

EMA Roundtable Meeting,
London, 27 November, 2015



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EU Innovation Network

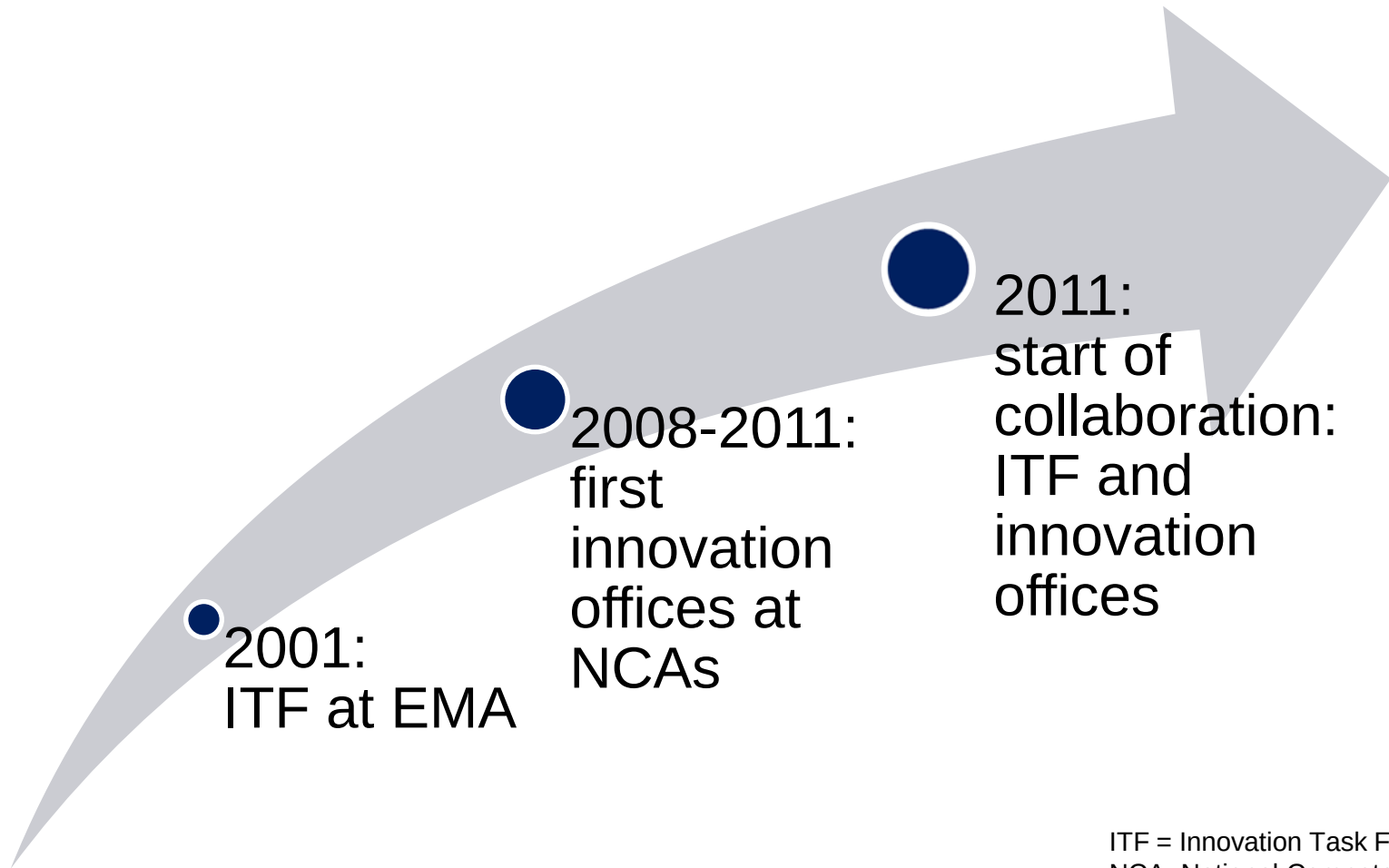
Paul-Ehrlich-Institut



Federal Agency for Vaccines and Biomedicines

Bettina Ziegele - Innovation Office

Start



ITF = Innovation Task Force
NCA=National Competent Authorities

Frame



- Network of innovation offices of NCAs*
- Coordinated by EMA: Marisa Papaluca
- Chair from NCA: Pekka Kurki
- Close cooperation with ITF
- Regular exchange via TCs



