

Cohort profile: SWEedish register-based Evidence for Pharmacovigilance (SWEEP)

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Why was the cohort set up?

Adverse event reporting systems form the foundation of post-marketing pharmacovigilance (PV), enabling timely identification of safety signals. Routine health data including register-based health records represent an important complementary resource in signal detection and assessment, but their practical use in real-world signal management remains underutilized. To address this, the SWEEP cohort was established to enable future integration of these data, alongside case reports, in PV signal management.

What are the research objectives?

To assess the value of routine health data, specifically Swedish register data, in PV signal management.

- Integration into real-time signal management workflows
 - The scope of signals that can be analysed with the data
 - How the data can support the assessment of signals
 - How the data can contribute to signal detection

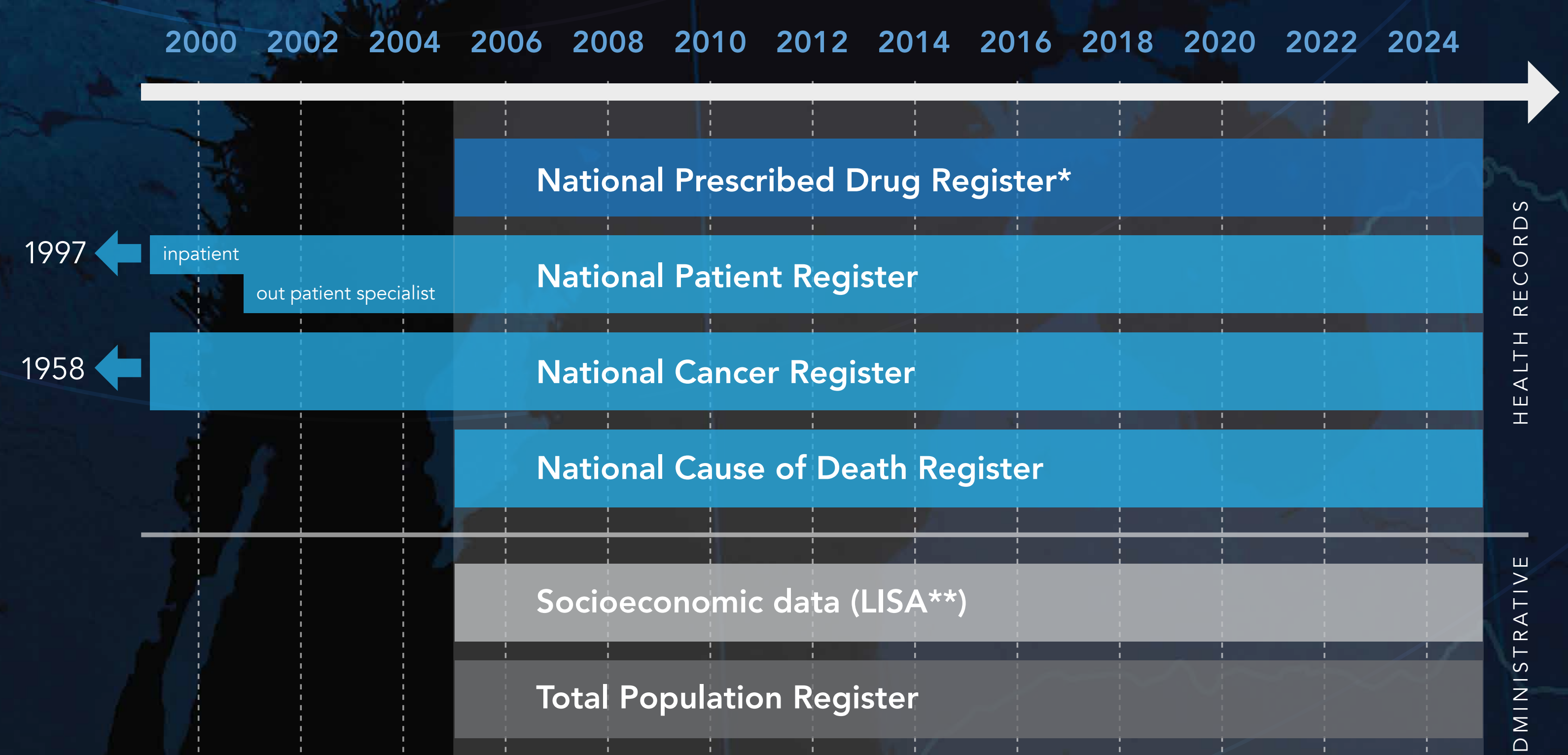
Who is included in the cohort, and what data are captured?

Current and future activities

The first complete data delivery was made on September 2025, and annual updates are planned to ensure the data remain timely for PV signal management. Project plans have been drafted, and preparations are underway to map the data to the OMOP Common Data Model (CDM), enabling collaboration as well as the development of methods and tools to support the use of the data in global signal management.

Conclusions

SWEEP is a nationwide Swedish register-based cohort designed to assess the value of routine health data in signal management including the development of methods and tools relevant to the post-marketing safety surveillance of medicines.



*Individuals aged 18 years or older with at least 1 filled prescription medicine (N~10M)
**Longitudinal integrated database for health insurance and labour market studies