EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

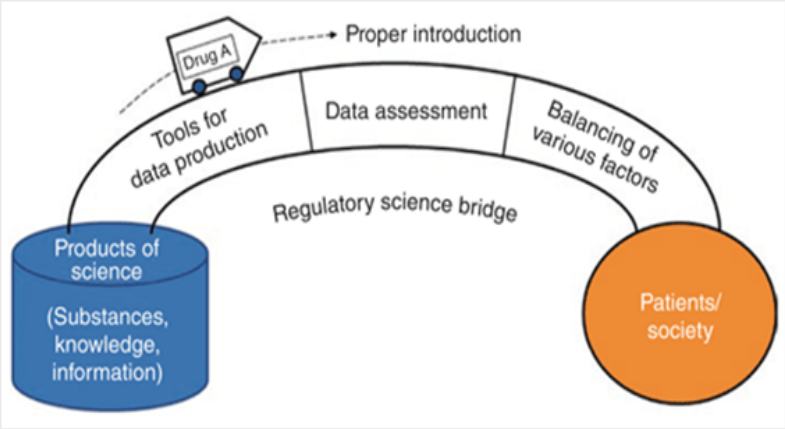
Innovation Task Force

SME workshop April 2013

Marisa Papaluca,M.D. Ph.D.
Head of Scientific Support and Projects
European Medicines Agency

Presented by: Marisa Papaluca

Regulators and science



The regulatory science "bridge" as a means to introduce products of science to patients and to society. Regulatory science performs three functions: providing tools for data production, a basis for data assessment, and methods for balancing various factors. All three functions are indispensable to a proper introduction of a new product of science (here, "Drug A").

FROM:
Regulatory Science as a Bridge Between Science and Society
T Tominaga, Y Asahina, Y Uyama and T Kondo
Clinical Pharmacology & Therapeutics ISSN: 0009-9236 EISSN: 1532-6535

Regulatory science

Regulatory science consists of the areas of science that are used in the assessment of the quality, safety and efficacy of medicines throughout their life-span, as well as the scientific areas used in regulatory decision-making.

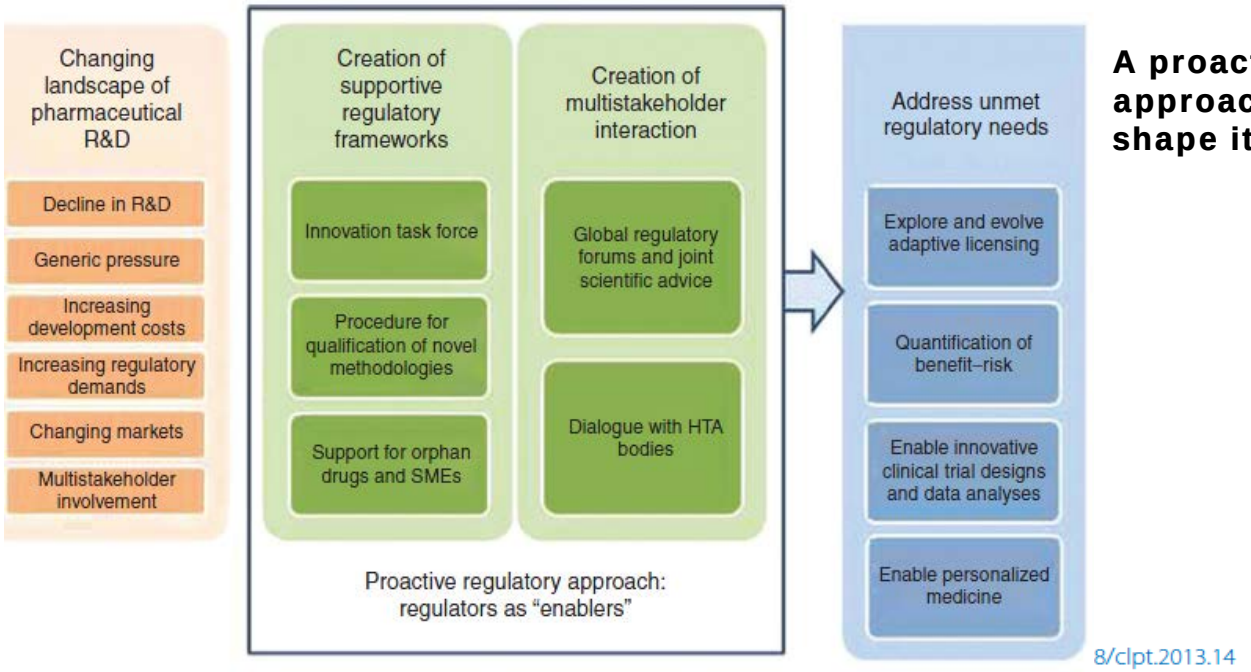
Basic and applied *biomedical sciences*, including chemistry, physics, genetics, pharmacology, biostatistics, [...], and social sciences such as *decision sciences*, *risk assessment* and *communication sciences*.

