Real world data (RWD) may offer possibilities to optimize health technology assessment; data captured along the life cycle through differing sources (observational studies, registries, and other) may complement evidence issued from RCTs in terms of safety and effectiveness, impact on patients outcomes and health systems. However, due to several challenges addressed when generating and using RWD, their use in the context of HTA needs to be carefully determined.

Today HTA agencies are faced with the difficult challenge of uncertainty as regards to the lack of robust data on new and potentially innovative products. Conditional coverage systems are being developed that require dynamic HTA evaluation and reevaluation of complementary data including RWD.

The presentation will describe key challenges for HTA, potential uses of RWD and impacts, based on experiences from the French national HTA agency and the EUnetHTA network.