III Congresso Internacional de Auditoria em Saúde ABEA

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Health Technology Assessment and Adoption in Germany

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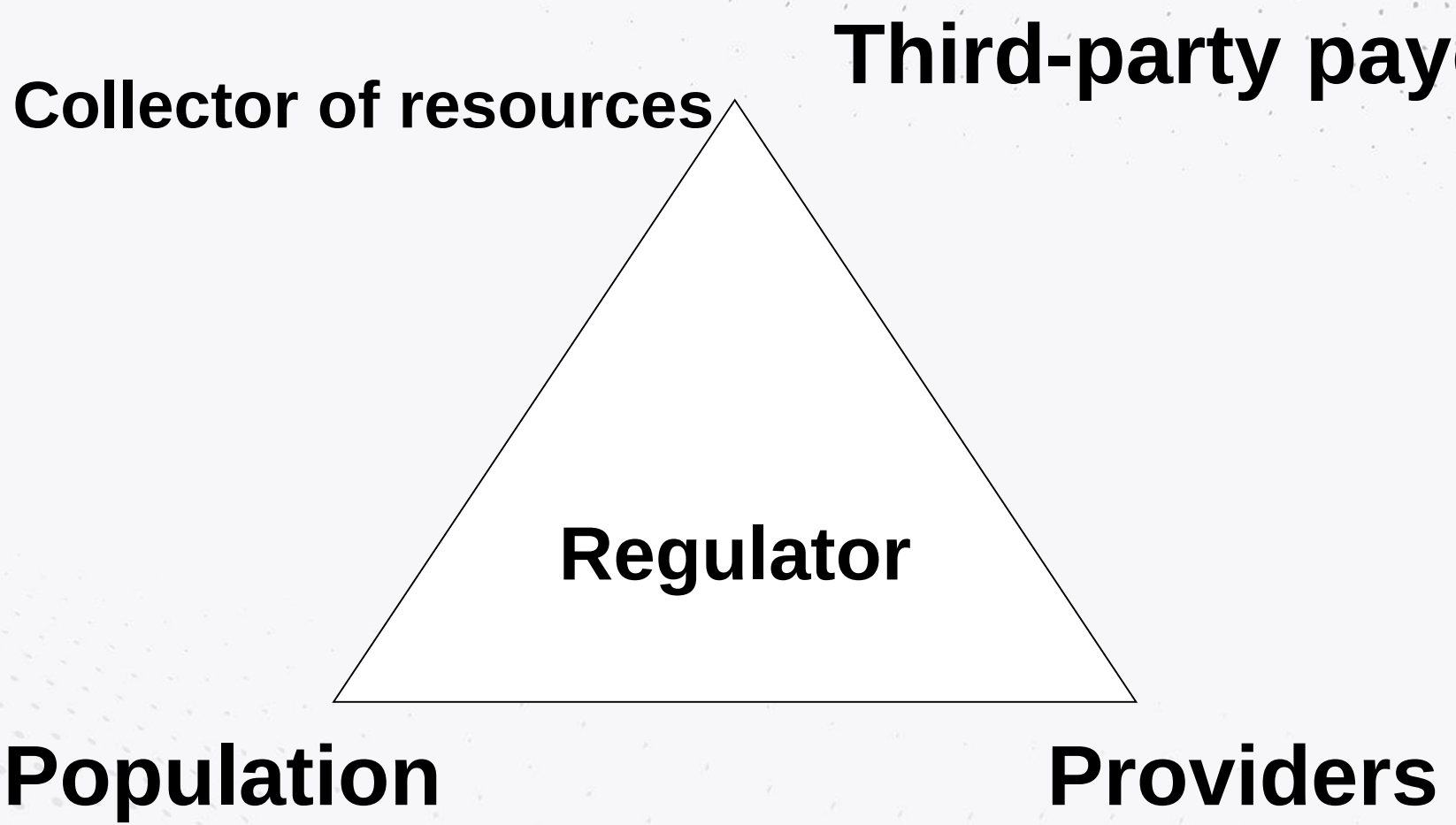
How we look at health systems



The German system at a glance (red SHI, blue PHI, purple both)

Collector of resources

Central reallocation pool

Uniform (set by law) + additional (set by sickness fund) wage-related contribution rate

