EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU scientific regulatory support mechanisms and initiatives for innovation in drug development: the EMA perspective

FAMHP Workshop, Brussels, 2nd May 2016

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An agency of the European Union

Acknowledgments

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Agenda

- European Medicines Agency: introduction
- The EMA Innovation Task Force
- The EMA SME office
- Priority Medicines (PRIME) initiative
- The European Innovation offices Network

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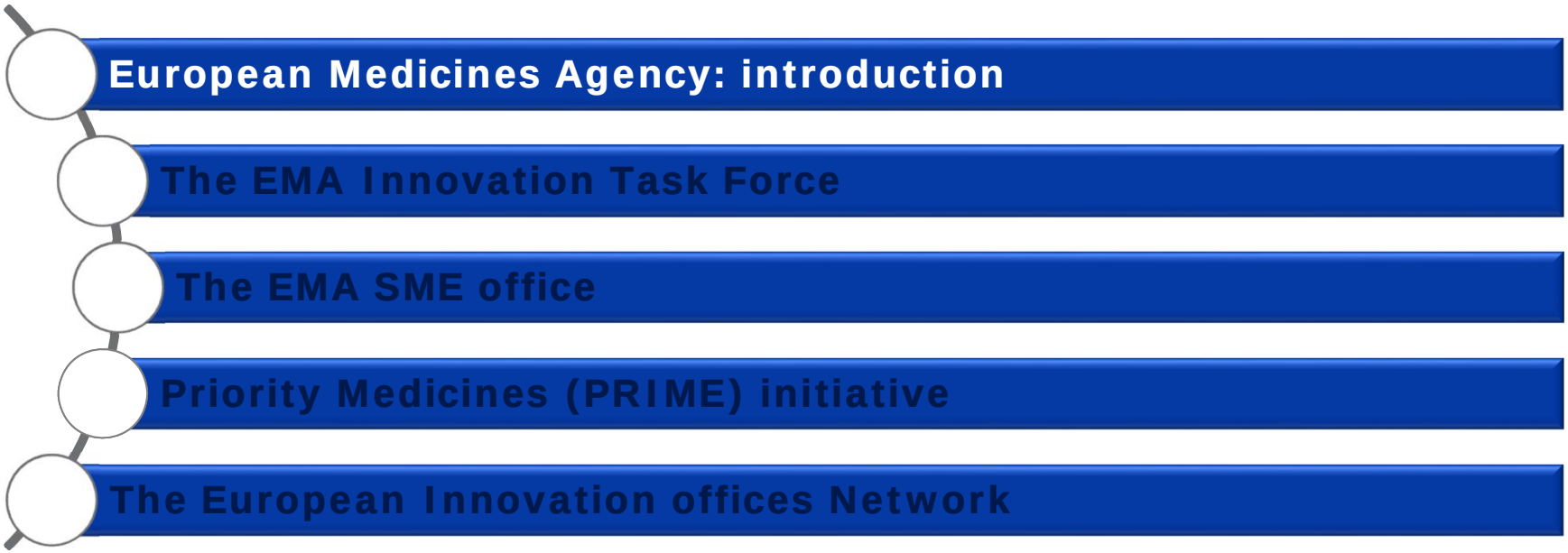
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EMA in the EU

Who do we work for?

tervist salud
zdravie saúde saħħa gezondheid
veselība
sundhed υγεία
zdrowie
Gesundheit
terveys здраве
egészségügyi
santé zdraví zdravie zdravlje
sveikata
health
zdravje hälsa
sláinte sănătate

over **500** million people living in the European Union

28 member states

27% of global sales of medicines

24 official languages

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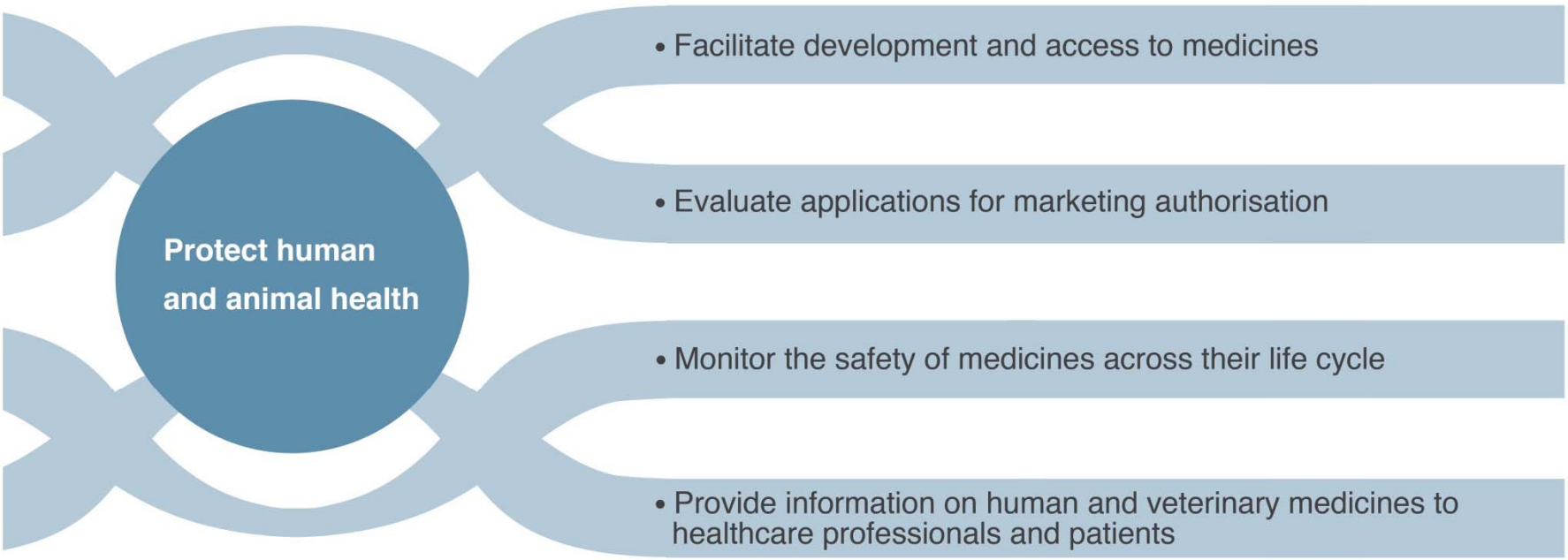
What do we do?



