

Inno-HTA: HTA-methodology for innovative healthcare technologies

Results

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Workshop "*Inno-HTA: Adding value to comprehensive early assessment of health care innovations*"

København, 4 December 2008



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Inno-HTA



Partners



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Aims

Make HTA more useful and better applicable

- for technologies in an early stage of development
- for more stakeholder groups and their decisions, e.g.
 - start next step of development
 - research funding
 - participation in clinical trial

by suggesting the relevant indicators (research issues, criteria) to guide innovation process.



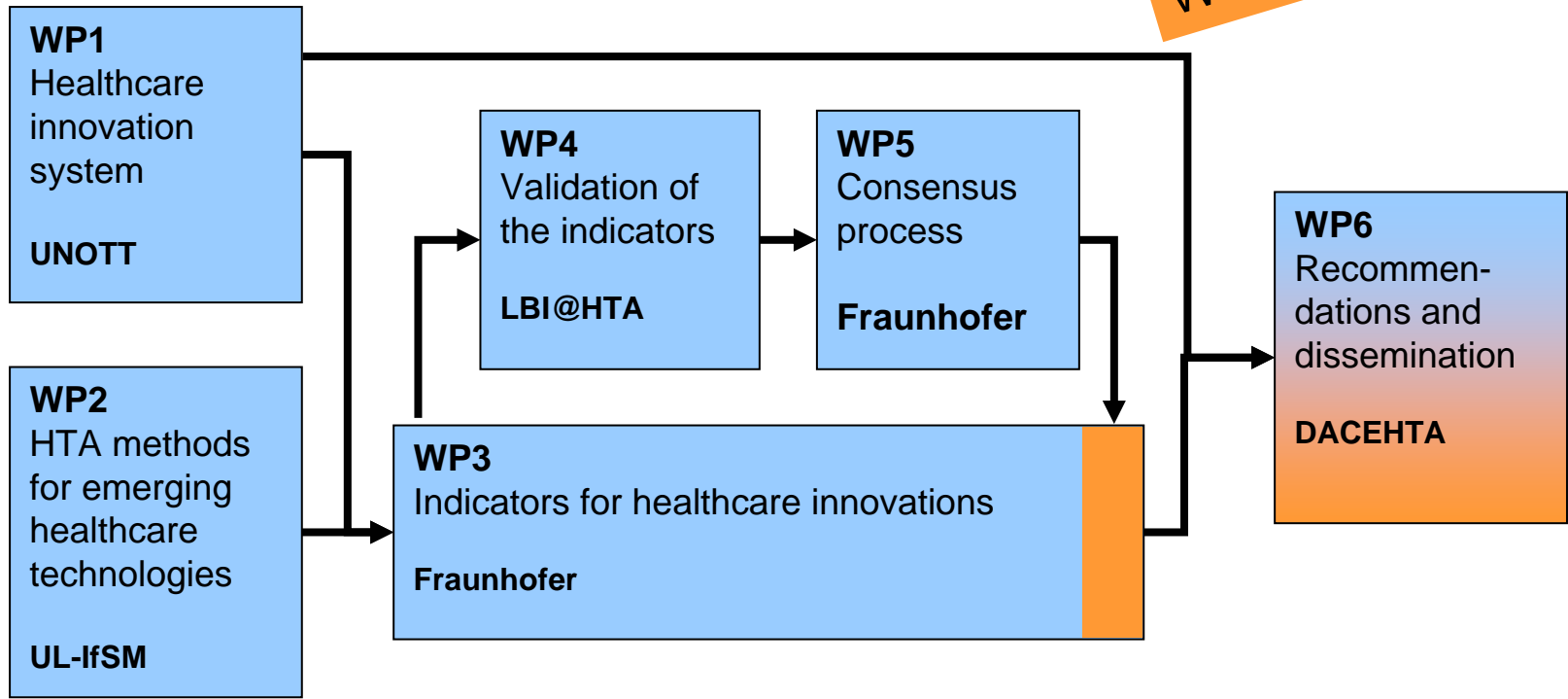
Methods

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Outline of the project

Work in progress!

