Article 57 Project

Scope

To deliver structured and quality assured information on medicinal products authorised in the EU that can support EU terminologies of products, substances, and organisations used to power pharmacovigilance and regulatory systems in the EU

Benefits

Facilitate the coordination of regulatory decisions and actions to safeguard public health and to fulfil regulatory actions and legal obligations including:
- literature monitoring service;
- repository of Periodic Safety Up-date Reports (PSURs);
- support referral procedures;
- support collection of pharmacovigilance fees;
- support identification of products and substances in reports of suspected ADRs

Strengthen transparency and communication with stakeholders by granting access to safety data, efficiently ex-changing data within the EU Network and international partners, and supporting communication between the Agency's Committees and the pharmaceutical industry;

Support the reduction of duplication of encoding and maintenance of the same information on medicines, thus reducing costs

High Level Timeline