



# AGES

Österreichische Agentur für Gesundheit  
und Ernährungssicherheit GmbH

*Health. Nutrition. Safety.  
Our Concern.*

## Added Therapeutic Value and Health Technology Assessment: „Relative Effectiveness Assessments in Europe“

DIA meeting Vienna 2007

AGES PharmMed  
Science & Information Unit  
Fabian Waechter, MD, MSc

*"None of the arts theorize about individual cases. Medicine, for instance, does not theorize about what will help to cure **Mr. X** or **Mr. Y**, but only about what will help to cure any or all of a given class of patients. This alone is business: individual cases are so infinitely various that no systematic knowledge of them is possible."*

**Aristotle. *Rhetoric*. book I, chapter 2: 1356b**

## What is this all about?

### The fourth hurdle



## Council Regulation (EEC) No 2309/93



...authorization of such medicinal products should be based on the objective scientific criteria of the **quality**, the **safety** and the **efficacy** of the medicinal product concerned **to the exclusion of economic or other considerations**; ...

The provisions of this Regulation **shall not affect the powers** of the Member States' authorities as regards the price setting of medicinal products or their **inclusion in the scope of the national health systems of the Member States' authorities or their inclusion in the scope of the social security schemes** on the basis of health, economic and social conditions. ...

# PharmMed – Relative Effectiveness



In 2005 the **Pharmaceutical Forum** was founded by Vice President Verheugen and Commissioner Kyprianou. A EU Commission High-level-group with the following aims:

- 1. Strengthening of the European Pharmaceutical Industry
  - 2. Improving Public Health in the EU
  - 3. But enabling containment of pharmaceutical cost at the same time
- How?  
Through  
Innovative  
drugs