*Up to now:

Austria, Belgium, Finland, France, Germany, Italy, Malta, Netherlands, Spain, Sweden, UK

Identification of

Common frame:

units providing regulatory support to SMEs (and academia) developing innovative medicines

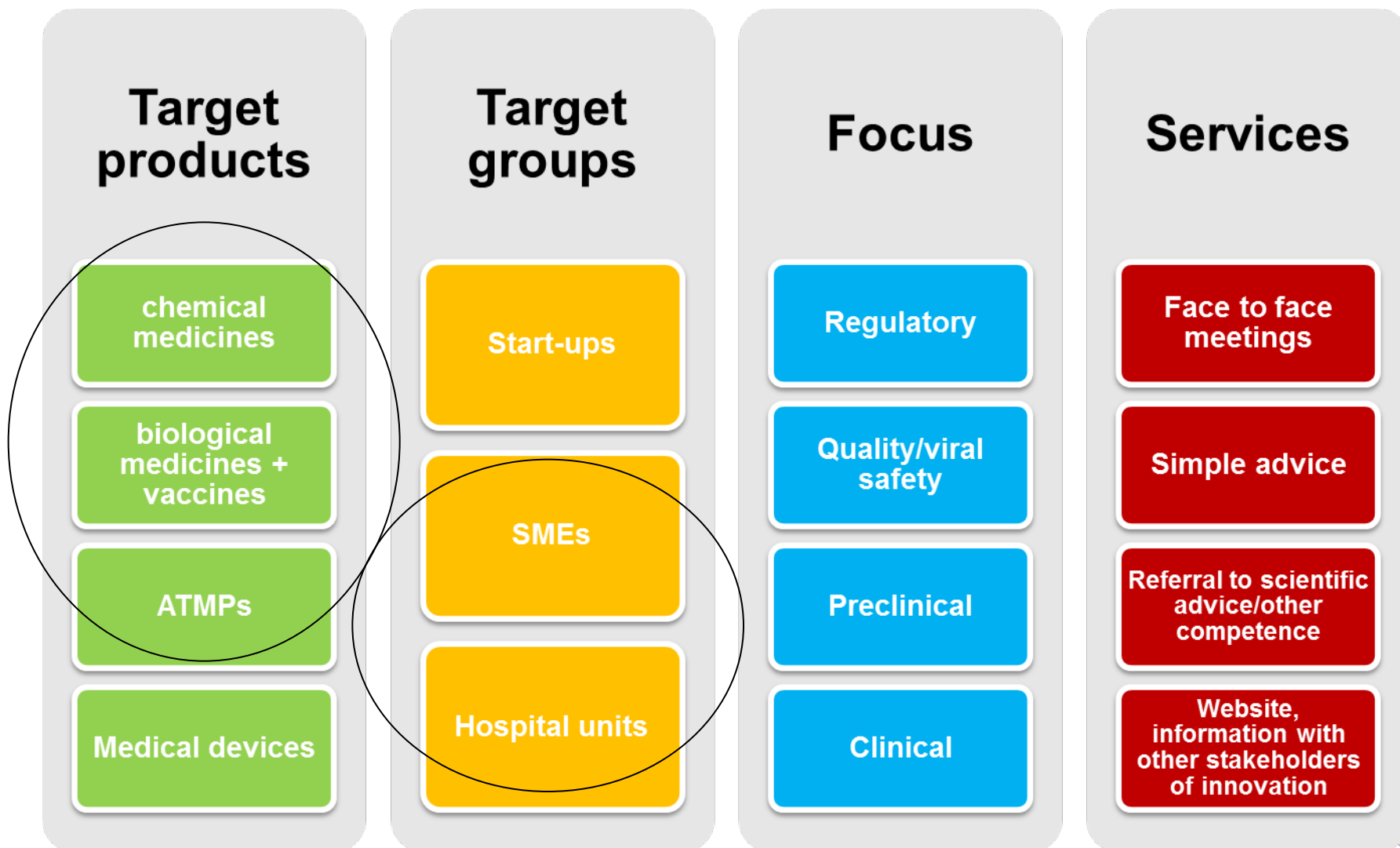
Common interest:

exchange information on challenging regulatory aspects and consistently guide promising (early) drug developments to the appropriate regulatory level(s)

