



EMA - focus on the future

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EMA Nominated Executive Director

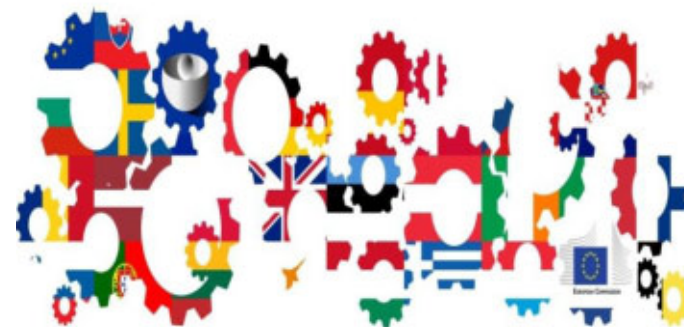
EMA-EuropaBio Information Day, London
15 October 2015



- Trends and strategic goals
- EMA tools to support innovation
- Focus on patients



1 - Trends and strategic goals

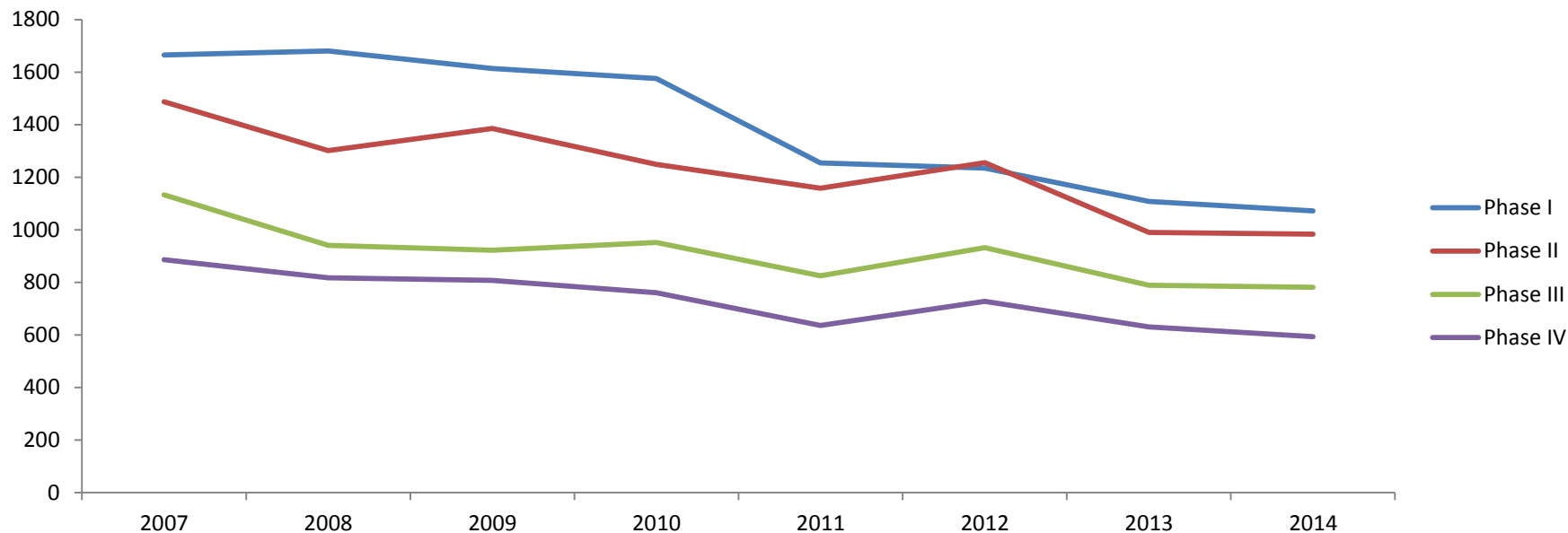


Global environmental changes / trends

- Costs for R&D are increasing
- Cost of innovative medicines are increasing
- Investments are moving away from Europe
- Ageing population will drive up consumption of medicines
- Number of expiring patents steadily decreasing
- Supply chain is increasingly complex, medicines shortages in some areas



