UNIVERSITÀ DEGLI STUDI DI MILANO

IEO Istituto Europeo di Oncologia

# Empowering patient's decision-making autonomy

**Patient advocates course:**
**'The Methodology of clinical trials in rare cancers'**
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# Phase I trials

- Serve to investigate the safety profile of novel drugs or treatment modalities
- Their primary aim is not to cure, but to test the drug or treatment safety, the safe dosage range and the potential side effects

- Only the most vulnerable patients can be enrolled in these studies

# Low participation rate

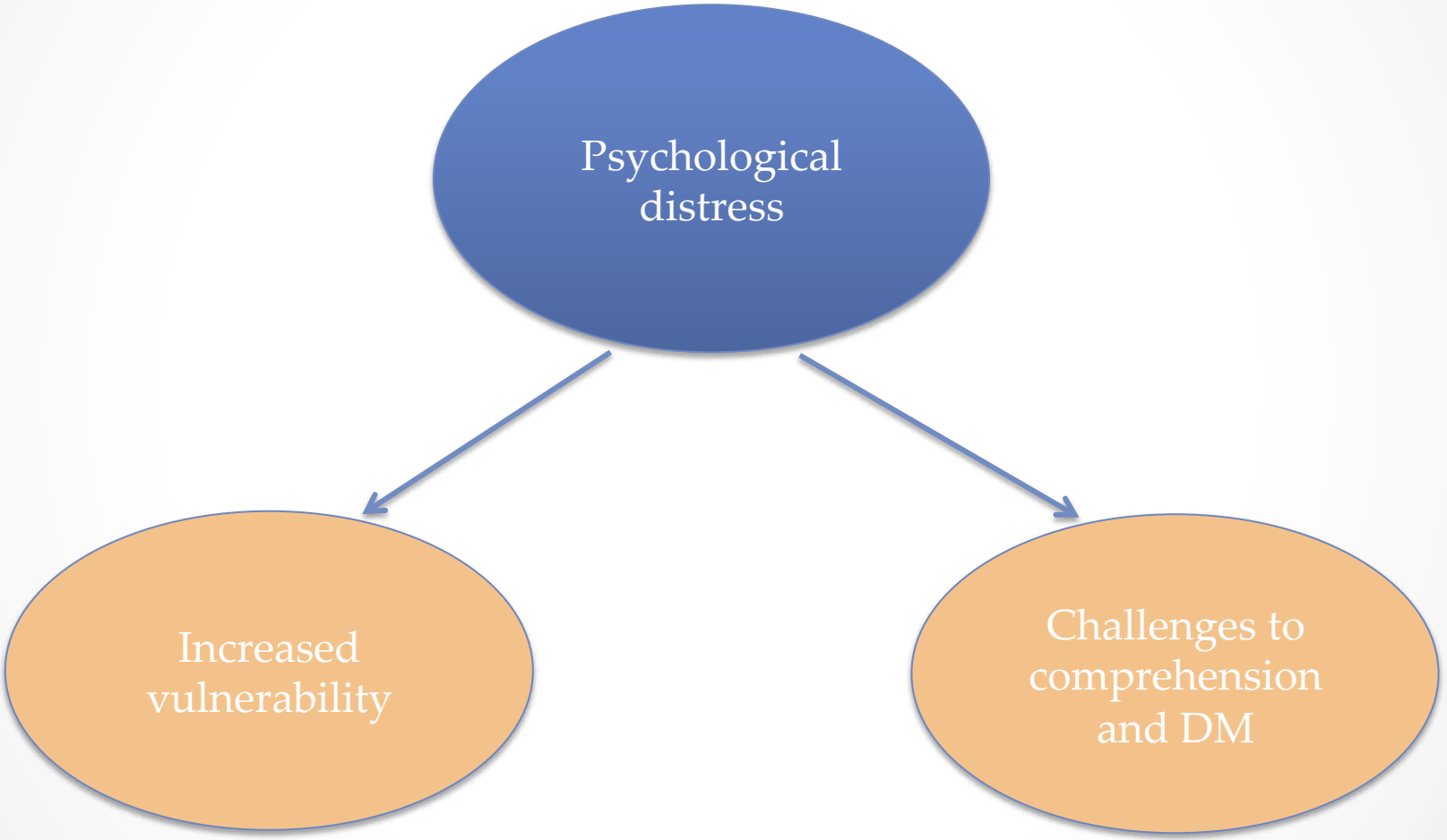
- Less than 5% of all adult cancer patients accept to participate
- This represents a **significant concern** for the necessary development of new drugs (especially in the era of personalized medicine in which targeted agents need to be developed to have therapeutic benefit in molecularly defined patient subsets)