**Anti-innovation?**

**To achieve these goals the Pharmaceutical Forum commissioned 3 Working Groups:**

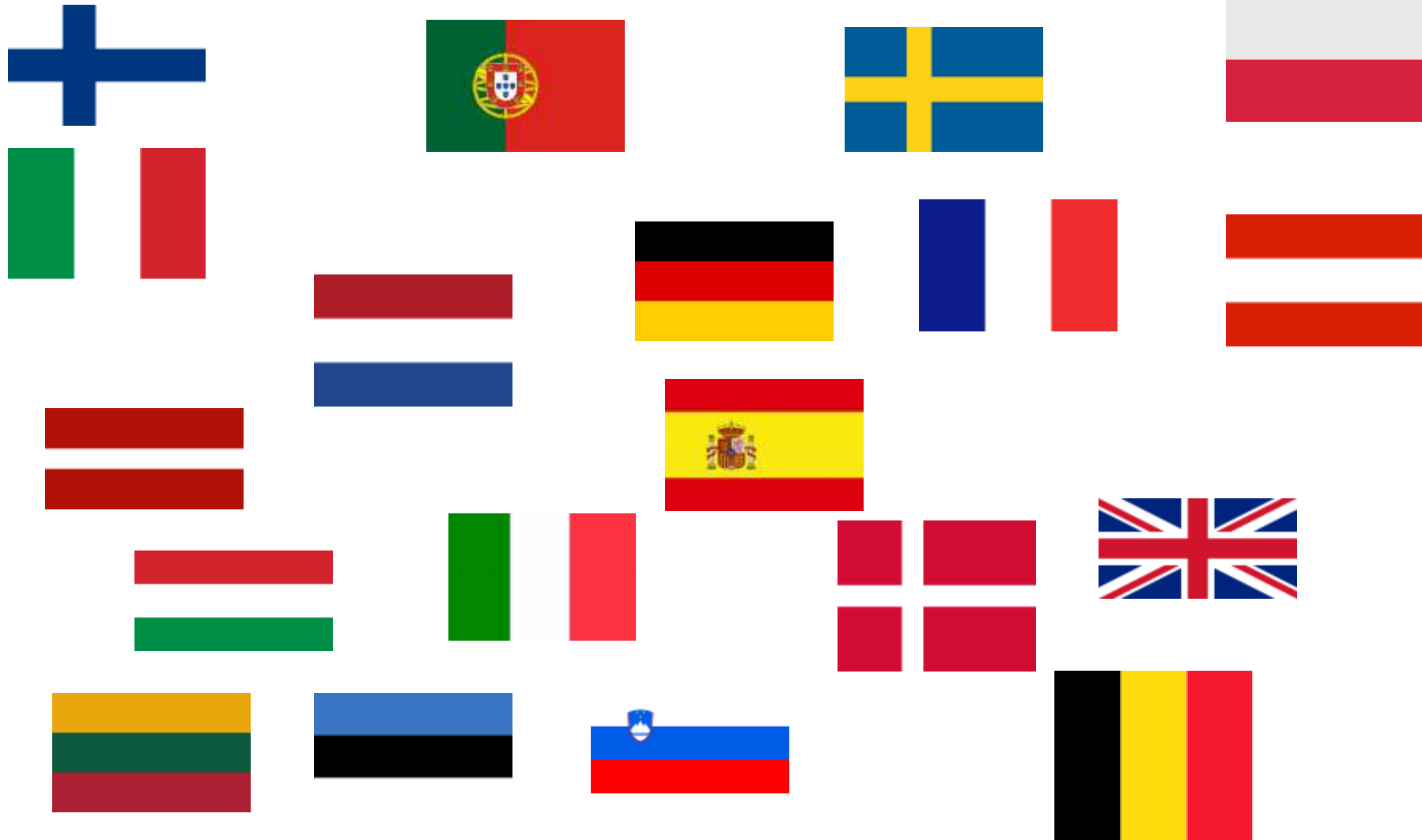
**1. Information to patients**

**2. Pricing and Reimbursement**

**3. Relative Effectiveness:**

- Is about methods to compare different drugs after their market approval
- The aim is to take the best possible decision regarding their reimbursement