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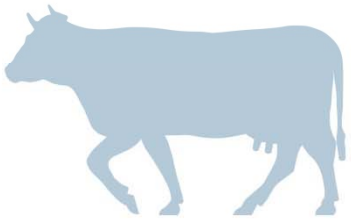
Who we are

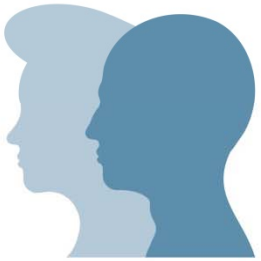
~4000 Scientific experts from right across Europe

7 Scientific committees

over 1000 marketing authorisations recommended



CHMP
CVMP
COMP
HMPC
PDCO
CAT
PRAC



1995 EMA established to evaluate medicines for use in the EU

28 Working parties

~890 Staff members

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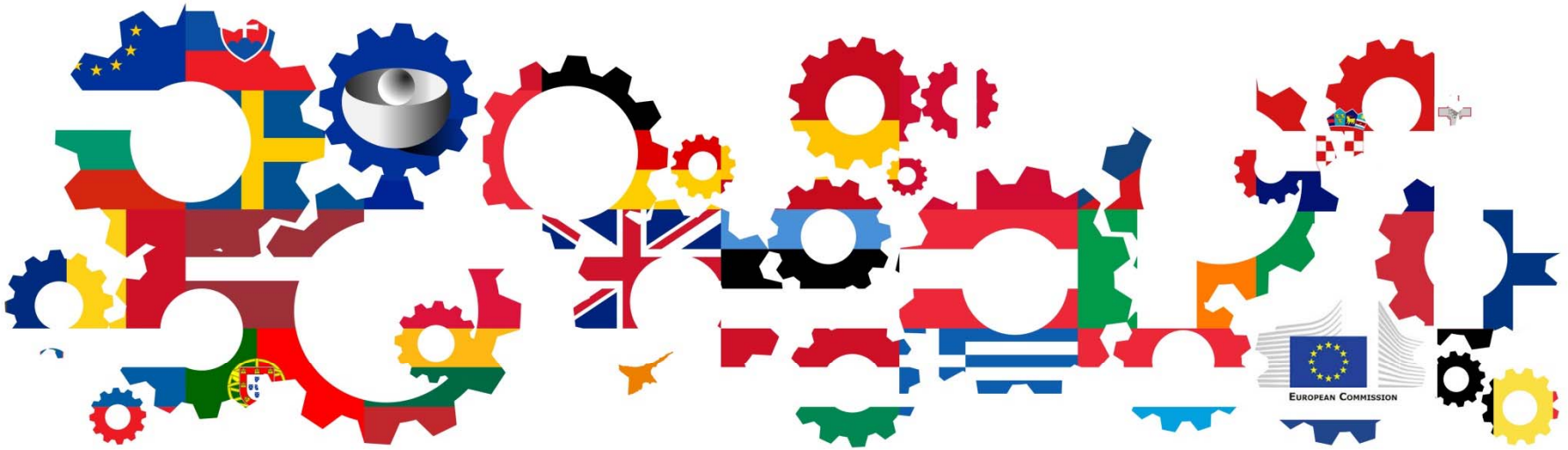
The European medicines regulatory network



~ 50 national regulatory authorities European Commission European Medicines Agency

How is EMA organised?

Management Board

Executive Director

EMA staff

CHMP | **CVMP** | **COMP** | **HMPC** | **PDCO** | **CAT** | **PRAC**

+ 28 working parties
+ 8 scientific advisory groups

National competent authorities
~4000 European experts

EU institutions

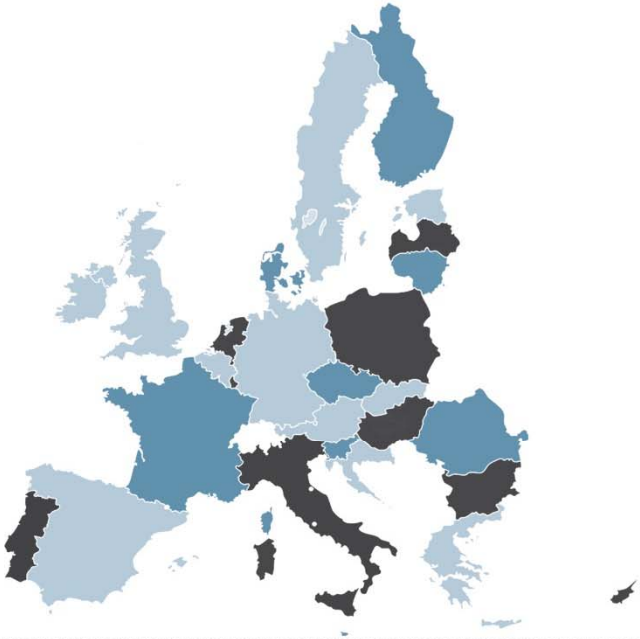
European Commission

European Parliament

How are medicines approved?

Different authorisation routes: one set of common rules

Centralised procedure (via EMA)



National procedures (via NCAs)

Which medicines are approved through the centralised procedure?

- Human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune, and other immune dysfunctions, and viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Officially designated 'orphan medicines' (medicines used for rare human diseases)

