

Final Multidisciplinary Workshop

*Designing the Future Conditions  
for Clinical Research in Europe*

17 March 2010 - Diamant Centre, Brussels, Belgium

# Survey on the Current Level of Consensus

*Ingrid Klingmann*

Chair, EFGCP

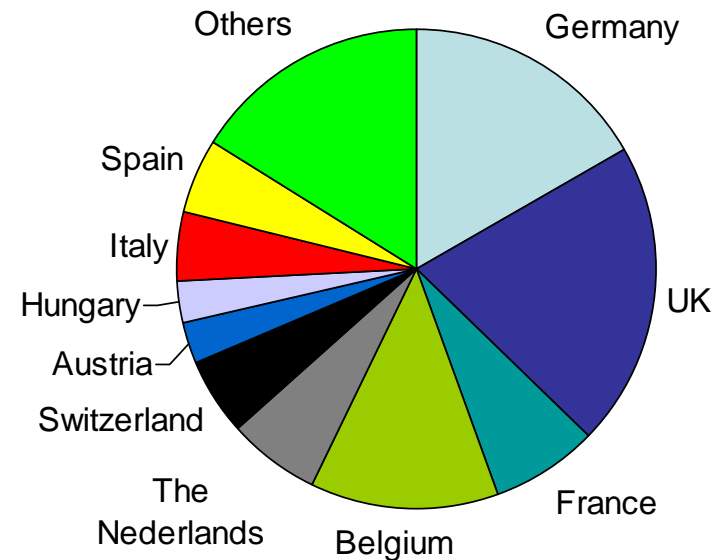


# Participants to the Survey & Countries Represented

Academia	90
Pharma Industry	37
CROs	30
Ethics Committees	10
Competent Authorities	5
Patient Organisations	11
Anonymous	2
<b>Total</b>	<b>185</b>

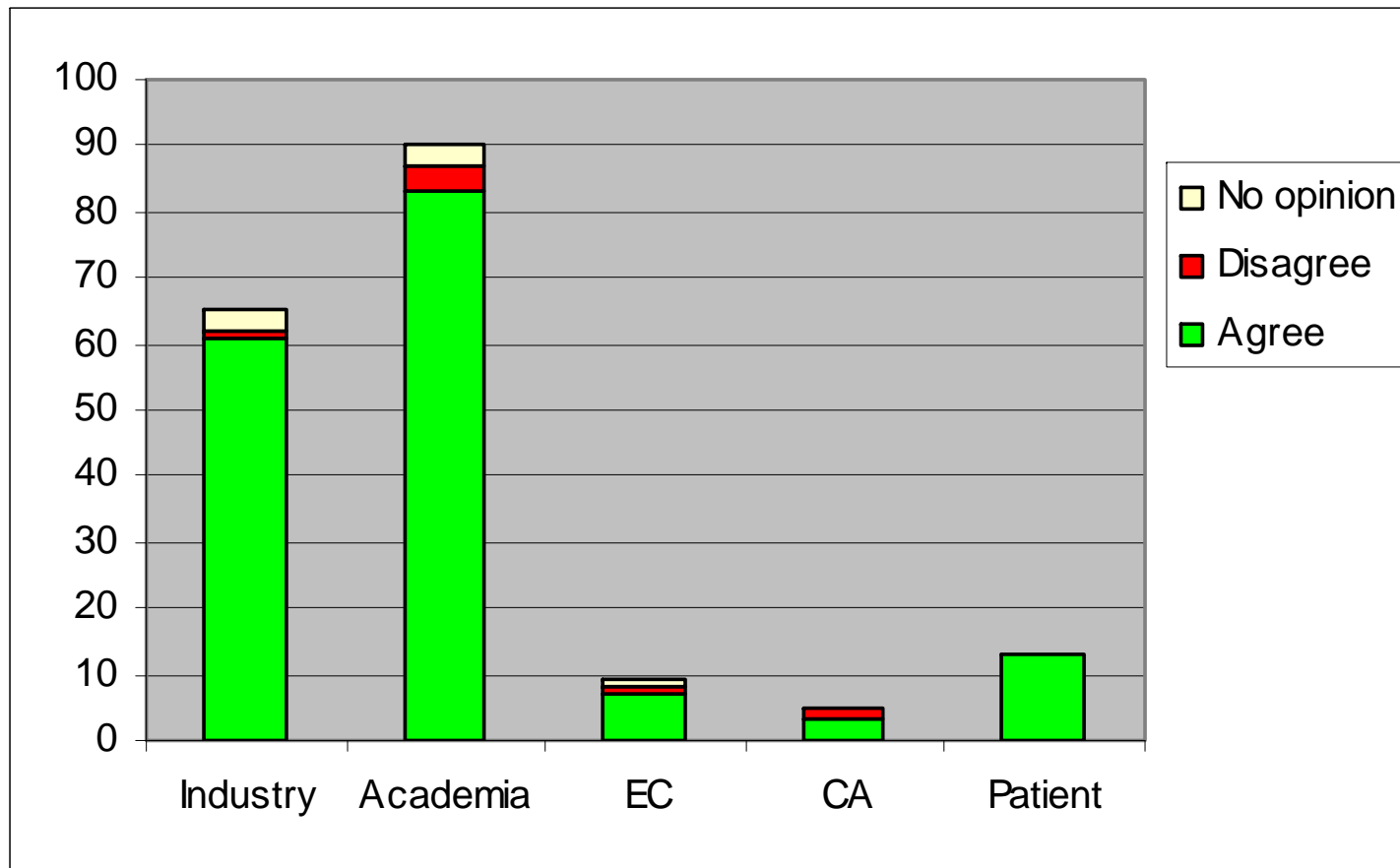
Personal responses	85
Institution responses	98

Country of Origin



## Topic 1:

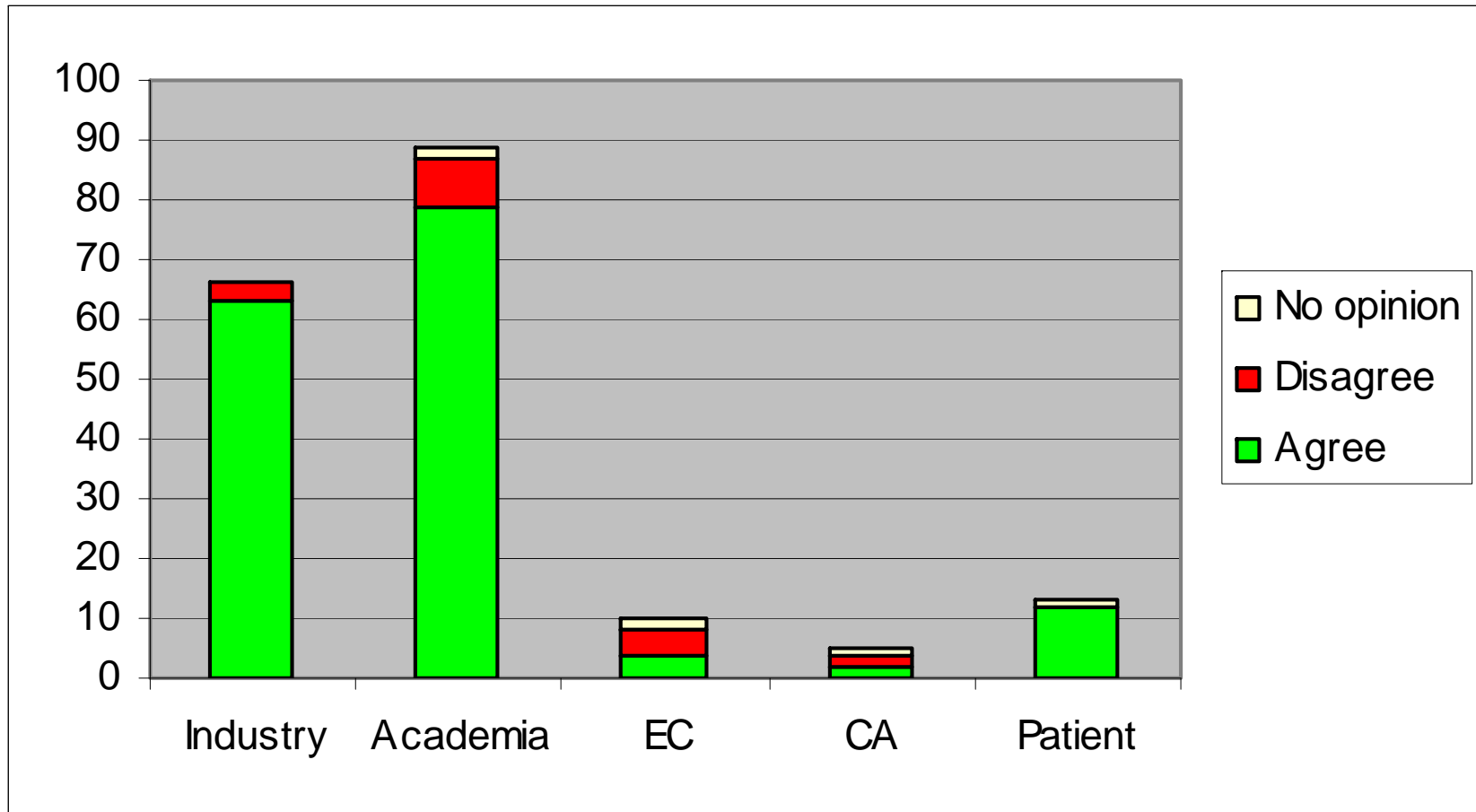
The "Road Map Initiative for Clinical Research in Europe" requests a rapid decision of the European Commission to revise the current regulatory system for clinical trials in Europe and to take appropriate actions soon.



