



HORIZON  
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# Accelerated Development of Appropriate Patient Therapies: a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes - Sofia ref.: 115890

## Reporting

### Project information

ADAPT-SMART

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[Project website](#)

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## Periodic Reporting for period 1 - ADAPT-SMART (Accelerated Development of Appropriate Patient Therapies: a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes)

Reporting period: 2015-07-01 to 2016-12-31

### Summary of the context and overall objectives of the project

Progress in life sciences and related technologies offers the potential to bring a wide range of beneficial new therapies to patients over the coming years. There will be more personalised or stratified medicines, combinations, borderline products, and advanced therapies that may require new ways of evaluation and managing/following utilisation in daily clinical practice while investigating patients' populations that could best benefit of them.

Today's paradigms of bringing innovation to patients are also challenged by transformative environmental developments:

- Growing patient demand for timely access to promising therapies, exacerbating the 'access versus

evidence conundrum'. In turn, this will require more flexibility and increased numbers of iterations of regulatory and reimbursement decisions;

- Increased fragmentation of patient populations due to better disease stratification, challenging the established drug development pathways, e.g. large conventional phase III randomised and controlled studies;
- Increased payer influence on product accessibility to patients in parallel with concerns over the budget impact of these new treatments; financial pressures on health systems and sustainability challenges raise questions on prioritisation of investment and value of innovation.
- Pressure on pharma/investors to ensure sustainability of drug development as pharmaceutical R&D attrition rates remain high while the cost of biopharmaceutical R&D continues to rise; this limits the absolute number of candidate products that can be brought forward into the development steps.

To address these environmental changes, while maximising the potential of scientific progress for patients in a timely and sustainable way, one needs major "adaptations" to current paradigms, albeit staying in the current EU legal framework.

The changes required go far beyond the well-defined remit of today's regulatory evidence standards. We posit that all decision makers and stakeholders in the healthcare ecosystem will need to explore a life-span approach to drug development, including use in clinical practice, marketing authorisation (MA) and pricing and reimbursement (P&R), use in daily clinical practice and monitoring viewed as a continuum. The life-span approach is hereafter referred to as Medicines Adaptive Pathways to Patients (MAPPs).

The overall scope of the ADAPT SMART Coordination and Support Action (CSA) is to establish an enabling platform for the coordination of MAPPs related activities within IMI 2, and engage a direct and open dialogue with all relevant stakeholders. MAPPs seeks to foster patient access to beneficial treatments for the right patient groups at the earliest appropriate time in the product life-span in a sustainable fashion. This is enabled by the overall objectives of ADAPT SMART, which are to:

- Identify relevant MAPPs activities, synthesizing the learnings from ongoing or completed pilots and case studies, creating a MAPPs repository of knowledge and opportunities;
- Identify the scientific challenges and opportunities related to MAPPs implementation and facilitate aligned understanding of consortium members and their constituents;
- Support new IMI2 research and innovation actions by facilitating the inclusion of MAPPs enablers (tools and methodologies) to address/exploit the identified challenges and opportunities;
- Conduct horizon scanning and gap analysis for each topic identified, for methods, tools, and other relevant activities and producing actionable advice and/or recommendations for future research

activities to IMI and other stakeholders to further the implementation of MAPPs.

Currently, several initiatives are exploring new pathways to market, e.g. the EMA's Adaptive Pathway project, the New Drug Development Paradigms (NEWDIGS) initiative at Massachusetts Institute of Technology (MIT, USA), or the UK's Early Access to Medicines Scheme (EAMS). Parties directly involved with

## **Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far**

An important result of the first year is the establishment of the multistakeholder platform to progress the discussion on the different aspects of the MAPPs concept. The platform is now up-and-running, and is able to accommodate additional members as needed. During the first reporting period, the project has conducted four stakeholder workshops on:

- 1) Engagement criteria for the adaptive pathway (29 February 2016)
- 2) Adaptive design laboratory, in cooperation with NEWDIGS and GetReal (1&2 June 2016)
- 3) The role of managed entry agreements (MEAs) in the context of adaptive pathways (5 July 2016)
- 4) The impact of a MAPPs 'seamless pathway' on decision making (6 July 2016)

These workshops have resulted in a number of reports, which provide input for future (peer-reviewed) publications.

In addition, ADAPT SMART has published a glossary of terms and has contributed to the public debate about adaptive pathways with 5 podcasts and 11 newsletters, which are available on the ADAPTSMART website.

It is important to note that the first 18 months of the project have also set in motion a number of activities that will bear fruit in the final year of ADAPT SMART, as we expect to deliver a significant number of workshops, events, peer-reviewed publications and reports during 2017.

## **Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)**

The project aims to move beyond the state-of-the-art by identifying what is needed to address potential barriers to the implementation of MAPPs, and to address and align approaches/concerns from policy makers, regulators, HTA bodies, payers, patients and prescribers.

This project is unique in that it is the most comprehensive attempt yet to involve all stakeholders in identifying relevant MAPPs activities, creating a knowledge repository and identifying scientific challenges and potential research/implementation activities that address unmet medical needs and

create the right incentives for public and private actors to move beyond current pathways in the EU, and provide recommendations on how to implement MAPPs.

The EMA pilots and the establishment of a large IMI consortium raised the profile of the MAPPs concept and generated considerable interest and engagement from the wider scientific community, healthcare payers, consumer groups and non-governmental organisation



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