



European Medicines Agency
Press Office

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PRESS RELEASE

EMA-coordinated PROTECT project has been accepted for funding by the Innovative Medicines Initiative Joint Undertaking

The PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) has been accepted for funding by the Innovative Medicines Initiative Joint Undertaking (IMI JU). PROTECT is a collaborative European project aiming to develop innovative methods in pharmacoepidemiology and pharmacovigilance.

The European Medicines Agency (EMA) coordinates the project and manages a multi-national consortium of 29 public and private partners.

In April 2008, the IMI JU issued its 1st Call offering research grants for projects to be jointly conducted by research groups comprising mainly public organisations (including academia, competent authorities, non-profit patient organisations and small/medium-sized enterprises) and EFPIA companies. Of the 18 call topics, PROTECT addresses topic no 6: Improving and strengthening the monitoring of the benefit/risk of medicines marketed in the EU.

PROTECT will run over five years, with a total funding of EUR 20 million. Half of the funding will be in-kind contributions from the participating EFPIA companies. The target start date of the project is September 2009.

PROTECT will look at limitations of current methods used in pharmacovigilance and pharmaco-epidemiology in order to strengthen the monitoring of the benefit/risk balance of medicines marketed in Europe. A set of innovative tools and methods will be developed and validated in specialised Work Packages, including: (i) modern tools of communication to directly collect data from consumers of medicines; (ii) improved tools for early and proactive detection of signals; (iii) a framework for the design, conduct and analysis of pharmacoepidemiological studies; and (iv) methods for continuous benefit/risk monitoring, with a particular emphasis on graphical methods to display benefit/risk profiles.

In addition to PROTECT, the EMA also contributes to the IMI-funded project Eu2P, which focuses on the development of a comprehensive and flexible pan-European training and education programme for both specialists and non-specialists in the fields of pharmacoepidemiology and pharmacovigilance.

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Notes:

1. The IMI JU is a newly established European body of the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). More information on the IMI JU is available at: <http://www.imi-europe.org>
2. This press release, together with other information on the work of the EMA, can be found on the EMA website: <http://www.ema.europa.eu>

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