



2023 PRAC's Work Plan

TRENDING TOPICS

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has published its [work plan for 2023](#). The document lists PRAC's key objectives for the year, such as:

- strengthening the systematic generation of information on the benefits and risks of medicines in pregnancy and breastfeeding.
- strengthening data analysis and routine use of real-world evidence (RWE) to support PRAC decision-making.
- provide expert input in support of the development of guidance on use of RWE for regulatory purpose.
- review impact research projects including related processes and provide advice on conduct of impact research through [DARWIN EU](#).

(Note: to find all DARWIN EU study protocols and reports, use [EU PAS Register](#); many studies conducted through [FDA's Sentinel Initiative](#) inform regulatory decisions on safety and can be a source of RWD. Disease registries are another source of RWD).