# Single CTA Workshop

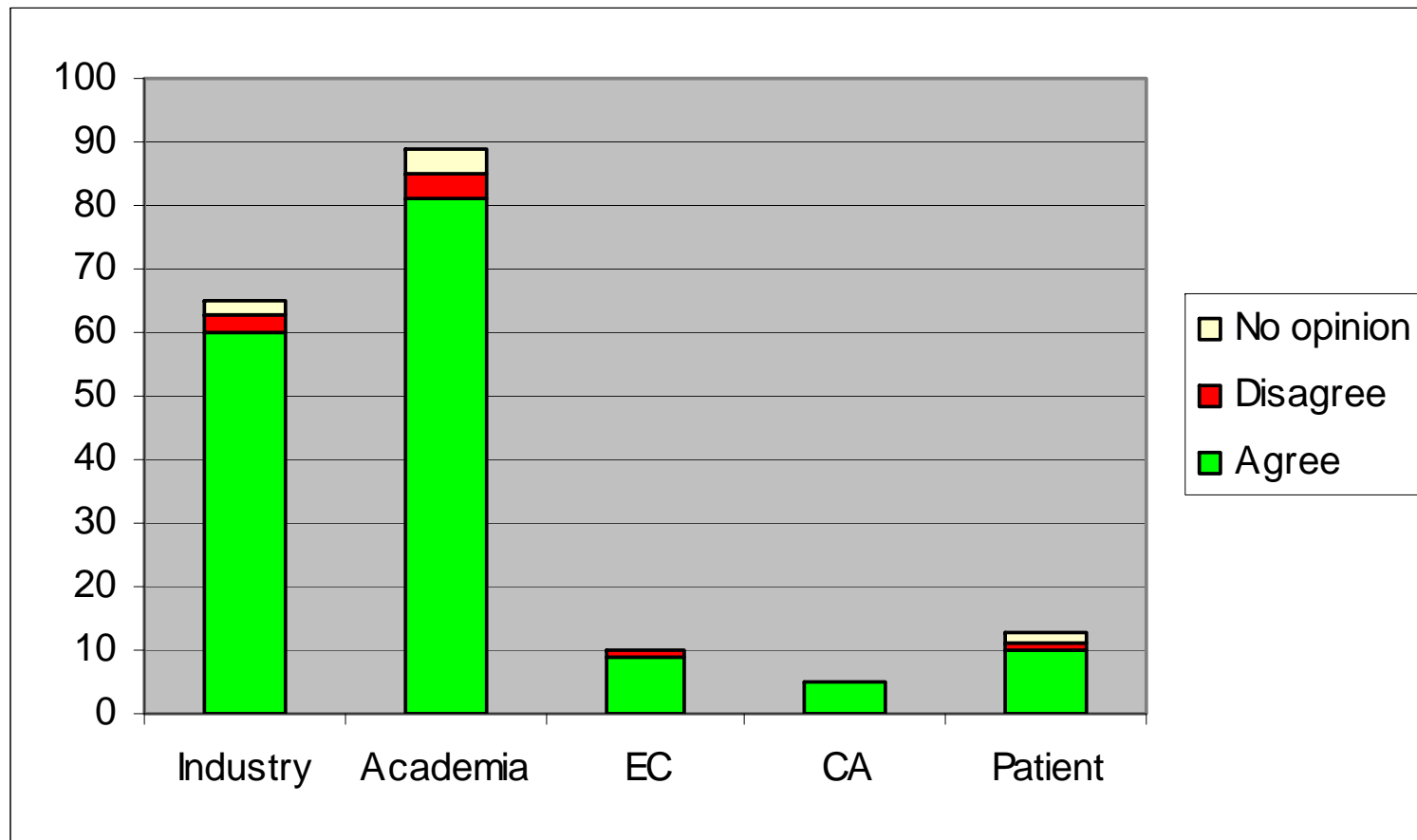
## Topic 2:

Instead of parallel reviews and approvals by all NCAs involved there should be a "Single CTA" for multi-national clinical trials.

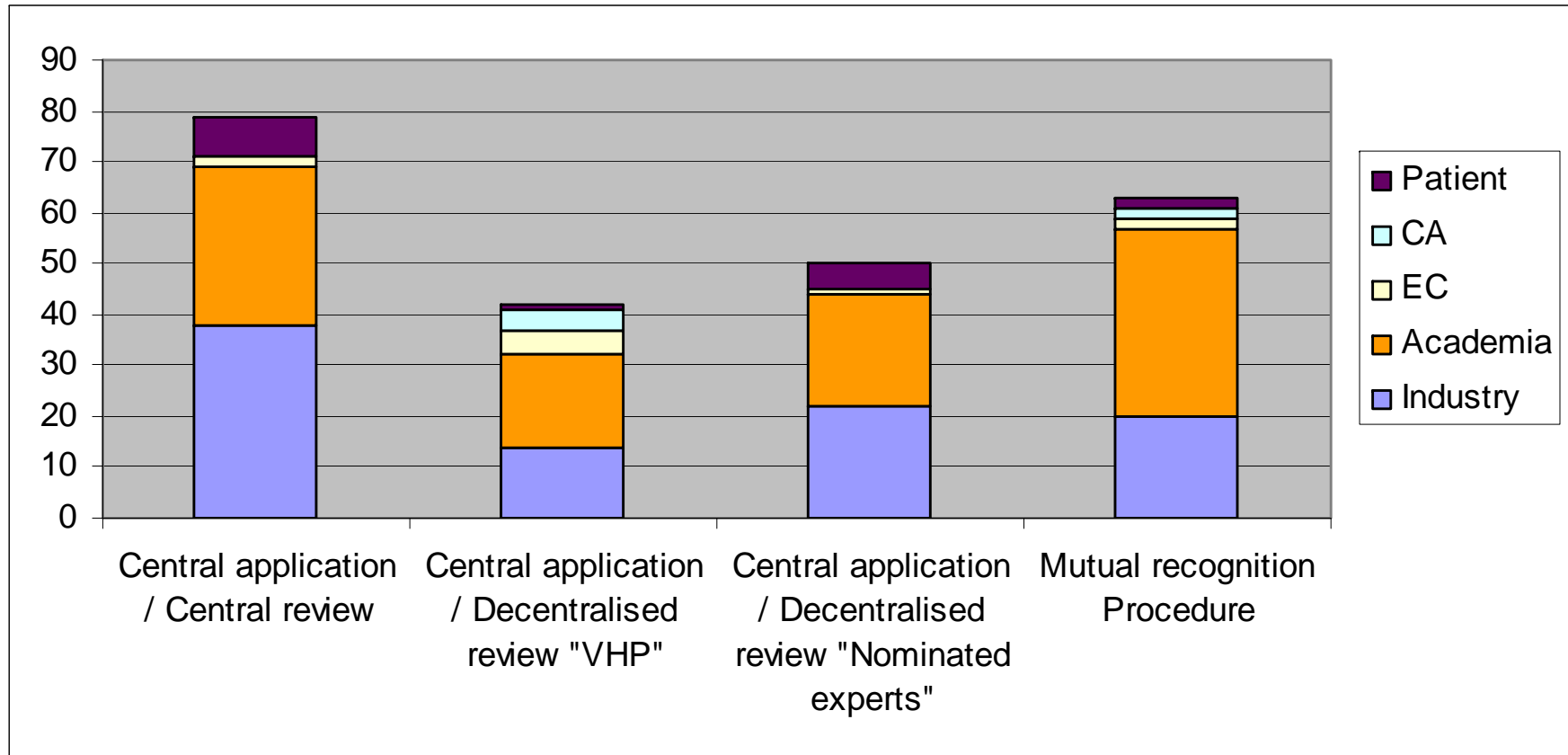


### Topic 3:

For single-centre and national multi-centre CTs, the CTA should be submitted to the competent NCA.

