EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role of European and National Regulatory Authorities: who advises on what?

CAT-ESGCT Workshop
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Frequently asked questions

- *Why I should talk to EMA about development of my ATMP?*
- *My goal is to progress the product from lab bench to the clinic, I am in contact with MHRA, why I need to talk to EMA as well?*
- *I do not have resources to ask for advice by EMA but I am liaising with the National Regulatory Authority in my country…we are only interested in the Clinical trial. Is this not sufficient?*
- *What is EMA? CAT?...yes I know you are also dealing with veterinary medicines*

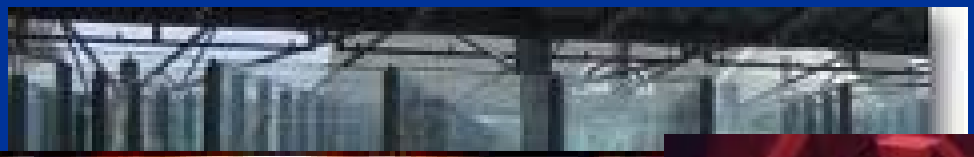
You have given the answer

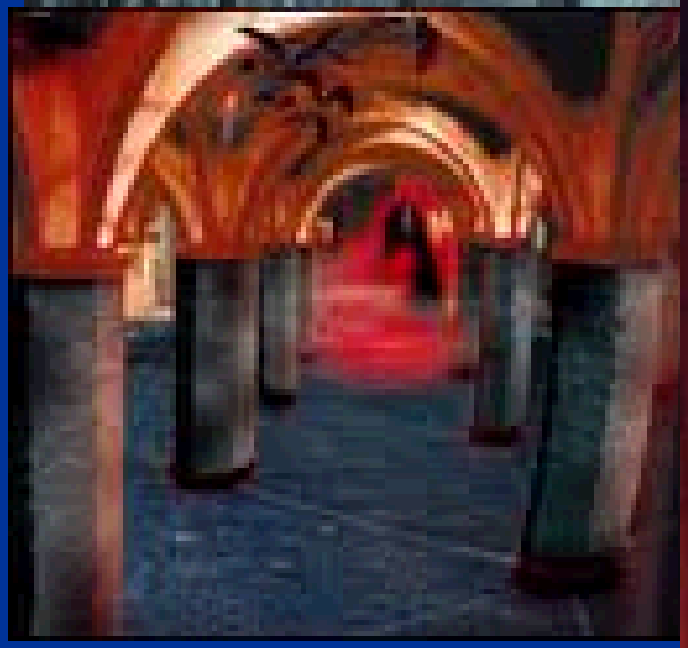
- **CAT held 7 meetings from 2009 to 2011 with more than 40 associations (Interested Parties) representing: Industry, SMEs, Academia, Charities & Trusts, Patients**

- **More than 70% of CAT Interested Parties are representing Academia, Charities & Trusts, University Hospitals, translational consortia, Patients.**

- *The regulatory system is a maze*
- *We need a path to navigate the complex regulatory system*
- *To attract investments we need predictability of regulatory outcome*

The mirror maze





We can indicate the path

Meet the ITF
Secretariat and core members

Who is the ITF?

A multidisciplinary group with "flexible design"

- **ITF secretariat (operational and scientific coordination)**
- **ITF core members and specialised EMA staff (competences and consistency)**
- **Experts from the EMA network (scientific expertise)**

ITF briefing meetings

Free-of-charge informal meetings to open the dialogue on regulatory, technical and scientific issues.

Scope:

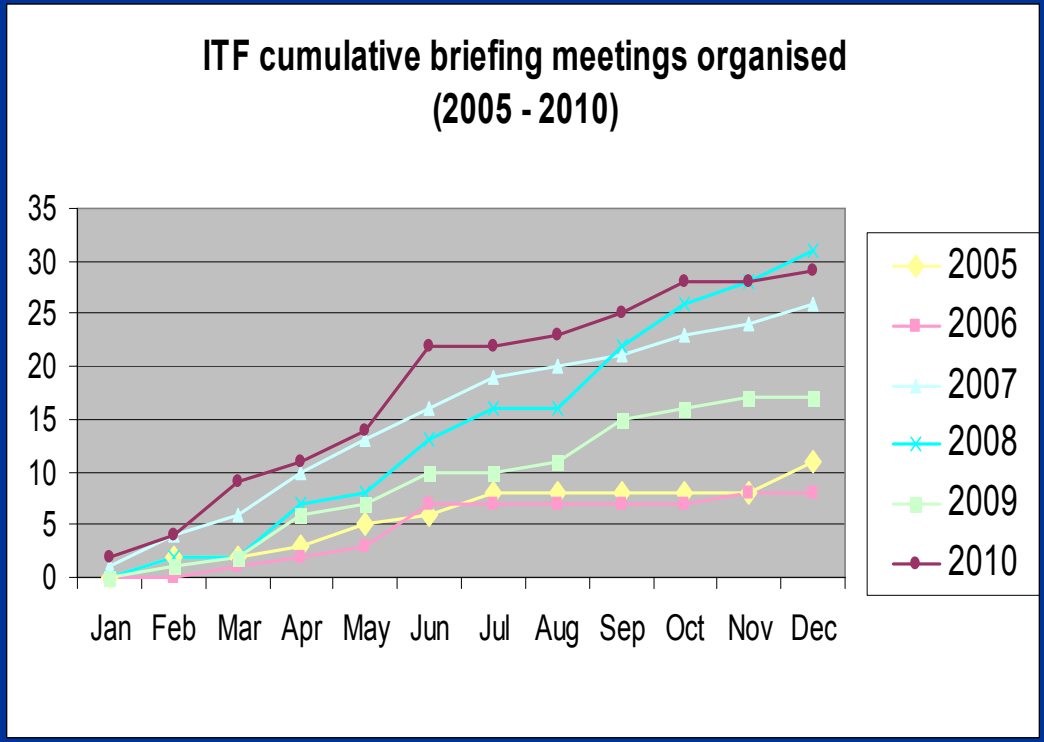
> Innovative therapies, methods and technologies, borderline and combined products

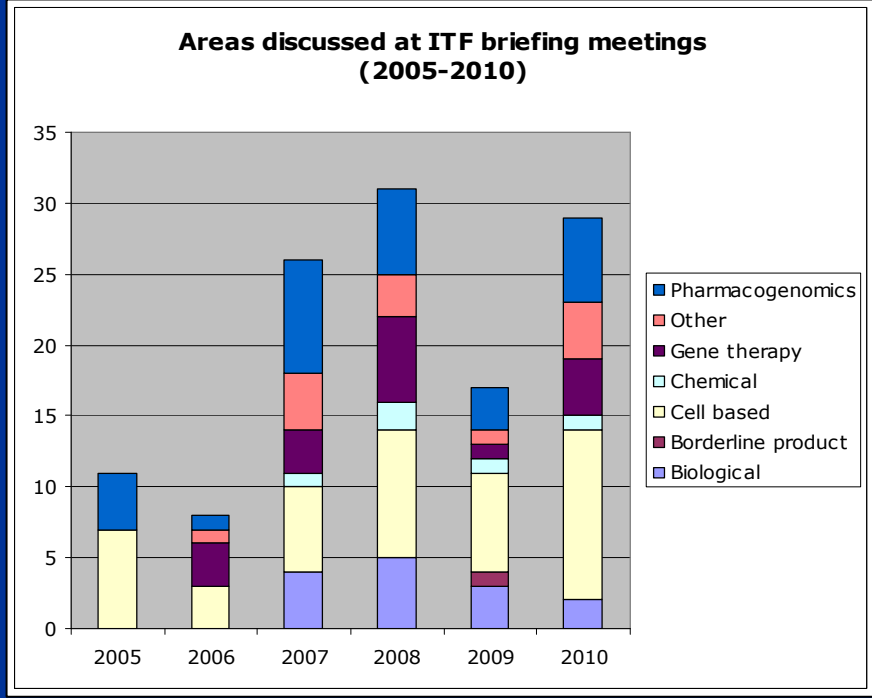
Objectives:

