



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CAT-Interested Parties (IPs) Focus Groups

A new model for a fruitful interaction between CAT and its stakeholders

CAT Stakeholders workshop
12 January 2011, EMA, London



CAT dialogue with stakeholders

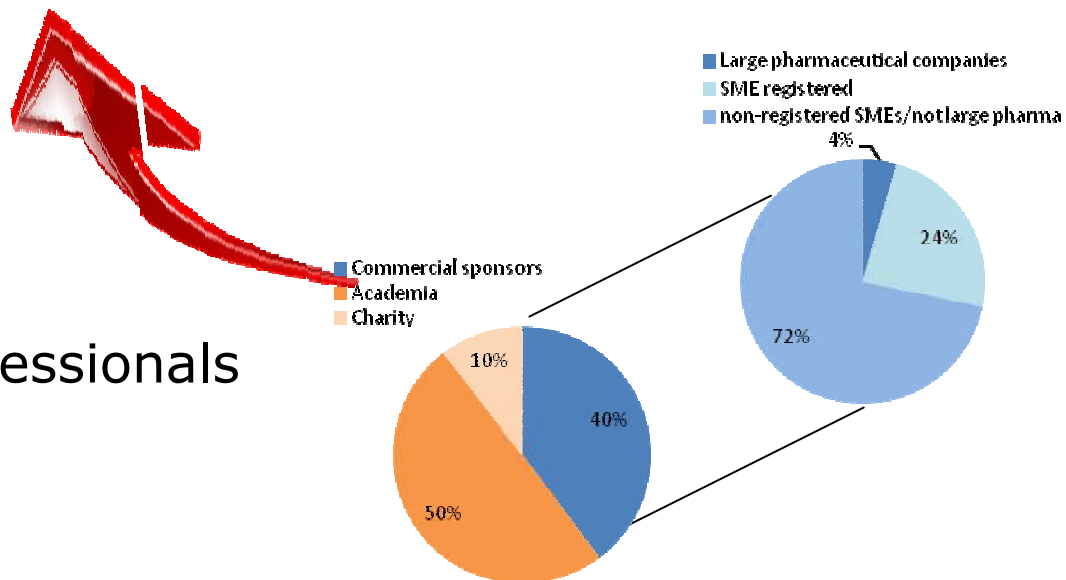


- ★ Who are the CAT stakeholders
- ★ Who are the CAT IPs
- ★ What kind of interaction



Who are the CAT stakeholders?

- ★ ATMP developers
- ★ Patients
- ★ Health care professionals
- ★ Regulators
- ★ RA professionals



Maciulatis et al. Clinical development tendencies for advanced therapy medicinal products in Europe: Evidence that regulators have to be proactive 2012 in press



Who are the CAT IPs?

- ★ Call for interest in July 2009
 - ★ 40 eligible associations in the list
 - ★ 6 large umbrella organisations (>250 members)
 - ★ Industry, Research groups, Academia
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- ★ 1st hearing in September 2009