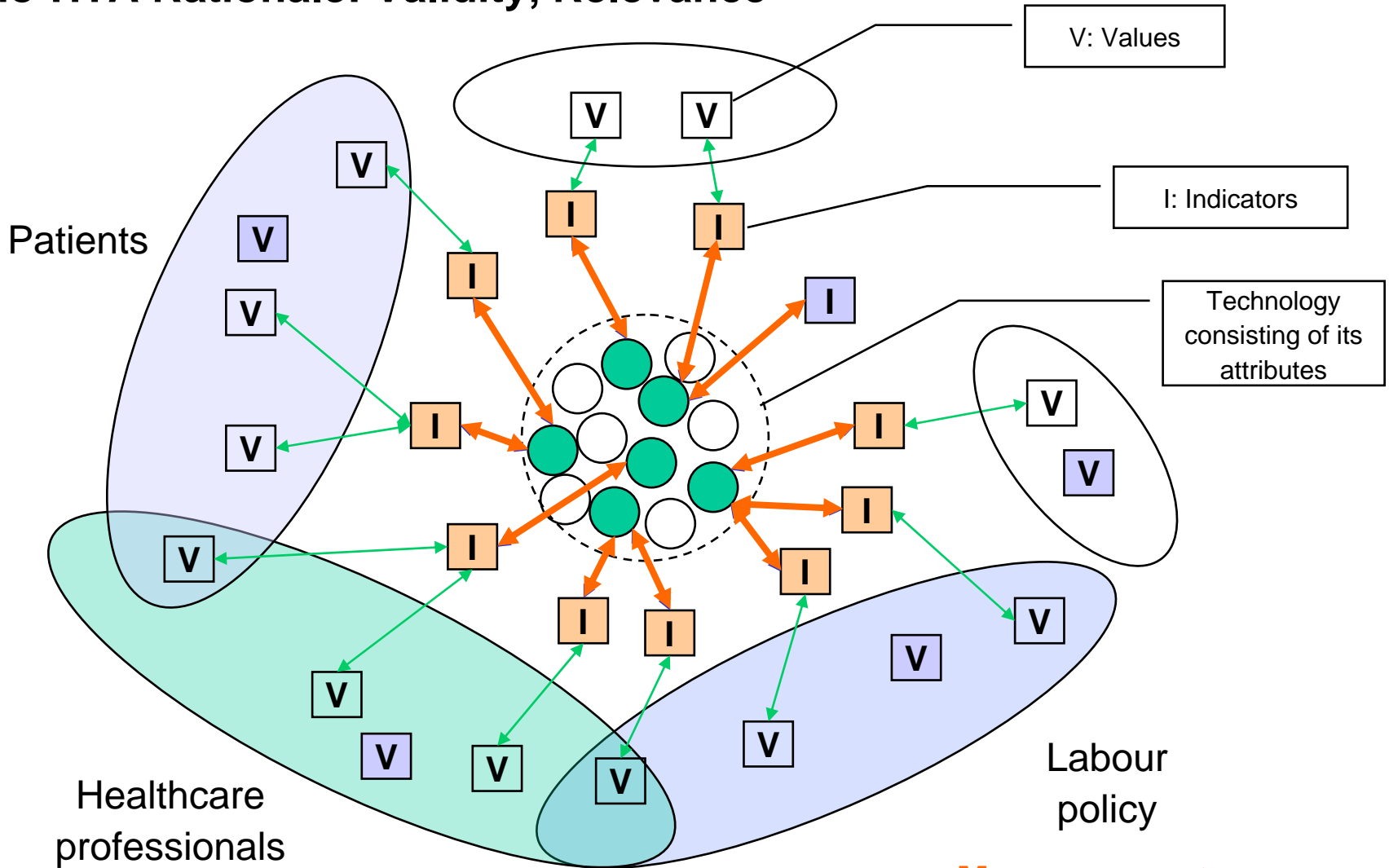


WP7 Project management Fraunhofer

January 2007 December 2008

WP: Work package and WP leader

Inno-HTA Rationale: Validity, Relevance



↕ **Relevance:** The indicator is relevant for important decisions of stakeholders.