Risk-related premium

Third-party payers

ca. 100 sickness funds

ca. 40 private insurers

Strong delegation

(Federal Joint Committee) & limited governmental control

Contracts, mostly collective *(uniform benefit package!)*

No contracts

Choice of fund/ insurer

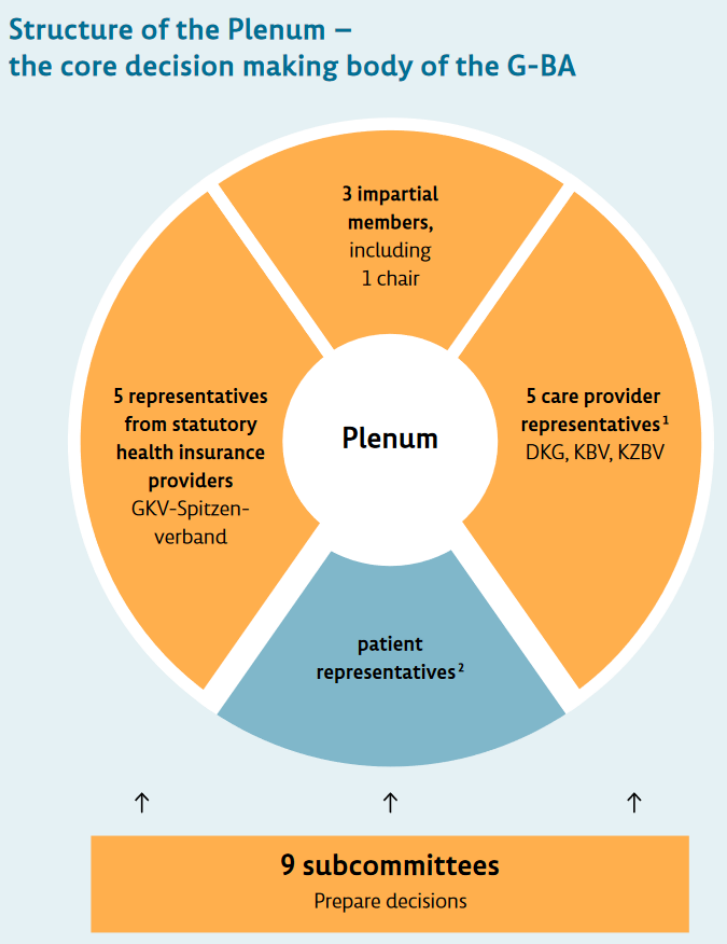
Population

Universal coverage: Statutory Health Insurance 88%, Private HI 11%

Choice →

Providers

Public-private mix, organised in associations ambulatory care/ hospitals



Objectives of Federal Joint Committee

- Main functions: to regulate SHI-wide issues of access, benefits and quality (and not primarily of costs or expenditure)
- Normative function of the G-BA by legally binding directives ("sub-law") to guarantee equal access to necessary and appropriate services/ technologies for all SHI insured
- Benefit package decisions must be justified by an evidence-based process (= Health Technology Assessment) to determine whether services, pharmaceuticals or technologies are medically effective in terms of morbidity, mortality and quality of life
- By law, evidence based assessments can only be used to select the most appropriate (efficient) service etc. from others – not to prioritize among service areas: if a costly innovation has a significant additional benefit,
  the sickness funds must pay for it

Questions regarding a technology's effectiveness and safety

- Is it safe to use (in the short term)?
- Does it function in healthy?
- Does it function in ill persons?
- Does it work compared to doing nothing?
- Does it work better compared with an alternative (study conditions)?
- Does it work better compared with an alternative under real life conditions?
- Is it cost-effective (vs. alternative)?
- Is it as (cost-)effective everywhere?
- By whom should it be used to be effective?
- Is it safe to use (in the long run)?

