IMI indicative Call topic

Leveraging emerging technology for pharmacovigilance

All information regarding future IMI Call topics is indicative and subject to change. Final information about the IMI's future Calls will be communicated after approval by the IMI Governing Board.

Background

The last five years have seen a number of changes in the consumer technology market that have revolutionised the way people communicate and use the Internet:

- the rise of digital media and Web 2.0 platforms such as Facebook and Twitter;
- the rapid adoption of computing categories such as smartphones and tablets from Apple, Samsung, Sony and others;
- the 'appification' of the Internet in the form of small packaged software or 'Apps'.

These trends offer a tremendous opportunity for pharmacovigilance: adverse reactions and other medical insights could be reported by patients via smartphones and tablet devices, or extracted from social media using data mining methodologies. This could be further expanded by allowing an interface for data display and exploration, including notifications, medical product updates, and potential alerts for the patient.

Need for public-private collaborative research

The development of a mobile platform for pharmacovigilance and pharmacoepidemiology surveillance faces two major challenges: the construction of the technical platform, and the establishment of the policy framework. To successfully surmount both, concerted efforts and commitments from policy makers and government agencies on one hand, and pharmaceutical companies, small and medium-sized enterprises (SMEs), academics, regulators, and most importantly patients and disease advocacy groups on the other hand, will be required.

Overall objectives

The overall objectives are threefold:

1. the implementation of a robust mobile reporting platform by providing applications enabling direct reporting of suspected adverse events to national competent authorities integrating with established workflows & tools (i.e. EudraVigilance);
2. the adoption of data mining methodologies to scan social media content for emerging, self-reported medical insights such as adverse events associated with medicines and medical devices;
3. the establishment of the policy and regulatory framework for social media pharmacovigilance surveillance.

Suggested key deliverables

1. Policy advancement: Provide policy and regulatory guidance on:
   - how social media surveillance can be put in practice taking into account the European Medicines Agency guidelines and the European Union's Data Protection Directives;
   - the need to track the provenance of data.
2. Technical advancement: A reference platform for social media surveillance:
   - for gathering content from different web sources in real time organised in a format suitable for analysis;
   - a series of algorithms that enable the extraction and identification of adverse events;
   - a series of algorithms that enable the provenance of data to be established across multiple social media sources.
3. Mobile platform development:
   - free to use EudraVigilance Patient Reporting app across multiple platforms;
   - free to use EudraVigilance Healthcare Professional Reporting app;
   - geographic interactive display illustrating patterns of ADR reporting in real time;
   - interface to the EudraVigilance system including potential for two-way communication (data interchange) with reporters;
   - online social marketing campaign for publicising and adopting the apps.