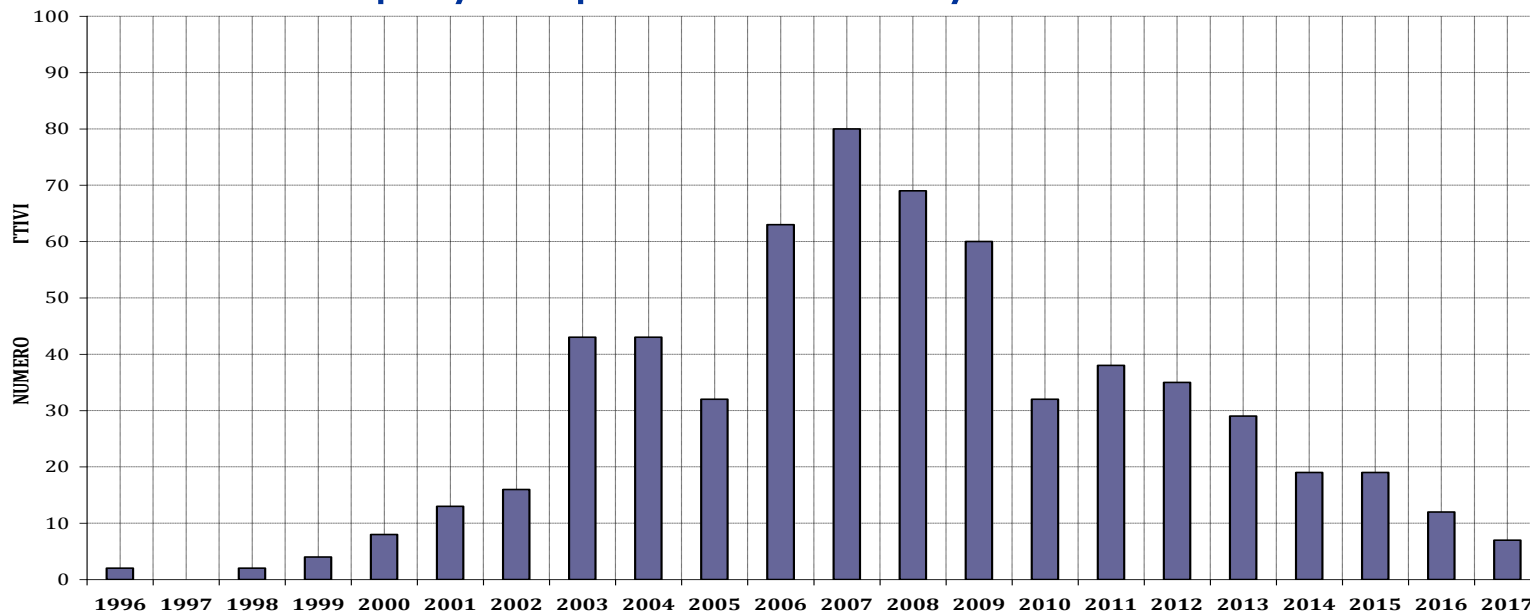
Clinical Trials in Europe





"Innovation"/Patent expiration

Expiry of patents - Italy 1996-2017



Strategic considerations (EU regulatory network challenges)

Sustainability

- Health systems (medicines cost, NCAs/EMA)
- R & D (patient access to innovation, Europe competitiveness)

Quality

- Scientific opinions (complexity)
- Medicines (safety, efficacy, availability)



Strategic priorities for EMA & the Network

- **Optimising the operation of the network of national authorities and EMA**
 - Common strategy to 2020
 - Common telematics governance strategy
 - Network training centre
 - Multinational teams
- **Access to innovation**
 - Adaptive pathways
 - PRIME



Strategic priorities for EMA & the Network, cont..

