



What do patients want and need to know when participating in clinical trials?



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European Liver Patients Association

The Structure

- General Remarks
- Some data
- What would I like a CT to address and respect



MY INVOLVEMENT IN CTS:



- European Liver Patients Association – Executive Director
- European Community Advisory Board (EATG) – Hepatitis Drugs Task-Force Leader
- Hepatitis Community Advisory Board, New York – European Representative
- Bulgarian National Patients` Organization - Chairperson



THE ACTORS:



- Patients
- Doctors
- Industry
- Academics
- Investigators
- Ethics Committees
- Regulatory authorities



Public Perceptions and Confidence in Clinical Research

Ken Getz

**Founder and Chairman, CISCRP, Senior
Fellow, Tufts CSDD**



PUBLIC CONFIDENCE AND TRUST IN THE CRE:

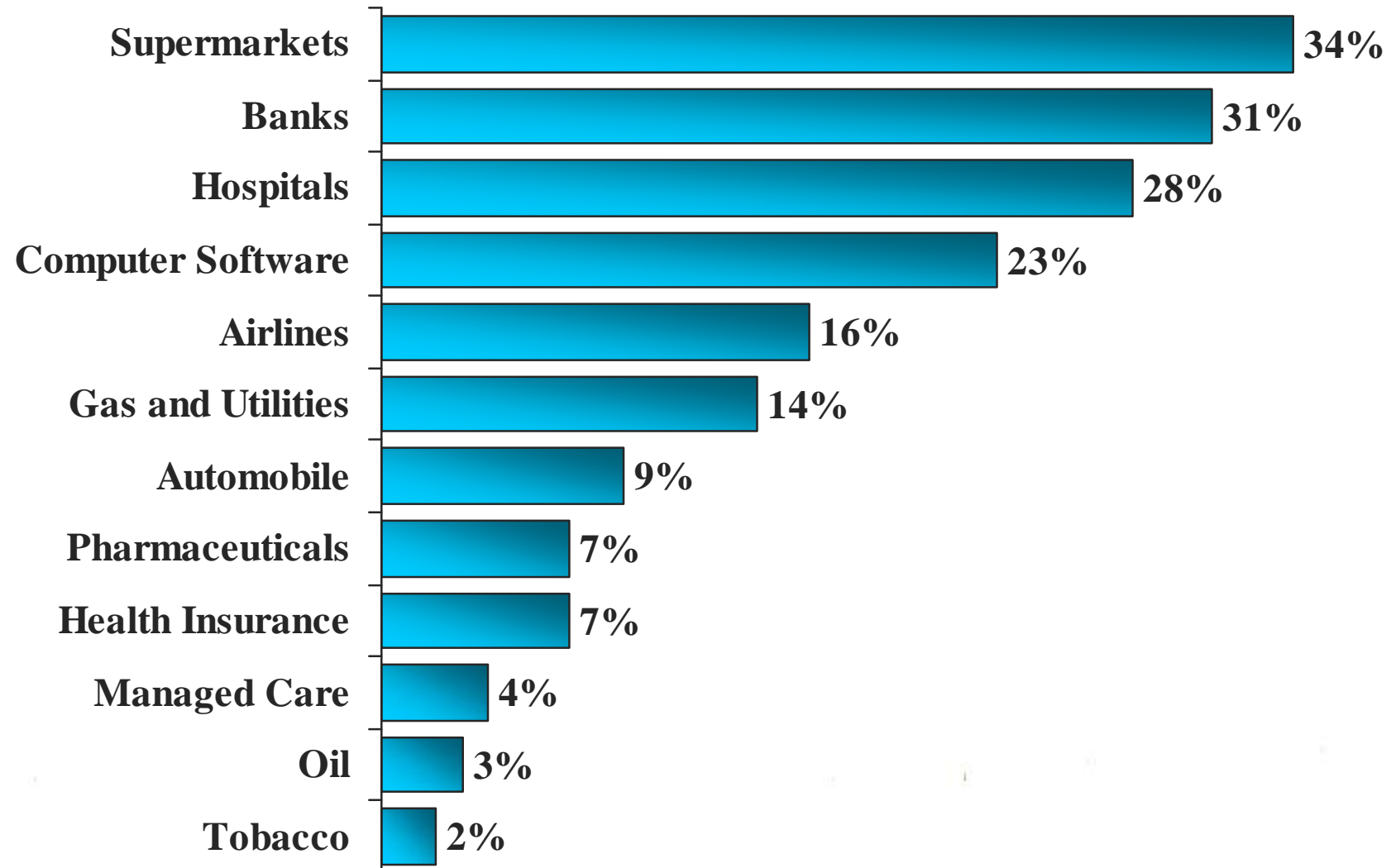


<i>General Public Attitudes</i>	<i>Perceptions of Clinical Research Professionals</i>
