



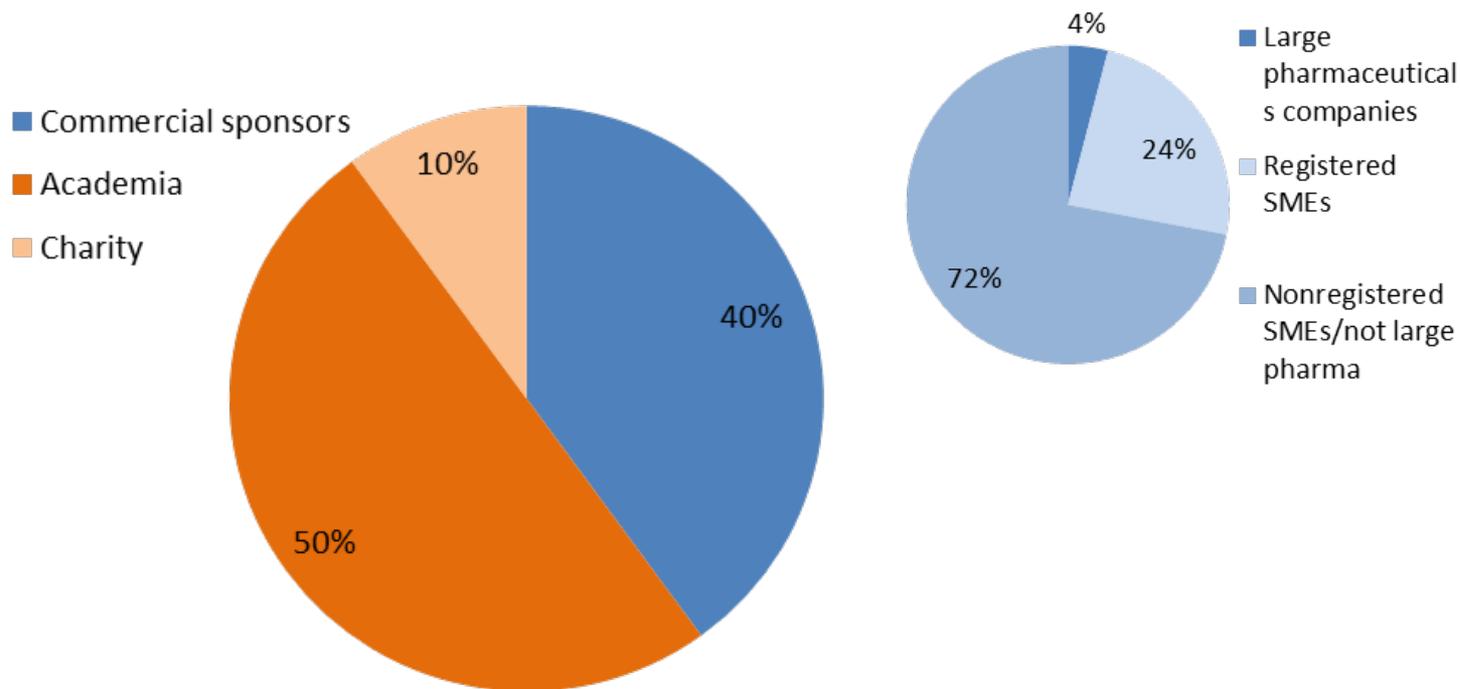
## Situation in 2014

- 654 Clinical Trials with ATMPs (187 TEP, 160 GT, 307 SCT), (of 42288 CTs recorded in the EudraCT DB)
- In 2014: 3249 Clinical Trials recorded in the EudraCT database (90 ATMPs: 17 GT, 43 SCT, 30 TEP)
- 2015 (November): 3636 Clinical Trials





# Situation in 2004-2010



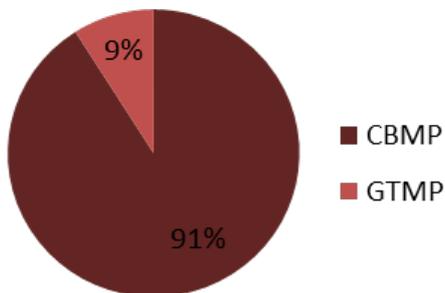
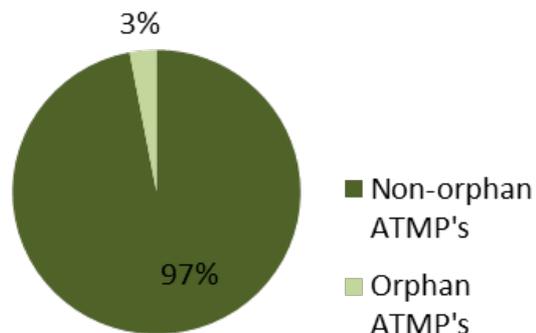
Maciulaitis et al, 2012