# PharmMed – Relative Effectiveness





# PharmMed – Relative Effectiveness



*Making Medicines Affordable*

EUROPEAN GENERIC MEDICINES ASSOCIATION



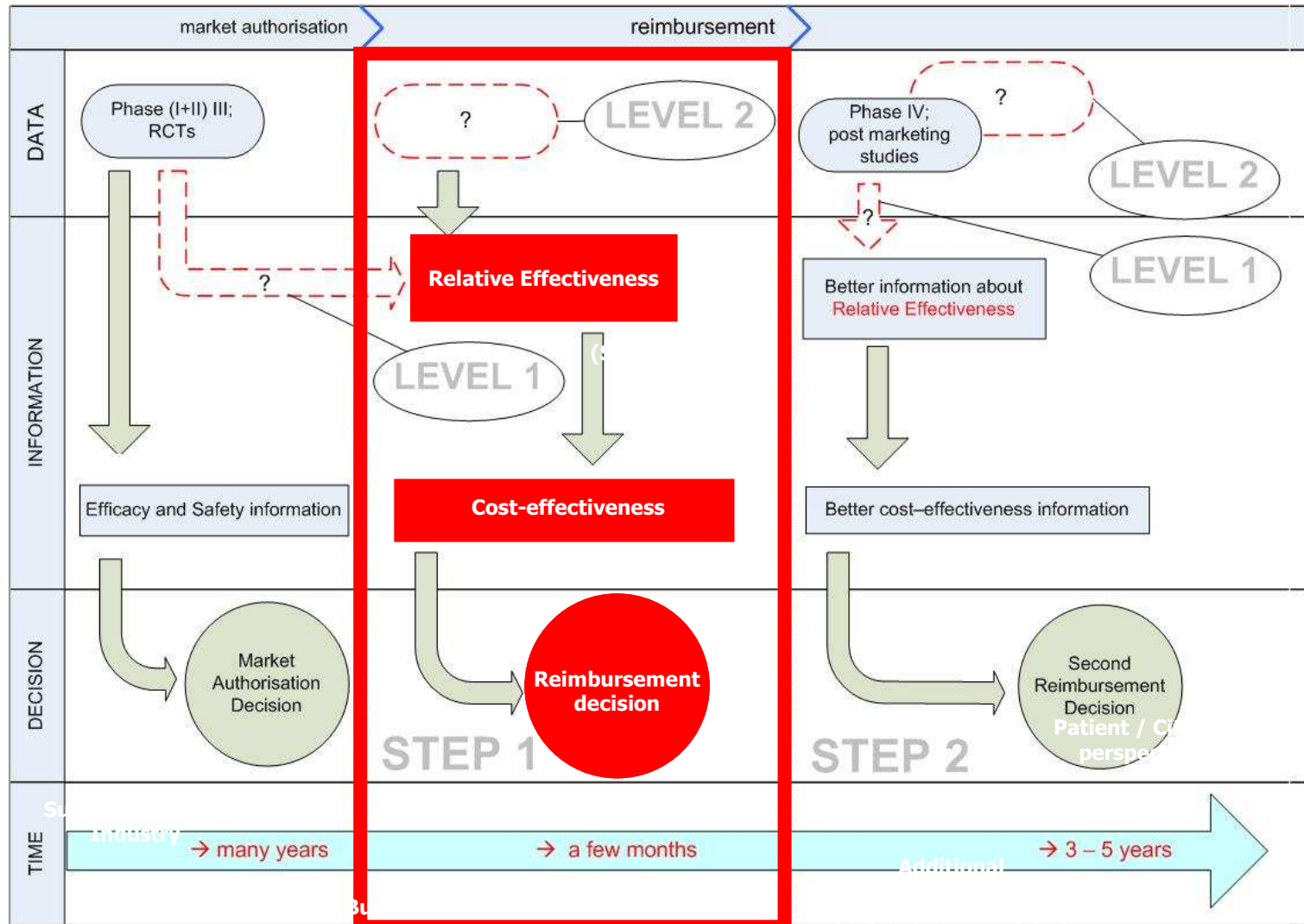