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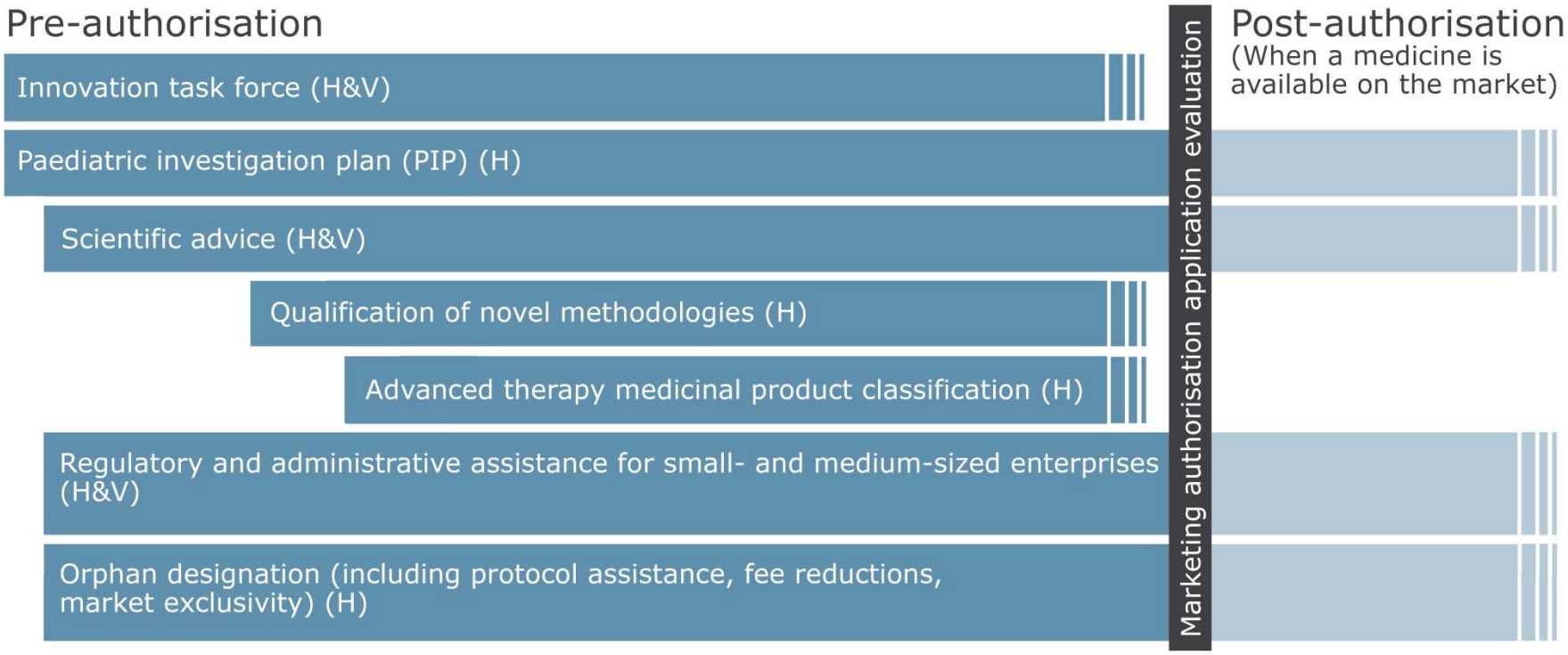
Supporting research and innovation of medicines



Innovation: origins of new medicines

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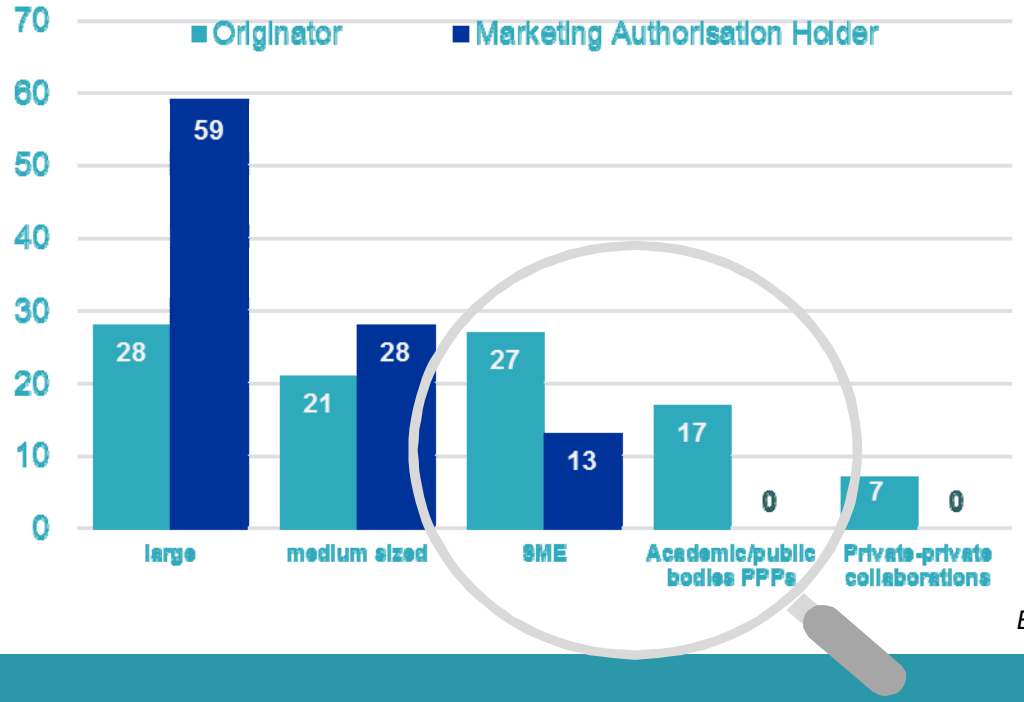

EU 2010-2012

Of 94 novel *authorised* medicinal products:

- Large majority marketed by large or intermediate sized companies.
- SMEs and academia at the origin of innovation.

Advancing public health

Innovation in healthcare brings new opportunities to treat certain diseases and is essential to advancing public health. Noteworthy therapeutic innovations in 2015 included:

Cancer	Blincyto - directing the immune system towards cancer cells Farydak - regulating the activity of genes Imlygic - using genetically engineered virus to kill cancer cells Opdivo, Nivolumab BMS and Keytruda - increasing the capacity of the immune system
Cardiovascular	Entresto - dual action to treat heart failure Repatha and Praluent - monoclonal antibodies to treat hypercholesterolemia
Haematology	Praxbind - targeted neutralisation of the anticoagulant effect of Pradaxa
Neurology	Wakix - action on histamine H3 receptors to treat narcolepsy

EU Medicines Agencies Network Strategy to 2020

Includes objectives to:

- Support for patient focused innovation and contribute to a vibrant life science sector in Europe
- Greater collaboration across network to support innovation
- Consider further regulatory incentives for innovation, particularly in certain areas of public health need

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EMA Innovation Task Force (ITF)