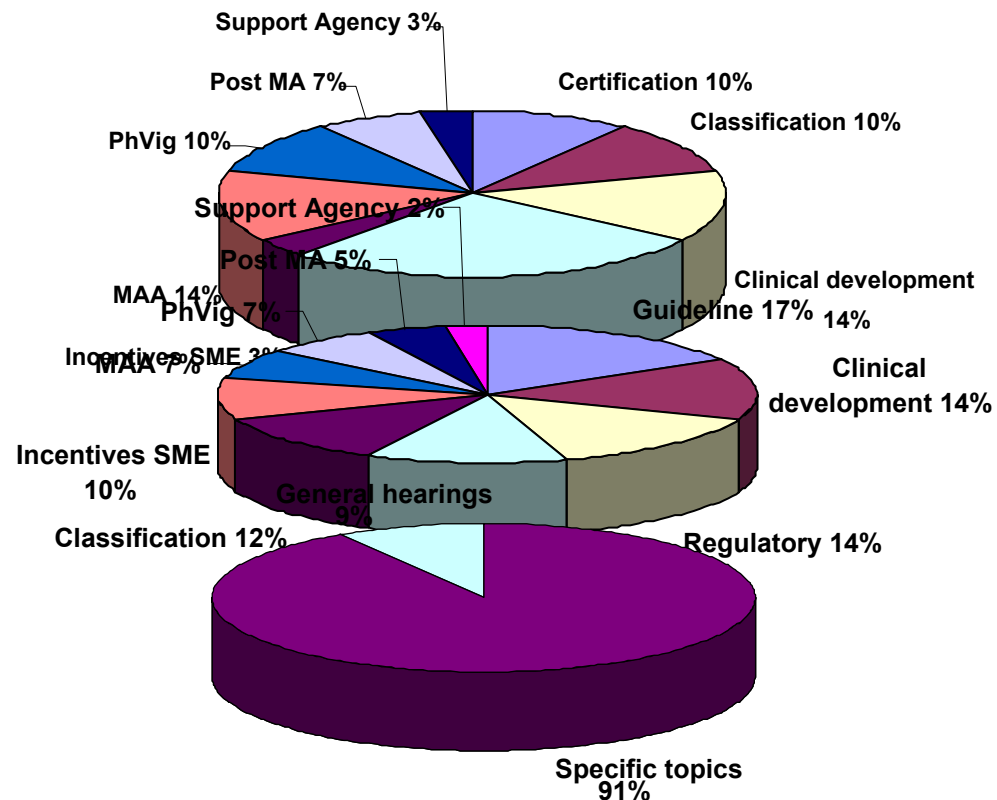
What kind of interaction

Outcome of the 1st hearing

★ Area of interest

★ Areas for CAT to develop

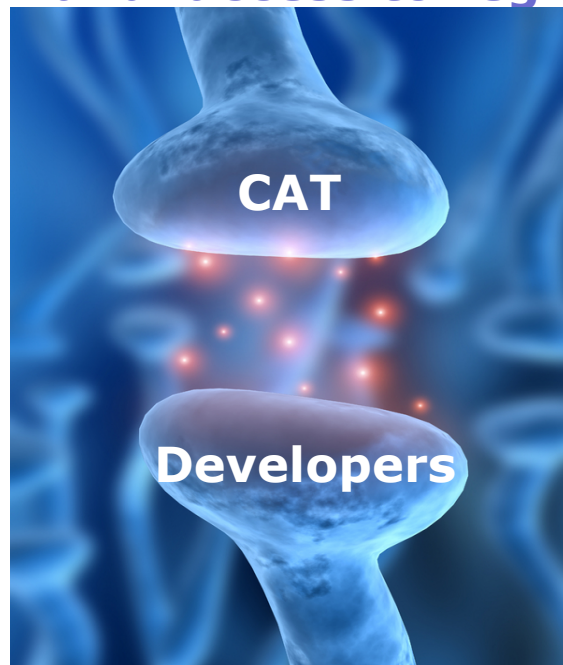
★ Structure of future hearings





Changed Interactions

- ▶ **Objective 2 of CAT Work Programme: Strengthen dialogue with stakeholders in order to facilitate development ATMP and access to registration procedure**



★ **Structured interactions**

★ **Dedicated hearings**

★ **Engage with all stakeholder**



The theory of small groups

Listen carefully to each other

Understand the different points of view discussed

Be respectful and maintain a good relationship regardless of their opinions

Try and find a common ground

Come up with new solutions to solve problems

Make proposals that will benefit everyone



CAT-IPs Focus group: a new model for a fruitful interaction

The CAT-IPs FG aim at improving CAT interaction with interested parties and propose shared solutions on some of the issues previously identified in general hearings with IPs.

Further to the analysis of the specific issues raised by IPs and subsequent proposal by the appointed Topic Leaders on priorities, the CAT identified three FGs for which initial action was needed

Focus groups are the result of the exercise under CAT WP with ultimate objective to strengthen dialogue with stakeholders to facilitate development of ATMPs



CAT-IPs Focus groups: duration and composition 1/2

The CAT-IPs FGs have 'real' temporary nature and are expected to be terminated by 4Q2011 before the planned workshop with stakeholders. Each FG will decide on the number and frequency of its meeting with the obligation to produce a comprehensive report to CAT on the outcome of their work

The CAT-IPs FGs should have a balanced composition of representatives: in terms of number of CAT members and IP representatives, both with relevant expertise for each topic. To achieve a focus discussion and increase productivity the number of participants to the FG should be limited to a maximum of 11 participants including the CAT Chair.