↕ **Validity:** The indicator gives clear evidence on a specific attribute of the diagnostic or treatment method.

**Measurement:
No task of Inno-HTA**

Overall results

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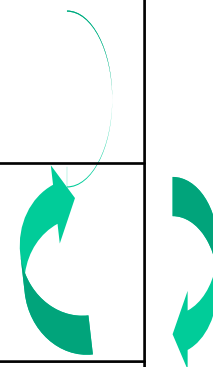


WP1: Different stages of development of healthcare technologies

Stage	Evidence base	Role of HTA
Discovery		Too early for any HTA role
Early product development	Proof of principle & general safety	Potential for new HTA role
Late development and experimental testing / use	Data on efficacy, safety & validity	
Market launch and early adoption	Limited data on cost-benefit	Main focus of classical HTA
Diffusion	Development of solid evidence base on cost-benefits	Main focus of classical HTA

WP2: Methodological approaches to the assessment of innovative technologies

Aims	HTA-Element	Methods
Finding „emerging“ technologies	„Scanning“	Literature searches Expert consultations Searching: research programs, press releases, gathering input from stakeholders ...
Sorting out technologies with high probability of relevant impact	„Filtering / Prioritising“	Criteria based approaches upon information from: clinical literature, epidemiology, bench research, preclinical and clinical research results, cost compilations, health system analysis, stakeholders preferences consensus methods, quantitative methods
Estimation of probable impact	„Early Assessment“	„Straightforward“ HTA “Component approach“ “Modelling, Prediction rules“ “Casuistry“
Generating Evidence	„Monitoring“ ELSI-Information	Clinical Trials Registries Postmarketing Surveillance Interactive / participatory assessments
Integrating social shaping perspective	“New HTA”	Constructive HTA Participatory HTA Interactive HTA



WP4: List of case studies

LBI@HTA:

- Drug for oncology before marketing authorisation
- Orthopaedic intervention: cervical artificial disk replacement
- diagnosis/ adherence monitoring: biomarker/biomonitoring in alcohol dependency

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- Tissue engineering in care of chronic wounds
- Genetic testing for TPMT and CYP2D6
- Drug decision making (cooperation with Pfizer)



WP4: Results from case studies

Evaluating the feasibility of the 70 indicators showed that there is low availability and validity of many data (e.g. cost data), but they would be of high relevance to a broad range of actors.

The indicators

- most feasible (because of highest scores in data availability/high data validity) are in the area of epidemiology and number of patients with indication, status of technology, efficacy and guidelines (but not effectiveness), alternatives, some cost factors.
- least feasible (because of lowest scores in data availability/low data validity) are in the area of effectiveness, compliance, some cost factors (cost-effectiveness, etc.) and macroeconomics.

Indicators that turned out to be unreliable, because data are missing are candidates for deletion, since they make no contribution to the reduction of uncertainty.

Conclusion: Uncertainty might be reduced by enforced data analyses and data generation at an early stage, but a certain degree will stay uncertain.