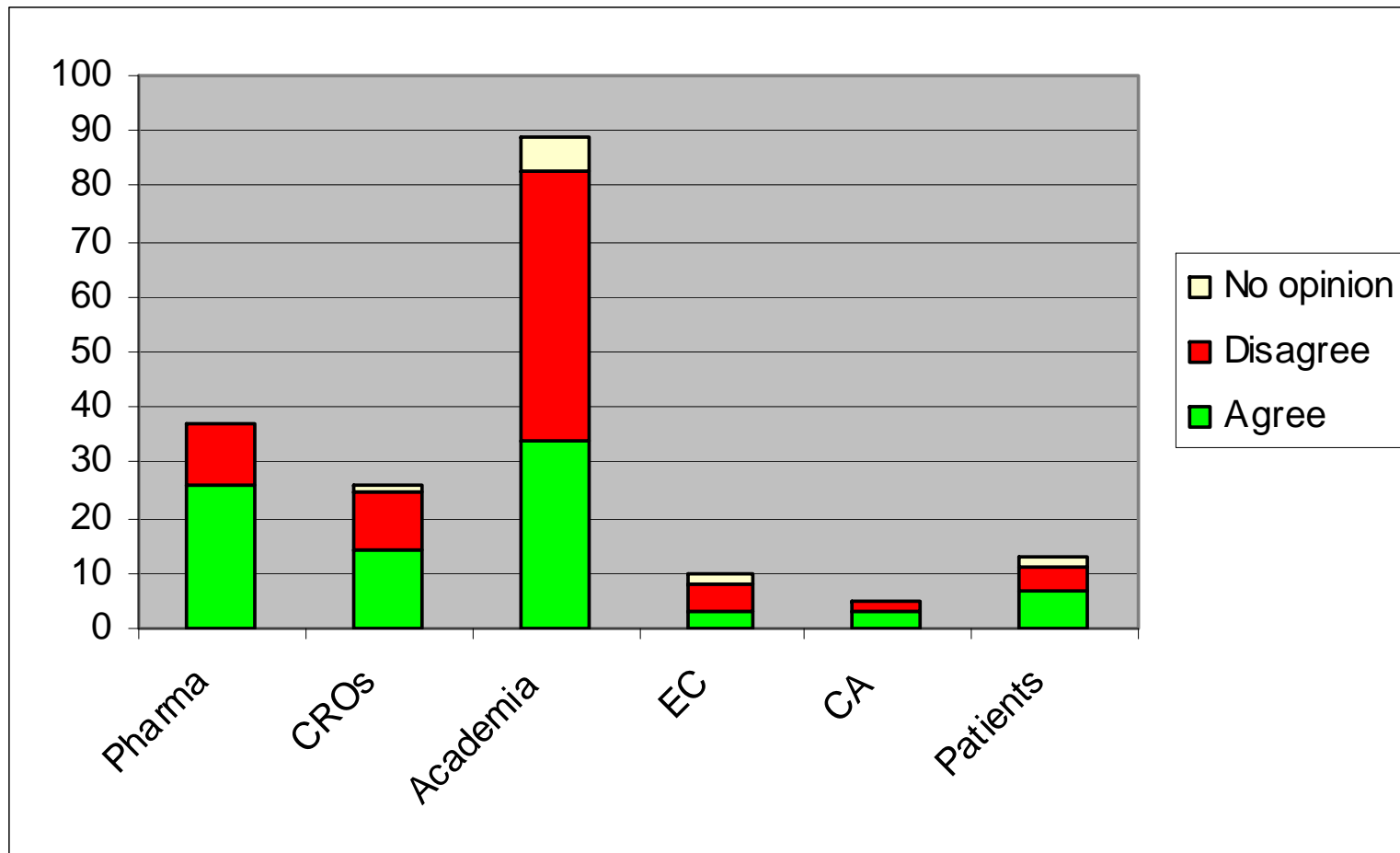


# Topic 4: For multinational clinical trial review options



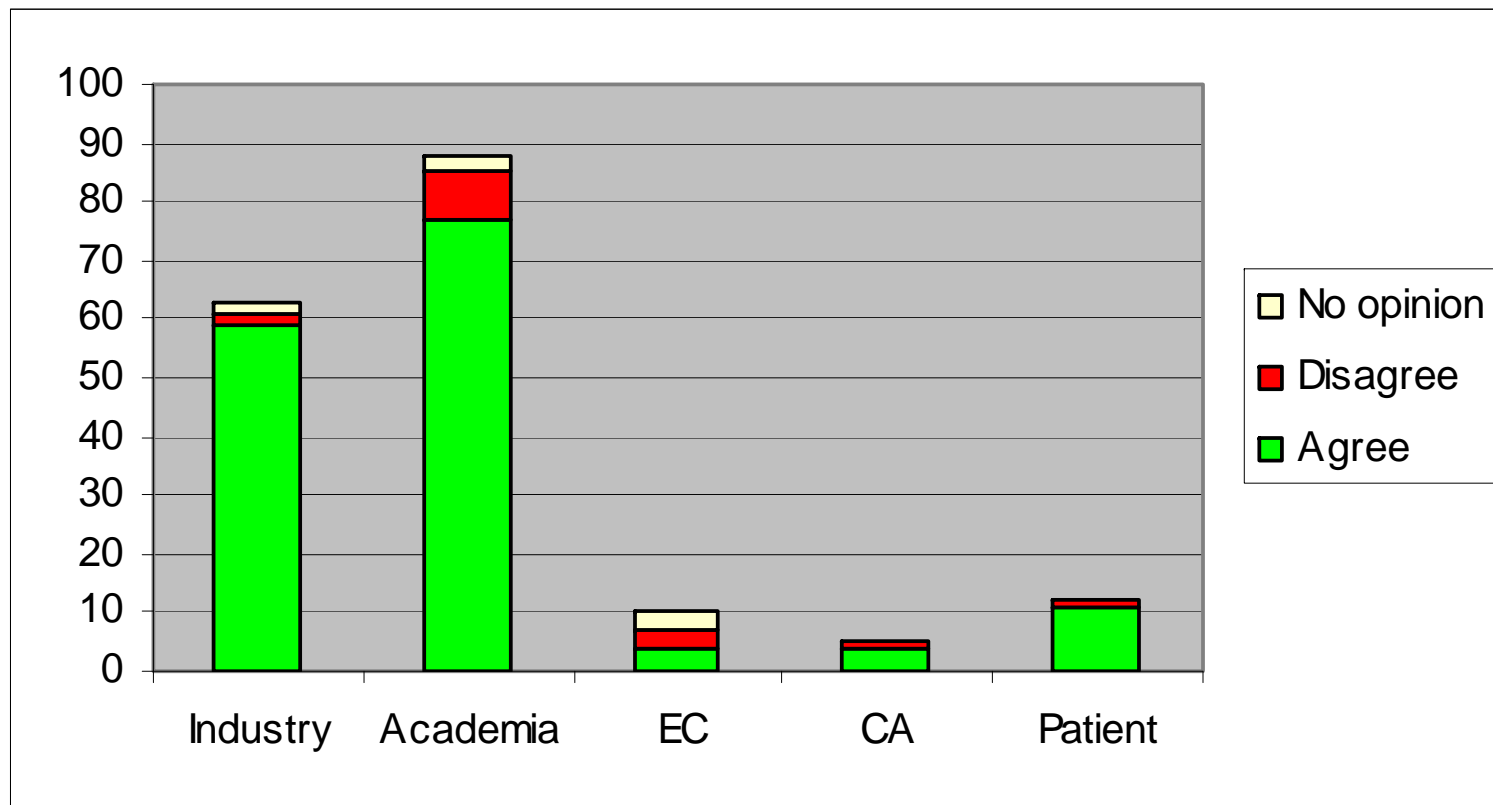
## Topic 5:

The current and the new procedure for CTA in multi-national clinical trials should run in parallel and the sponsor should be free to choose his favourite option.



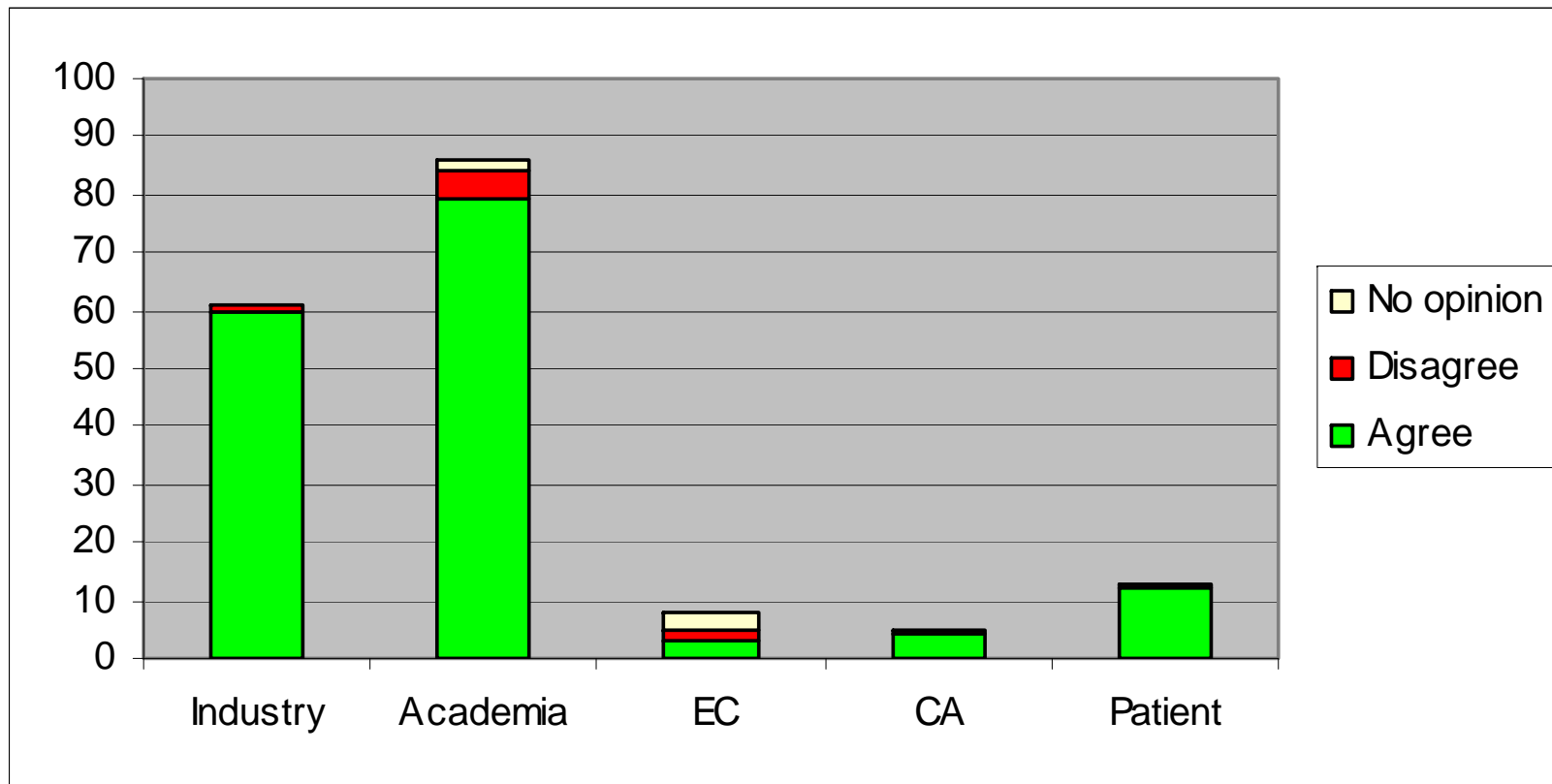
## Topic 6:

There should be a single application dossier, submitted at a central location (e.g. EudraCT) with access for the reviewing NCA(s). No additional national documents would be requested.

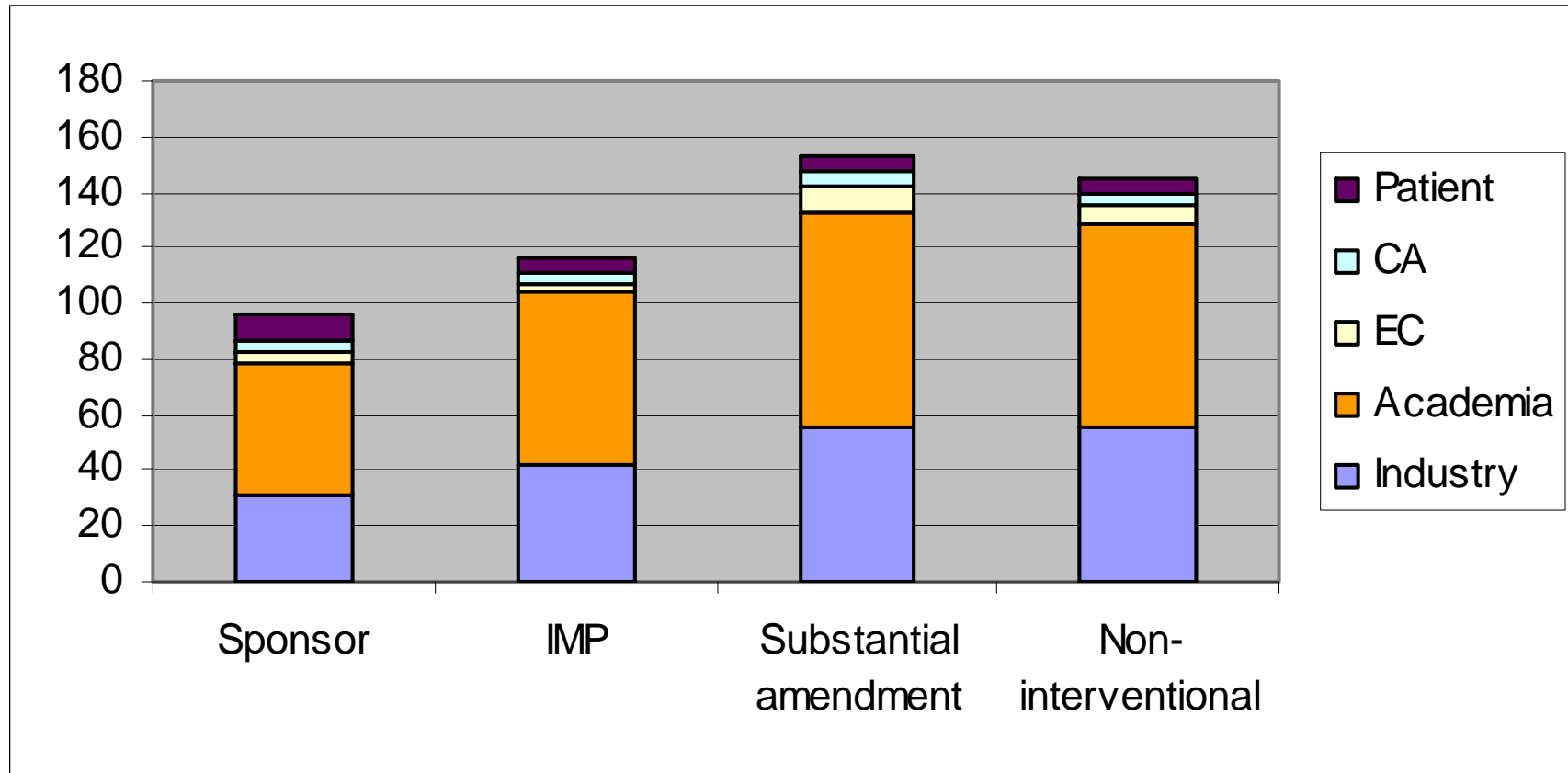


## Topic 7:

The single dossier should be submitted in English with national language translations of the Informed Consent documents.