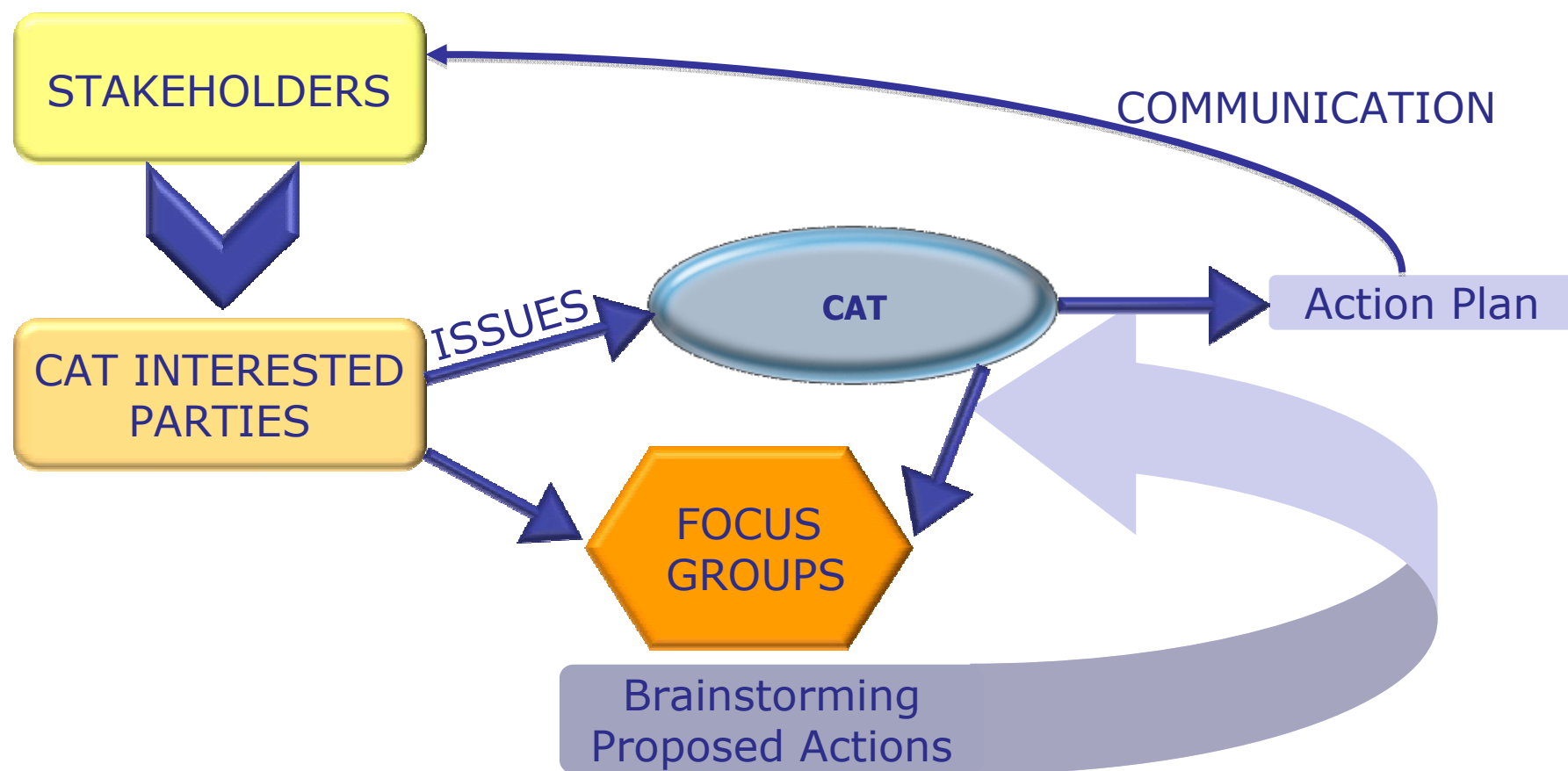
CAT-IPs Focus groups: duration and composition 2/2

The CAT members are nominated by CAT for each focus group based on their voluntary expression of interest;

IPs involved in each FG are selected by CAT based on the expertise in the field and ability to represent stakeholders in the sector.



Process for changed Interactions





What we did in 2011

- Focus working group on non-clinical development: to discuss for example
 - Relevant animal models for non-clinical studies
 - Pre-clinical data needed when clinical data exist
- Focus working group on how to navigate the guidelines and procedural advice documents for ATMPs (for SMEs and Academia): to discuss a tool to facilitate the identification of the applicable guidance documents
- Focus working group on incentives for Academia, hospitals, charities: to listen and collect a list of incentives identified by these IPs but currently not extended to them



CAT Stakeholders workshop today

- ★ COMMUNICATE the outcome of FG discussions in 2011
- ★ ENRICH the scientific discussion on the three identified topics
- ★ SHARE the proposed action plans for 2012



Thank you for your attention!



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