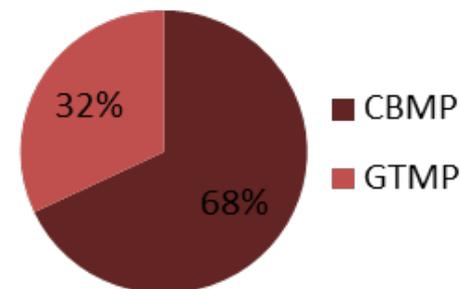
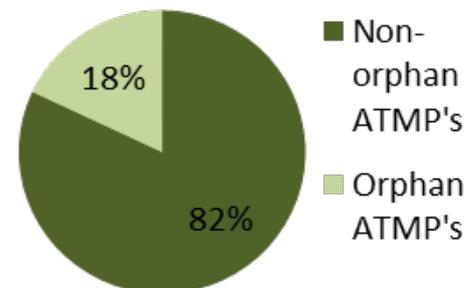


# Situation in 2004-2010

## Non-commercial



## Commercial



Maciulaitis et al, 2012





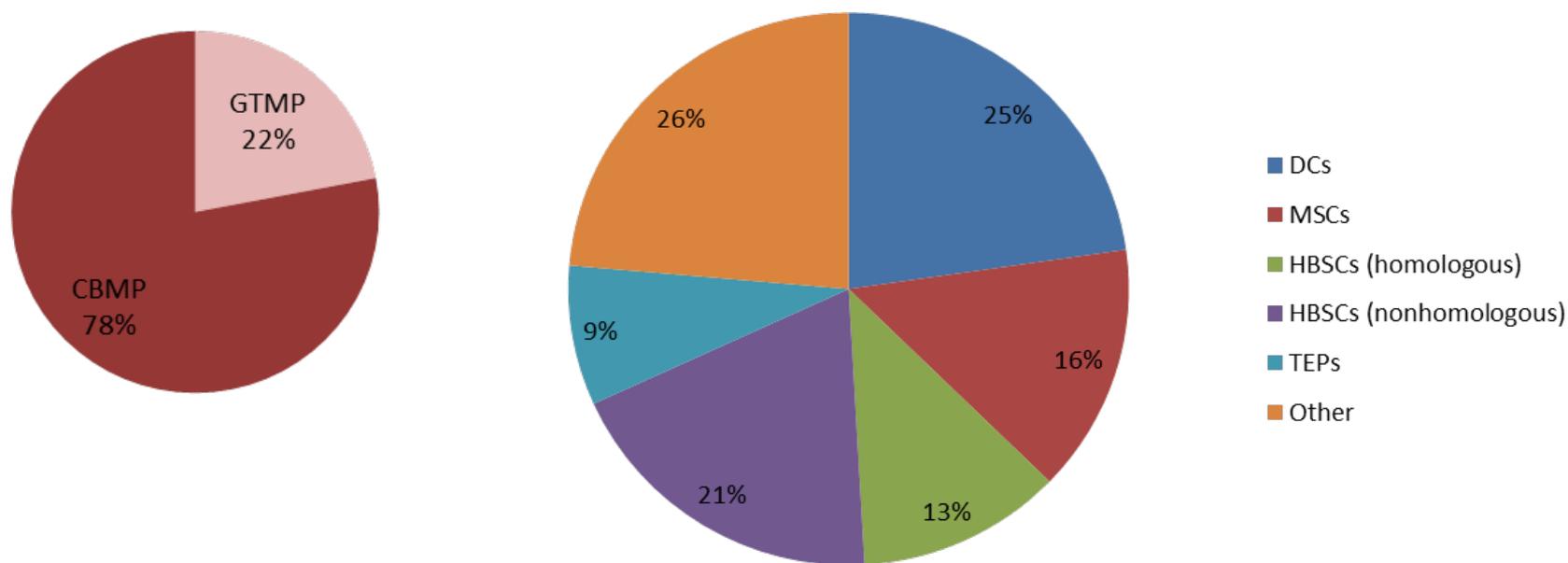
## ...and now

- Increasing number of Commercial Sponsors
- Big Pharma Companies start to be interested e.g. in GTMP



# Situation in 2004-2010

Products:



Maciulaitis et al, 2012





## ...and now

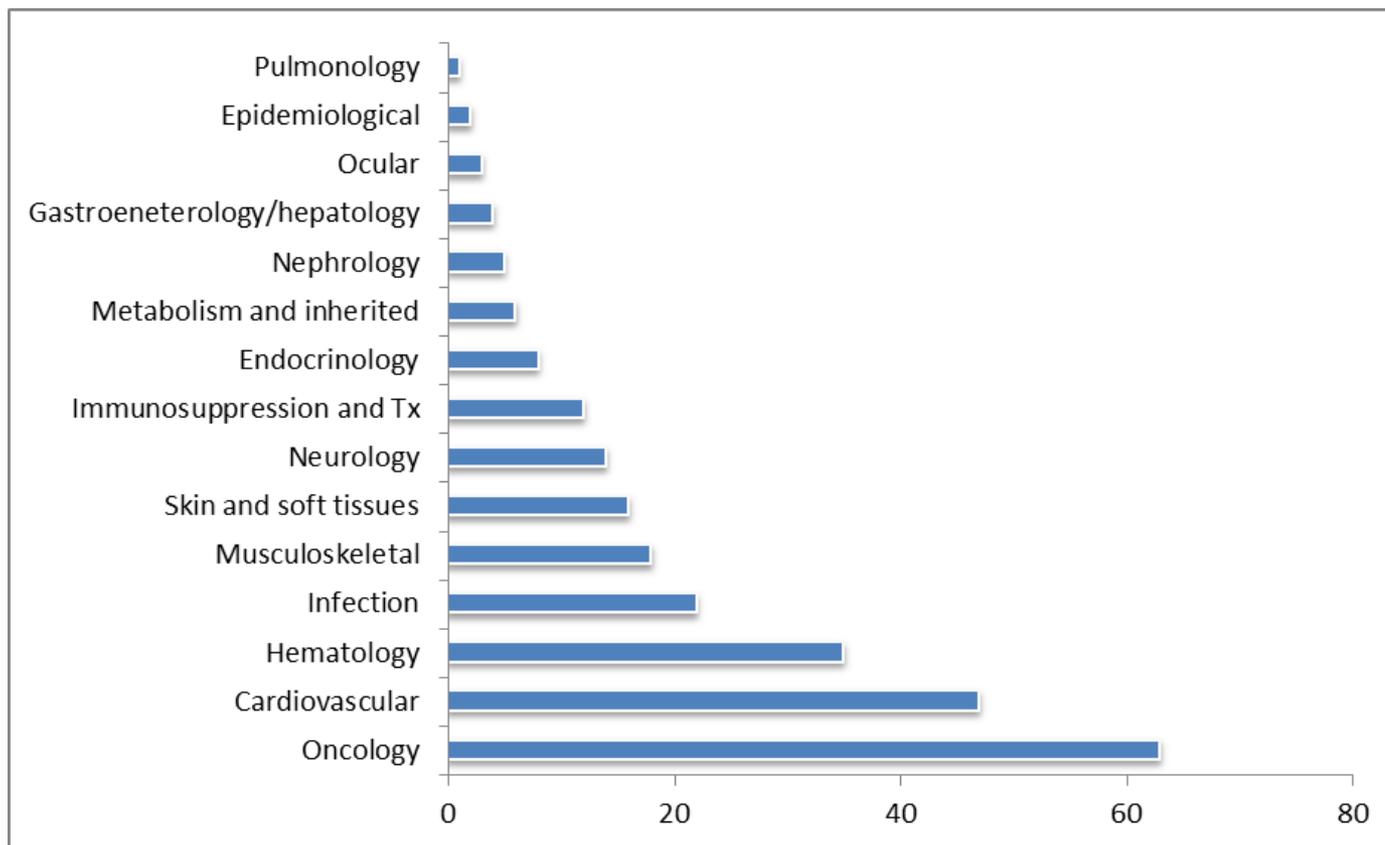
- Increasing number of Clinical Trials with MSC
- Increasing number of Clinical Trials with GTMP
- TEP – new biomaterials and nanomaterials



# Situation in 2004-2010

Major disease areas studied:

Maciulaitis et al, 2012





## ...and now

- no change (oncology/haematooncology, cardiovascular and neurology)
- promising field - ophthalmology



# Challenges

- GMO / ERA (different bodies than NCAs, different approach)
- SOHO (different donors testing requirements)
- Importing human T&C from 3<sup>rd</sup> countries
- Reimbursement
- Classification of ATMPs not legally binding
- CTs with Medical Devices – different approach in different MS
- Update to scientific progress
- Hospital Exemption





# CAT procedures

Scientific recommendation on advanced therapy classification								
	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	22	19	12	22	20	28	13	136
Adopted	12	27	12	16	23	29	15	134

Certification of quality and non-clinical data for small and medium-sized enterprises developing ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Submitted	1	0	0	1	3	1	0	6
Adopted	0	1	0	1	1	2	1	6

Scientific advice procedures on ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Discussed*	25	30	36	31	36	48	45	245
Number of procedures	17	19	21	19	23	33	25	157

\* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure



Development challenges and bringing science to the market: Experience from CAT



# Thank you for your attention