*Pharmaceutical Group of the European Union  
Groupement Pharmaceutique de L'Union Européenne*



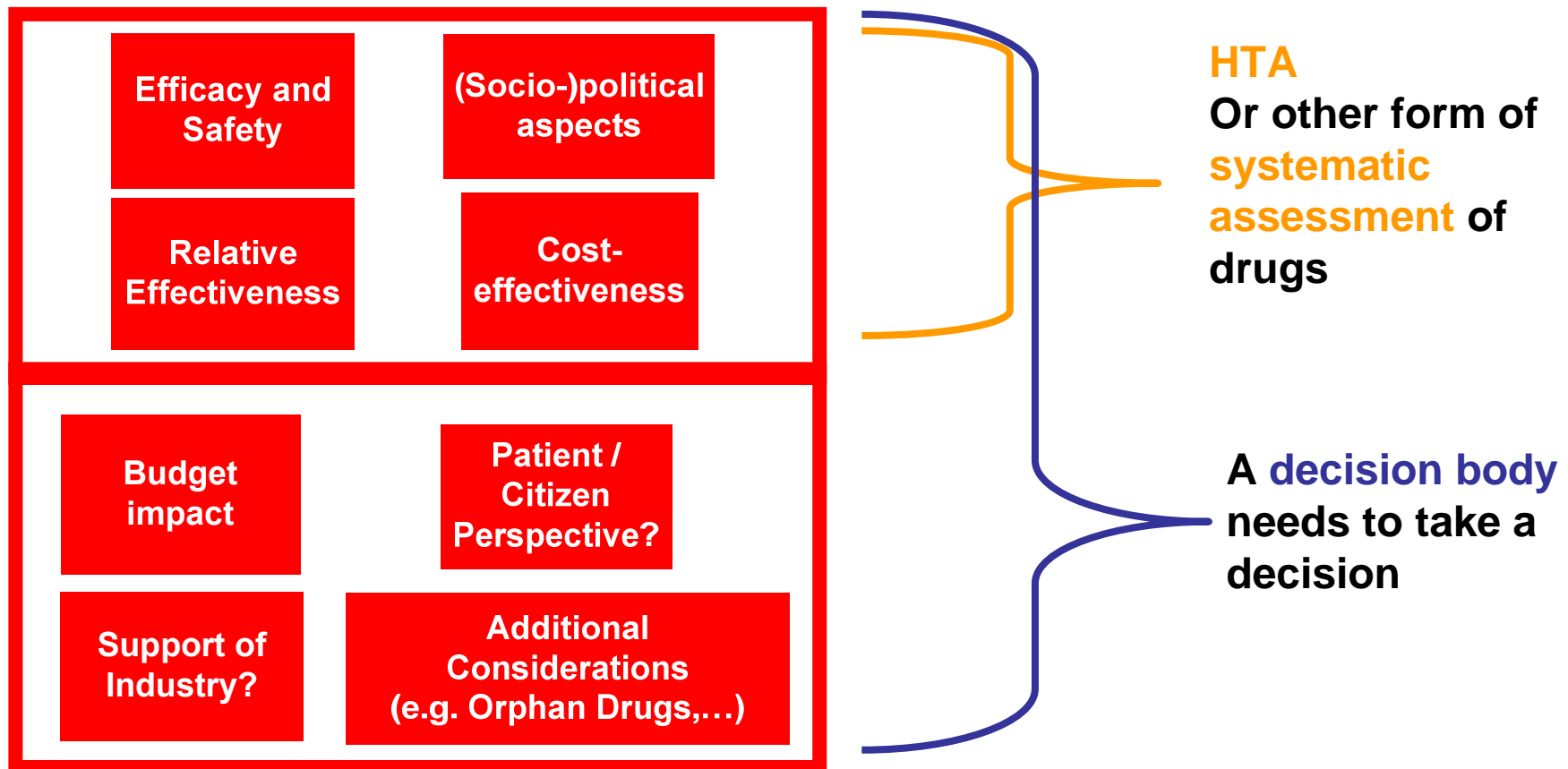
## **Some important topics from the report on data and methodology of Relative Effectiveness:**