It aims to contribute towards the development of medicines, standards and tools [...]

Gatekeepers and Enablers: How Drug Regulators Respond to a Challenging and Changing Environment by Moving Toward a Proactive Attitude

F Ehmann[1,2], M Papaluca Amati[2], T Salmonson[3,4], M Posch[5], S Vamvakas[6], R Hemmings[7,8], HG Eichler[9] and CK Schneider[10,11]

This article analyzes the role of regulatory authorities in facilitating innovation in the pharmaceutical sector. We describe how regulators are expanding their role to be not only gatekeepers but also enablers of development. They have already responded to the challenging and changing environment by moving toward a proactive attitude beyond evaluation of products, thereby more actively contributing to their development. Regulators have to continuously evolve their knowledge and standards alongside evolution in science. Creation of supportive regulatory frameworks and multistakeholder interaction will help address unmet regulatory needs.



A proactive regulatory approach: "Be part of it and shape it together."

8/clpt.2013.14

EMA Innovation Task Force/ Biomarkers Qualification/Scientific Advice

Innovation Task Force (ITF)

The **Innovation Task Force (ITF)** is a multidisciplinary group that includes scientific, regulatory and legal competences, set up to ensure Agency-wide coordination in the areas of interest and to provide a forum for early dialogue with applicants.

- Mandate of the Innovation Task Force
- Medicines and emerging science

Briefing meetings

The scope of the briefing meetings covers regulatory, technical and scientific issues arising from innovative medicines development, new technologies and borderline products.

The ITF, within 60 days of receipt of a valid request from an applicant, arranges free-of-charge briefing meetings to facilitate the informal exchange of information and the provision of guidance early in the development process.

The scientific discussions are led by experts from the Agency network, working parties and committees, where the best available scientific expertise is represented.

Briefing meetings are meant to complement and reinforce existing formal regulatory procedures (e.g. ATMP classification, ATMP certification, designation of orphan medicinal products, CHMP scientific advice, etc).

- Standard Operating Procedure for organisation of briefing meetings

Microsoft office documents

Important note on document formats: All Microsoft Office documents submitted to the European Medicines Agency must be in a format compatible with MS Office 2003. Office 2007 and Office 2010 formats cannot currently be accepted.

Contact point:

Requests for information on the ITF should be sent to ITFsecretariat@ema.europa.eu and/or info@ema.europa.eu

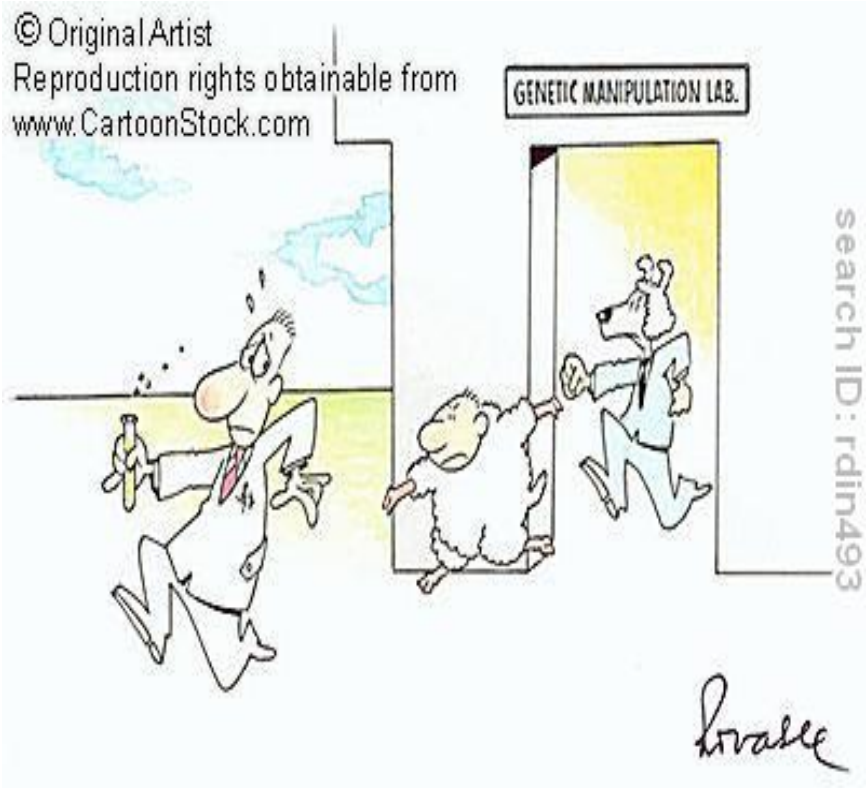
Innovation Task Force (ITF)

