers.
3. Analyse the specific guidelines and compliance requirements for the application of neurological PET radiotracers in clinical practice within the EU.
4. Comprehend the process for obtaining marketing authorization for new brain imaging biomarkers in the European Union.
5. Explore the criteria and evidence required by regulatory agencies for the approval of novel biomarkers.
6. Examine case studies of successfully authorized brain imaging biomarkers to illustrate best practices and common challenges in the approval process.
7. Understand the reimbursement landscape for neurological PET imaging in the European Union.
8. Identify the steps and documentation required to secure reimbursement from public and private healthcare payers.
9. Evaluate the economic impact of neurological PET imaging on healthcare systems and how to effectively present this data to justify reimbursement.

Summary

This educational module covers the comprehensive landscape of neurological PET imaging in the European Union. Participants will gain an understanding of the regulatory framework governing the use of neurological PET radiotracers, including the roles of key regulatory bodies and specific compliance requirements for clinical practice. The module also delves into the process of obtaining marketing authorization for novel brain imaging biomarkers, detailing the necessary criteria, evidence, and regulatory considerations. Additionally, it addresses the reimbursement landscape, outlining the steps and documentation needed to secure funding from healthcare payers and evaluating the economic impact of neurological PET imaging to justify reimbursement effectively. Through case studies and practical examples, learners will be equipped with the knowledge to navigate the regulatory, approval, and reimbursement processes for neurological PET in the EU.

Key Words

Regulatory; marketing authorization; brain biomarkers; reimbursement