Characterisation of databases (DBs) used for signal detection (SD) – results of a survey among Innovative Medicines Initiative PROTECT work package (WP) 3 participants

Authors

Background
PROTECT aims to strengthen monitoring of benefit-risk of medicines in Europe by developing new methods to enhance early detection and assessment of adverse drug reactions (ADRs). WP3 includes assessment of SD methods applied to DBs of spontaneous ADRs. Partners surveyed include 3 national regulatory agencies (RAs), 3 pharmaceutical companies (PCs), the European Medicines Agency (EMA) and Uppsala Monitoring Centre (UMC).

Objectives
To describe different spontaneous reporting DBs with regard to size and content to provide context for future evaluations of SD and duplicate detection algorithms and their relative performance in these DBs.

Methods
The survey was completed online and was divided into 5 sections: i) general information including types of therapeutic agent, coding dictionaries, use of meta data and signal and duplicate detection algorithms; ii) counts including those based on seriousness, reporter type, country of origin, therapeutic agents and events; iii) data elements including presence of demographic data and drug details; iv) database coverage with regard to predominant drugs and events and v) vaccine specific information. Data were summarised descriptively.

Results
Data from the eight respondents were obtained between Sep 2010 and Aug 2011. DB size varies greatly (range 69,000–5,391,000 spontaneous reports). DBs are comparable in terms of: the proportion of serious to non-serious reports; country of origin; predominant body systems to which events are coded; availability of certain data elements such as gender, age, date of initial report and country of case. There is little comparability in the SD algorithms employed or use of meta-data (e.g. flags for targeted, designated or important medical events). Predominant drugs and drug-event pairs vary and appear to reflect historic
parochial issues. Annual report numbers continue to rise in PC, EMA and UMC DBs. The pattern of reporters, particularly in PC DBs, has changed over time.

Conclusions
The heterogeneity of spontaneous DBs is likely to be an important consideration when assessing the performance of SD algorithms in future studies.