<p>70%-83% of Americans believe clinical research is 'very important' or 'essential' to advancing public health</p> <p>65% of Europeans believe that clinical research plays an important role in advancing public health</p>	<p>42% of Americans and 36% of Europeans distrust biopharmaceutical companies</p> <p>31% of Americans believe the FDA is effective at ensuring public/patient safety</p> <p>25% of Americans and 17% of Europeans believe that physicians and study staff are primarily motivated by greed</p>

Sources: *Research!America (JAMA, 2005); Ohmann (2004); HarrisInteractive (2002, 2004, 2007)*



WHICH OF THESE INDUSTRIES DO YOU THINK ARE GENERALLY HONEST AND TRUSTWORTHY?:

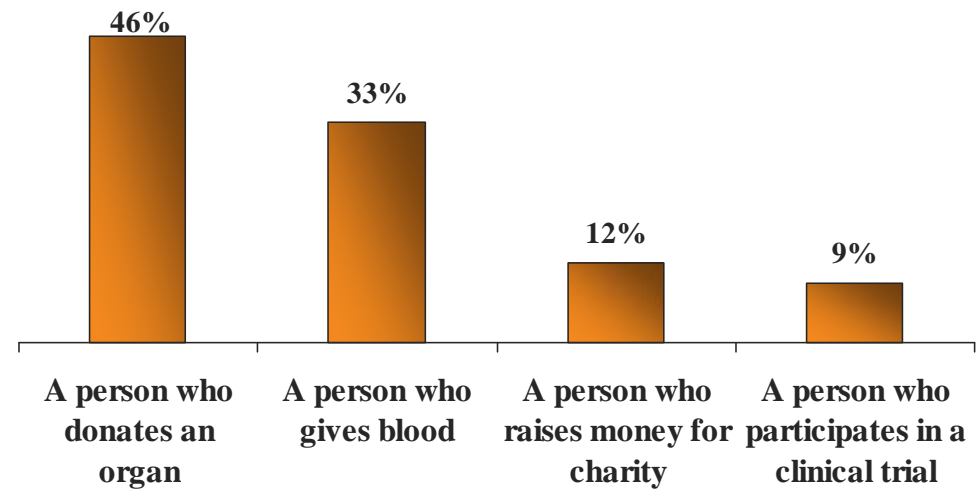


WHICH OF THESE INDUSTRIES DO



- Desperate (~29% believe only seriously-ill participate)
- Risk Takers (80% believe participants are ‘gambling’ with their health)
- Ambivalently respected (34% ‘Don’t Admire’ study volunteers)

