EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feasibility and impact assessment of regulatory science: application to PROTECT

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1. Background

Regulatory agencies are at the forefront of regulatory sciences aiming to improve the evaluation of quality, efficacy and safety of medicines. These projects generate a large number of outputs that are not immediately transferable into regulatory or public health outcomes. EMA developed a framework for feasibility and impact assessment to prioritise outputs for further validation or implementation into regulatory practice.

2. Objective

To apply the framework for feasibility and impact assessment on results of the Pharmacoepidemiological Research on Outcomes of Therapeutics by An European ConsorTium (PROTECT) project to test its feasibility and utility.

3. Methods

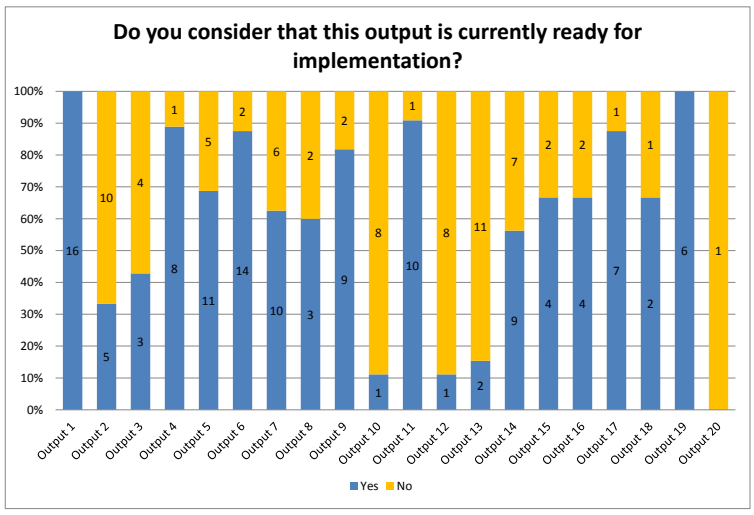
Selection of 20 outputs among 101 PROTECT deliverables	
Recommendations for pharmacoepidemiology	
Output 1	Inventory on drug utilisation data
Output 2	Comparison of methods to control for confounding
Output 3	Balance measures for propensity score models
Output 4	Comparison of covariate adjustment methods
Output 5	Recommendations for pharmacoepidemiological
Methods for signal detection	
Output 6	Evaluation of disproportionality analysis
Output 7	Adverse Drug Reaction Repository
Output 8	Lessons learnt from a characterisation of databases used for signal detection
Output 9	Grouping of existing adverse drug reaction terminologies
Output 10	Novel groupings for adverse drug reactions
Output 11	Subgrouping and stratification in statistical signal detection
Output 12	Statistical signal detection from clinical trials
Output 13	Statistical signal detection from electronic health records
Benefit risk integration and representation	
Output 14	Methodologies for benefit-risk evaluation
Output 15	Methodologies for graphical representation
Output 16	Final tools for graphical B:R representation
Output 17	Recommendations on methodologies for B-R integration and representation
Output 18	Development of accessible material to patients
Output 19	Repository of training material
Output 20	Enhanced ADDIS software

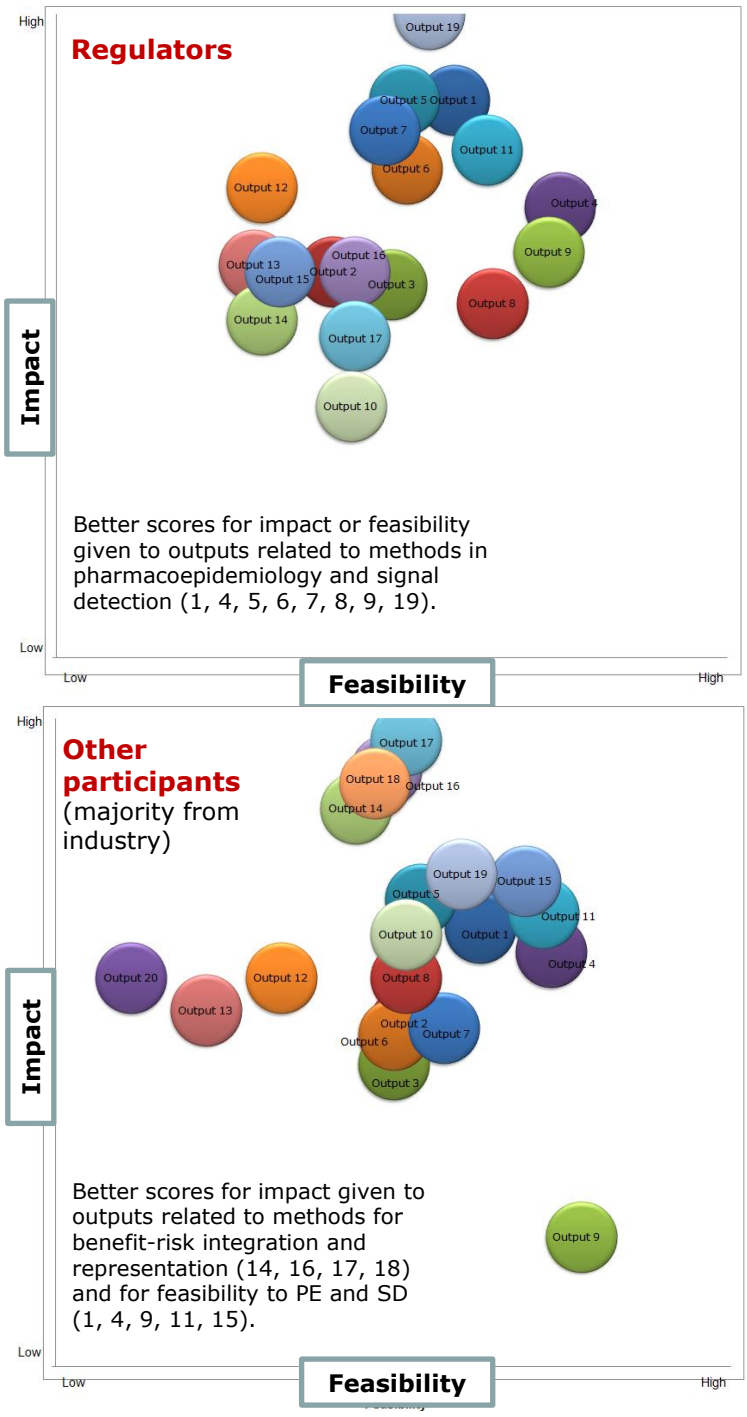
- **Survey among participants to the Final PROTECT Symposium (18-20 February 2015)**
- ≥ 3 outputs to be chosen by participants, with links to reference documentation
- For each output, scoring of the following criteria:

Scoring of outputs	
Dimension: Impact	
Potential impact on public health	None/small/moderate/important
Acceptability by stakeholder's group	Small/moderate/important
Dimension: Feasibility	
Degree of scientific development	Inadequate/incomplete/nearly complete/complete
Delay needed for implementation	>2y./1-2 y./<1 y.
Impact of implementation on IT	Small/moderate/important
Impact of implementation on human resources	Small/moderate/important

- **EMA panels on assessment of signal detection and pharmacoepidemiology outputs**
- **For each output, average scores calculated for each dimension**

4. Results





5. Conclusions

- Method tested with non-random sample of symposium participants
- Differences in scoring of outputs between regulators and other participants, probably reflecting expertise and work priorities
- Visual representation potentially useful for prioritisation
- Assessment criteria, survey methods and scoring matrix to be further developed

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