# Facing with uncertainty

- Uncertain and low potential for individual benefit
- Uncertain and significant potential for side effects

- Ethical concerns about informed consent process

# Effects on decision making




Is informed consent free and informed?

# Reasons to participate

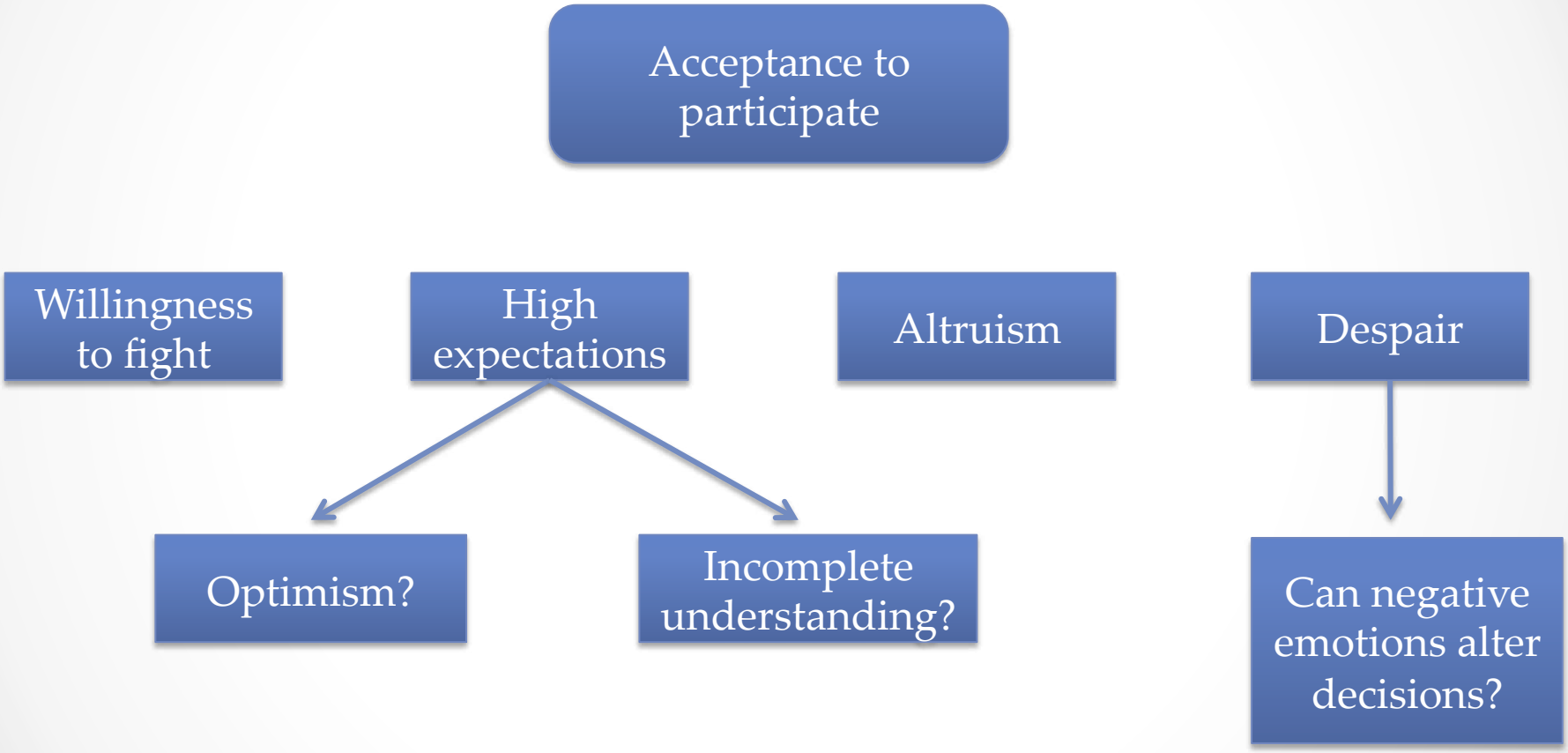
- The awareness to have **no other chances**
- The willingness to **"fight aggressively until the end"**
- The presence of **altruistic feelings**
- **Therapeutic optimism**: patients consider their own chance of obtaining medical benefit as high or even as higher than participants in general expressing and trusting their hope rather than considering facts (less than 5% of patients enrolled in phase I trials benefit from participation)