1. Relationship of Relative Effectiveness and Cost-effectiveness
2. The difference between Relative Effectiveness and the overall Reimbursement decision
3. The difference between Relative Effectiveness and HTA (Health Technology Assessment)
4. The „Two Step – Two Level approach“

# PharmMed – Relative Effectiveness



## What do you need to come to a Reimbursement decision?



- **Do we all mean the same thing when we say HTA?**

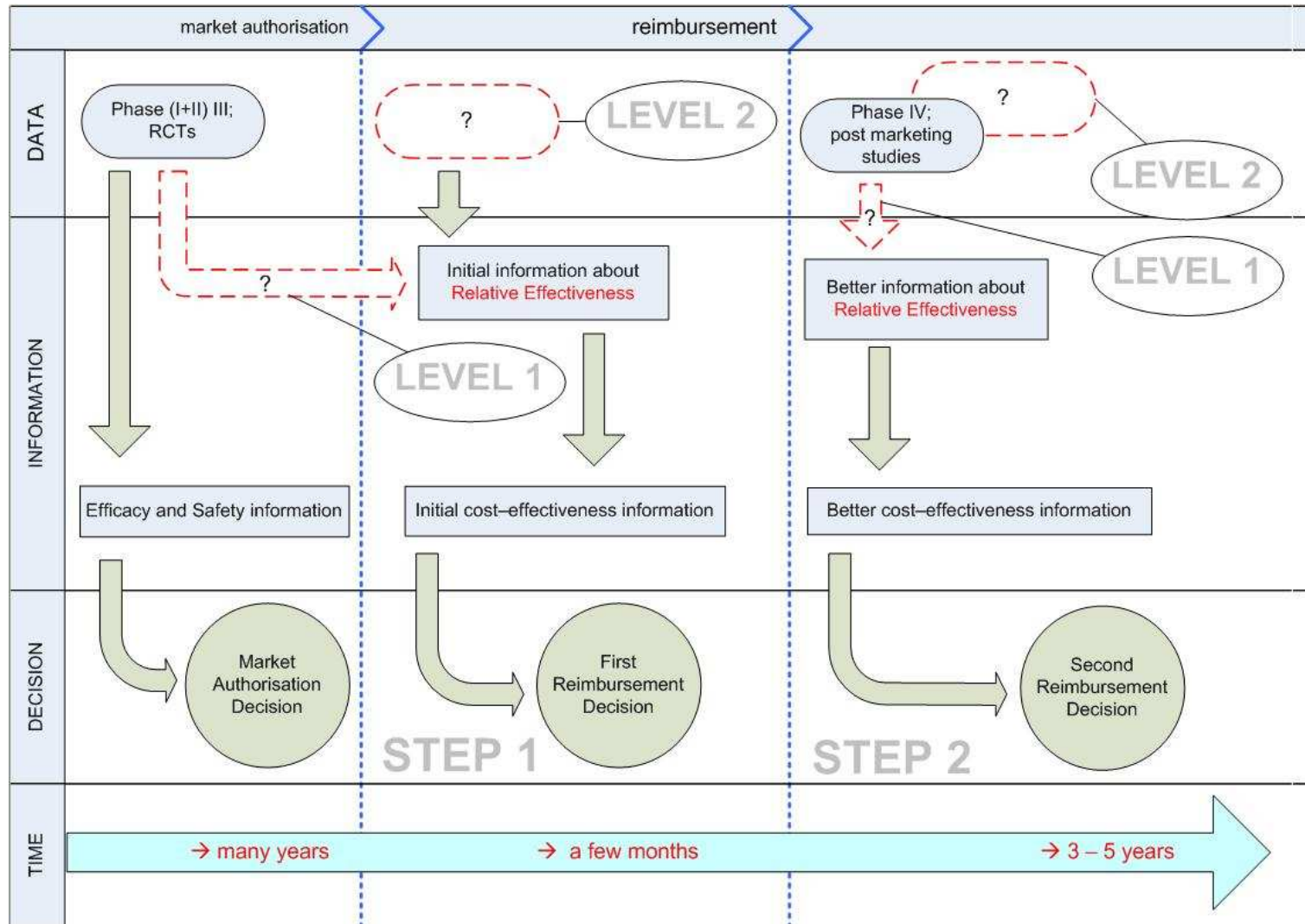
*"All over Europe HTA is used to assess drugs after their market approval. To evaluate costs and benefits of new and old drug."*



HTA is not a synonym for the overall decision process that leads to a reimbursement decision

Sometimes HTA is an important part of the overall process.

# PharmMed – Relative Effectiveness



## Relative Effectiveness in 2 minutes



**Efficacy**



**Effectiveness**

What is the difference between Efficacy and Effectiveness:

- **Efficacy - a typical clinical trial:** very high standards, highly selected patients, high quality standards, few mistakes,...
- **Effectiveness – sometimes called pragmatic trials:** closer to real life, less standardized procedures, more mistakes, „real patients“,.....



## TAKE HOME:

1. Not every systematic assessment of drugs is HTA
2. For all assessments of drugs (including HTA) there is a lack of optimal data
3. Until better data can be produced most assessments will be based on the efficacy & safety data produced for regulatory purposes
4. When taking reimbursement decisions the assessment of Medical effects should be completely separated from the economic effects
5. Reimbursement decisions should be as transparent as possible!