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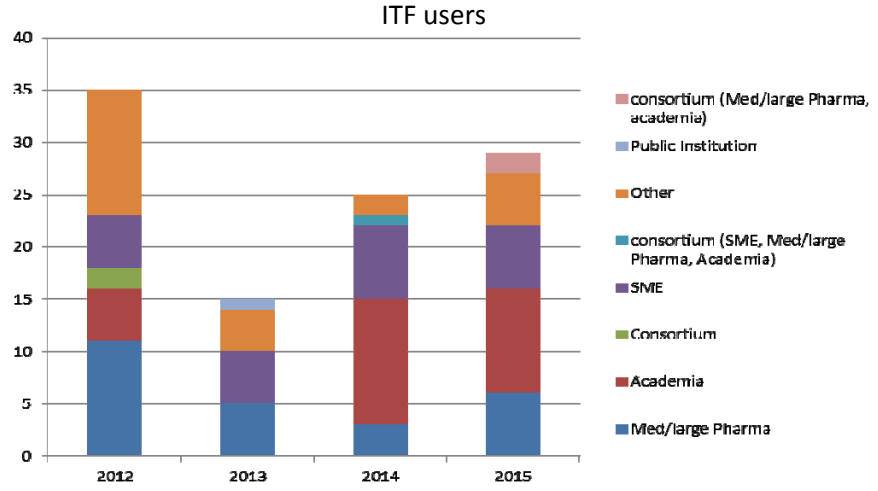
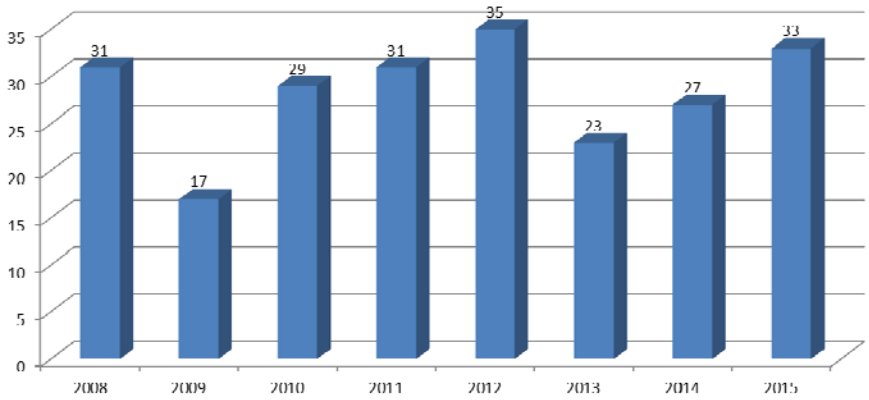
Multidisciplinary platform for preparatory dialogue and orientation on innovative methods, technologies and medicines

- Early dialogue on scientific, legal and regulatory issues
- Address the impact of emerging therapies and technologies on current regulatory system
- Identify the need for specialised expertise at an early stage
- Provide advice on the eligibility to Agency procedures relating to research and development, e.g. borderline products
- Increase awareness and learning in emerging therapies and technologies at the Agency

EMA ITF briefing meetings





- Informal exchange of information and provision of guidance early in the development process.
- Discussions led by experts from the Agency's network, working parties and committees
- Complement and reinforce existing formal regulatory procedures, such as ATMP) classification and certification, designation of orphan medicinal products and scientific advice.

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The EMA SME Office

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SME Office launch

December 2005.

A single interface

"One-stop-shop."

Assistance to SMEs

Regulatory, administrative and procedural support.

Facilitates communication

Of SMEs in veterinary and human pharma sector.

Coordinating & networking

Working closely with EU.

SME Office
tailoring assistance to SMEs

"A strategic regulatory toolbox to promote innovation and development of new medicines by SMEs."

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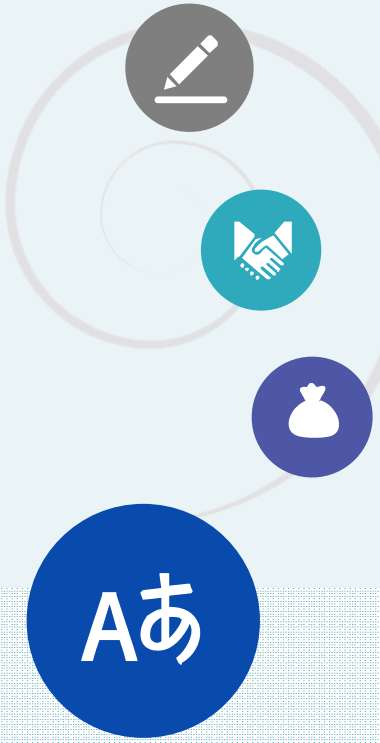
1. Validation of SMEs status
2. Regulatory Assistance
3. Fee Incentives
4. Translation Assistance
5. Training and Awareness



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PRIME scheme - Goal & Scope

To foster the development of ***medicines with major public health interest.***

Reinforce scientific and regulatory advice

- Foster and facilitate early interaction
- Raise awareness of requirements earlier in development

Optimise development for robust data generation

- Focus efficient development
- Promote generation of robust and high quality data

Enable accelerated assessment

- Facilitated by knowledge gained throughout development
- Feedback of relevant SA aspects to CHMP

Building on existing framework;

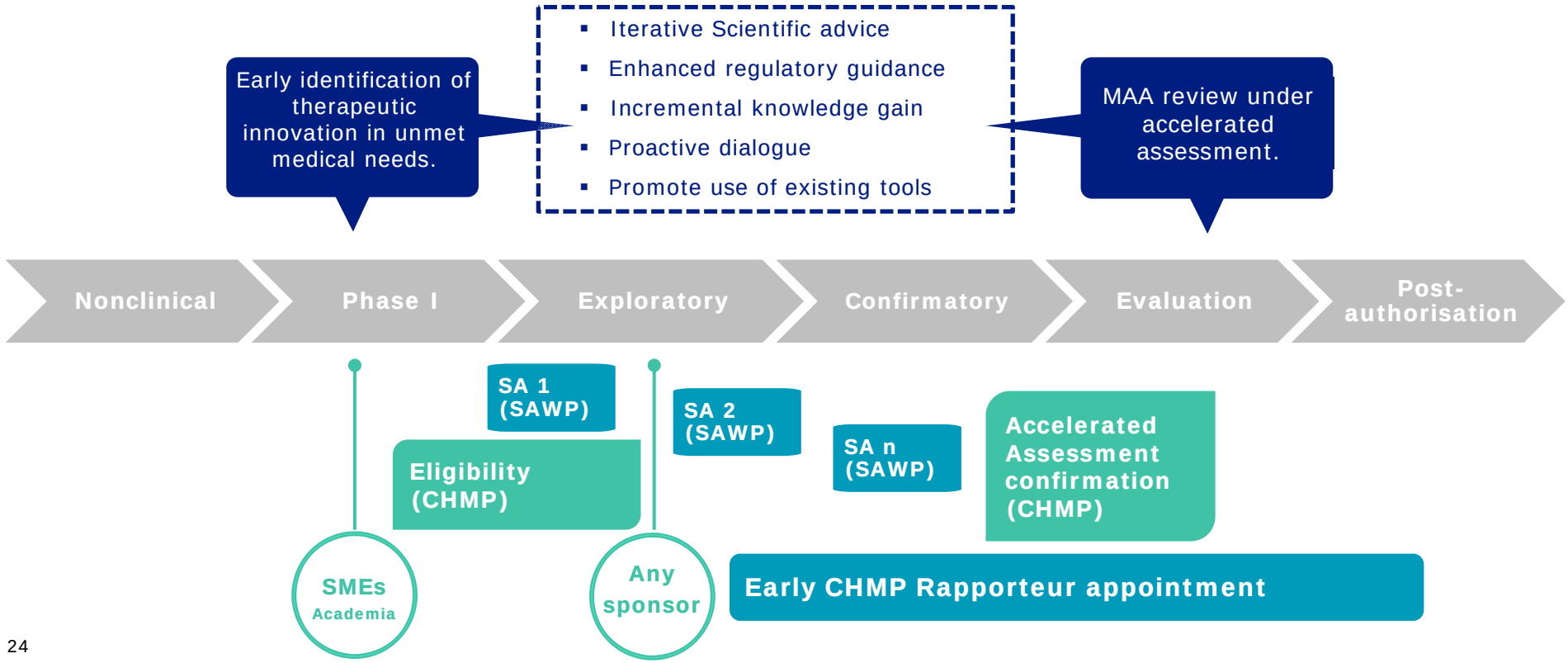
Eligibility according to existing 'Accelerated Assessment criteria'

Features of the PRIME scheme

Early access tool, supporting patient access to innovative medicines.

