



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR frequencies for active substances with DLP 2025 based on a risk-based approach

17th Industry Stakeholders Platform- Operation of EU Pharmacovigilance

Presented by Marta López Fauqued on behalf of Granularity and Periodicity Advisory Group (GPAG) on 7th November 2022

An agency of the European Union





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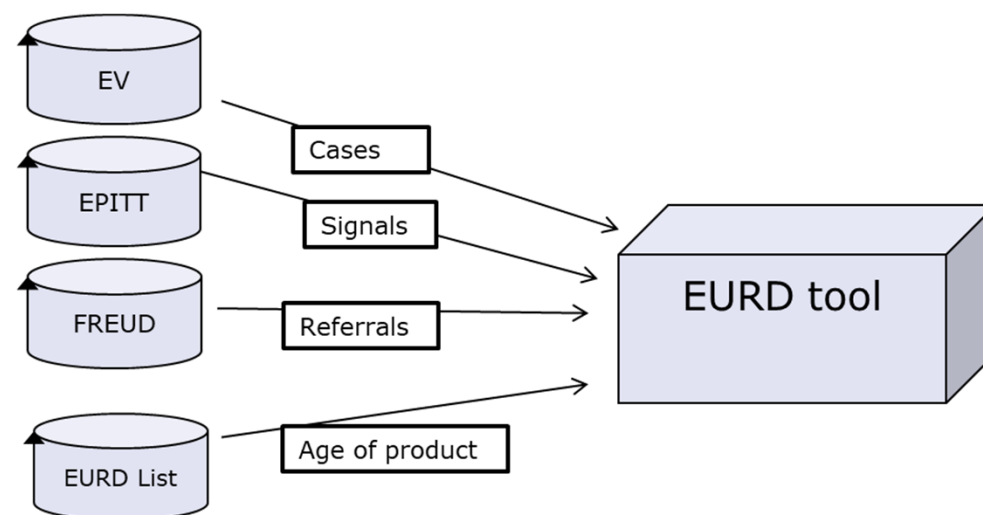
Background- Problem statement

- EURD list is a comprehensive list of active substances and combinations of active substances contained in medicinal products subject to different marketing authorizations (**> 3,000** active substances)
- EU reference dates, frequencies for submission of periodic safety update reports (PSURs) and related data lock points (DLPs).
- GVP VII provides risk-based criteria to define the frequency of PSUR submission
- EURD list contains a set of ~ 1,000 entries which PSURs assessments were initially deferred as other active substances were prioritised. These deferred PSUSAs are due in 2025 → PSUSAs have never been evaluated by PRAC