Collaborative approach:

strengthen EU regulatory support to innovations and new concepts in pharmaceutical development

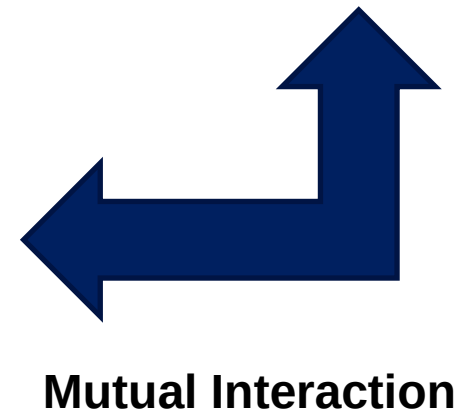
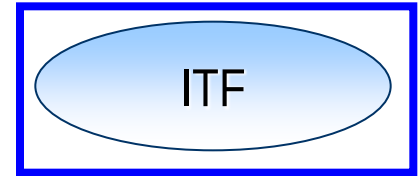
Core profile within the network



DIVERSITY IS THE STRENGTH to

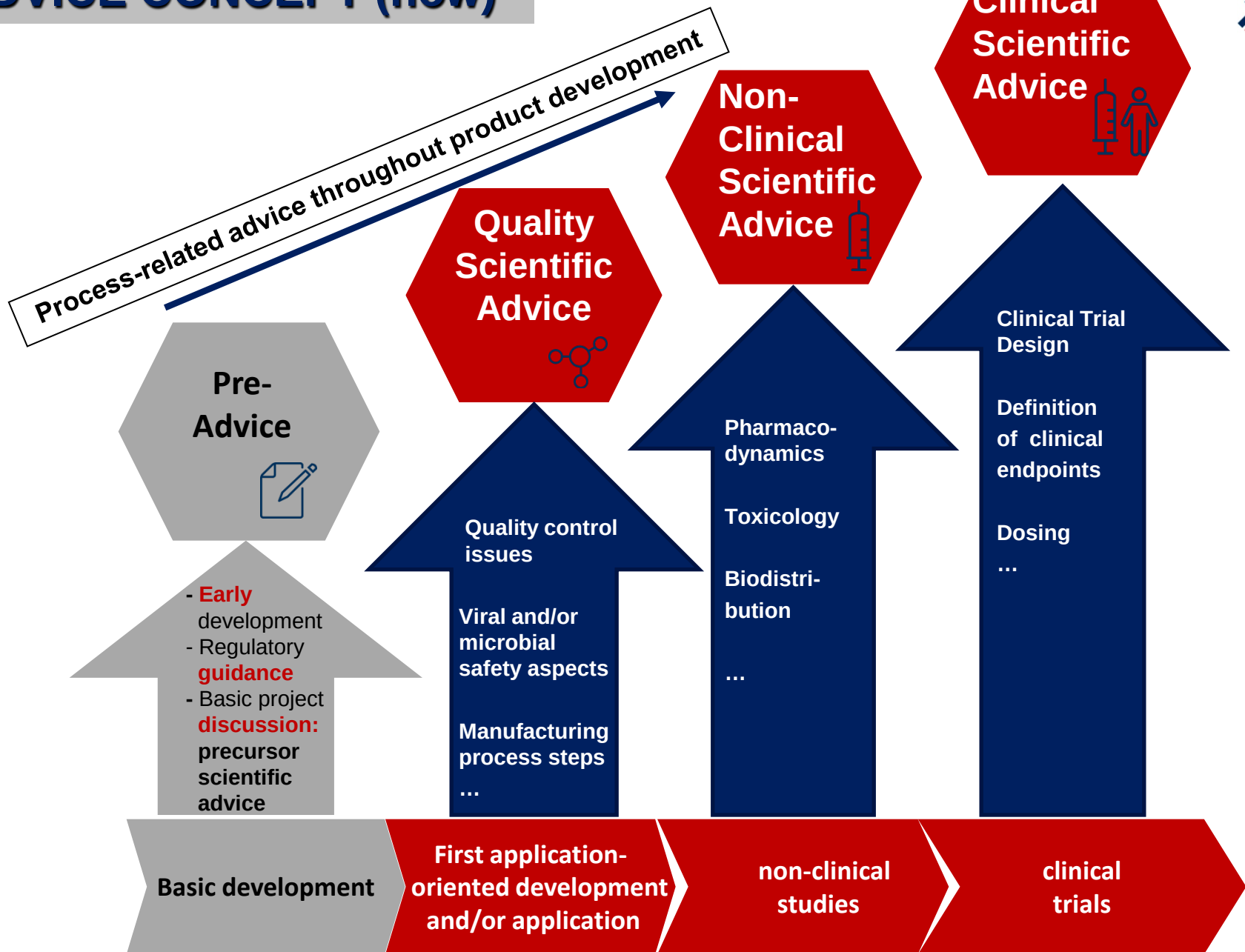


- share experience and knowledge, e.g. discuss case studies