- **Written confirmation of PRIME eligibility** and potential for accelerated assessment;
- **Early CHMP Rapporteur appointment** during development;
- **Kick off meeting** with multidisciplinary expertise from EU network;
- **Enhanced scientific advice** at key development milestones/decision points;
- **EMA dedicated contact point**;
- **Fee incentives** for SMEs and academics on Scientific Advice requests.

Overview of PRIME scheme



Justification for eligibility to PRIME

For products under development yet to be placed on the EU market

Unmet medical need

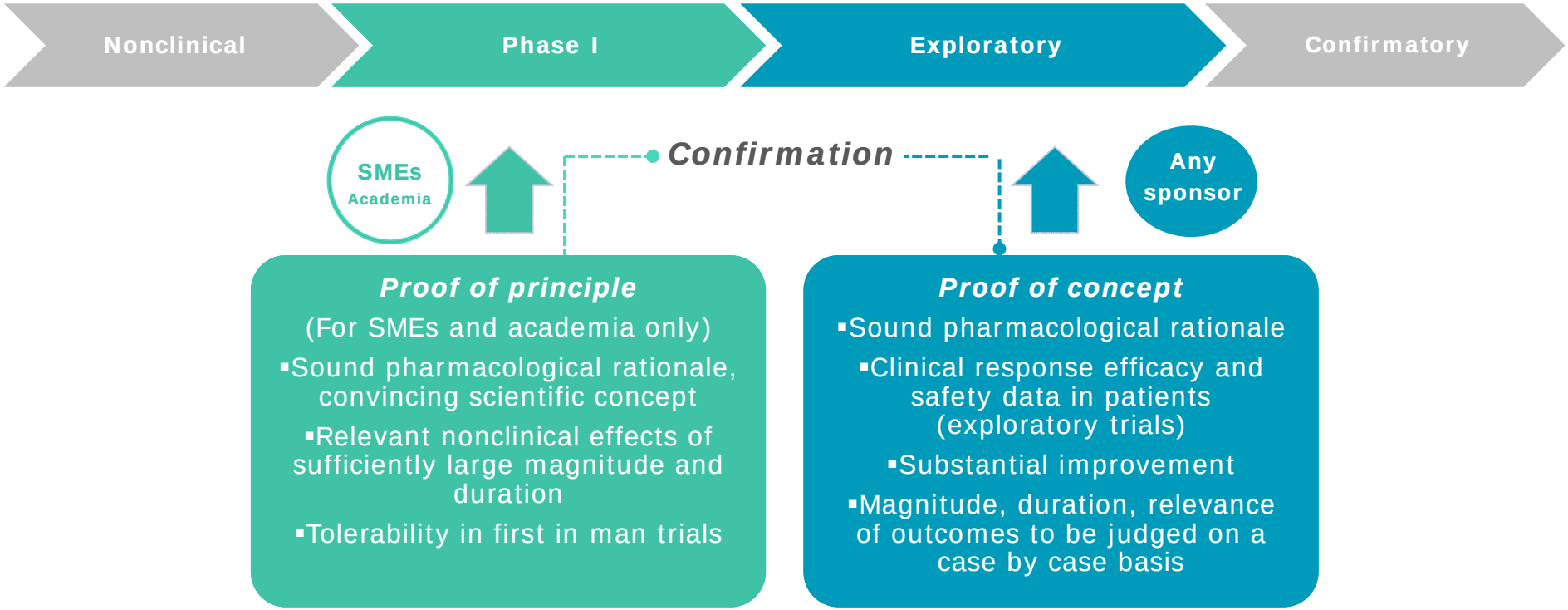
- Epidemiological data about the disease
- Description of available diagnostic, prevention and treatment options/standard of care (SOC), their effect and how medical need is not fulfilled

Potential to significantly address the unmet medical need

- Description of observed and predicted effects, clinical relevance, added value and impact
- If applicable, expected improvement over existing treatments

Data required at different stages of development

Entry points PRIME eligibility and required evidence



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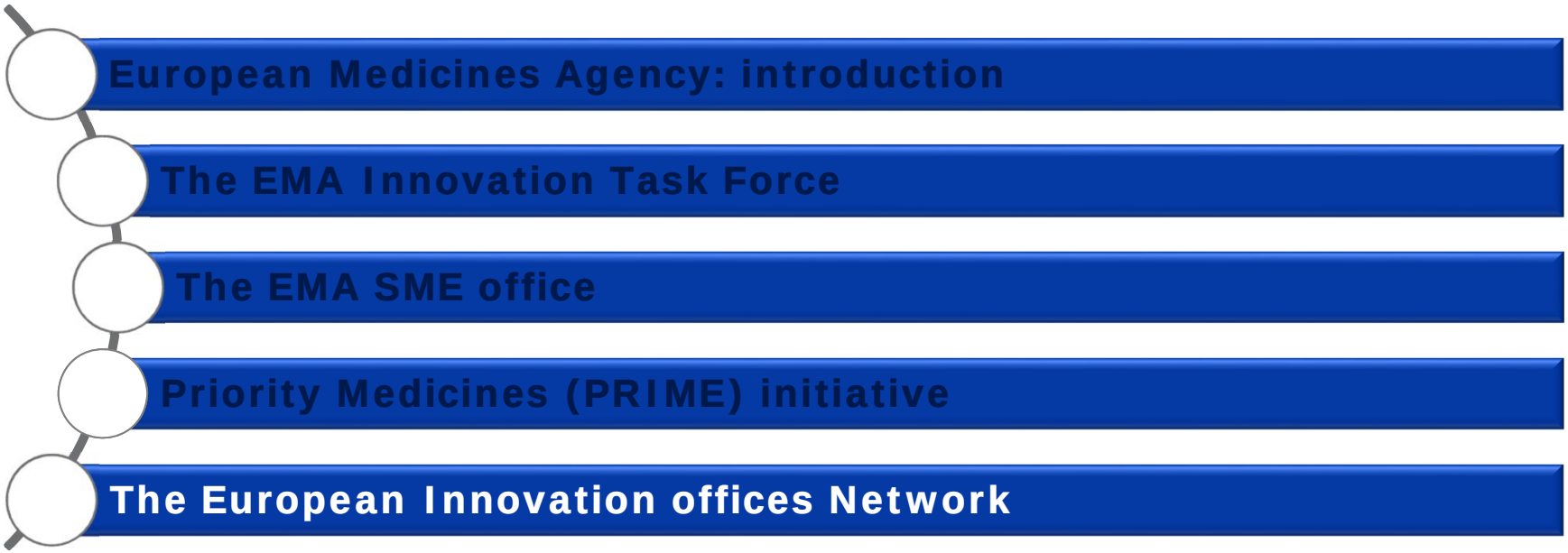
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EU innovation network (EU-IN)