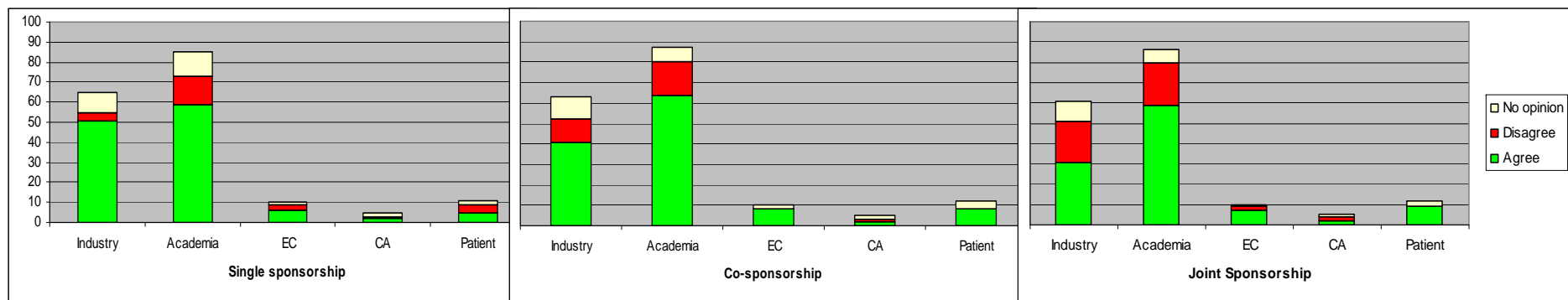


# Topic 8: There should be clearer definitions

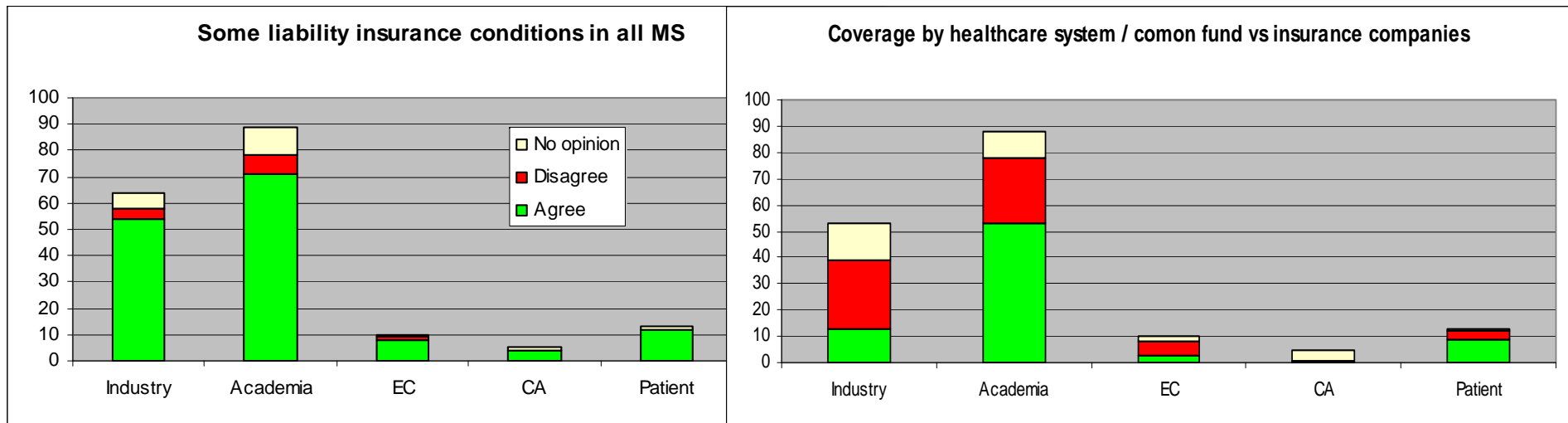


# Co-sponsorship Workshop

# Topics 9 and 10: Sponsorship options

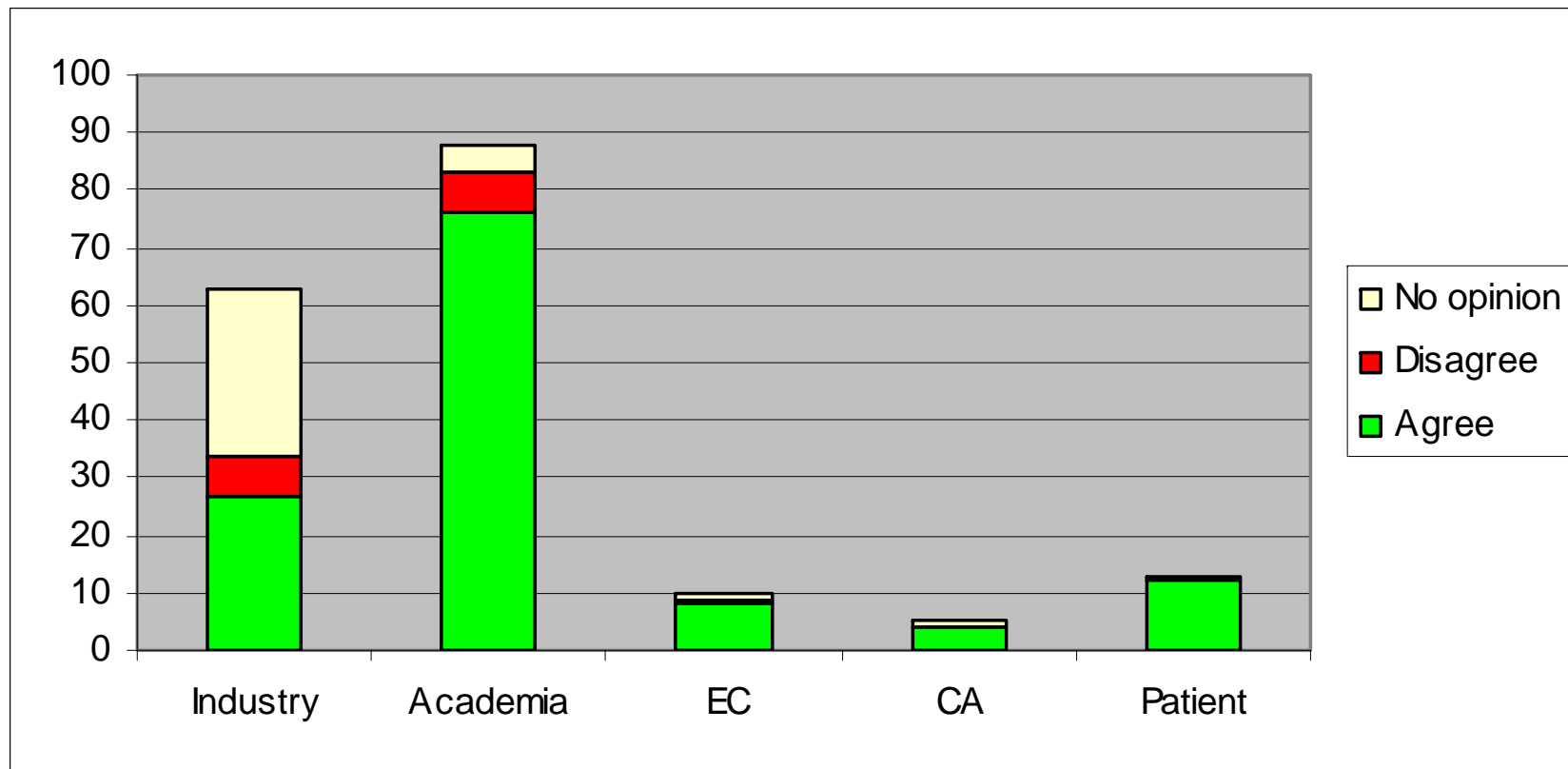


# Topics 11 and 12: Liability insurance conditions for CT participants



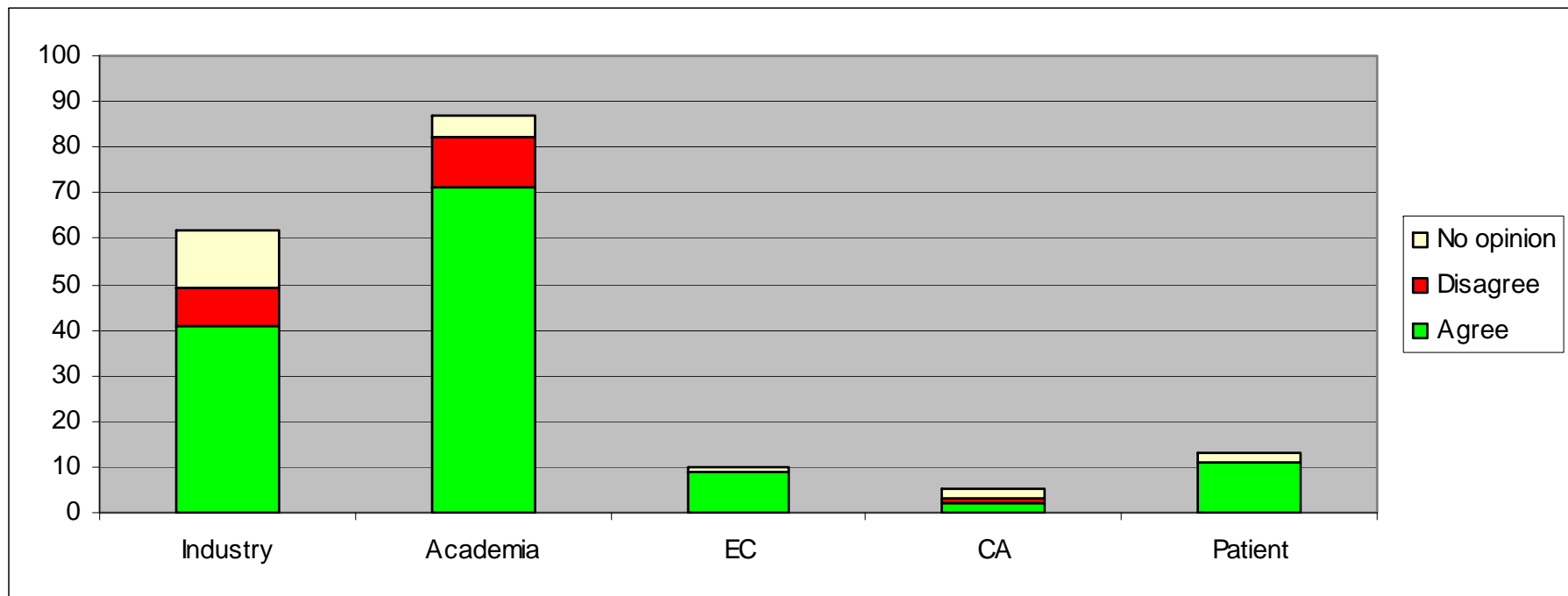
## Topic 13:

Support for multi-national CTs should be developed by creating CT funding options on a European level (e.g. "European NIH")



## Topic 14:

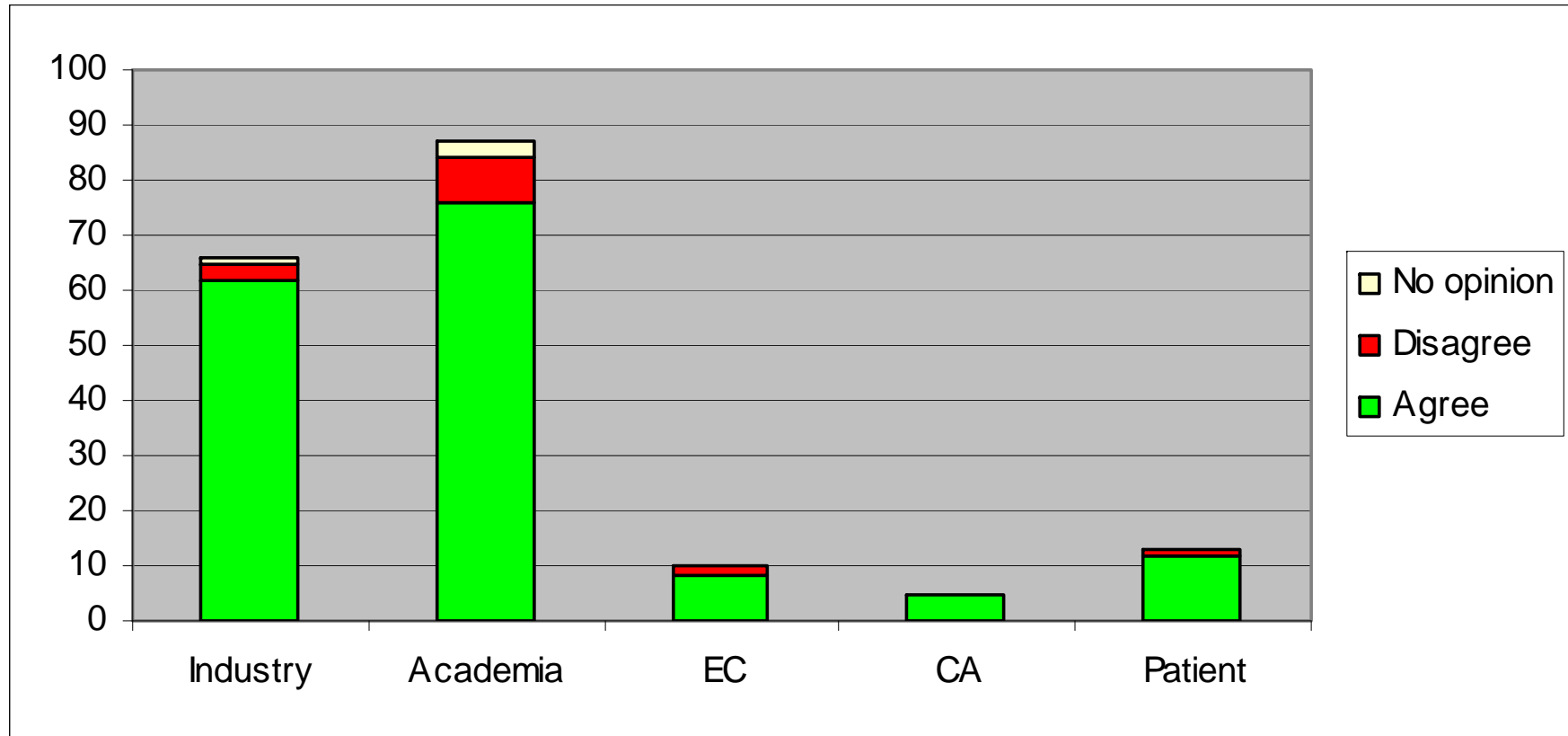
Collaboration in public-private CTs should be facilitated by allowing co-sponsorship and by clearly defining rights/obligations and responsibilities of the partners in such a collaboration on a European level.



# Ethical Review Workshop

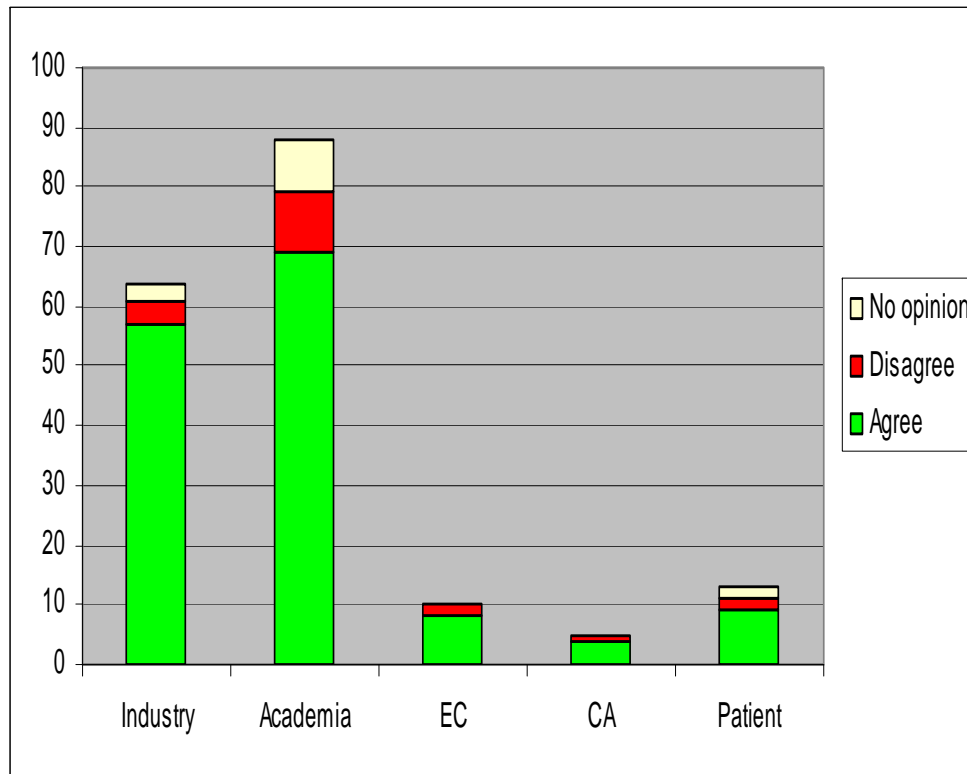
## Topic 15:

There should be a more harmonised Ethical Review process in the EU

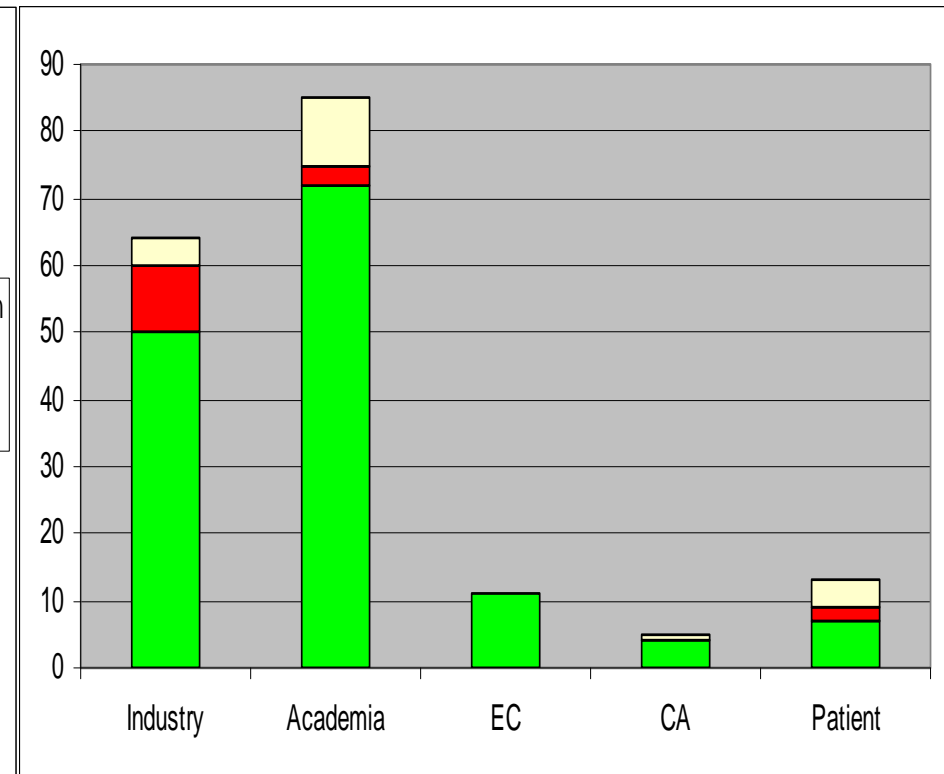


## Topics 16 and 17: Improvement of ethical review

The quality of the ethical review  
should be improved and  
harmonised through accreditation  
of ethics committees



