Feasibility Assessment on Pediatric Low-grade Glioma (pLGG) in Europe (France, Germany, The Netherlands, The United Kingdom)

Study Description	
Background	The annual incidence of pLGG is approximately 4 cases per 100,000 children and accounts for 30–40% of all pediatric CNS tumors, making pLGG one of the most common brain tumors in childhood. Although overall survival is generally favorable, current treatment options — including chemotherapy and off-label targeted agents — offer limited benefit for many patients and are associated with notable toxicity. A substantial proportion of pLGG tumors are driven by molecular alterations, highlighting opportunities for improved outcomes through targeted therapeutic approaches. However, comparative real-world evidence across regions remains limited, which can affect health technology assessments and access to emerging therapies. To help address these evidence gaps, the possibility of developing an external control arm study is being explored.
Objective	The aim is to: • **Conduct a preliminary assessment** to determine the feasibility of a potential external control arm study, with a particular focus on the availability and quality of relevant data sources. • **Obtain aggregated data** on the epidemiology and care structure of the target populations from primary sources, defined as relevant institutions treating pLGG in selected countries (Germany, France, the Netherlands and the United Kingdom) in order to enable a representative sample of patients and institutions. • **Identify and contract data sources**, defined as relevant entities that treat pLGG – with a particular focus on the target subpopulation – to assess the ability to conduct chart reviews.
Methodology	In the initial project phase, a comprehensive analysis of the oncology care structure in selected countries (France, Germany, the Netherlands and the United Kingdom) will be conducted to build a representative sampling frame. This will include identifying institutions involved in the treatment of patients with pLGG. Furthermore, the feasibility assessment is intended to gain a better understanding of the following aspects:

	• the presence of a pLGG patient population • Standard of Care Practices and Treatment Pathways • Access to relevant patient data • interest of the centres and their capacity to participate • estimated total sample size and country-specific recruitment targets This process results in a stratified list of oncology centers across three essential care sectors: • University Hospitals • Non-university hospitals • Oncologists in private practice This stratification forms the foundation for a representative sample and allows for extrapolation of prevalence and incidence data within the target population.
Period of data collection	The start of the data collection phase is planned for **March 2026** and is currently planned to be completed by the **end of April 2026** at the latest.
Study Period	Aggregated data from patients with pLGG are collected for the period spanning **January 1, 2017**, through **December 31, 2025**.