# The Health Stock Risk Adjustment model

- "As one's perception of future health, relative to baseline health, declines, a patient will tend to overvalue potential benefits and undervalue potential risks in deciding whether to choose an experimental treatment"

- The elderly does an exception: they are less willing to accept toxic treatment that can eventually increase their survival rate affecting their quality of life

# Major ethical concern



# Reasons to NOT participate

- Fears of additional burdens and adverse effects
- Misunderstanding of trial information
- Family members recommend patients against trial participation
- Lack of trust in medical research
- Preference for a better quality of life rather than an uncertain, possibly worse quantity of life

# Is it possible to help patients to make a responsible and satisfying decision?

- **Decision quality** refers to the extent to which the patient's choice is:

- informed
- consistent with her personal attitudes (i.e., her "values") about the therapeutic options' pros and cons
- acted on

# Information provision and understanding

- **Evidence: correct understanding between 33-43%**

- Possible reasons:
- Suboptimal patient-physician communication
- Excessive anxiety

- Possible consequences:
- Unexpressed misconceptions and fears
- No shared decision making
- Consequent regret

# Analysis of patients' values and attitudes

- **Evidence: scarce attention to the patients' values by physicians**

- Possible intervention:
- Using a "values tool" that elicites patients' preferences

- Possible effects:
- Patients express their needs
- QoL and expectation of survival increase

# Act on

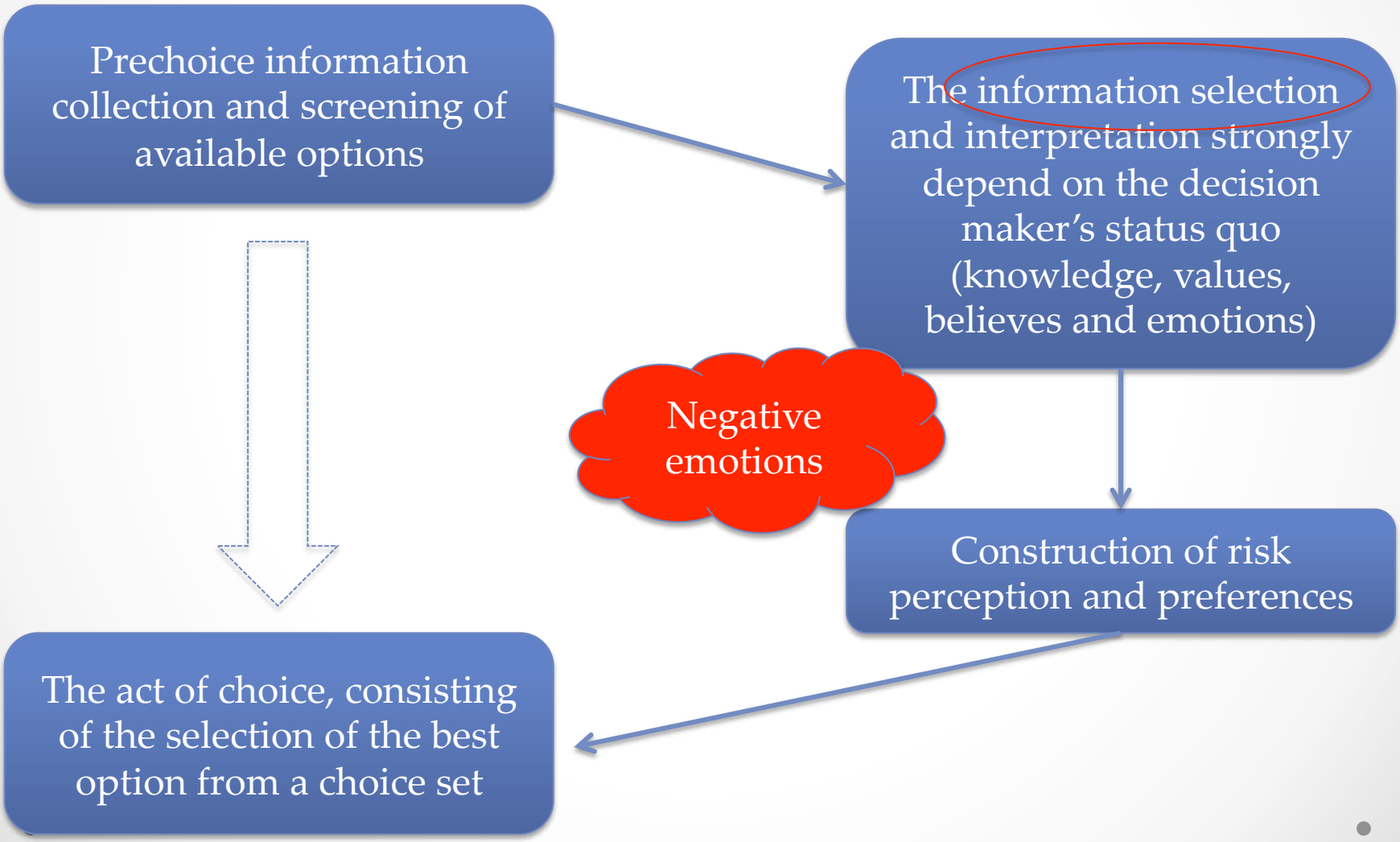
- 47% of patients take a passive DM role
- 38% take an active role
- 15% take a shared role (Meropol, 2003)