Phase I
"clinical investigation"
Phase II

uncontrolled one-armed studies

pharma-ceutical licensing

medical device certification

Phase III

controlled studies

HTA

vigilance monitoring/ product registries

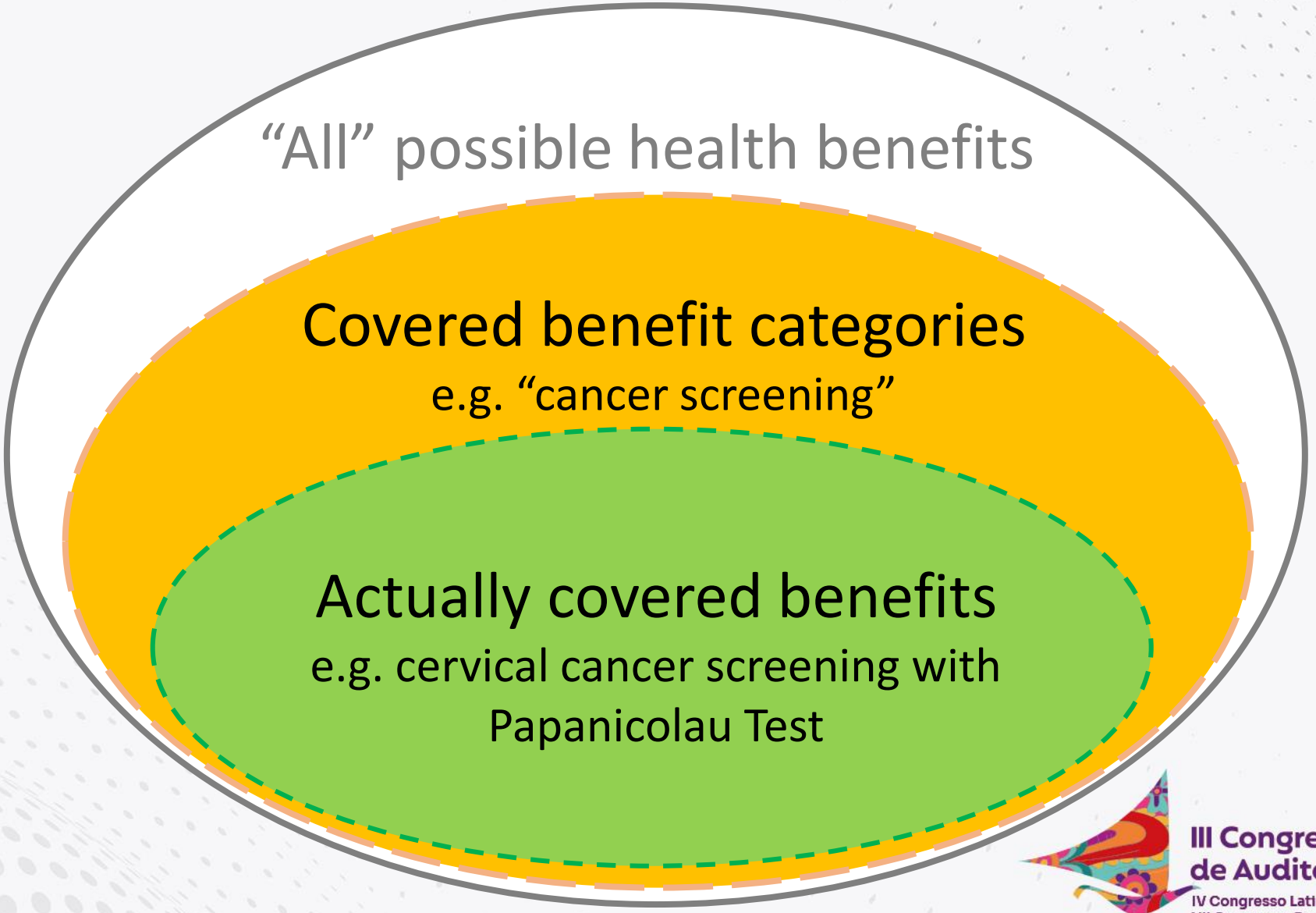
Two, still little connected worlds of decision-making on technologies

Safety	Efficacy	Effectiveness	Efficiency
Measure of adverse effects	Measure of effect under ideal conditions	Measure of effect under "real life" conditions and vs. other drugs	Relationships between costs and benefits

