

*A public-private collaboration for better patient engagement co-led by the European Patients' Forum (EPF) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).*

<b>Project Scope</b>	Operationally European - Results to be disseminated globally
<b>Duration</b>	<b>30 months</b>   March 2018 - September 2020
<b>Partners</b>	<b>34</b>   <b>4 European patients organizations; 2 Competent authorities; 3 Academic teams; 1 Non-profit organization; 2 SMEs; 1 Hospital; 21 Industry partners:</b> 3 associations, 17 bio-pharmaceutical companies, 1 contract research organization ( <a href="http://imi-paradigm.eu/project-partners">http://imi-paradigm.eu/project-partners</a> )
<b>Funding</b>	PARADIGM has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777450. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA, as well as from private partners from the consortium.
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## OBJECTIVE

PARADIGM's objective is to develop much needed patient engagement processes and tools for three key decision-making points of the medicines development lifecycle:

- Research priority setting
- Design of clinical trials
- Early dialogue with regulators and HTA bodies

## OUTPUTS

- Strengthen the understanding of stakeholders' needs and expectations for patient engagement
- Develop concrete metrics to help demonstrate the impact of patient engagement practices
- Enhance system-readiness towards patient engagement across a wide range of stakeholders
- Build synergies with other patient engagement initiatives like PFMD and EUPATI
- Design a workable sustainability roadmap to optimise patient engagement in key decision making points across the medicines lifecycle.

## DELIVERABLES

WORKING MODULES	DELIVERABLES	March 2018	April 2018	May 2018	June 2018	July 2018	August 2018	September 2018	October 2018	November 2018	December 2018	January 2019	February 2019	March 2019	April 2019	May 2019	June 2019	July 2019	August 2019	September 2019	October 2019	November 2019	December 2019	January 2020	February 2020	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	
		Defining stakeholders' preferences, needs and expectations	Survey analysis report on stakeholder-specific preferences, needs and expectations																													
Criteria to assess how patient engagement expectations are met																																
Assessment of practices and processes	Report on the assessment of practices and processes																															
Development of metrics for monitoring and evaluation	Review existing methods for Monitoring & Evaluation (M&E) of outcomes and impacts of patient engagement at different points in the medicines-development lifecycle																															
	M&E frameworks for assessing outcomes and impact																															
Co-designed recommendations and resources for patient engagement	Recommendations for capacity needed for PE																															
	Code of conduct and guidance for patient engagement in R&D																															
	Patient engagement toolbox																															
Dissemination and engagement	Report on the first open Patient Engagement Forum																															
	Communication and external engagement plan																															
	Report on interim open Patient Engagement Forum																															
	Report on final Open Patient Engagement Forum																															
Sustainability strategy	Sustainability roadmap																															
Project coordination and management	Ethical Framework																															
	Ethics Expert Panel brief activity report																															
	Ethics Expert Panel final activity report																															

## PARTNERS