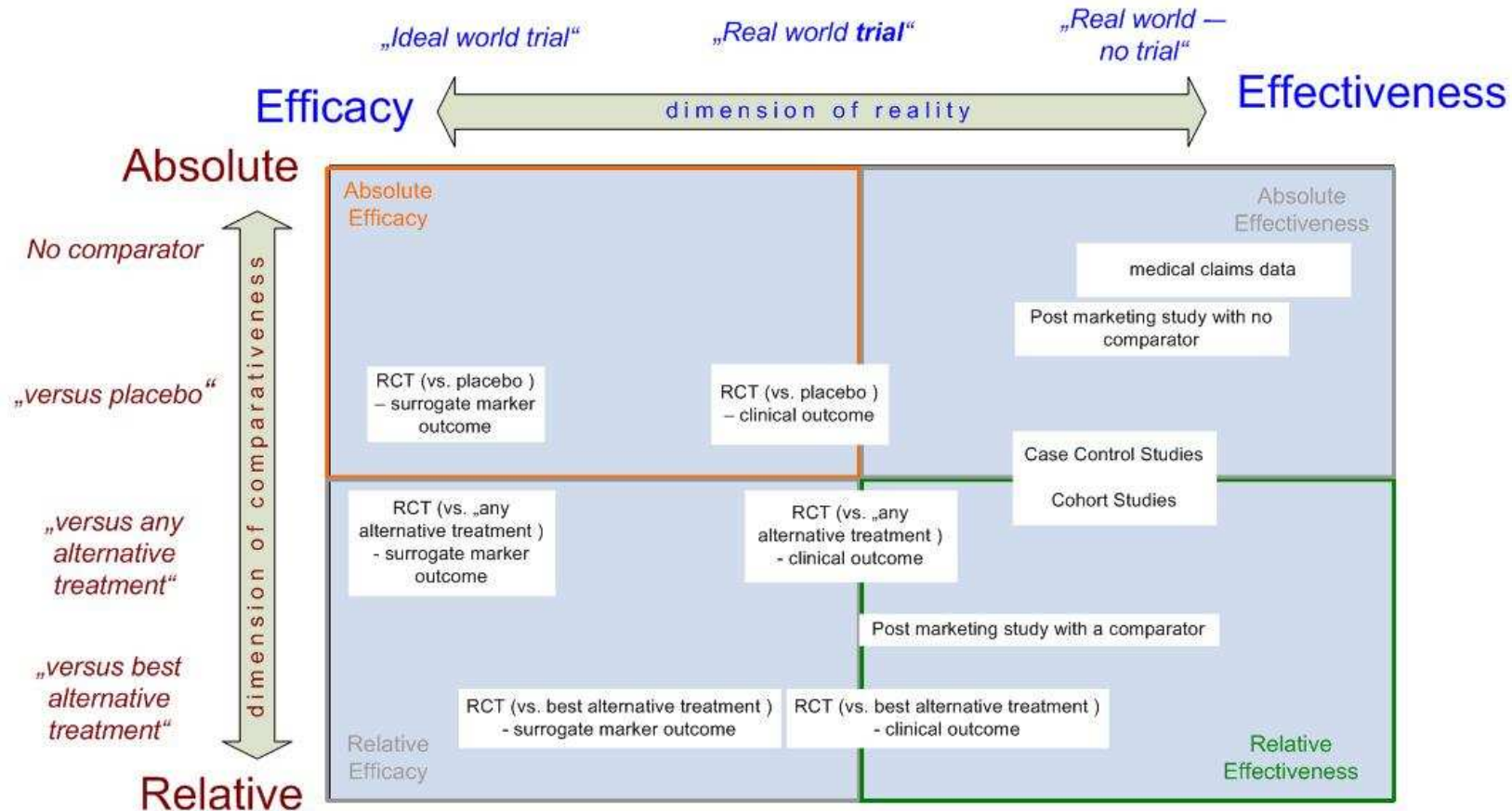
# PharmMed – Relative Effectiveness



Flintstone's car or PLACEBO car

**THANK YOU FOR YOUR KIND ATTENTION!**

# PharmMed – Relative Effectiveness



## Beispiel:

### Gardasil / HPV Impfung

- Nachbeobachtung 3 Jahre !
- Keine Unterschiede bei Karzinomen gemessen sondern nur in Karzinom vorstufen (CIN)
- Nur die attributable Fraktion, der Teil der Cervixkarzinome der durch HPV (16 und 18) verursacht wird, würde verhindert werden
- Das sind NICHT alle Cervixkarzinome in denen HPV 16 und 18 nachgewiesen wurde



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*Gesundheit. Ernährung. Sicherheit.  
Unsere Verantwortung.*

**[www.ages.at](http://www.ages.at)**