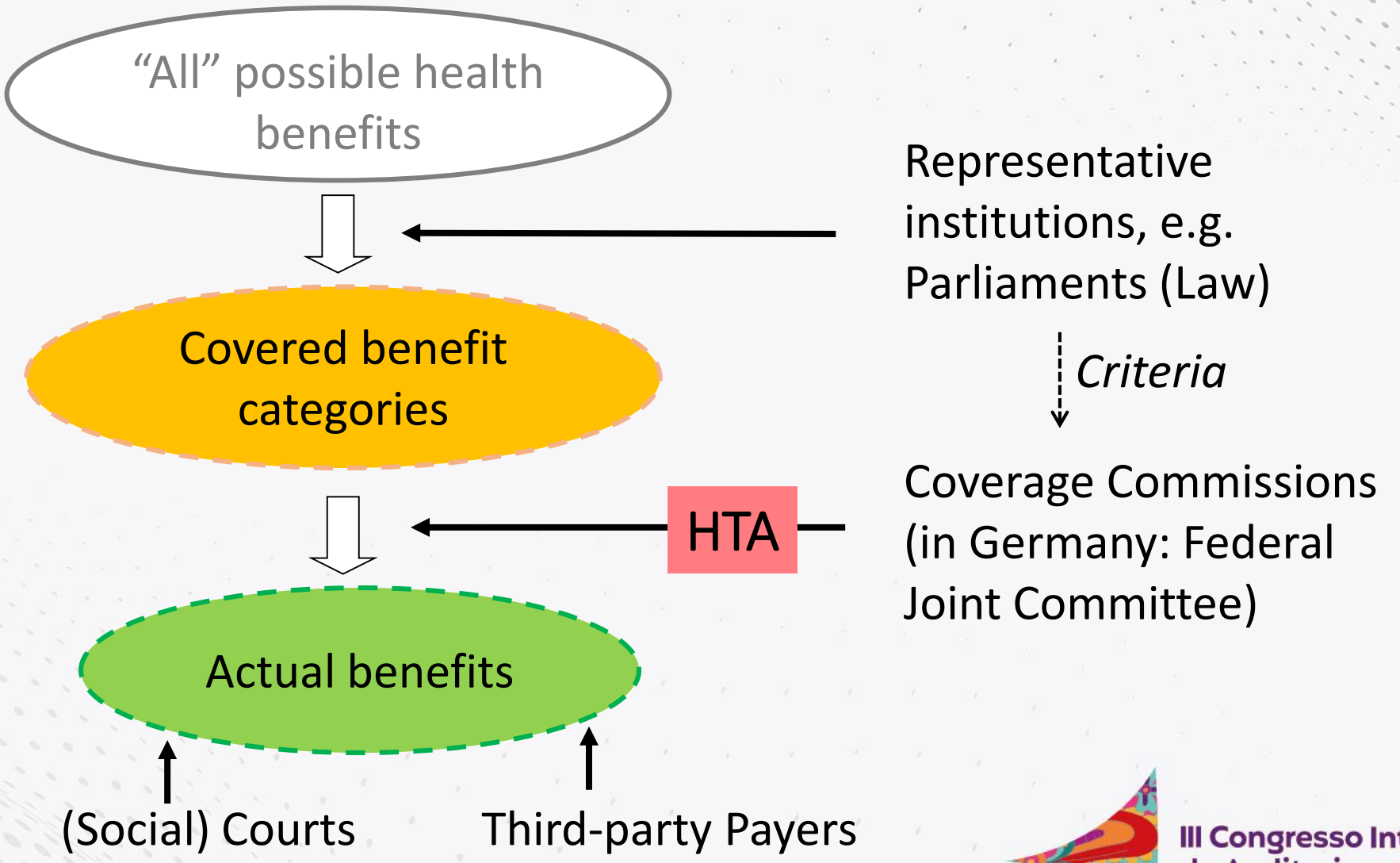
Licencing/ market access

Health Technology Assessment (HTA): coverage? reimbursement price?

Understanding the concept of HTA for making decisions on coverage of services/ technologies (I)