■ **Global regulatory environment**

- Data integrity
- Global capacity building
- Convergence of global standards

■ **Transparency and communication**

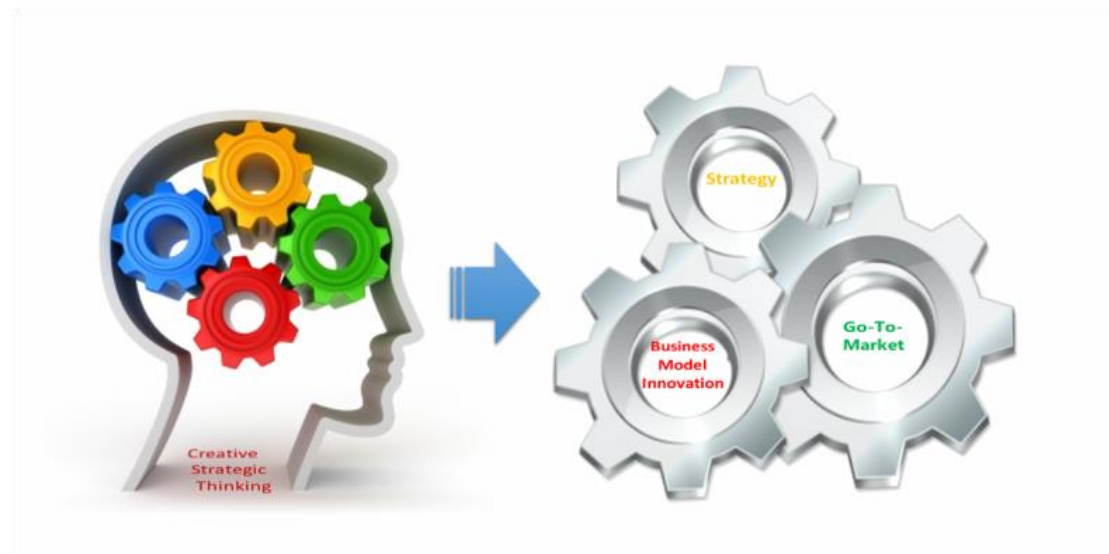


	Sustainability		Quality	
	Health systems (medicines cost, HTA/payers, NCAs/EMA)	R & D (patients access, competitiveness)	Scientific opinions (legal, procedural complexity)	Medicines (pharmacovigilance, inspections, supply chain/shortages)
Network Training Centre	✓		✓	✓
Multinational teams	✓	✓	✓	✓
Telematics	✓	✓	✓	✓
PRIME	✓	✓	✓	
Adaptive licensing	✓	✓	✓	✓
Clinical data publication		✓	✓	
Joint advice (HTA/Payers)	✓	✓	✓	
Fee impl rules	✓			
Big data	✓	✓	✓	✓