Multidisciplinary platform

for **preparatory dialogue and orientation on**

innovative methods and medicines

ITF Established in 2001 …→ horizon scanning and preparedness



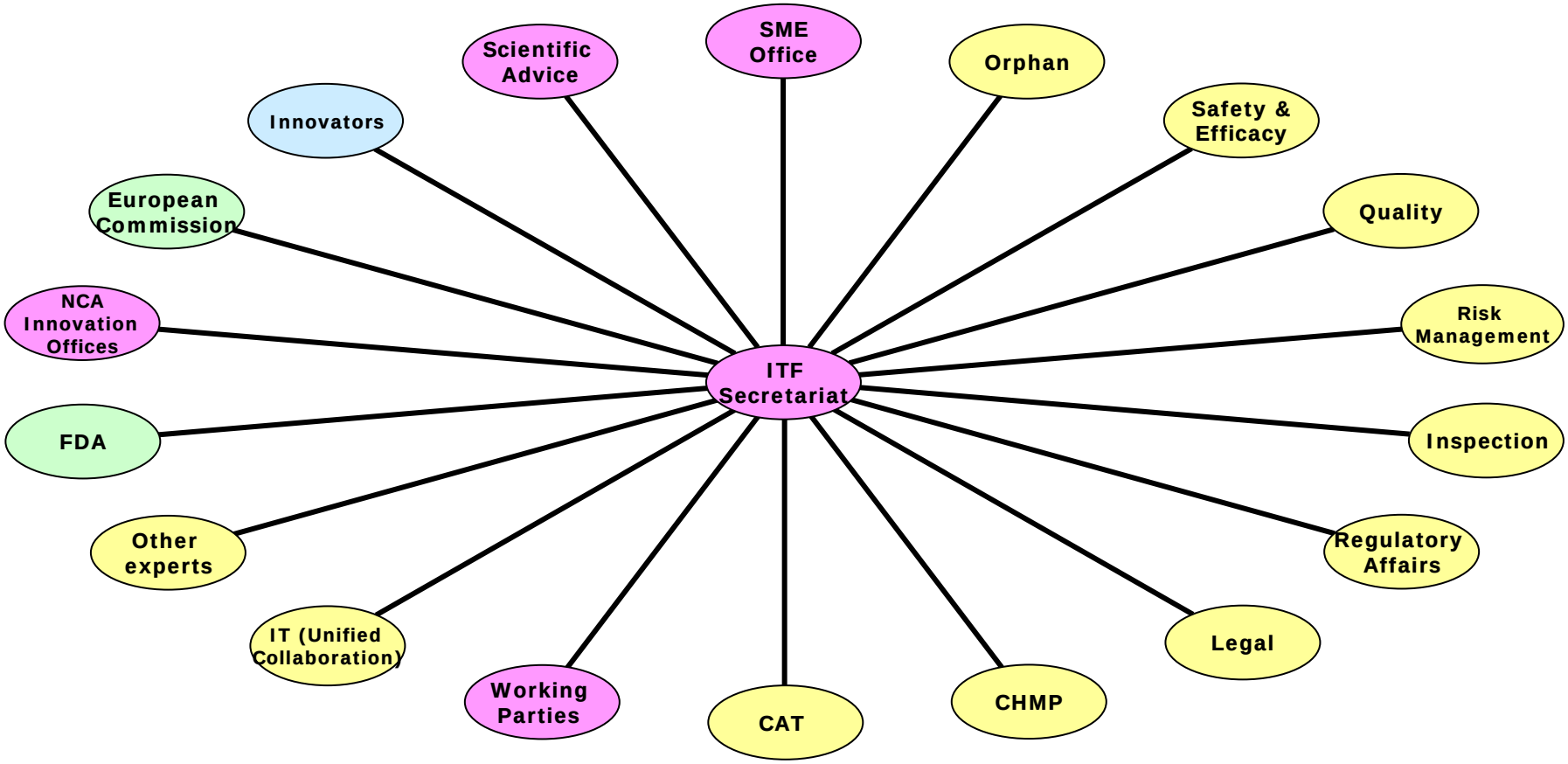
- Briefing meetings with innovators
- ATMP classification review
- Borderline and combination products