EMA ITF + 12 National innovation offices/contact points

Regular teleconferences

Aims to share information related to innovative drug development and initiate early dialogue with developers

Supporting Innovation in the EU NCAs

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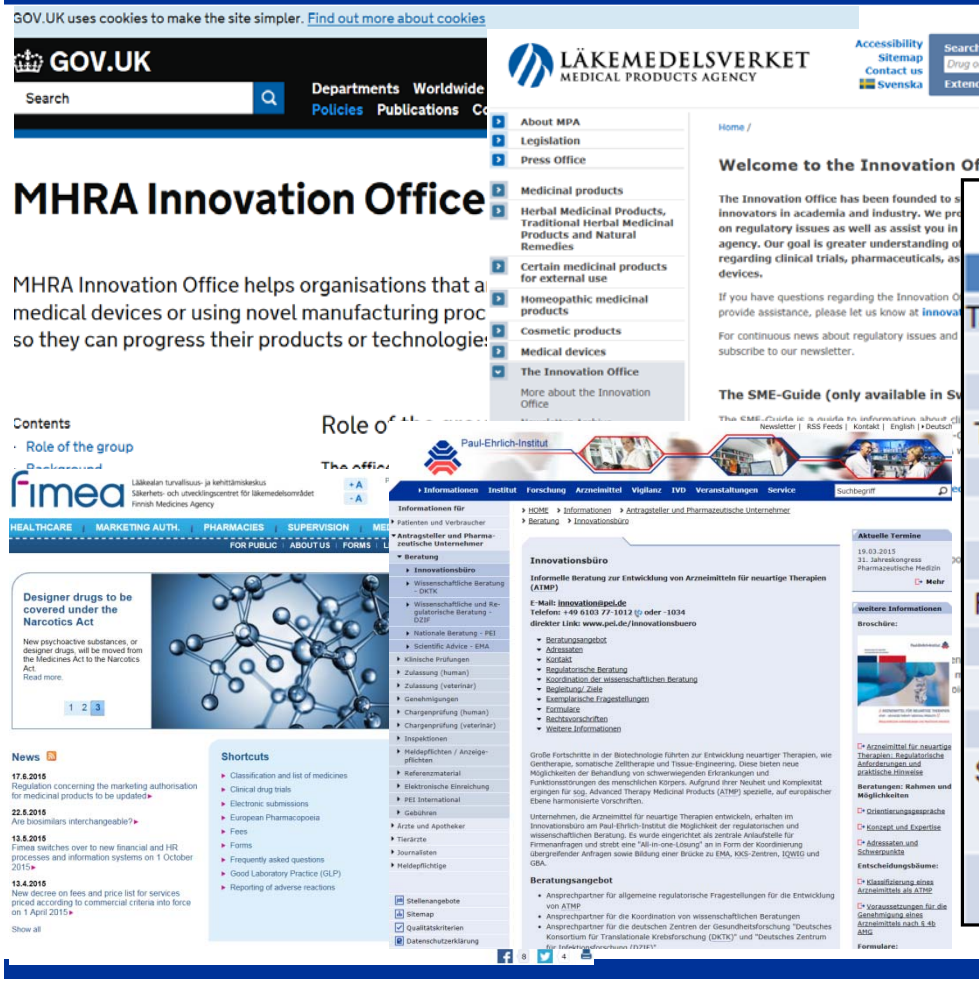
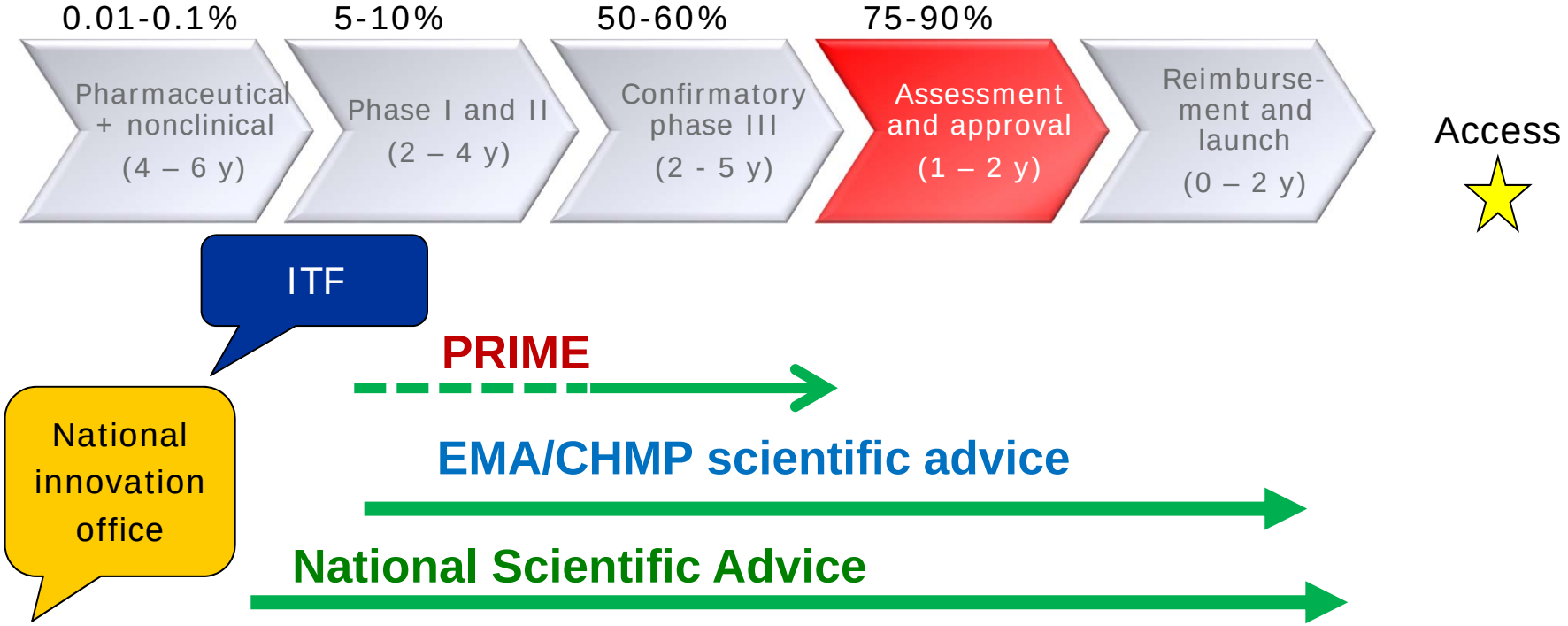