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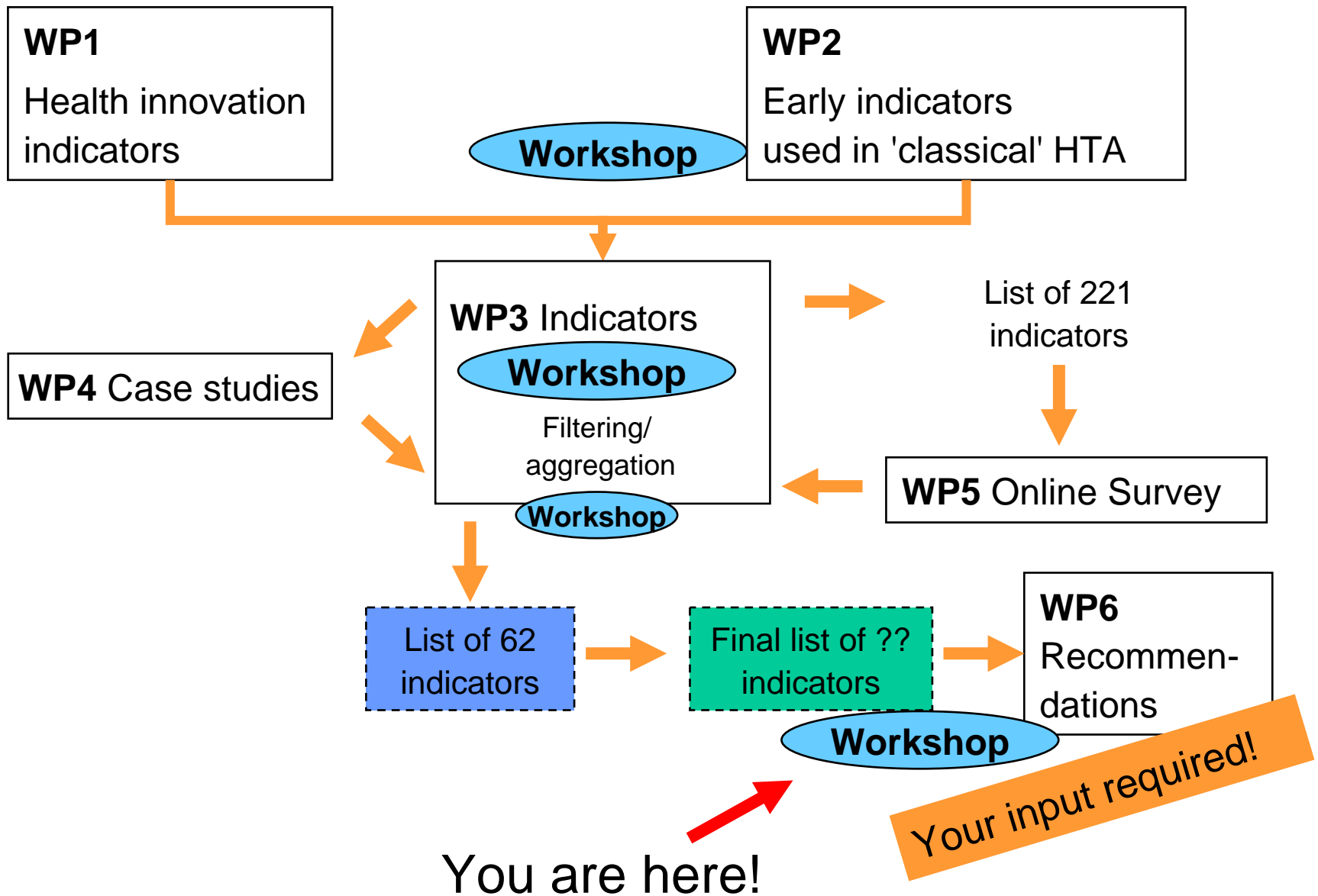


Indicators

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WP3 Inputs/outputs



Selection process

Generation of draft list:

- Results from WPs 1-3

Input for selection

- Results from WPs 4 and 5
- Results from workshops
- Discussions within consortium

Criteria for selection

- Relevance for important HTA decisions
- Relevance for early phase decisions
- Similarity \Rightarrow Reduction
- Results from Online survey



Domains of indicators: Where does Inno-HTA add most?