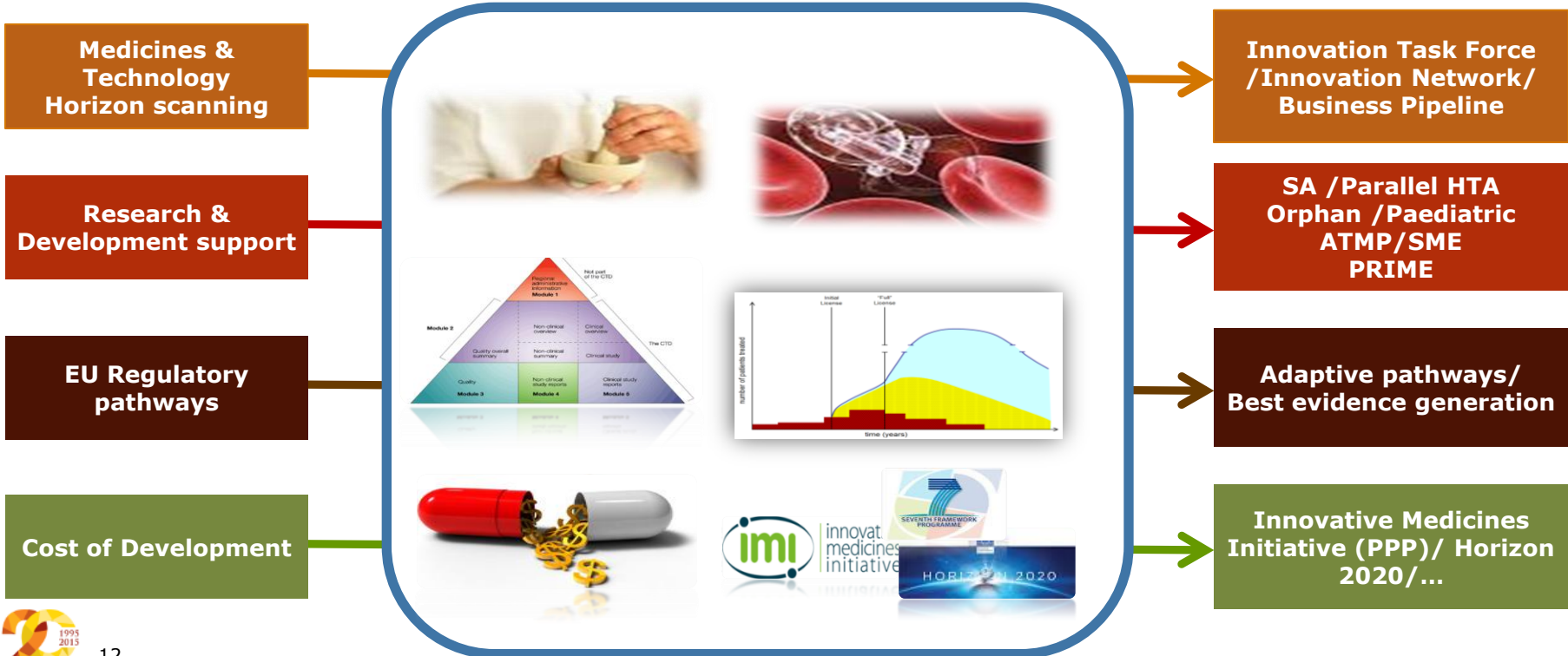
Strong EU Regulatory Network for sustainability and quality

- Hub of expertise for the centralised and national assessment
- Hub for local industry (*National scientific advice and link with the centralised advice*)
- Hub for pharmacovigilance and market surveillance capabilities
- Link to HC systems, Health Care Professionals and patients
- Hub for post marketing data generation (HTA/payers)