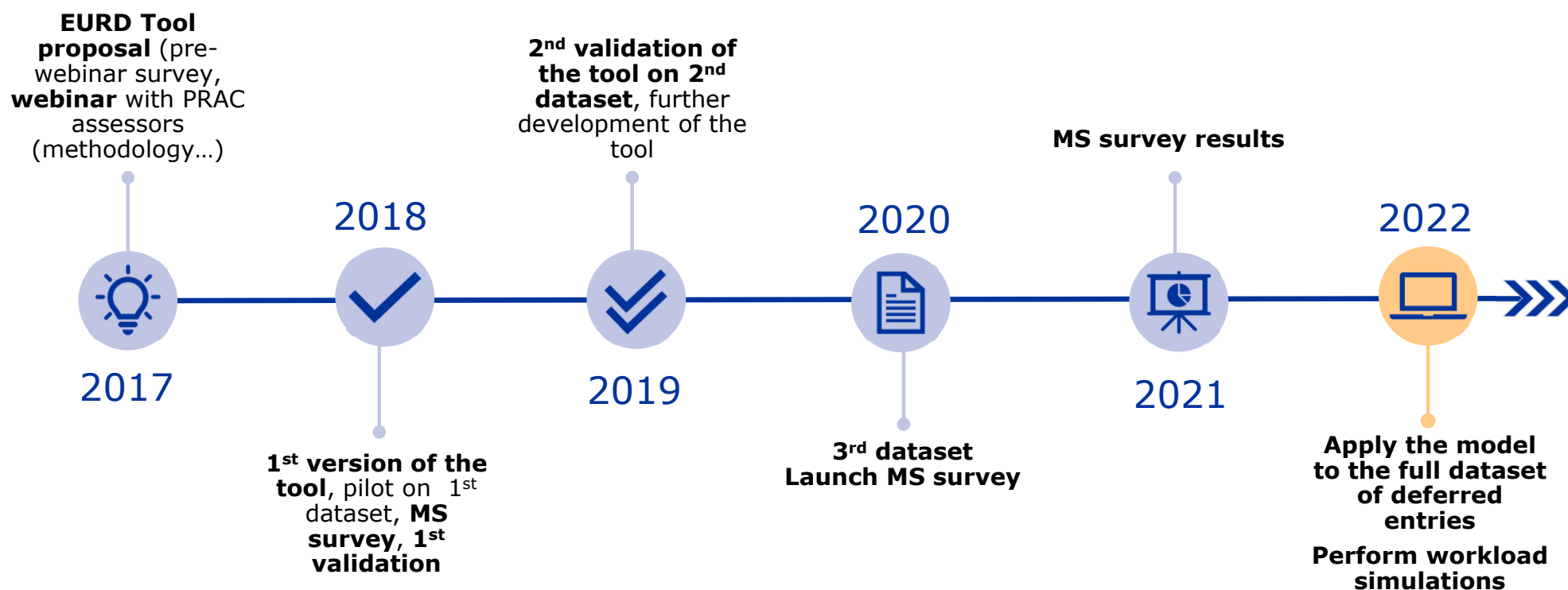
EURD tool

- Project leaded by **Granularity and Periodicity Advisory Group (GPAG)**, who provides advice to the **Pharmacovigilance Risk Assessment committee (PRAC)**
- Statistical tool** to support decision making for determining PSUR frequencies of EURD List entries centered on on readily available safety-relevant data



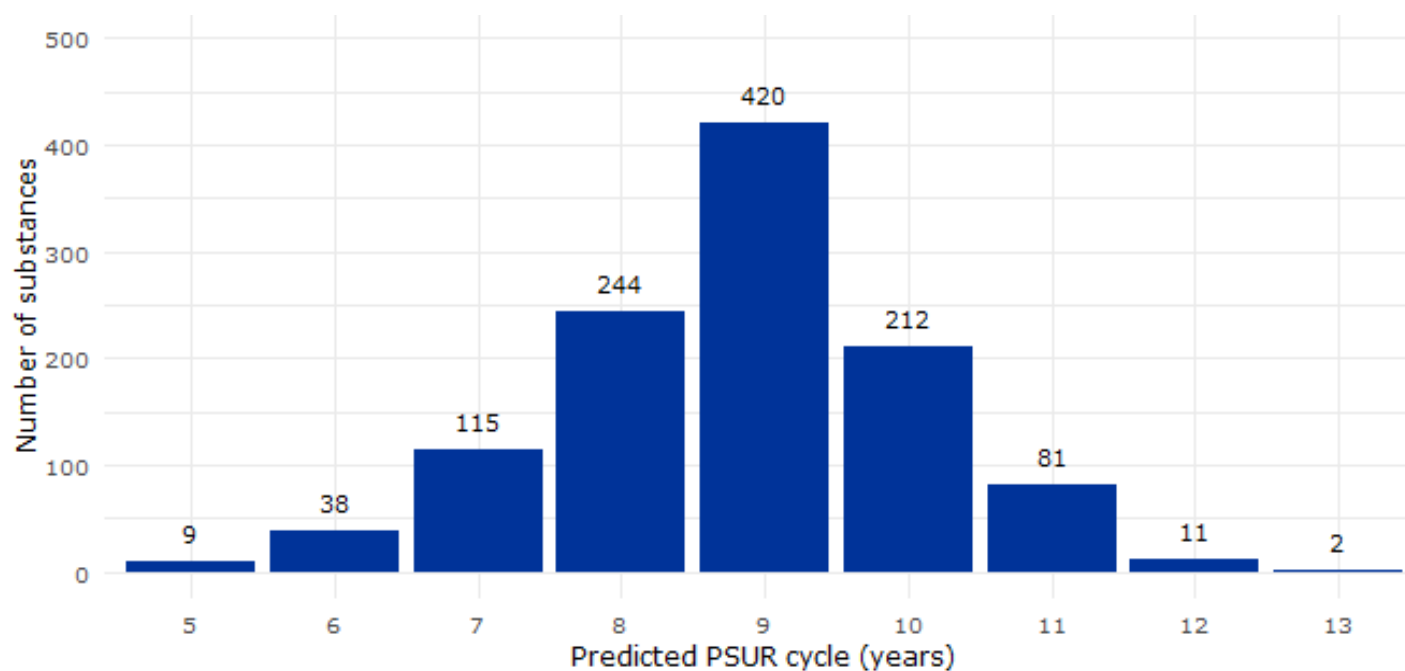


EURD tool project timeline





EURD tool frequency prediction – Deferred entries





Key messages

- GPAG has carefully evaluated different scenarios considering the impact to the distribution and workload under different workload simulations
- GPAG has presented to PRAC the different workload simulations
- Details are still under discussion
- Recommendation to assess all substances in the upcoming years
- All impacted substances **will receive a new Data Lock Point and a new frequency for the first PSUSA**
- Implementation **in EURD List planned in 2023** - different phases
- Work in progress



Any questions?

Further information

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