The core profile of an innovation office

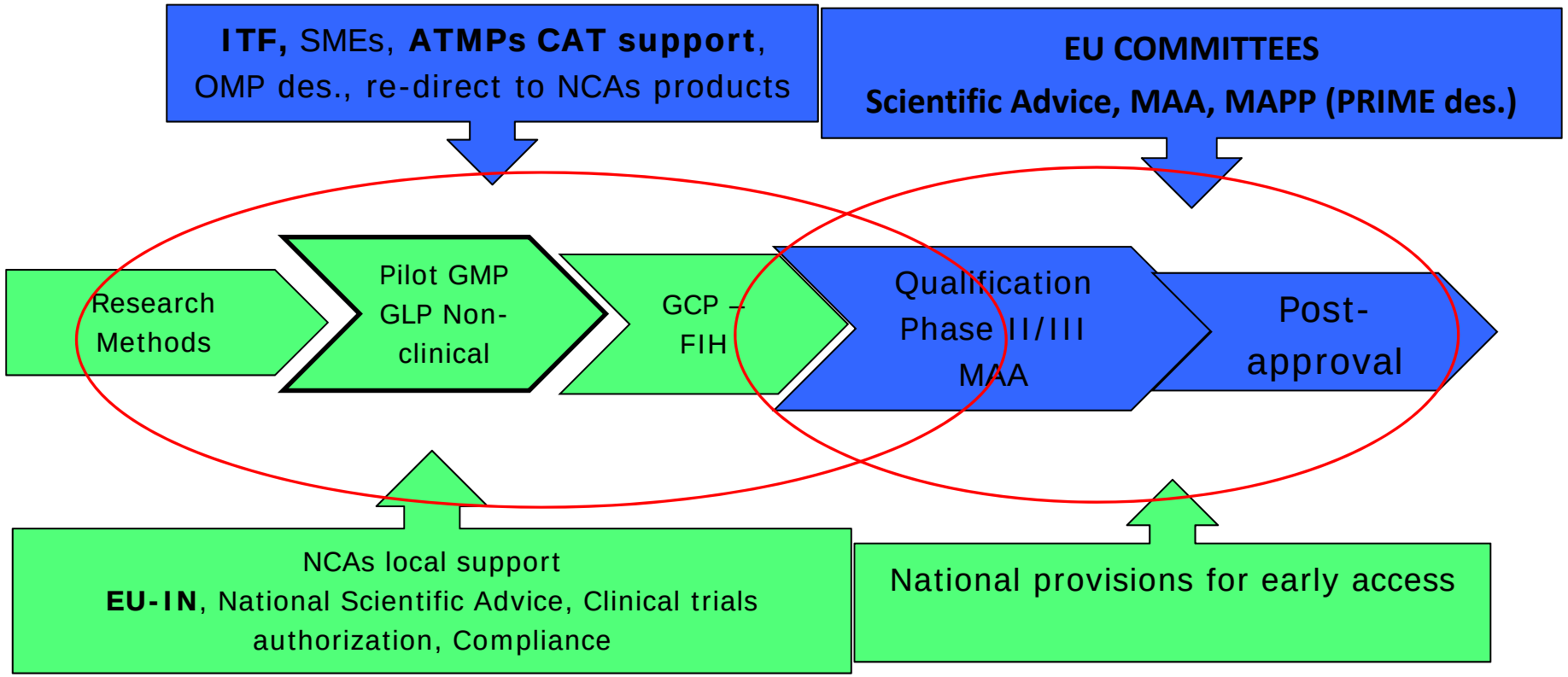
Target group	Hospitals units
	Start-ups
	SMEs
Target products	Chemical medicines
	Biological medicines + vaccines
	ATMPs
	Medical devices
Focus	Quality / viral safety
	Preclinical
	Clinical
	Regulatory
Services	A f2f meeting: Simple advice, referral to scientific advice or other competence
	Other information: website, Interaction with other stakeholders of innovation