> Contribute to preparedness of both EMA and Applicants

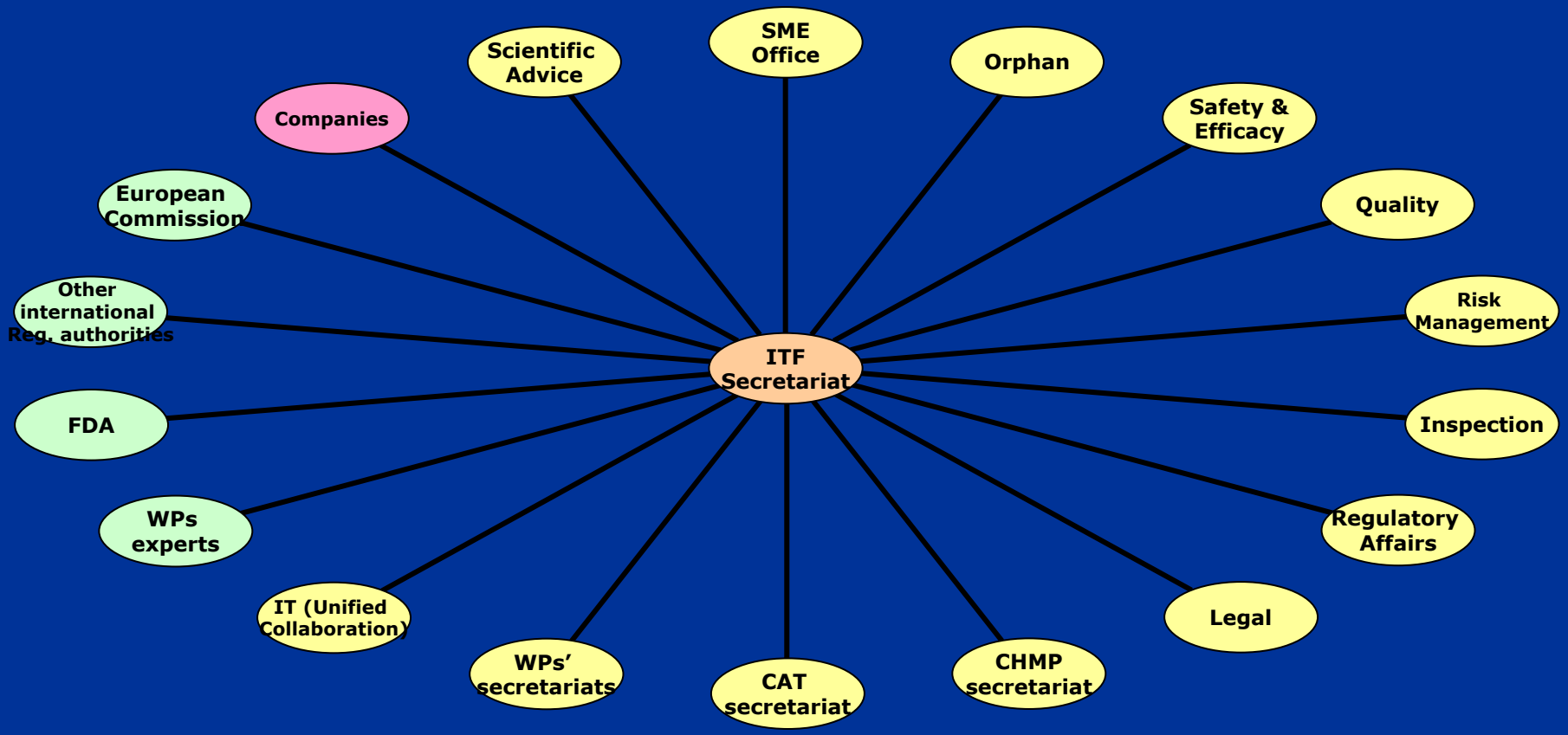
> Complement and reinforce existing formal regulatory procedures