There should be substantial  
funding for training of EC  
members

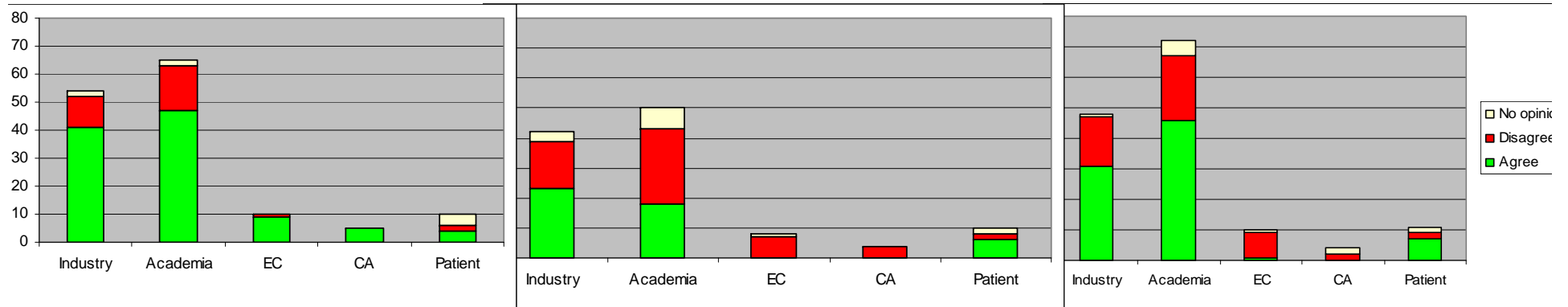


# Topic 18: Ethical review options

Current system  
remains for national CTs

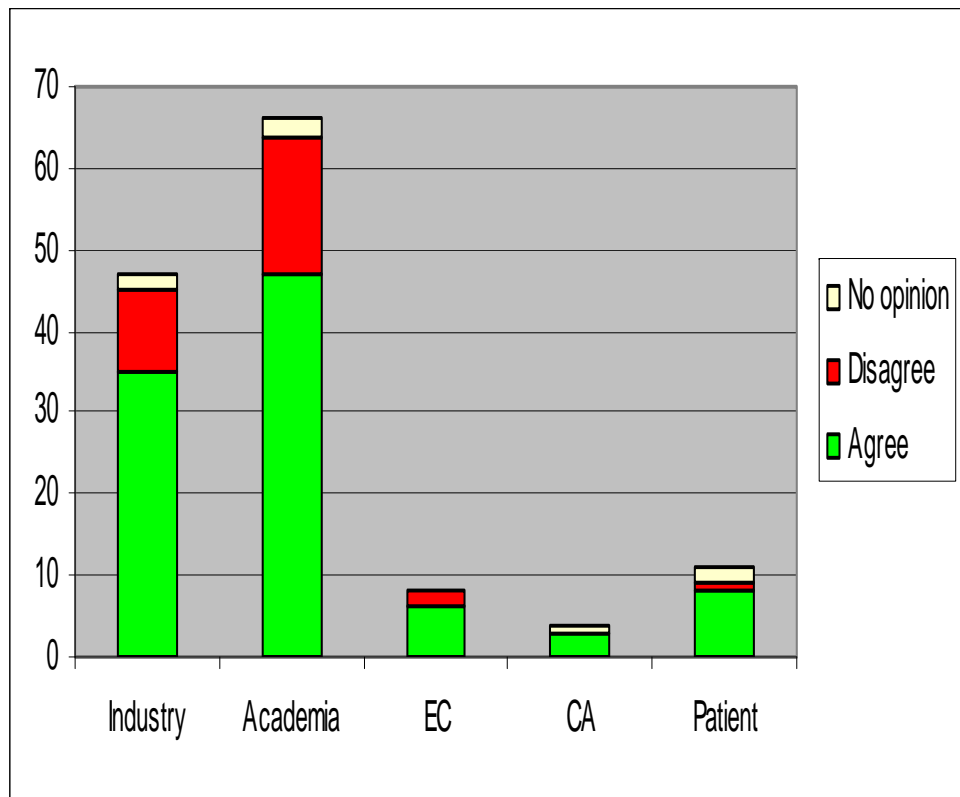
Multi-national CTs:  
Single EU opinion  
Central EC

Multi-national CTs:  
Single EU opinion  
Mutual recognition

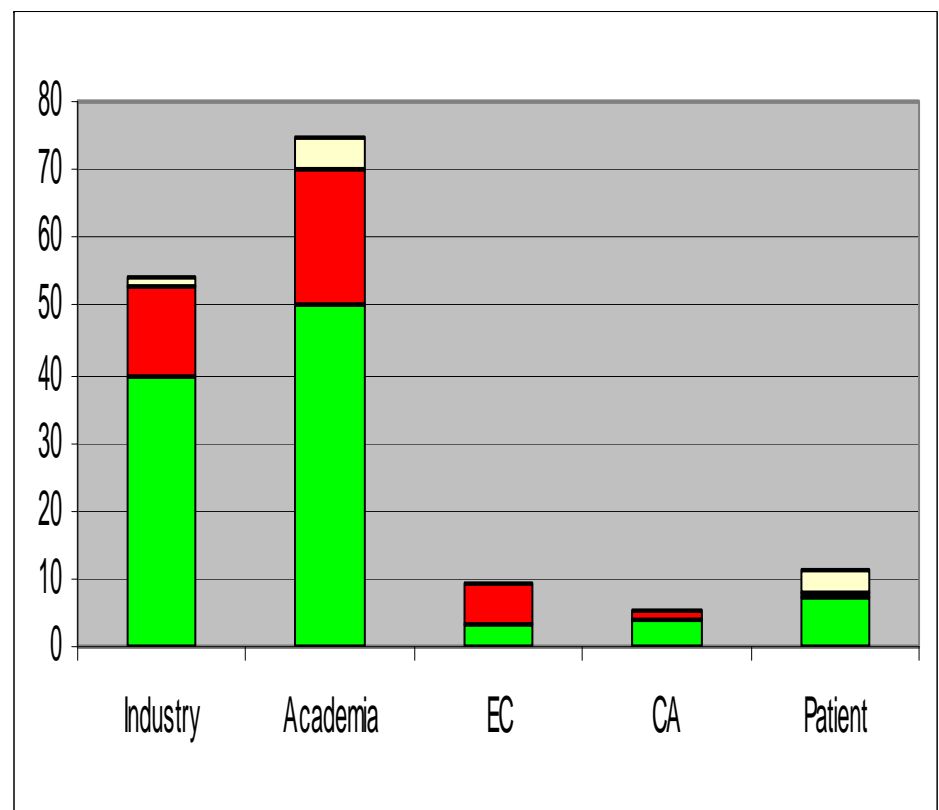


# Topic 19: Common ethical review dossier

EC

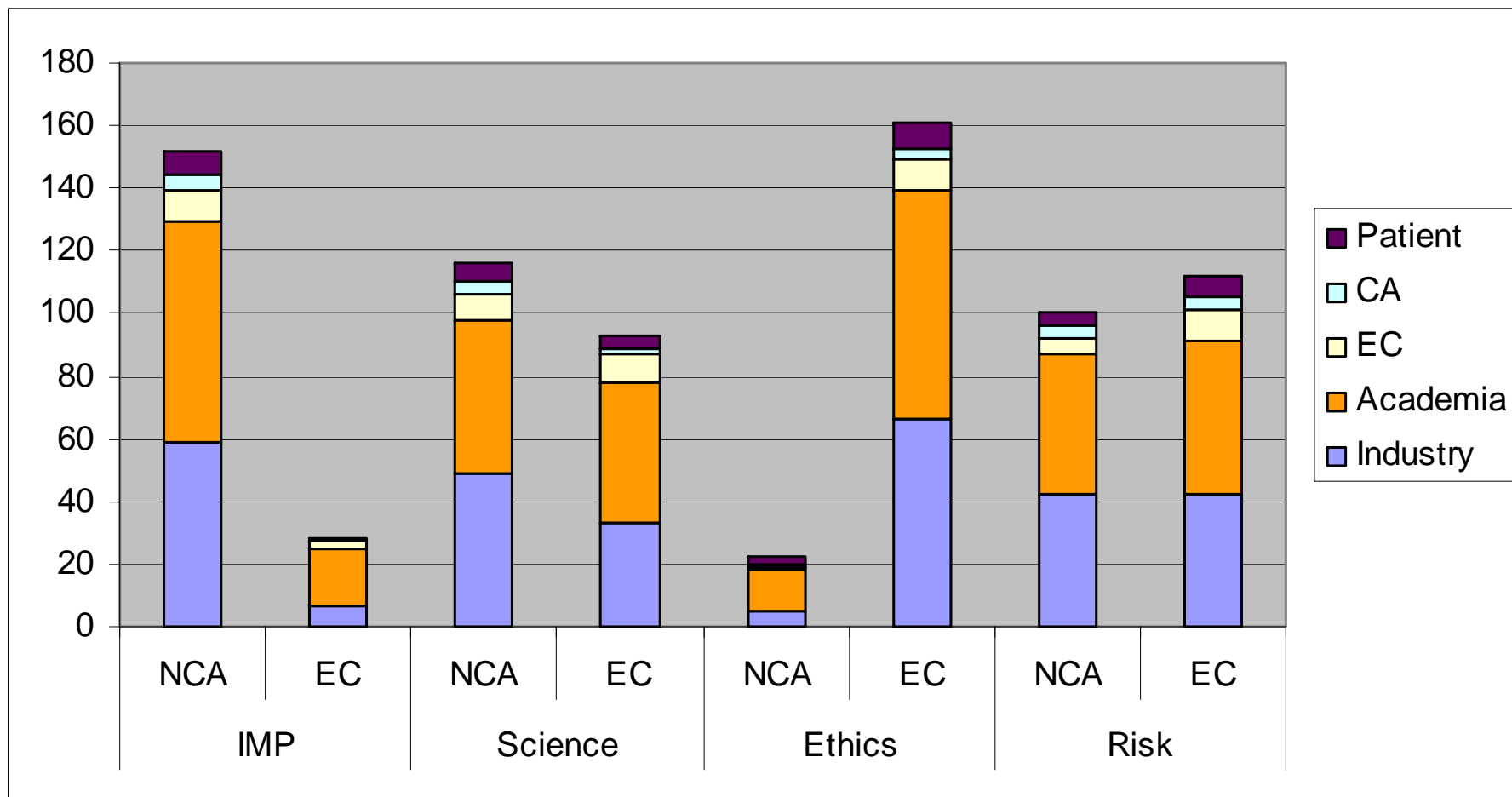


Common EC/NCA Dossier



## Topic 20:

There should be clear definition of which aspects in the review process are to be covered by NCAs and which by ECs