e.g. devices, cosmetics, food

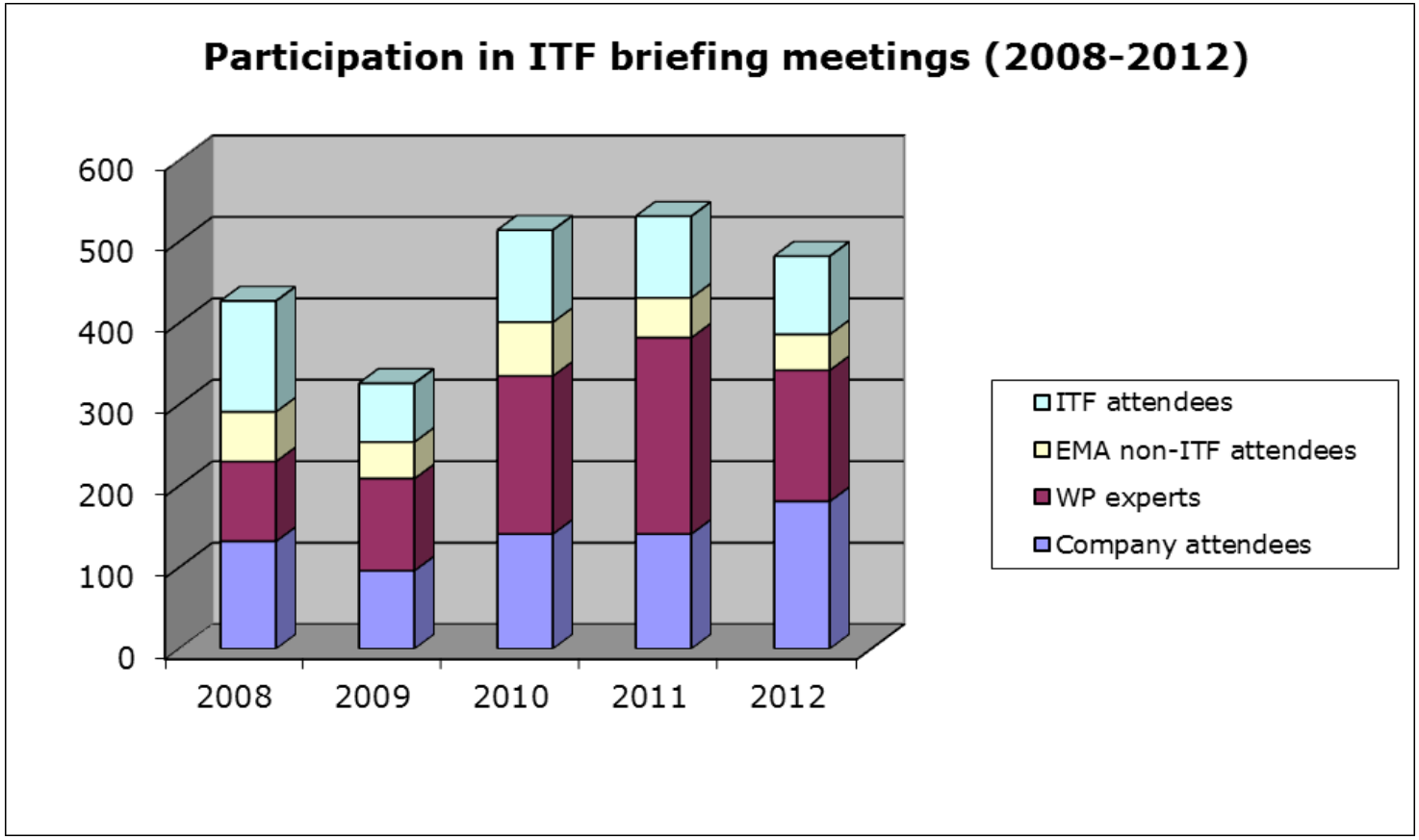
- Emerging therapies, methods and technologies

e.g. Genomics Biomarkers, Epigenetics, Novel non-clinical models, Nanomedicines, Synthetic Biology, Statistical models, etc.

