There is ongoing debate regarding the premature effectiveness data of oncology drugs and the associated uncertainty in determining their cost-effectiveness during reimbursement decisions. The European Medicines Agency (EMA) is increasingly accepting oncology drugs with limited evidence of effectiveness through early access programs, while the costs for these products rise rapidly. Recent research indicates that a significant portion (approximately 40%) of oncology products ultimately demonstrate no added clinical value. Conversely, for more than half of these products, research and development costs are recouped within three years.

Health Technology Assessment (HTA) bodies face challenges with the rapid pace of decision-making and the acceptance of uncertainty around (cost-)effectiveness. A cost-effectiveness model must accurately reflect current clinical practice at the time of modeling. However, because such models only incorporate information available at the time of modeling, they represent the situation at a specific point in time, namely at the time of the reimbursement decision.

In this session, we will explore the balance between early access to oncology drugs and the acceptance of uncertainty regarding their (cost-)effectiveness, as well as potential strategies to address these challenges.