Feasibility Assessment of Advanced Endometrial Cancer (aEC) in Europe
(Germany & France)

Study Description	
Background	Endometrial cancer (EC) is the most common malignant neoplasm of the female genital tract and, with approximately 11,000 new cases per year, ranks among the five most frequent cancers in women in Germany[1,2] and approximately 8,400 new cases per year in France.[3] The median age at onset is 68 years.[4] Because the disease often becomes apparent through early clinical symptoms, in particular atypical uterine bleeding, diagnosis is made in the majority of cases at the locoregional stage, with a consequently curative treatment approach. In approximately 25% of patients, however, a primary advanced stage is already present at the time of initial diagnosis, which is associated with a significantly reduced prognosis.[5] The treatment landscape of advanced or recurrent EC (aEC) has changed substantially in recent times: with the biomarker-independent approval of immune checkpoint inhibitors in combination with platinum-based chemotherapy (carboplatin/paclitaxel), a new first-line standard for the overall population has been available for the first time since 2024/2025.[6,7] Despite these therapeutic advances, robust real-world data on the oncological care reality of aEC in Germany & France are still lacking. The present feasibility study pursues the goal of establishing the foundations for a structured TherapieMonitor, with regard to center representativeness, data availability, and the quality of care-relevant parameters in routine clinical practice. **References** [1] Zentrum für Krebsregisterdaten, Robert Koch-Institut. Cancer of the uterus (endometrial cancer). https://www.krebsdaten.de/Krebs/EN/Content/Cancer_sites/Uterus_cancer/uterus_cancer_node.html [2] Scharl A, et al. A 10-Year Retrospective Cohort Study of Endometrial Cancer Outcomes in Germany. PMC. 2024. https://pmc.ncbi.nlm.nih.gov/articles/PMC11311640/ [3] Lapôtre-Ledoux B, et al. Estimations nationales de l'incidence et de la mortalité par cancer en France métropolitaine, 2023. INCa / Santé publique France. https://www.sante.fr/les-facteurs-de-risque-du-cancer-de-lendometre [4] Emons G, et al. Epidemiology, Real-World Treatment Patterns, and Patient Outcomes of Primary Advanced or Recurrent Endometrial Cancer in Germany, 2015–2021. Oncology Research and Treatment. 2024. https://karger.com/ort/article/48/3/92/916840/ [5] Colombo N, et al. Endometrial cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Annals of Oncology. 2022. https://www.annalsofoncology.org/article/S0923-7534(22)01207-8/fulltext [6] Mirza MR, et al. Dostarlimab plus carboplatin/paclitaxel in primary advanced or recurrent endometrial cancer (RUBY/ENGOT-EN6-NSGO/GOG-3031). NEJM. 2023. Referenced in: https://pmc.ncbi.nlm.nih.gov/articles/PMC10894756/ [7] Eskander RM, et al. Pembrolizumab plus carboplatin/paclitaxel in advanced endometrial cancer (NRG-GY018/KEYNOTE-868). NEJM. 2023. Referenced in: https://www.emjreviews.com/oncology/article/advancements-in-endometrial-cancer-research-in-2024-2-s130125/
Objective	The objectives are: • To conduct a **preliminary assessment**, to determine the feasibility of a potential study using a TherapieMonitor, with particular focus on the availability and quality of relevant data sources.

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	• **To collect aggregated data** on the epidemiology and care structures of the target populations from primary sources, defined as relevant institutions that treat aEC in selected countries (Germany & France), in order to enable a representative sample of affected individuals as well as institutions. • **To identify and contractually engage data sources**, defined as relevant institutions that treat aEC, particularly within the target subpopulation, in order to assess the feasibility of chart reviews.
Methodology	In the first project phase, a comprehensive analysis of the oncological care structures in the selected countries (France & Germany) will be carried out in order to develop a representative sampling frame. This includes identifying the institutions involved in the treatment of individuals with aEC. In addition, the feasibility assessment is intended to enable a better understanding of the following aspects: • ICD diagnosis of uterine/endometrial cancer (ICD-10: C54.1 or ICD-9: 182.0) • Initiation of systemic treatment for endometrial cancer (adjuvant or advanced setting) on or after 1 January 2025 • Possible evidence of treatment with an IO regimen (immuno-oncology) in any setting (adjuvant or advanced) • Estimated total sample size and country-specific recruitment targets This process results in a stratified list of oncology centers across three key care sectors: • University hospitals • Non-university hospitals • Office-based oncologists This stratification forms the basis for a representative sample and enables the extrapolation of prevalence- and incidence data within the target population.
Data Collection Period	The start of the data collection phase is planned for **August 2026**.
Study Period	Aggregated data from cases with aEC will be collected for the period from **1st January 2025** to **31st December 2025**.

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