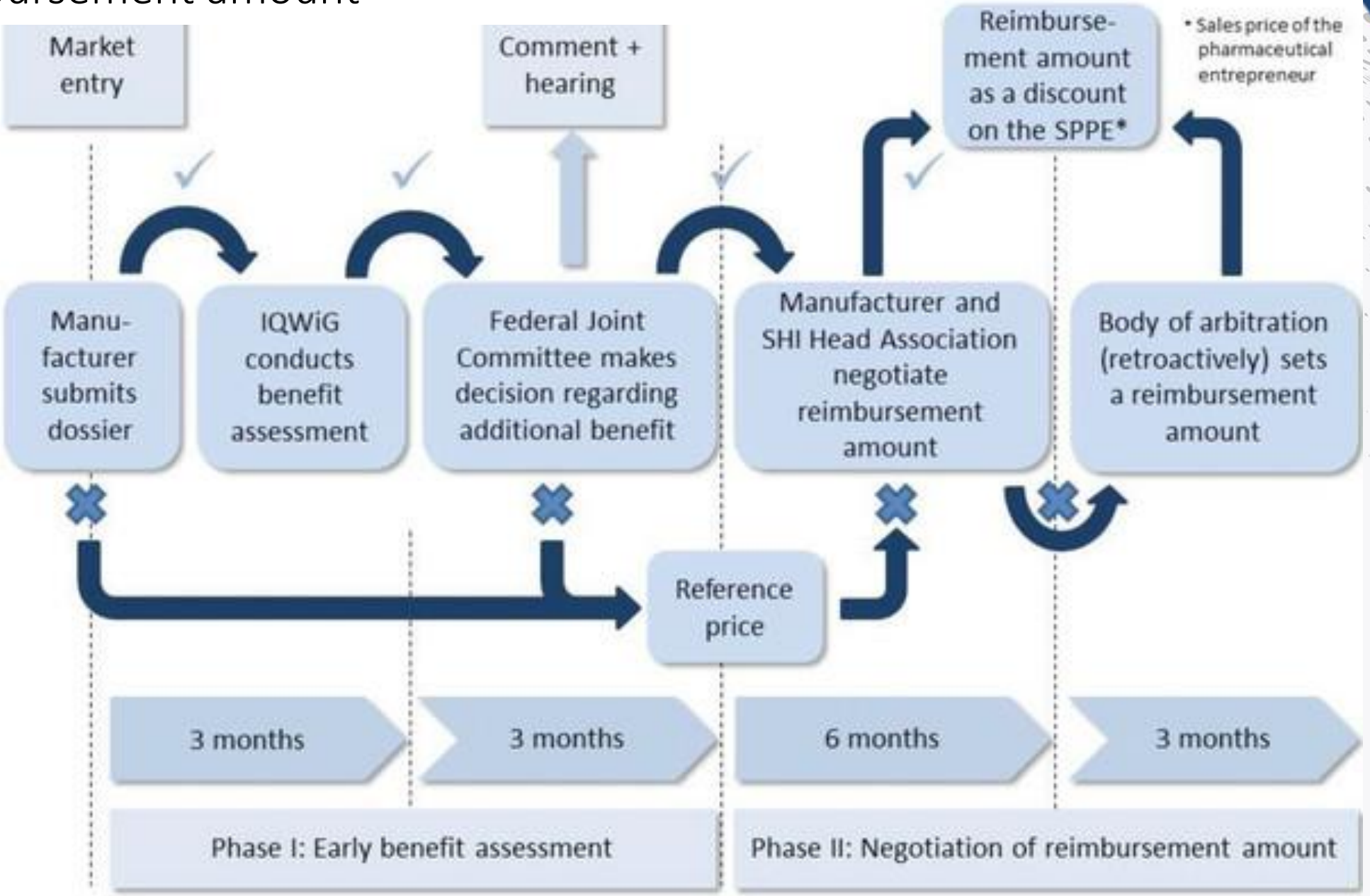


Understanding the concept of HTA for making decisions on coverage of services/ technologies (II)