2 – EMA tools to support Innovation



Facilitating medicines research and development





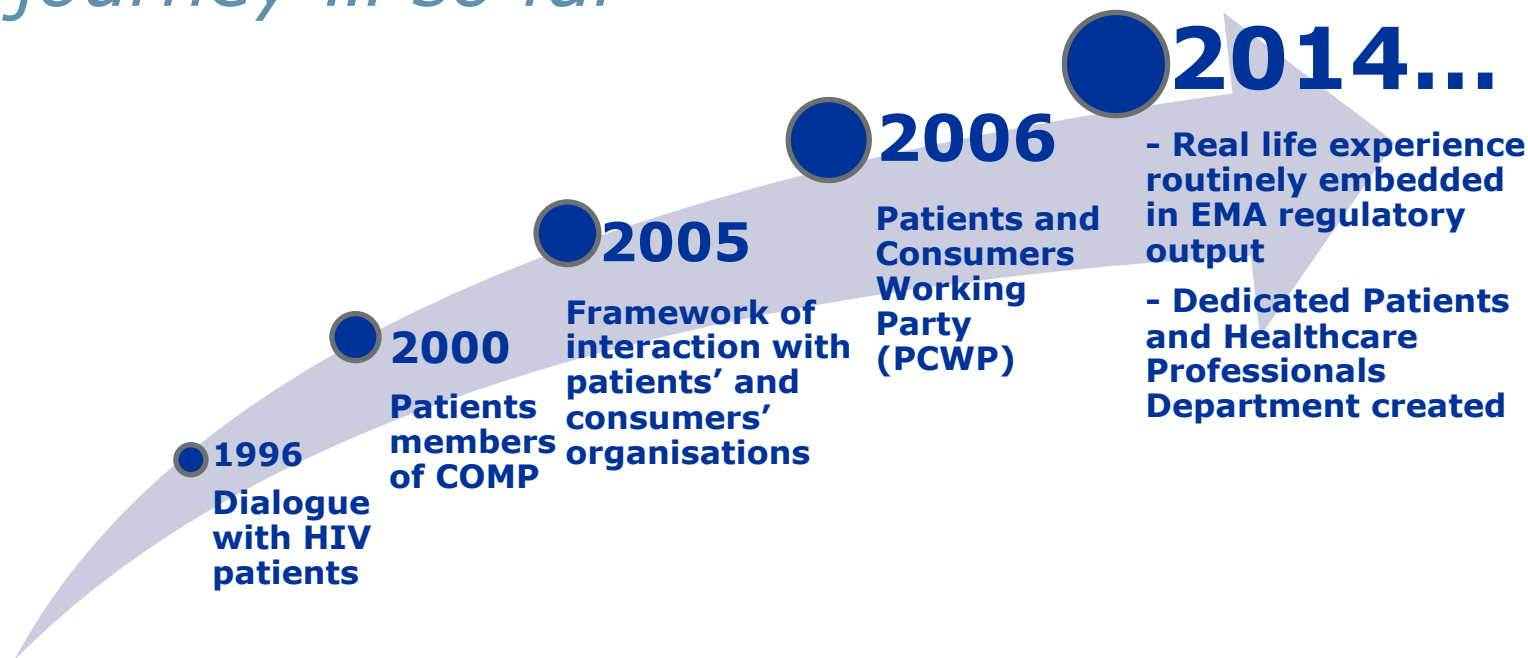
3 – Focus on Patients



Nothing About Us Without Us.