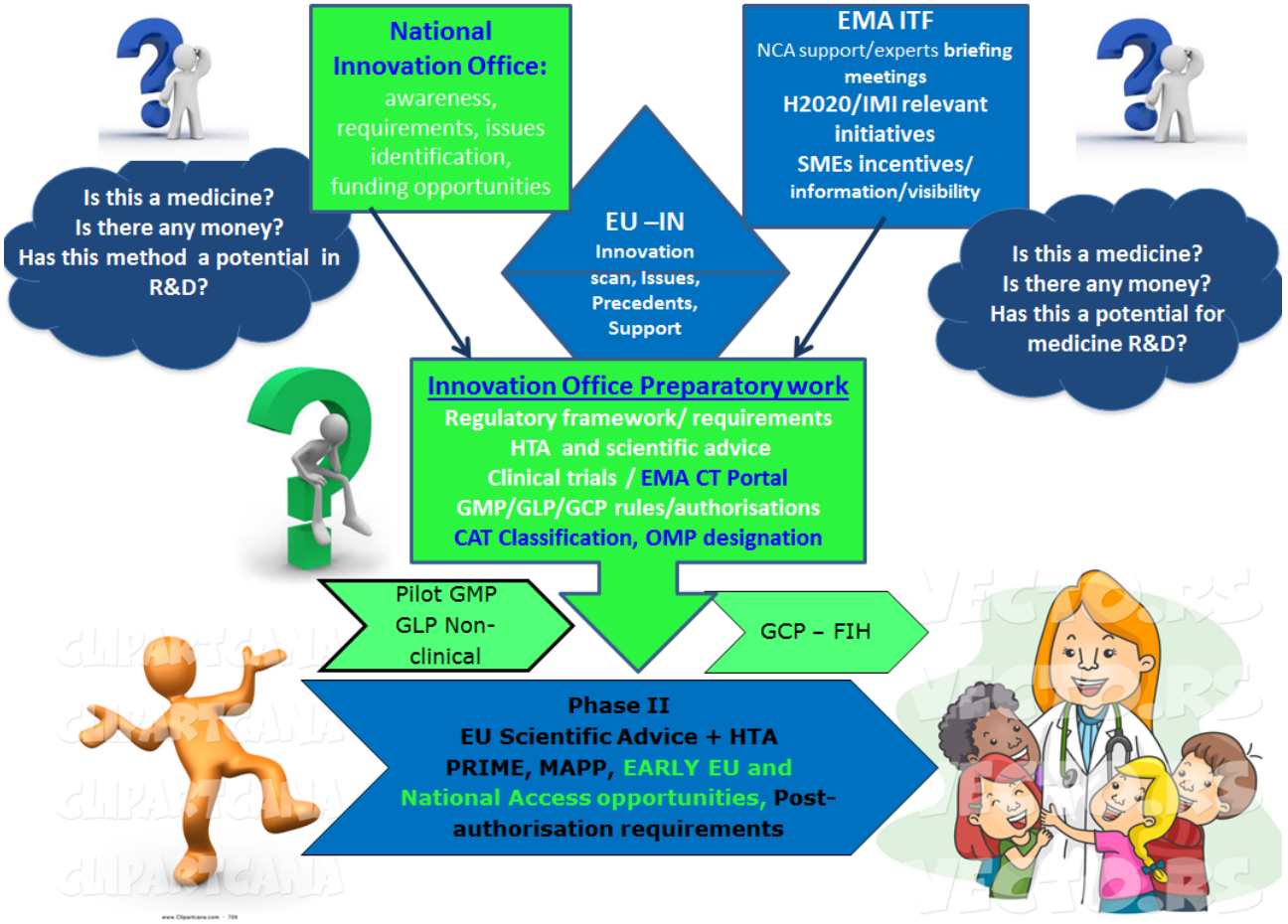
The typical long route of medicines to patients

Chance of reaching access for a product entering the development phase:

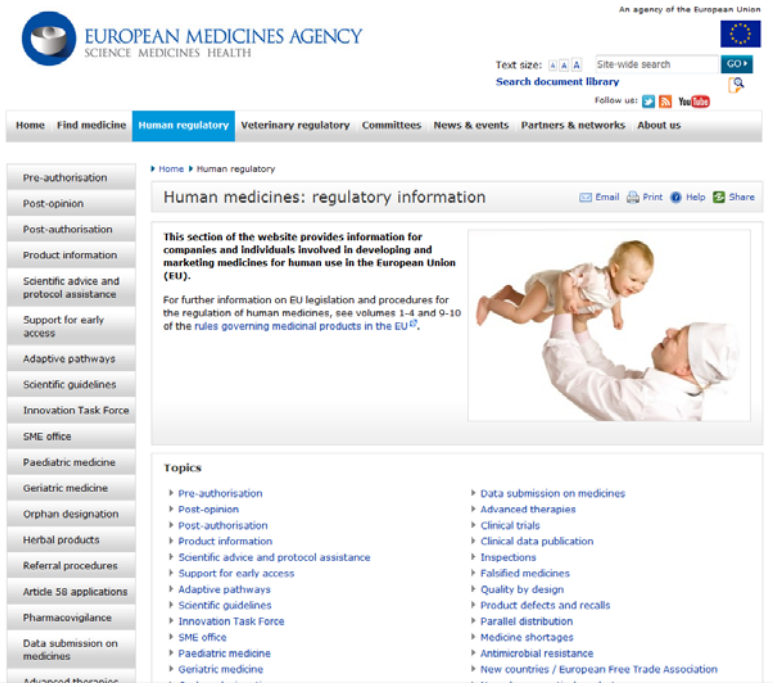


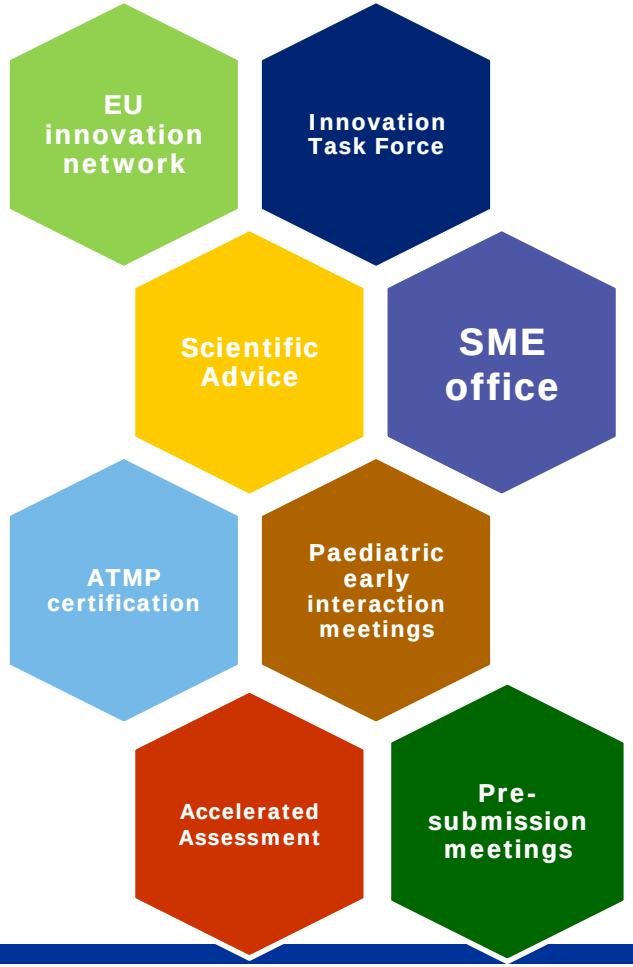
For an EU seamless support to Innovation




National Innovation Office: awareness, requirements, issues identification, funding opportunities
EMA ITF
NCA support/experts briefing meetings
H2020/IMI relevant initiatives
SMEs incentives/ information/visibility
EU –IN
Innovation scan, Issues, Precedents, Support
Is this a medicine? Is there any money? Has this method a potential in R&D?
Is this a medicine? Is there any money? Has this a potential for medicine R&D?
Innovation Office Preparatory work
Regulatory framework/ requirements
HTA and scientific advice
Clinical trials / EMA CT Portal
GMP/GLP/GCP rules/authorisations
CAT Classification, OMP designation
Pilot GMP GLP Non-clinical
GCP – FIH
Phase II
EU Scientific Advice + HTA
PRIME, MAPP, EARLY EU and National Access opportunities, Post-authorisation requirements

Collaboration across EU network to support innovation





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Thank you for your attention

Further information

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