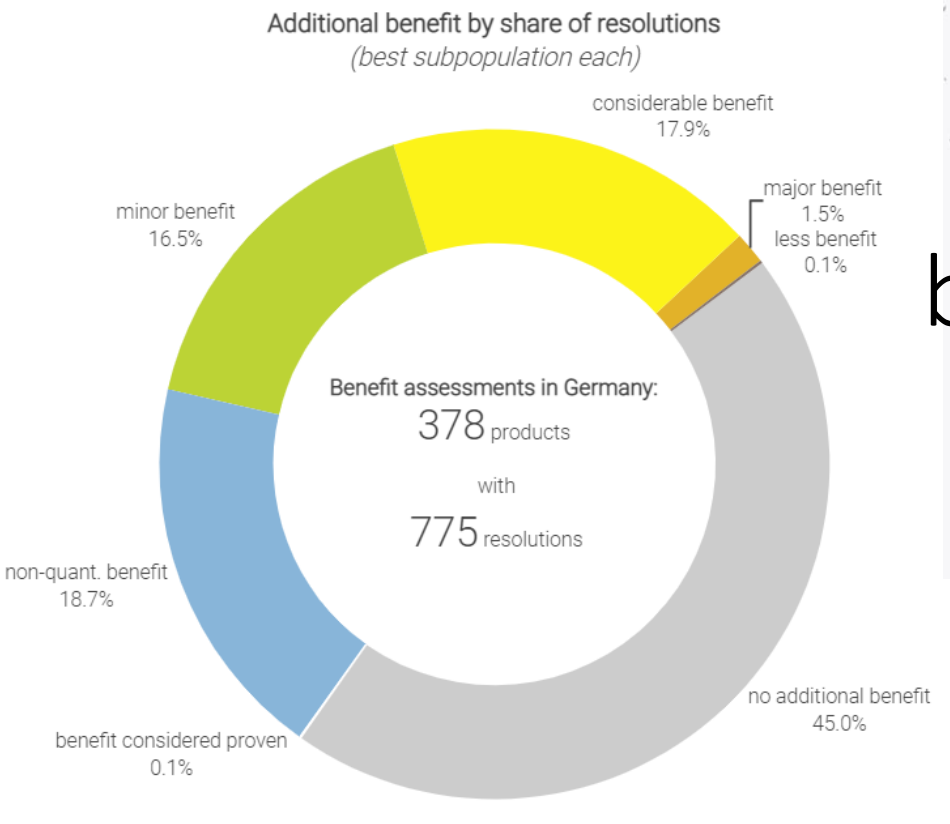


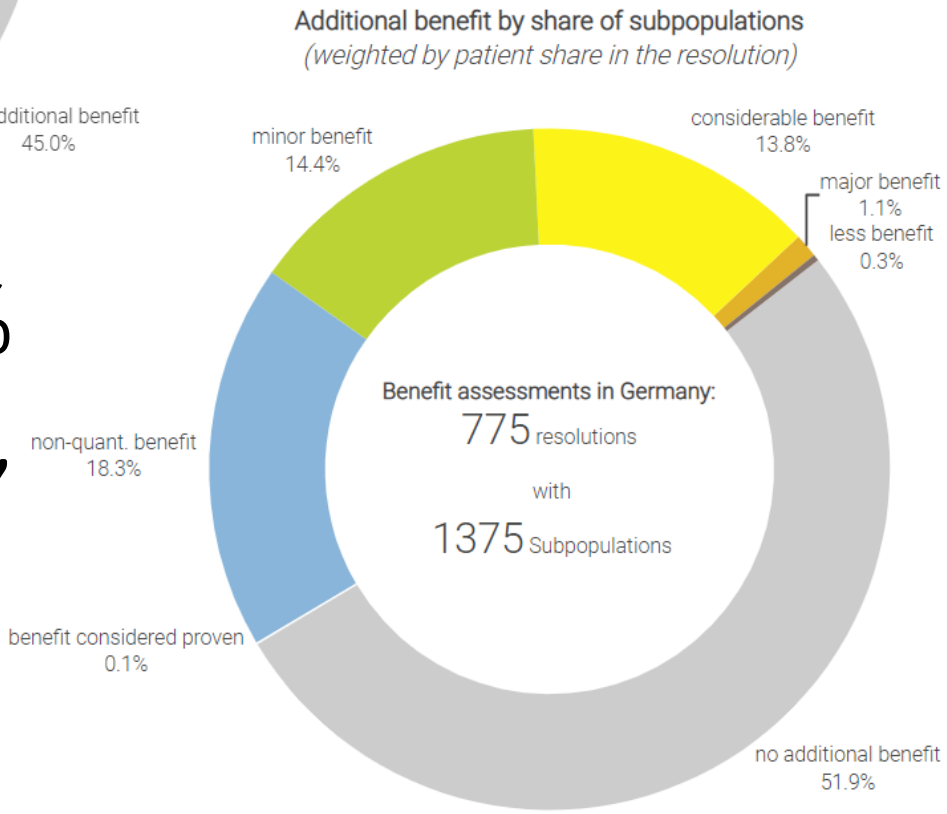
Pharmaceuticals: the process of HTA (assessing added benefit) and finding a reimbursement amount

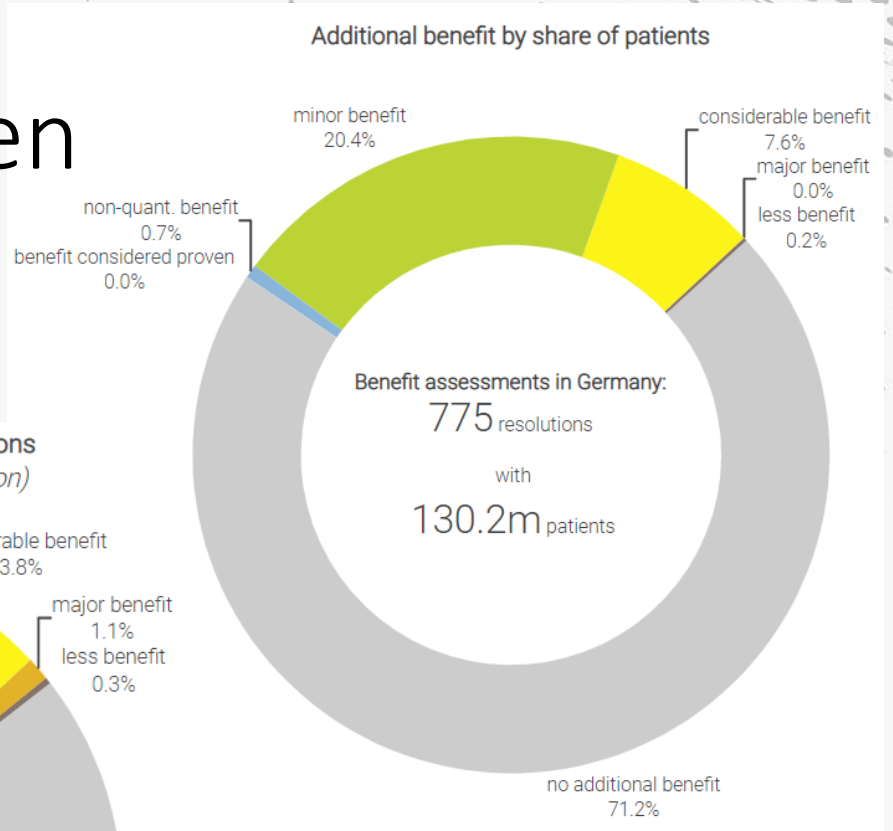
IQWiG is the Institute for Quality and Efficiency in Health Care