ITF multidisciplinary network



ITF multidisciplinary network



ITF briefing meetings: innovation platform

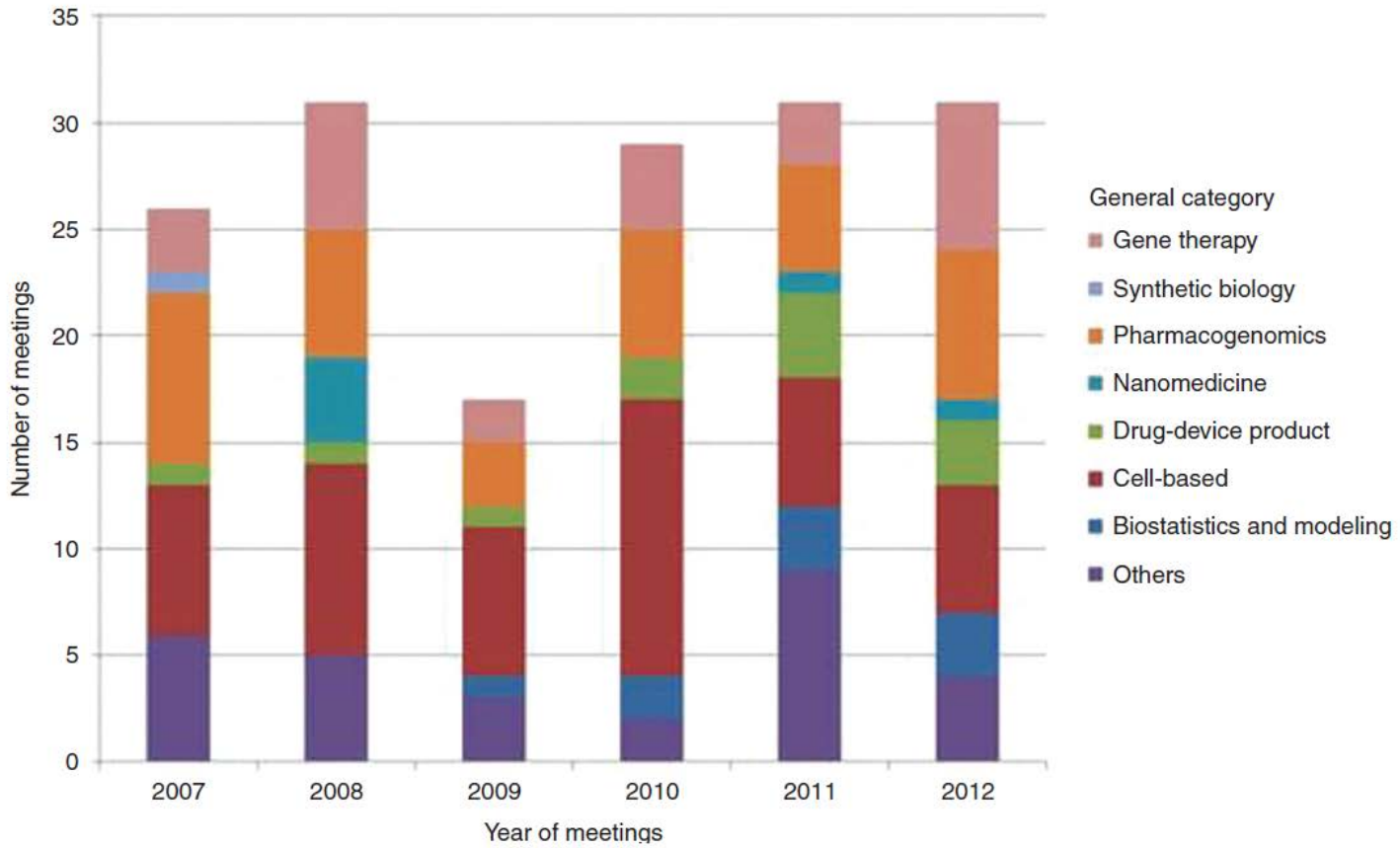


Figure 2 Numbers of innovation task force briefing meetings at the European Medicines Agency per year by different main category.