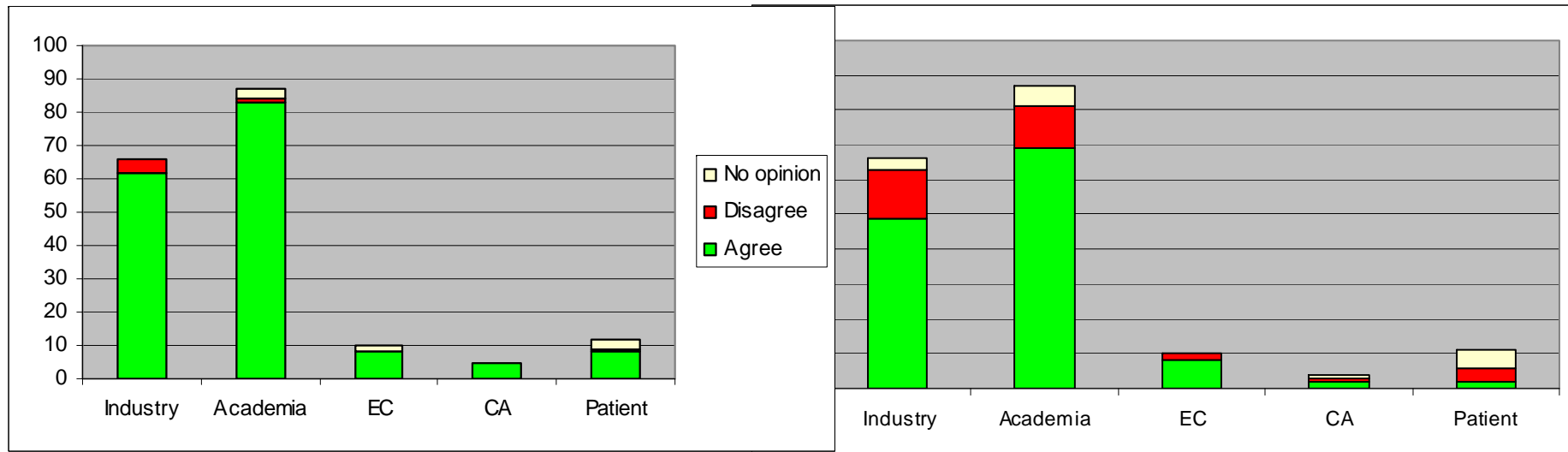


# Pharmacovigilance Workshop

# Topics 21 and 22: SUSAR reporting

Single entry in EVCTM -  
e-copy to CA

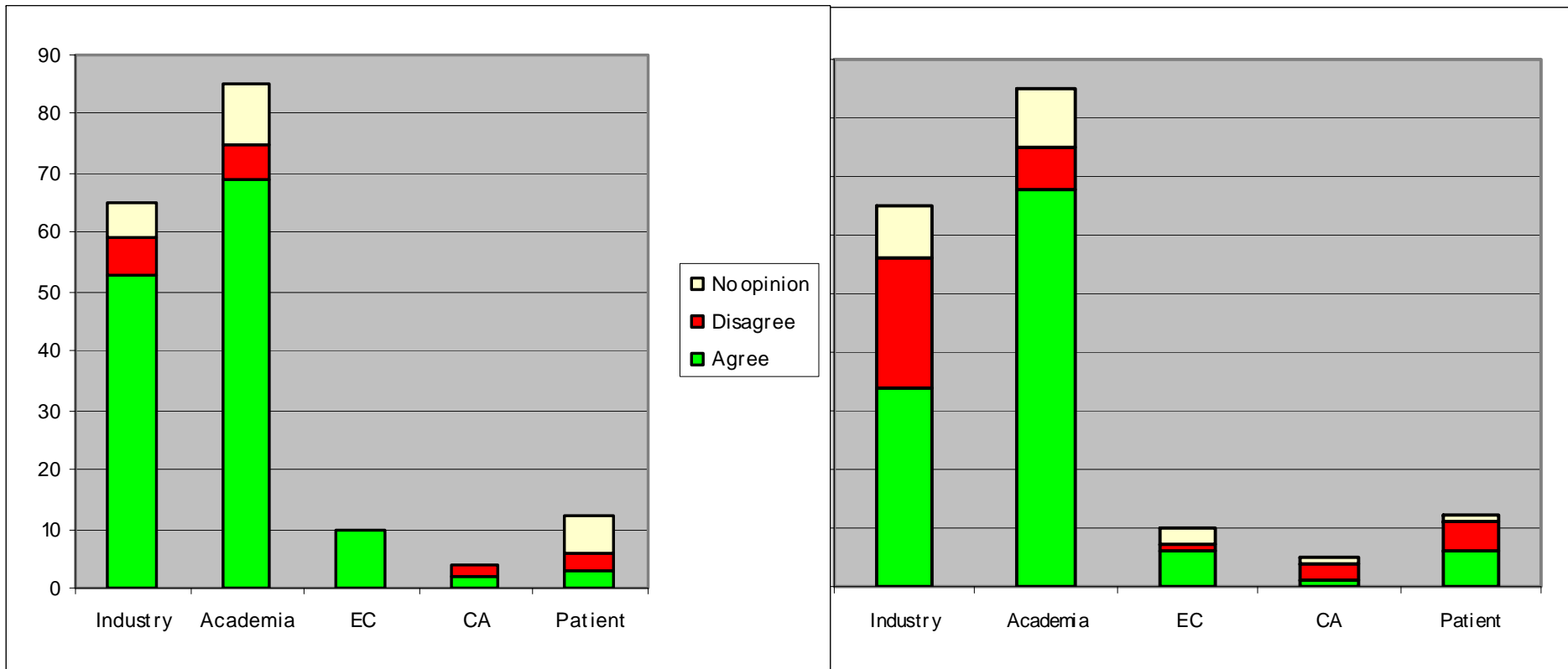
No expedited SUSAR  
reporting to EC and PI



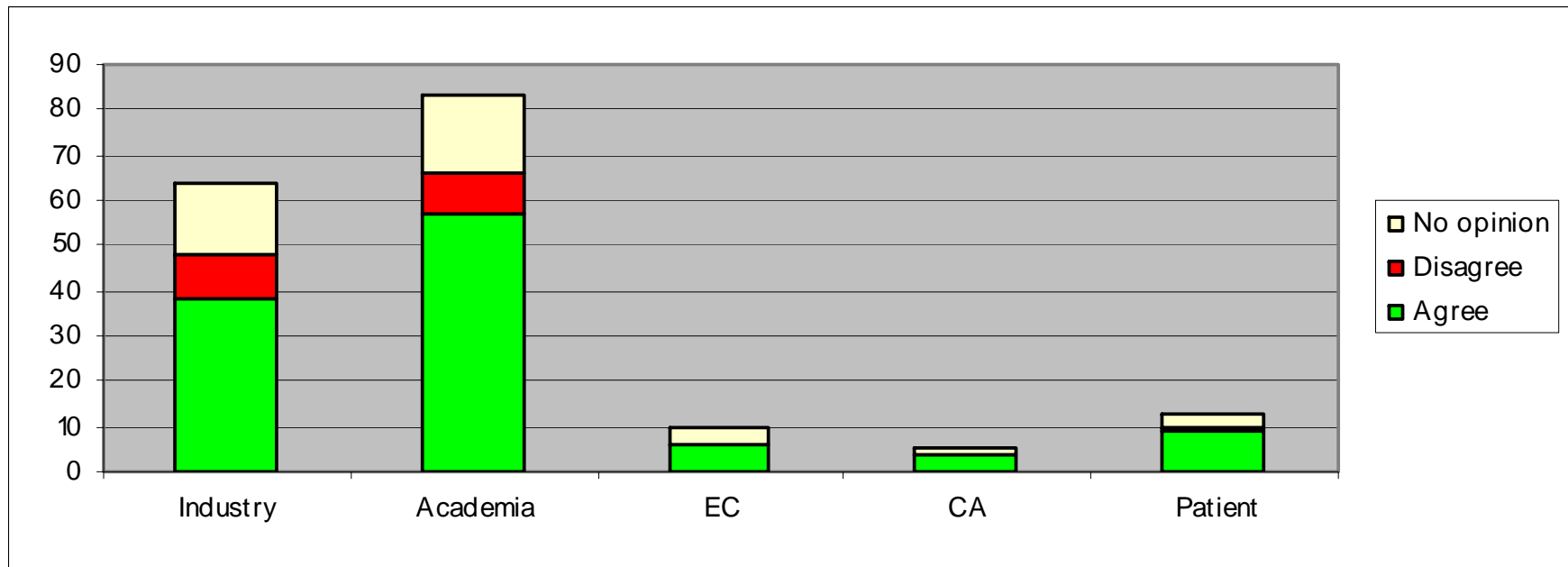
# Topics 23 and 24: SUSAR reporting in CTs with licensed drugs