- Understanding the patient's DM style contributes to prevent regret and its negative related effects

# Barriers seen by physicians

- Lack of time
- Patient's misunderstanding
- Patient's (and family's) anxiety

# The decision making process



# The role of physician

- In these circumstances professionals should pay great attention to:

- how information is provided
- whether or not information is understood
- How to handle patients' emotions

- In particular, they should pay attention to the generation of cognitive biases…

# The framing effect

- People tend to focus on information that is explicitly presented in the context
- Choices can be presented within a neutral, positive, or a negative frame
- A **positive** framing (probability of positive outcomes and improvements in QoL, etc) will create a positive mindset improving patients' participation

# The meaning of numerical information

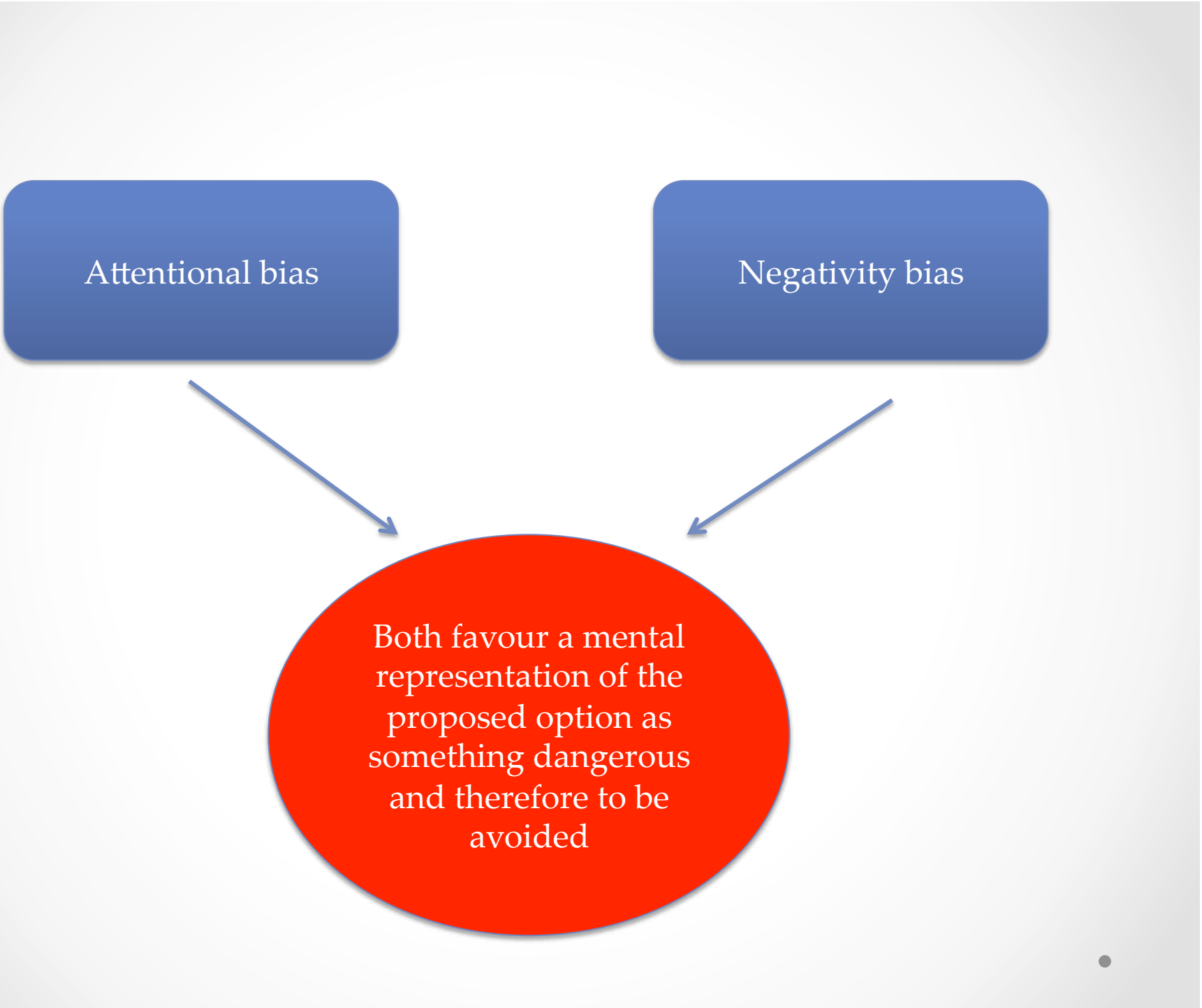
- "20 out of every 100 similar patients would be likely to have important side effects" (frequency frame)
- "20% chance will have important side effects" (percentage frame)
- While using numerical information brings a more precise meaning than a verbal quantifier (e.g., low, medium, high), using frequency vs percentage formats may impact the information processing

# The negativity bias

- Negative emotions such as fear, anxiety and depression affect the choice process making anxious and depressed patients less likely to volunteer for participation

# The attentional bias

- When feeling anxiety, fear or sadness people tend to assign more weight more negative than positive stimuli
- High levels of fear or anxiety allocate most of attentional resources on threat stimuli, neglecting the positive ones
- When consequences are uncertain, and positive and negative information compete, anxious and depressed patients are more likely than non anxious ones to select more threatening versus non-threatening meanings


Attentional bias
Negativity bias
Both favour a mental representation of the proposed option as something dangerous and therefore to be avoided

- Awareness of the existence of such bias is particularly important in the patient-physician communication and in the construction of informed consent forms

- Neglecting the existence of the aforementioned cognitive processes impair understanding of how people react to the information, even when carefully provided

## Evidences

- The way information is framed makes specific pieces of information more salient than others
- The patient's personal status quo guides the attribution of weight to information
- The doctor-patient communication affects the allocation of relevance to that information

## Consequences

- The majority of patients refusing to participate in clinical trials might not comprehensively understand the information provided
- If patients do not understand protocol information they cannot make a values-coherent decision
- Low participation rate blocks research that might have benefits for future patients

# Conclusions…

- An integrated approach is necessary to:

- Improve communication regarding phase 1 cancer trials
- Builds a sense of alliance
- Gives personalised support and provides tailored medical information
- Design trials around the patient's real life and needs, enhancing shared decision making and choice utility for both patients and researcher-physicians

# …and operative proposal

- Such approach could be reached through the development of a validated and calibrated computer modeling including all the patients' variables aimed to maximize information gained from the patient's evaluation to bridge current knowledge gaps and to advance cancer clinical care and research

# *Thank you for your attention!*

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