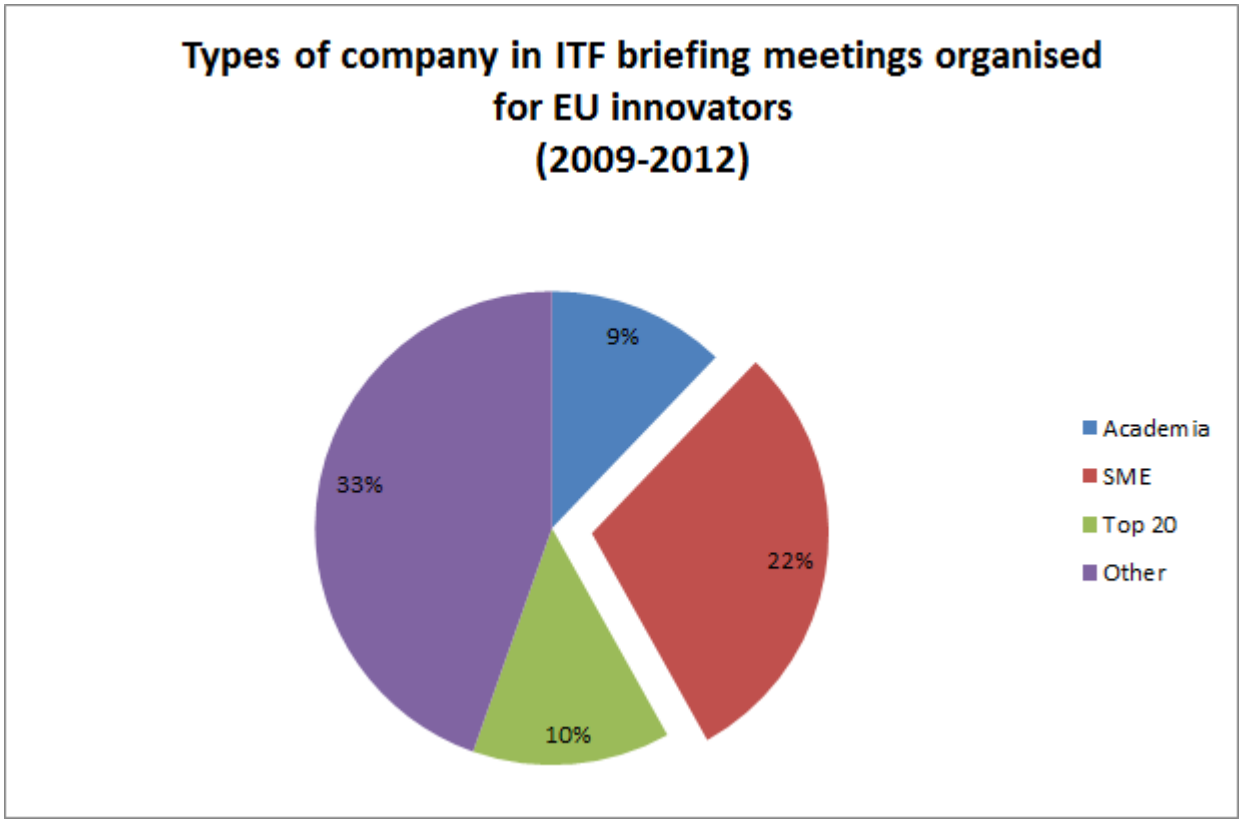
ITF briefing meetings

EUROPEAN MEDICINES AGENCY

Topics

- *stem cells* ATMPs, heterologous vs homologous use, “sequential products”
- *Omics biomarkers* and biomarkers sets: identification methods and platforms, limitations, further development and potential role; companion diagnostics
- *antibiotic resistance*: metabiomics and the bacterial film, phages “mixtures”
- my product can be considered a medicinal product? Polyfunctional proteins,nanopolimers conjugates, borderline, combined and ancillary
- general discussion on applicability of certain requirements

SMEs in ITF briefing meetings



Benefits

- start the dialogue with the Agency
- facilitate knowledge exchange on innovative strategies: update on progress, address new science and question to regulators, understand concerns and prepare for possible solutions
- provide orientation on hot regulatory topics in drug development
- identify issue of particular interest to regulators in preparing for formal procedures (e.g. biomarkers qualifications, scientific advice, orphan medicines designation etc)