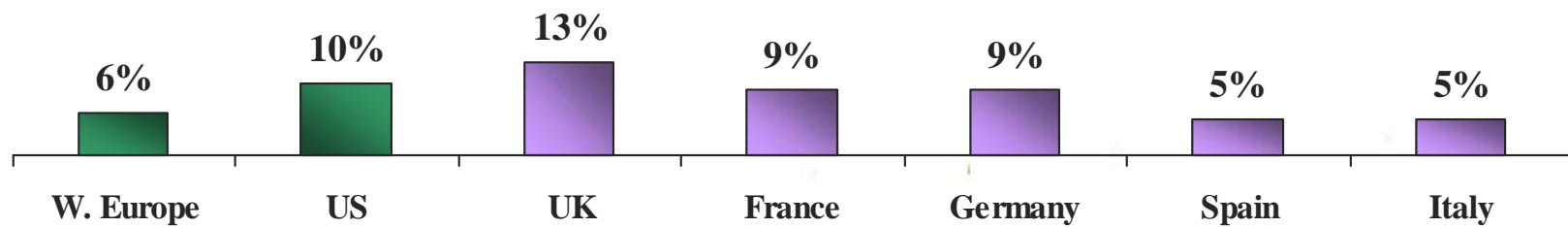
‘Who makes a better contribution to mankind?’



INTERNATIONAL VOLUNTEERISM RATES



*Percent of Population
'Ever' Participated*



Sources: HarrisInteractive, 2005

PREFERRED METHODS OF LEARNING ABOUT CLINICAL TRIALS



	US	W. Europe	UK	France	Germany	Italy	Spain
My Physician	51%	53%	40%	55%	58%	63%	52%
Email	28%	30%	34%	29%	30%	31%	27%
Media	21%	27%	17%	18%	25%	35%	30%
Advocacy Group	21%	21%	17%	18%	29%	15%	25%

Sources: *HarrisInteractive, 2006*





- I want simple explanation of the research question
- I need adequate time and space to review the trial and consider participation
- What are all my options with existing interventions
- What are the risks
- Protections and insurance is in place
- Confidentiality of my data



WHAT DO I WANT?



- Find out about trials
- Review by patient group
- Be informed of due process
- Who can I ask about what is presented to me?
- Other research on the same condition?
- How many people and for how long have been tested with this new interventions/drug



WHAT DO I WANT?



- Is there something better coming in the near future and can I wait for it?
- When and how will I get the results of the trial?
- Is this trial addressing everybody?
- Will there be a follow up?
- Is my time respected?



EXAMPLE: HEPATITIS C TREATMENT



- IFN/RBV
- INF/RBV+TPV or BOC
- INF/RBV+ other DAAs
- INF-free combinations

Resistance, duration, tolerability, success rates, compliance, disease progression?





- How many patients have the expertise to find and understand the answers of all these question before making a decision to enter a CT?
- How many CTs are designed and planned to meet these expectations of the patients?





- Involvement in Drug Development & Clinical Trials Designs
- Increased institutional involvement in Regulatory agencies
- Scientific Societies, Conferences & Guidelines, Research Advisory Boards
- Involvement in the recruitment process





- How many Patients Organisations are prepared to be involved in CTs?
- Do we have enough Patients Experts?



What is EUPATI?



The EUPATI project receives support from the European Union (IMI JU) and EFPIA companies



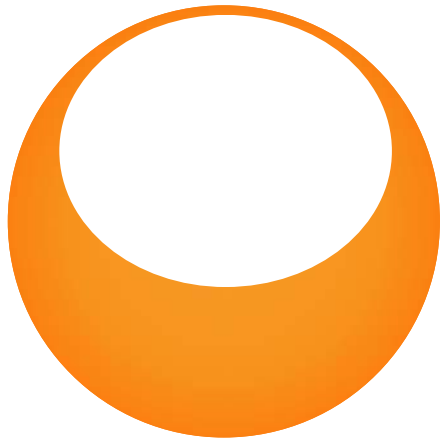
WHAT IS THE EUROPEAN PATIENTS ACADEMY ON THERAPEUTIC INNOVATION?



The European Patients' Academy on Therapeutic Innovation is:

- **initiated and led by key European Patient Advocacy organizations**
- the key European initiative that will develop and provide **objective, credible, correct and up-to-date public knowledge** about medical research
- a paradigm shift in **empowering patients and the public to understand medical research** and how to contribute to it
- a **strong multi-stakeholder consortium** of patient organizations, academia, NGOs and industry





THANK YOU FOR THE ATTENTION