- discuss best practices and establish innovation contact points
- reinforce the dialogue with innovators
- identify and analyse gaps in regulatory science
- identify priority areas with a need to develop supporting tools and communicate guidance, e.g. by reflection or white papers, publications etc.



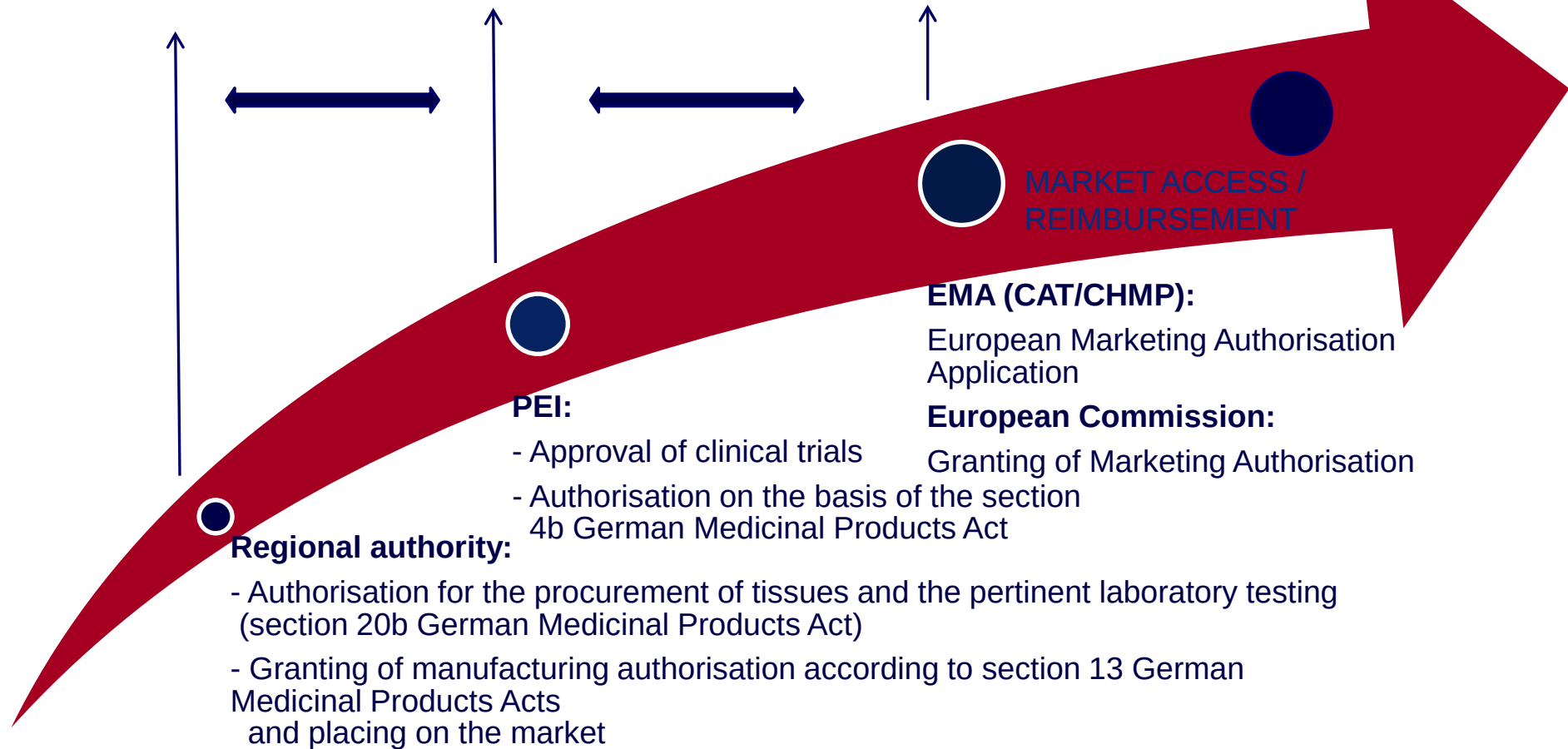
➡ „facilitate, educate, advices and gives guidance to further development“