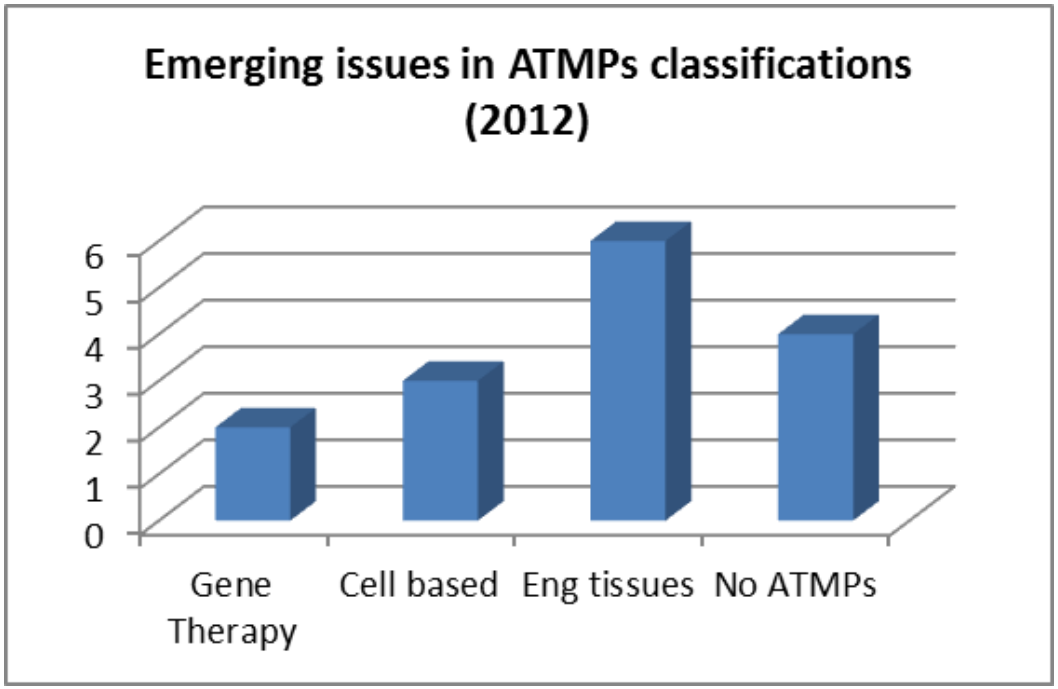
CAT ATMPs classification

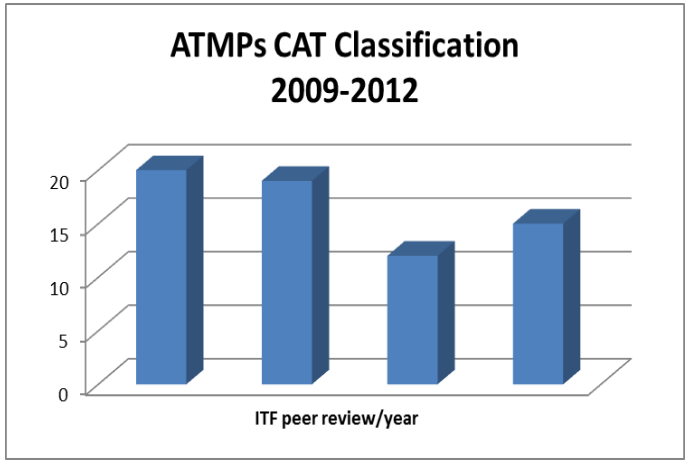
Purpose: Product classification: genes, cells or tissues, i.e. Advanced Therapy Medicinal Products (ATMPs)

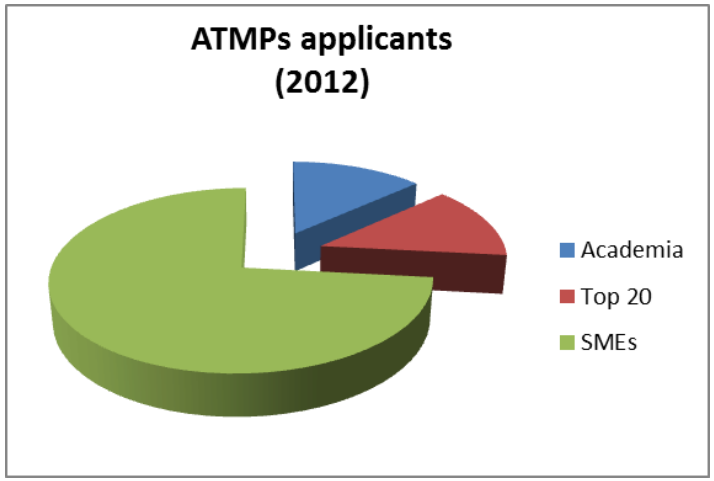
Benefits:

- special support to ATMPs of SMEs
- early identification of MAA requirements
- identify potential borderline with other areas (device, cosmetic, food)

CAT ATMPs classification







European Innovation Task Force Network

January 2012, 13:00-14:00

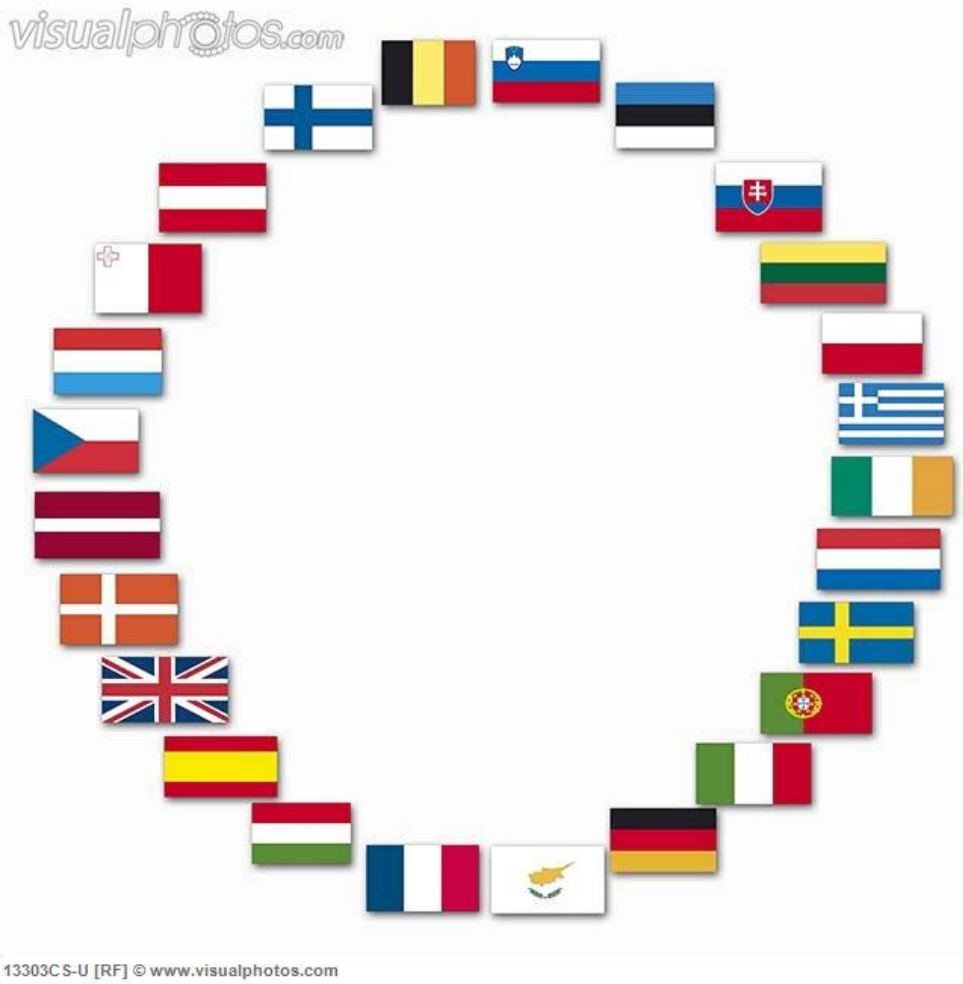
Attendees: Ian Hudson (UK, MHRA), Stéphane Paliès (FR, AFSSAPS), Paolo Daniele Siviero (IT, AIFA), Bettina Ziegele (DE, PEI), Pekka Kurki (FINAM), Marisa Papaluca-Amati (EMA).

Moderator: Falk Ehmann

Aim: Knowledge sharing to advance innovation

2 virtual meetings so far

- Topics included:
  - ATMP
  - Innovation level for HTA assessment
  - Novel technologies
  - Combined and borderline products
  - Clinical trials



Be part of it

Shape it

EU Innovation Task Force Network: preparedness in times of transforming science

ITFSecretariat@ema.europa.eu

Thanks for your attention

Acknowledgements

Falk Ehmann
Hans-Georg Eichler
Florence Borrelly-Konyakhin