An additional benefit has been found for …







55% of drugs, 48% of subpopulations, but only 29% of potential patients

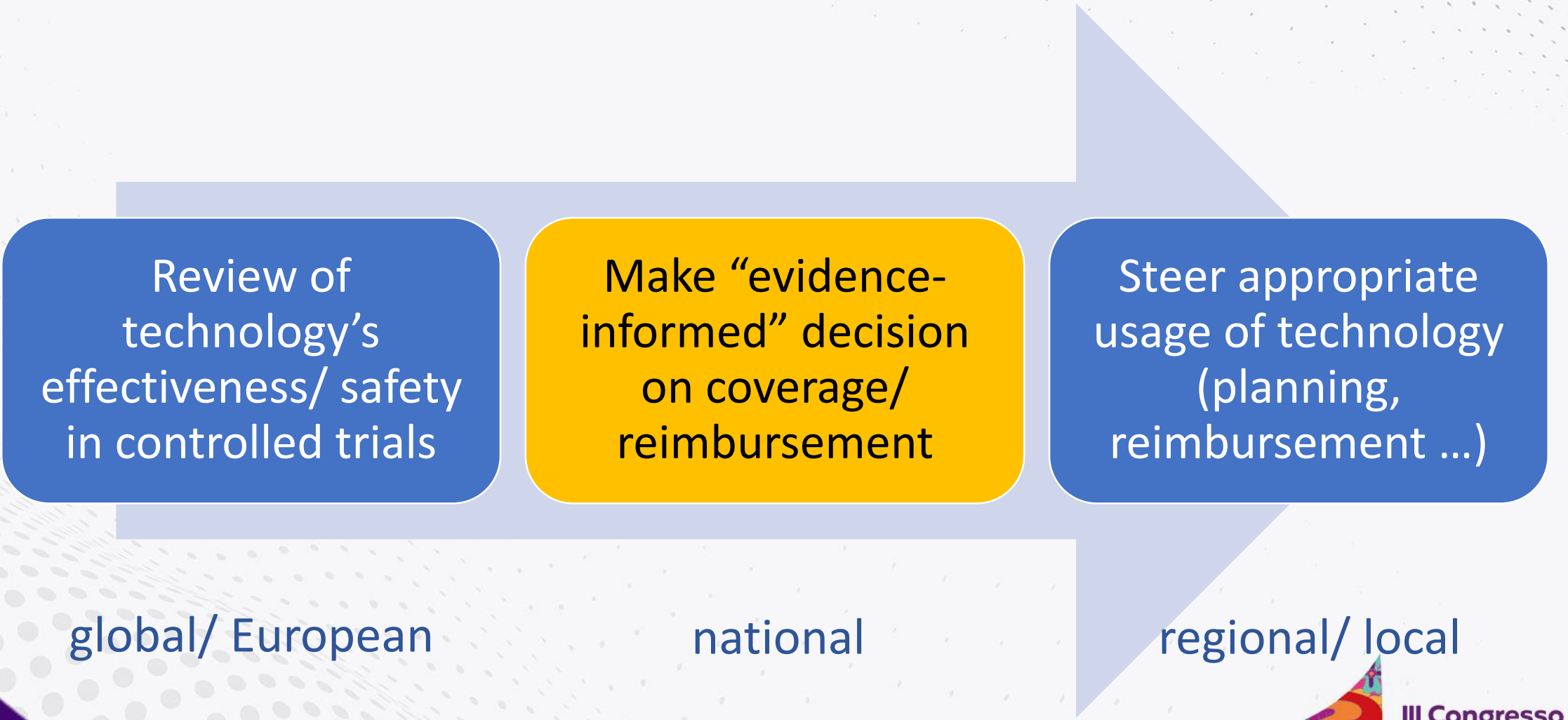
Disentangling the phases of HTA

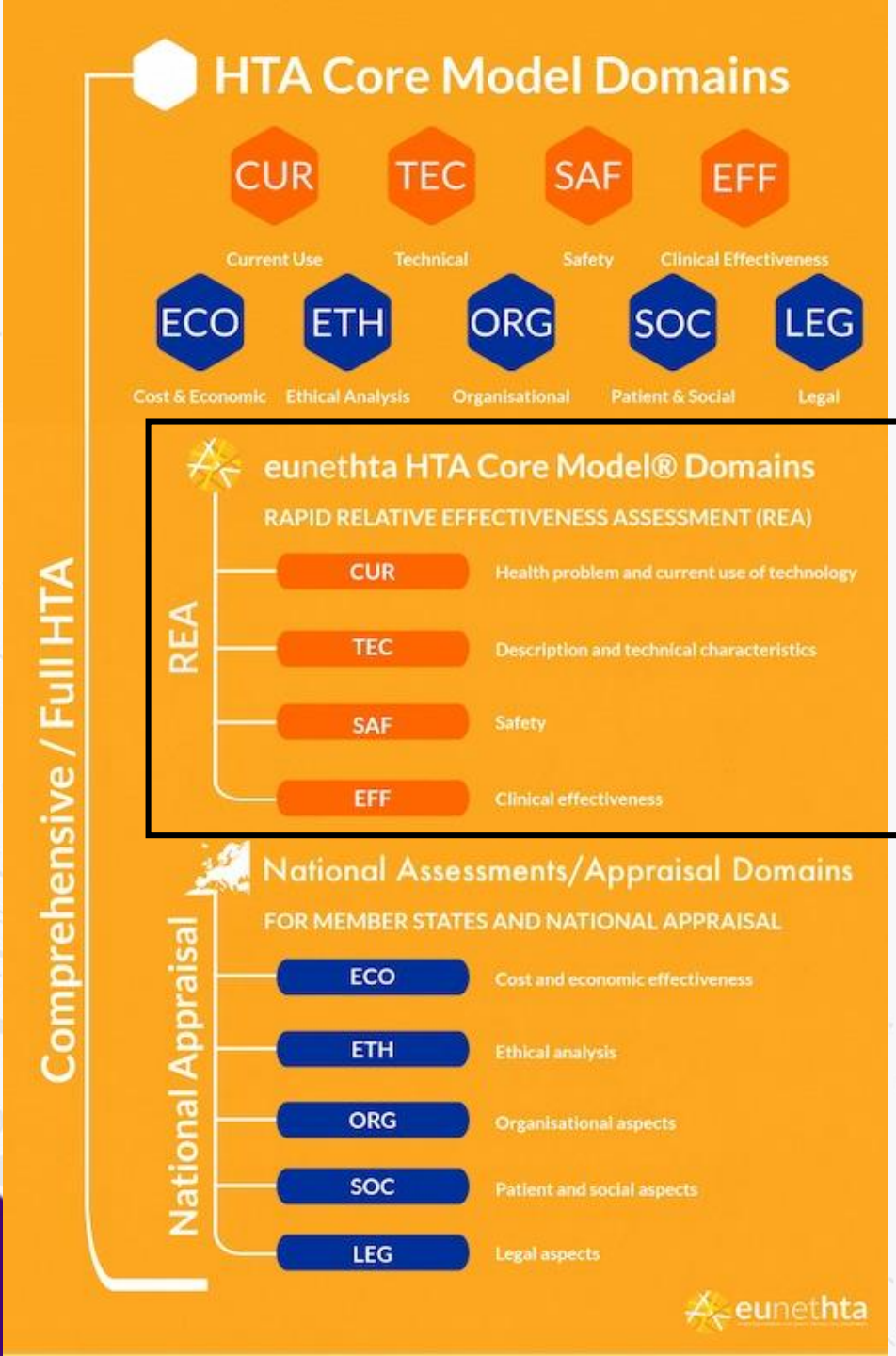
Review of technology's effectiveness/ safety in controlled trials

Make "evidence-informed" decision on coverage/ reimbursement

In Germany: IQWiG Federal Joint Committee

Disentangling the phases of HTA





If the HTA base is "global/ European", why not creating it together?

Regulation (EU) 2021/2282 (15th Dec 2021) …

- creates "Joint Clinical Assessments" for pharmaceuticals (licensed by EMA) and high-risk medical devices, which have to be taken into account in national decision-making

From 2024

- offers Joint Scientific Consultations to technology developers
- prepares annual reports on emerging health technologies

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Summary

In Germany, with its multi-payer system, the Federal Joint Committee has an important role in defining common rules, e.g. for defining the benefit basket

For HTA, the Federal Joint Committee (as decision-maker) is supported by the Institute for Quality and Efficiency (IQWiG; assessing the evidence)

Part of IQWiG‘s role will go to the European level, starting with oncologic drugs and high-risk medical devices