

## [H2020-JTI-IMI2-2015-05-two-stage](#)

H2020-JTI-IMI2-2015-05-two-stage-Master-1

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<b>Opening Date</b>	09-07-2015	<b>Deadline Date</b>	13-10-2015 17:00:00 (Brussels local time)
<b>Publication date</b>	09-07-2015	<b>Total Call Budget</b>	€45,783,000
		<b>Stage 2</b>	15-03-2016 17:00:00 (Brussels local time)
<b>Programme</b>	Horizon 2020		
<b>Status</b>	<span>Open</span>	<b>Main Pillar</b>	Societal Challenges

**Topic: Patient perspective elicitation on benefits and risks of medicinal products, from development through the entire life cycle, to inform the decision-making process by regulators and Health Technology Assessment bodie**

**H2020-JTI-IMI2-2015-05-01**

- [Topic Description](#)
- [Topic Conditions & Documents](#)
- [Submission Service](#)

SpecificChallenge:

While there is an emerging consensus among stakeholders that patients' values and perspectives are important to inform decision-making processes during the development of medicines as well as during the approval and post-approval phases, it is not clear when patient perspective elicitation on benefits and risks of medicinal products is most valuable, and how this can best be performed.

Scope:

To establish recommendations with the view of supporting the development of guidance for industry, regulators and health technology assessment (HTA) bodies on how and when in the product life-cycle to consider patient perspectives on benefits and risks of medicinal products to inform the decision-making process by regulators and HTA bodies.

ExpectedImpact:

Consensus between patients, physicians, regulators, HTA bodies, academia and industry stakeholders on an approach, including a set of methodologies suitable for patient involvement, acceptable to

regulators and HTA bodies for inclusion of patient preferences to inform benefit-risk decision-making throughout the product life-cycle: