WEB-RADR

Work-Package 1 – Governance and Policy

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OBJECTIVES

Support assessment of stakeholder needs, expectations and challenges

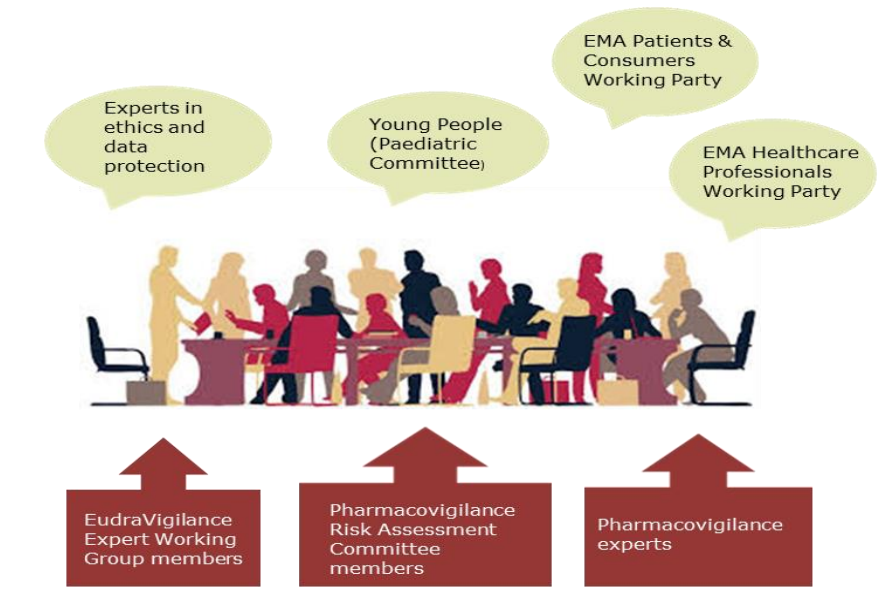
Provide advice and guidance on pharmacovigilance, ethical and data protection aspects

Review legal, regulatory, personal data protection requirements and ethical aspects

Elaborate a policy framework with recommendations towards future utilisation of the new WEB-RADR technologies and methods in the EU

1- Two stakeholder workshop: December 2014 & October 2016

- ✓ **Workshop report available on project website**



Key workshop discussions for WP1

- Data protection law should strengthen public health by ensuring the successful use of data within the constraints/boundaries of the law and safeguarding individual rights in an ethically rigorous manner
- Opportunities and challenges related to digital media and 'mHealth' will be looked at by EDPS
- Declaration of Helsinki principles should apply for all medical research; 'Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity'
- Make best use of data protection tools. This includes making sure there is clear and transparent information about the use of the data, purpose limitation, data minimization, privacy and security measures

2- Survey of regulatory framework – social media and ADR reporting

- ✓ **Gathering all applicable requirements and assessing variability**
- ✓ **Survey report**
- ✓ **Publication under preparation**

1) Initial survey in Q3 2014 and update in Q2 2015 of 182 countries worldwide

2) Results: 145 countries with no applicable policies

3) 37 countries have local docs on use of social media and ADR reporting of which 31 are equivalent to GVP

4) Of 37, 6 have more detailed provisions than GVP (France, Italy, Sweden, Turkey, United Kingdom and Unites States of America

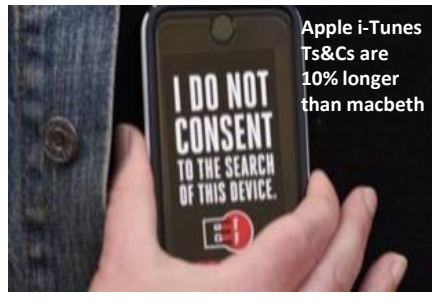
3- Assessment of data protection requirements in line with EU data protection legislation

- Focus on current legal framework- Directive 95/46/EC and e-Privacy Directive (Directive 2002/58/EC), Regulation (EC) No 45/2001 (GDPR [1] will enter into force after project close)
- Need to determine the roles and responsibilities of (joint) controller(s) and processor(s) for the processing of personal data
- Transparency principle - inform users proactively about data processing in a clear and understandable way
- Possibility to opt-out from data collection
- Rights of the data subject - Access and rectification rights of the data subject must be clearly visible and available to the user
- App development - privacy by design and default including data privacy statement to be taken into account
- Data security – application of technical measures to protect personal data

[1] General Data Protection Regulation

Next steps…

- **Elaborate policy framework with recommendations on future utilisation of the new technologies and methods in the EU, based on results from WP 2-4**
- **Key areas for future**
  - **Use of mobile apps for ADR reporting**
  - **Data quality principles**
  - **Monitoring of social media websites**
  - **Reporting of ADRs from social media websites – individual case safety reports vs aggregated review – pros and cons**
  - **Current challenges with social media monitoring, impact on signal management**



Apple i-Tunes Ts&Cs are 10% longer than macbeth

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