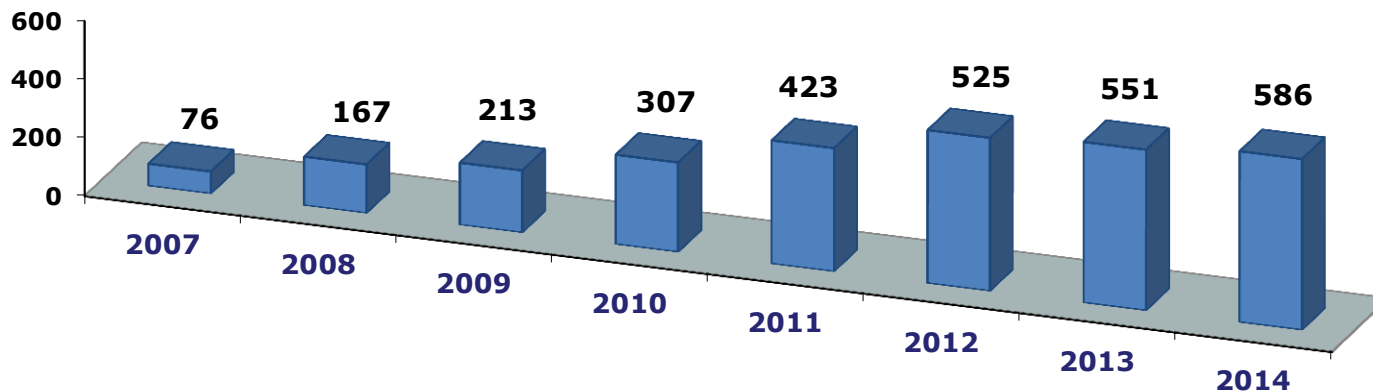


EMA interaction with patients: The journey ... so far



Increasing number of patients in EMA activities

**Number of cases of patient involvement in EMA activities
(2007–2014)**

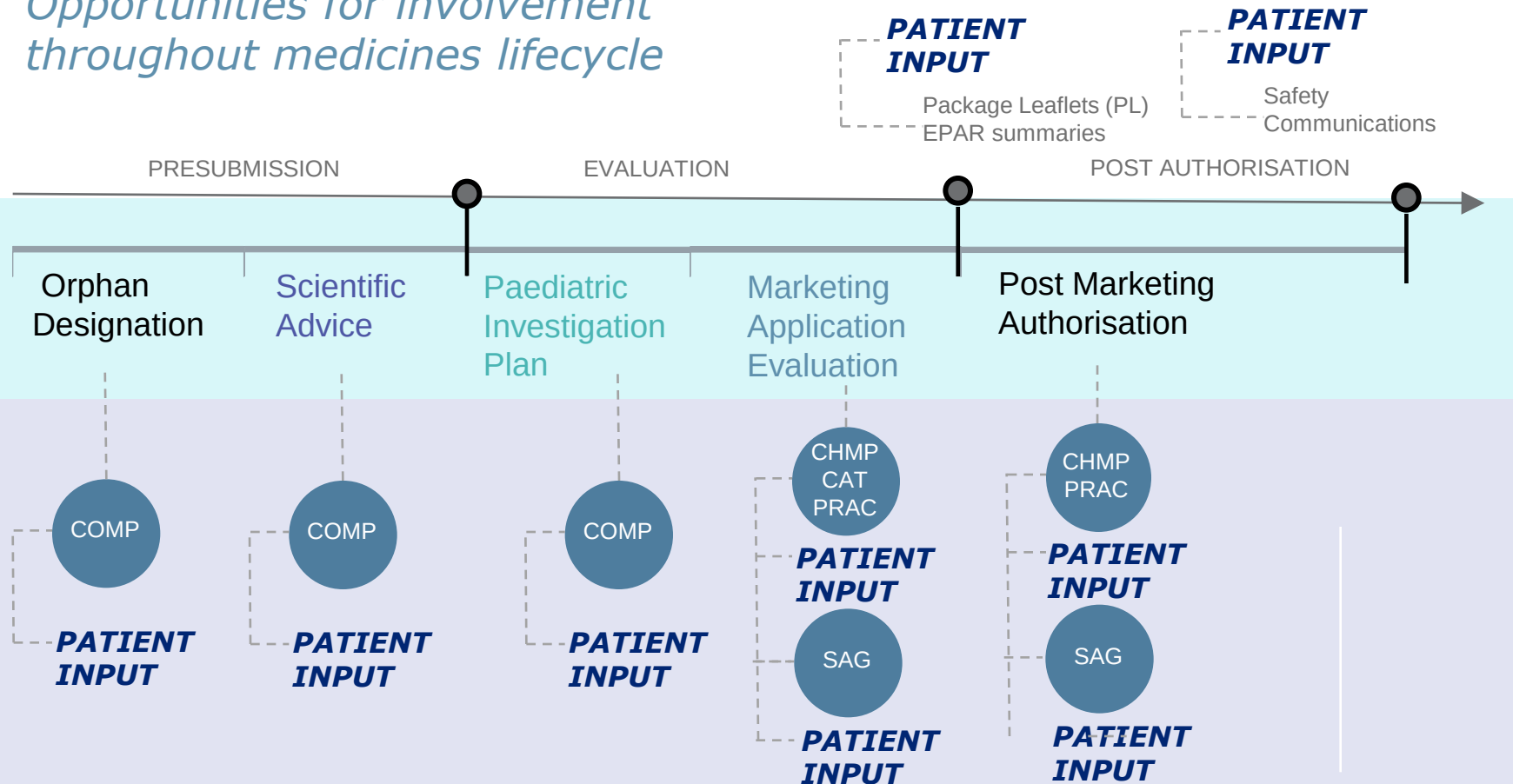


Opportunities for involvement throughout medicines lifecycle

DOCUMENTS
FOR THE PUBLIC

REGULATORY
PROCEDURE

COMMITTEES
AND WORKING
PARTIES





Thank you for your attention

Further information

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