Overview ISPOR panel session "303: EU HTA Regulation: Ready for 2025 EU Joint Clinical Assessment (JCA)"

The EU HTA Regulation (EU 2021/2282) represents a significant shift in the way how new health technologies are evaluated across Europe. Implemented in January 2022, the regulation comes into full effect in January 2025. While regulatory decisions are centralized in the EU, most countries have their own Health Technology Assessment (HTA) process. HTA methods and processes vary by country leading to differences in ratings, access to medicines, and delay in time for patients in the EU. The HTA Regulation aims to improve and accelerate patients' access to new health technologies in the EU by harmonizing clinical assessment across Member States.

As the EU HTA Joint Clinical Assessment (JCA) will go in parallel with the review and approval process by Regulators, time for preparation of both dossiers, review and decision making, and alignment with following national reimbursement and value decisions are anticipated to provide new challenges for the involved stakeholders. There may also be interference of the content discussion between the two processes, as data analysis will continue during the review phase.

This panel discussion will dive into the questions if and how the implementation of EU HTA will affect the regulatory process and vice versa, which challenges there are and how EMA, the Coordination Group with its Subgroups and industry are preparing for those significant chances.

Panel experts:

- **Anne Willemsen,** Senior Advisor Zorginstituut Nederland (ZINL); *HTA CG, Co-chair JCA subgroup*
- **Michael Berntgen,** Head of Scientific Evidence Generation Department, Human Medicines Division, European Medicines Agency (EMA)
- **Inka Heikkinen,** Director Regulatory Policy Lead, Lundbeck; *EFPIA HTA Working Group*

Moderator: **Stephanie Rosenfeld,** Global Head of Cell & Gene therapy and early portfolio, Market Access, Bayer AG

Yours sincerely

Stephanie Rosenfeld