ITF briefing meetings: figures

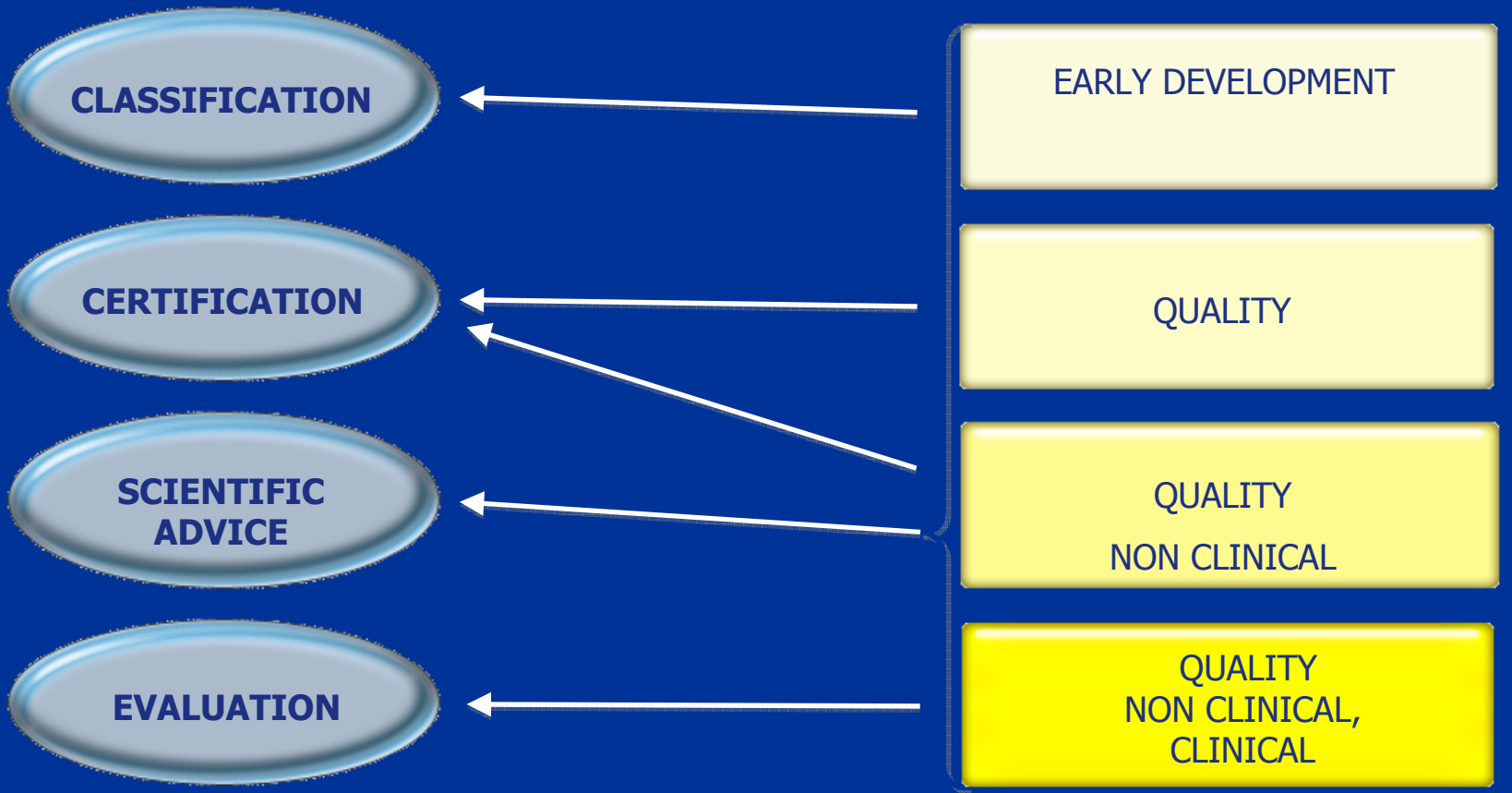




The ITF coordination "Wheel"



CAT Main Functions



Is my product an ATMP?

- To define Borderline e.g. with medical device, transplant, cosmetics.
- Incentive for applicants, not legal requirement
- Fast procedure (max 60 days)

How we advice on product development

- Scientific Advice can be given on ANY scientific question
  - Quality, non-clinical and clinical
- At any time point of the development
  - Post-marketing advice is also available
- Broad advice, Conditional approval and Exceptional circumstances
- Confidential

Are the data generated so far sufficient?

- Incentive for SMEs
- Assessment of early quality and non-clinical data
- Fast procedure (90 days)
- Certificate may attract investments

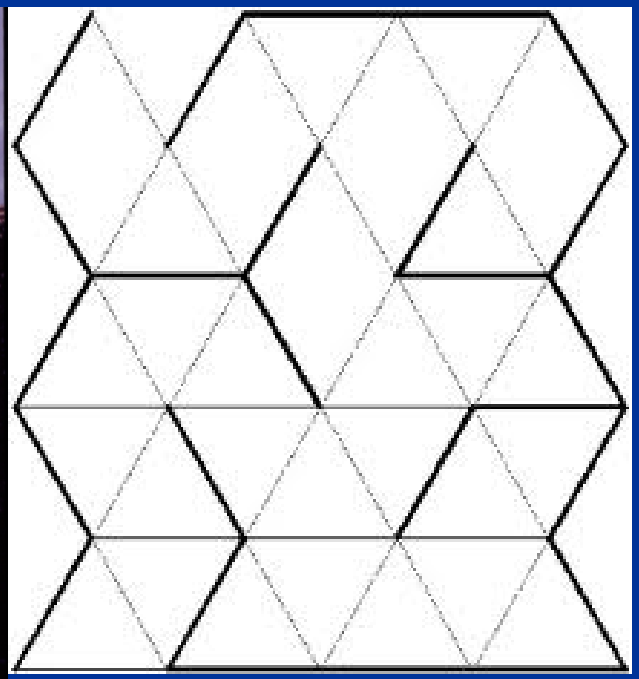
Unique features in the ATMP Regulation

- ✓ Risk-based approach to determine level of data
- ✓ Post-authorisation follow-up of safety and efficacy
- ✓ Incentives and fee reductions

Take home messages

- EMA-CAT and National Authorities are part of the same EUROPEAN SYSTEM: their activities are like complementary colours in the regulatory rainbow!
- We encourage the dialogue with ATMP developers
- We are ready to walk with you through the maze!

Thank you for your attention!



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