ADVICE CONCEPT (now)



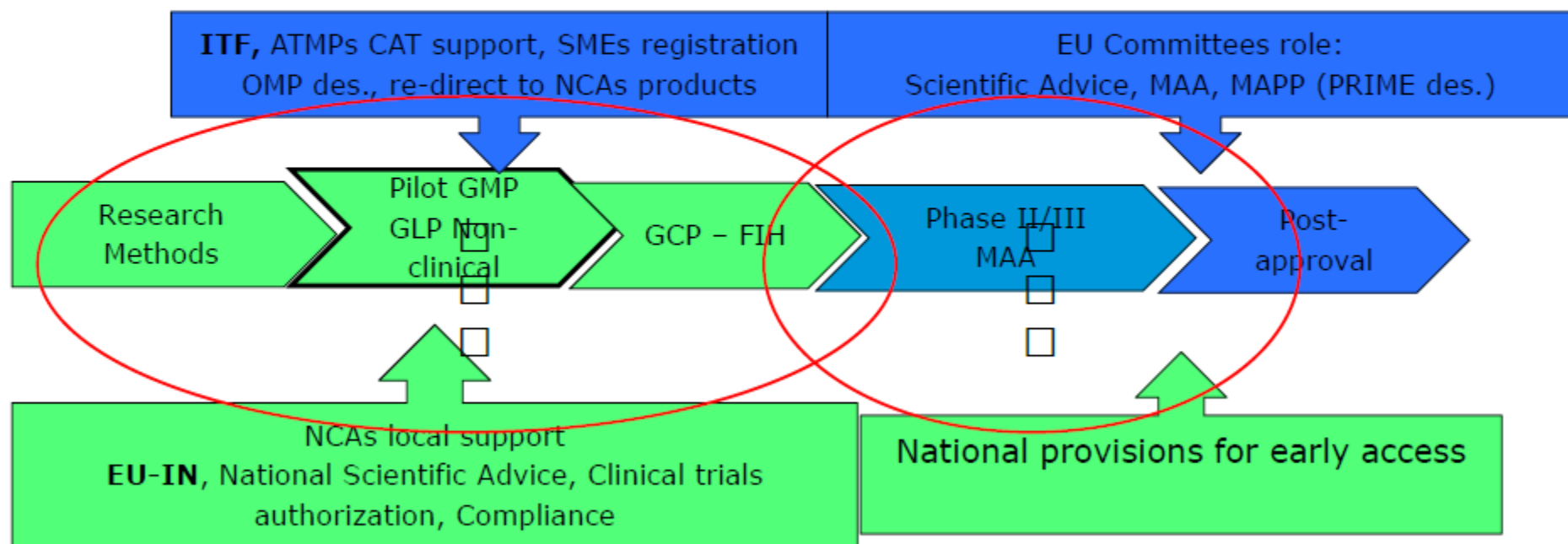
REGULATORY DEVELOPMENT OF AN ATMP

Classification as ATMP on basis of regulatory and scientific aspects



Supportive process-related advice throughout the development of the medicinal product

EU-IN for the EU seamless support to Innovation



National and EU-advice overlap in a rolling assessment procedure

AIMS...



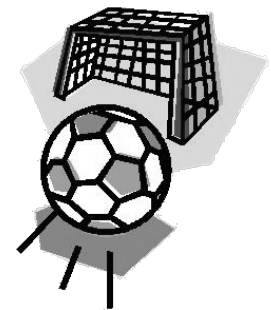
Thank you for your attention...



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...and hope to see you soon...



DISCLAIMER

The views expressed in this presentation are the views of the author.

Decision are made while considering individual cases on scientific grounds.

Neither the Paul-Ehrlich-Institut nor its experts obtain any finances from industry developing medicinal products.

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