- Clinical effectiveness
 - Patient-related outcomes
- **Broader health impacts**
- Safety
- Economic evaluation
 - **Economic evaluation – producer perspective**
- Societal aspects
- Ethical aspects
- Legal aspects
- Health problem and current use of technology
- Organisational aspects
 - **Knowledge/education**
 - **Efforts necessary for treatment**
- Description and technical characteristics of technology
 - **Innovativeness**
 - **Status of development**
 - **Research activities**

EUnetHTA core set
Inno-HTA additions



Indicators (1)

Clinical effectiveness

Patient-related outcomes

effects on mortality caused by target disease

effects on morbidity caused by target disease

effects on general health-related quality of life

effects on disease-specific quality of life

effects on life expectancy with vs. without technology

effects on progression of disease (from start (e.g. infection) to outbreak or death)

rate of severe treatment failure

Broader health impacts

improvement in care for patients for which no adequate treatment existed

sick days of patients under new treatment

effects on compliance: share of patients adhering to recommended use

degree of achieved control of the disease through technology

pharmacodynamic or pharmacokinetic improvement of existing therapeutic principle



Indicators (2)

Safety

frequency of severe adverse effects

toxicity of new technology e.g. in cell or animal studies

probability of dosage errors

risk-benefit-ratio

fear of adverse effects

► risks associated with producing or applying the new technology



Indicators (3): Economic evaluation

Costs

costs of technology (including all relevant indirect cost aspects)

Health economic evaluation

incremental cost-utility ratio

incremental cost-effectiveness ratio

incremental cost-benefit ratio

effects on cost-of-illness to society

▶ **affordability of technology**

consumers' willingness to pay

▶ **reimbursement that health-care professionals receive for technology**

Economic evaluation – producer perspective

▶ **profits of producer with new technology**

▶ **potential of the market to reward the costs of R&D**

▶ **duration of time in which the technology will be effective (e.g. until resistance occurs)**

▶ **R&D investments necessary for new technology**

▶ **seed or venture capital available for R&D**

Economic evaluation - Society perspective

▶ **jobs created through R&D, production and application of the technology**

Indicators (4)

Societal aspects

acceptance of technology

► institutional support for translation, clinical research and HTA

eco-efficiency of the new technology

Ethical analysis

factors impeding equal access to technology (e.g.: gender, age, geographical location)

generation of sensitive personal data during application

challenge of religious, moral or cultural convictions or beliefs

animals necessary for R&D or production

Legal aspects

compliance with requirements of regulatory bodies

► efforts and time necessary for compliance with regulatory requirements



Indicators (5)

Health problem and current use of technology

burden of target disease (incl. economic)

current state of the art of care for the target disease

current use of the new technology



Indicators (6)

Organisational aspects

effects of new technology on therapeutic process

effects of technology use on patient satisfaction

▶ effects of technology use on job satisfaction of health-care professionals

Knowledge/education

▶ familiarity with new technology

▶ information/training needs of health-care professionals for correct treatment

▶ information/training needs of patients

Efforts for treatment

convenience/ease of use

▶ costs for introduction (replacement of standard with new technology)



Indicators (7)

Description and technical characteristics of technology

Innovativeness

relevance of differences to already marketed product

▶ **alternative technology currently in development**

Status of development

marketing authorisation status of technology

new technology is in clinical testing

new technology is available for clinical application or in use

new technology is available on prescription

reimbursement status of technology

sales of new technology

good evidence on costs, benefits, cost-effectiveness etc. available

▶ **intellectual property (patents, licences) or products to be used/sold/transferred**

Research activities

▶ **funding of R&D available from public or other non-profit source**

Recommendations



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General line for recommendations

"Depending on the specific decision situation, these indicators could be useful to make better assessments"