SUSARs in CTs with licensed drugs  
EudraVigilance

ASRs should only cover  
safety of the current CT

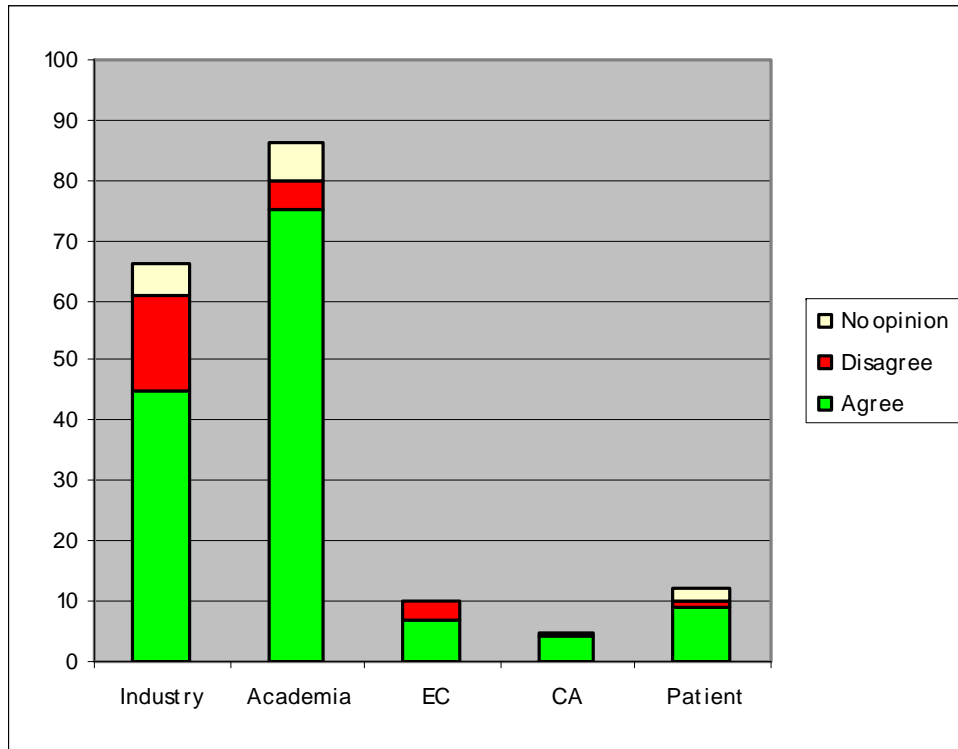


## Topic 25: Strengthened role of Safety Data Monitoring Boards

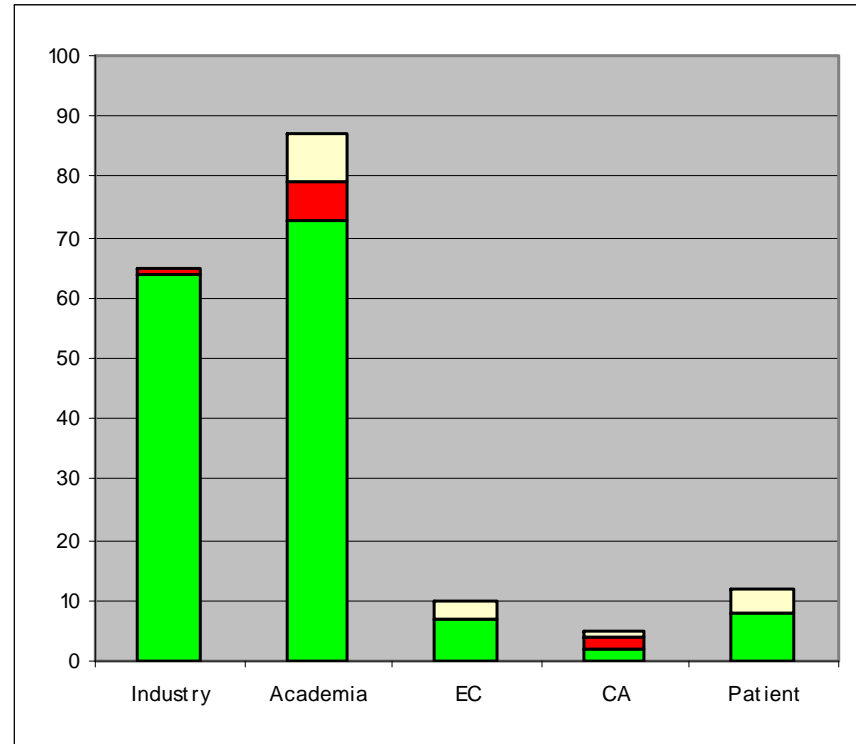


# Topics 26 and 27: Access to EudraVigilance

## ECs



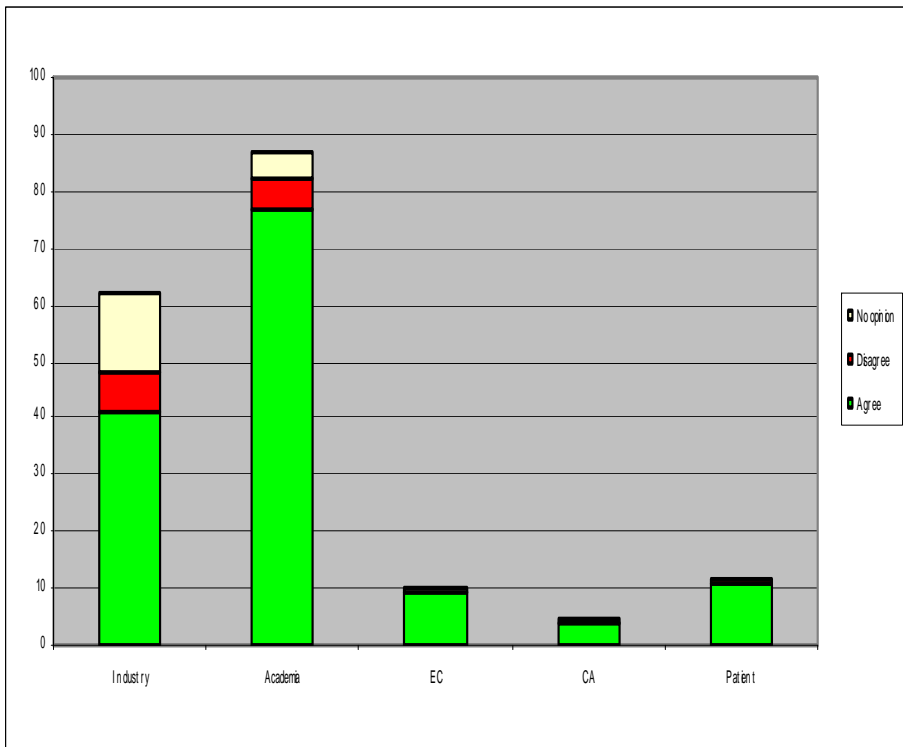
## Sponsors



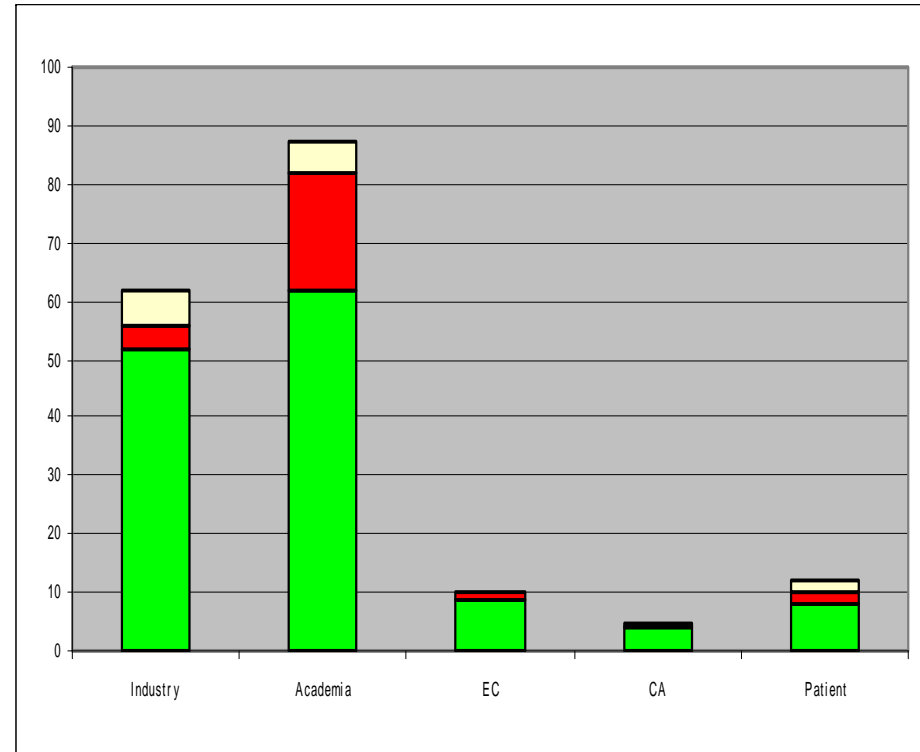
# Risk-based Approach Workshop

# Topics 28 and 29: The risk-based approach

Replacement of „one-fits-all“ by risk-based approach

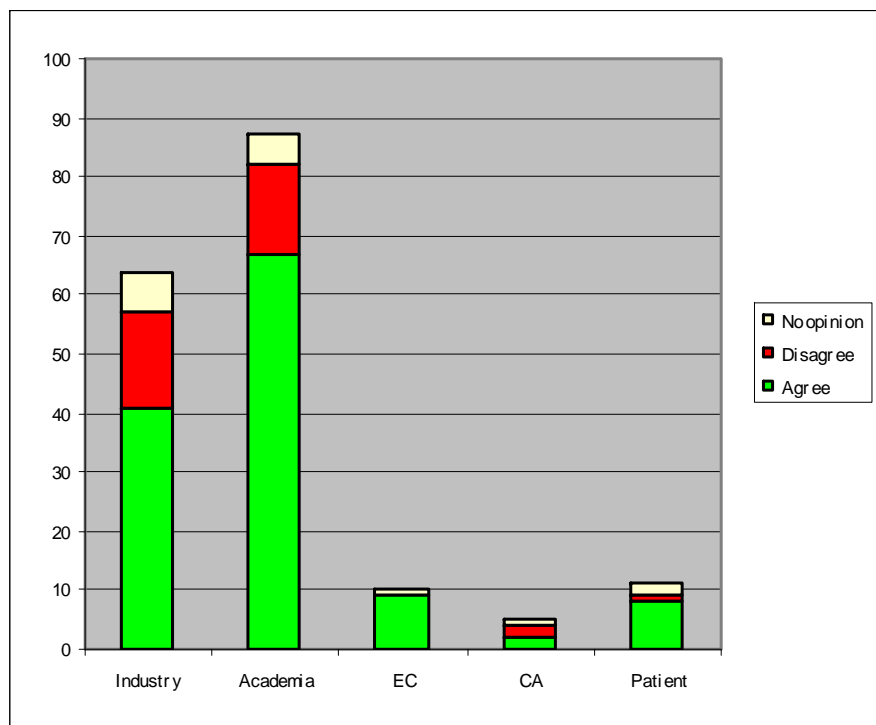


Implementation of risk categories

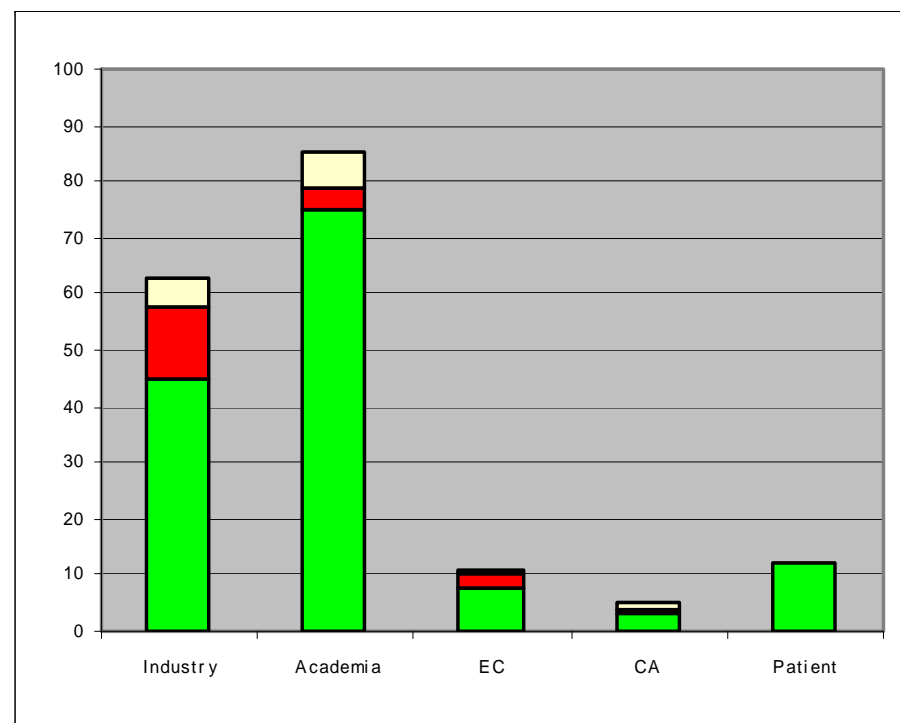


## Topics 30 and 31: Proposal for 3 risk categories

Agreement to proposed  
3 risk categories



More work required to define  
facilitation options for categories 2+3



## Topic 32:

### New CT legislation for all types of clinical research?

