



What is on the horizon for Medicines Adaptive Pathways to Patients (MAPPs)?

Key European scientific and policy developments in the next 2-3 years

(Executive summary – Manuscript in preparation)

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The work leading to these results was conducted as part of the ADAPT SMART consortium (Accelerated Development of Appropriate Patient Therapies: a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes). For further information please refer to www.adaptsmart.eu. This paper is the result of the collective input from working group D1.03 and only reflects the views of the authors.

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Executive summary

ADAPT-SMART is a multi-stakeholder consortium that was set up as a Coordination and Support Action under the EU Innovative Medicines Initiative 2 (IMI2^a). The ADAPT SMART consortium comprises most stakeholders in the healthcare ecosystem: patients' organisations, academics/providers, medicine developers mainly represented by the research based industry, regulators, and health technology assessment (HTA) bodies. Payers were not formal partners but provided some input throughout the project as observers.

The medicines adaptive pathways to patients (MAPPs) concept is a scientific concept for the development and managed access of innovative and transformative medicines and has three key components:

- a prospectively planned approach to medicine development through early multi-stakeholder engagement;
- an interactive medicine development via approval in stages, confirming positive benefit/risk, and cycles of evidence generation and assessment;
- and the use of real world data to supplement data from randomised control trials (RCT).

Work package 1 has focused on evidence generation (in a MAPPs context) throughout the product life-cycle. Earlier work has reviewed IMI and non-IMI projects (D1.02) that might further support the development and/or implementation of the MAPPs approach. This review resulted in a gap analysis that identified a number of areas where more research is needed to develop tools and methods that will support the MAPPs approach. The initial gap analysis was presented to a multi-stakeholder workshop in January 2017 to identify consensus on the gaps identified and to agree on priority topics for formulating more detailed research recommendations. These topics were the following:

1. payer requirements
2. single-arm studies
3. indirect comparisons and observational data

The research recommendations were drafted by Consortium leads and shared for several rounds of review by ADAPT-SMART Consortium partners, the International Advisory Board, and the Navigator Group (D1.04).

This horizon scanning report is the final deliverable for ADAPT-SMART's work package 1. It identifies the main scientific and policy developments in Europe that are of relevance to adaptive pathways during the first two years after the project is finalised (2018-2019). This might help the Consortium and IMI in further developing MAPPs-related activities beyond the time horizon of the project.

^a <http://www.imi.europa.eu/>