TOWARDS AN ADAPTIVE MINDSET

S. Corriol-Rohou, AstraZeneca; J. Bouvy, NICE; H-G. Eichler (EMA); A. Broekmans (Lygature)

Facts & Figures

Start date: 01/07/2015
End date: 30/04/2018
Contributions
IMI funding: 1 130 000 €
EFPIA in kind: 2 187 631 €
Other: 760 715 €
Total Cost: 4 078 146 €
Project website: adaptsmart.eu

Approach & Methodology

An unprecedented multi-stakeholder platform to address the operational and strategic challenges within the current EU regulatory framework.

Challenges

- High attrition rates in medicine development
- Regulatory environment lagging behind rapidly evolving science
- No longer financially viable R&D and pricing/reimbursement models

⇒ Need for change in people mindset to support a change in the drug development paradigm

Take home messages

To successfully deliver a MAPPs product:
- Are engagement criteria met?
- Smartly combine ‘building blocks’
- Early multi-stakeholders’ engagement
- Make best use of the MAPPs pathway
- Consider managed entry agreement

Smart use of building blocks

- Unmet need
- Timely access
- Iterative development and assessment
- Increase of the evidence-to-uncertainty ratio
- Use of real world data
- Expansion of treatment eligible population
- Adaptive pricing and reimbursement
- Ensure appropriate utilisation

Collaboration of all stakeholders (sponsors, patients, regulators, HTAs, payers, health care providers)

VISIT THE ADAPT SMART INFOGRAPHIC

This work has received support from the EU/EFPIA/ [Associated Partner] Innovative Medicines Initiative [2] Joint Undertaking [ADAPTS SMART] grant no [115890].