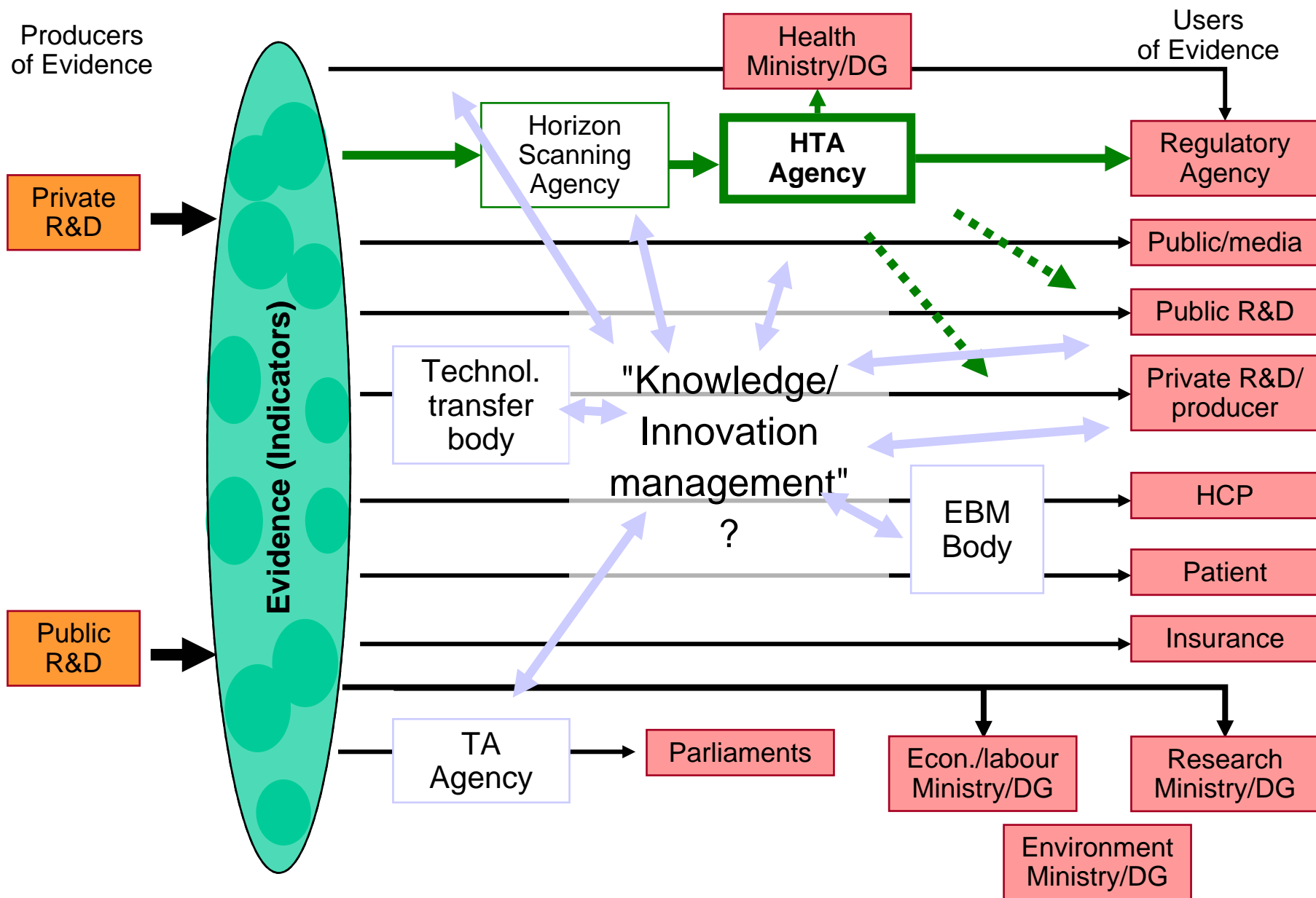
Recommendations for specific target groups (methodol. development, HTA researchers, policy-makers, other decision-makers?)



Outlook



Coordination of production and use of early evidence



Thank you for your kind attention and support!

please visit
www.inno-hta.eu

