

**synergus RWE**

evidence for decisions

# 101 introduction to reimbursement / funding for e-health and diagnostic companies

Why the obvious is not so obvious!?

[CLICK HERE TO SEE THE FULL WEBINAR](#)

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# Agenda

1 Synergus RWE

2 Introduction

3 Funding and Reimbursement

4 Health care systems

5 Decision making

6 Conclusion

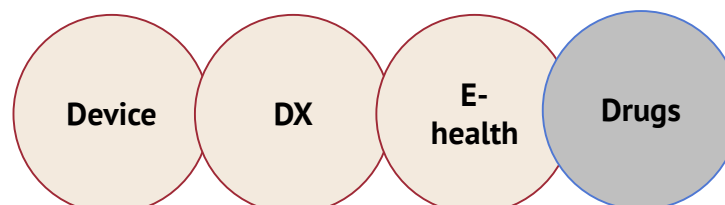
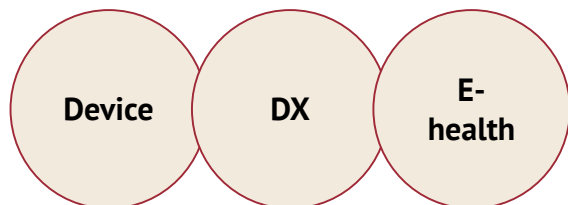
# Core services

## Securing Market Access

- Reimbursement analysis and strategy
  - Procedure coding
  - DRG
  - Evidence requirements
  - HTA Analysis
  - Market access pathway
- Hands-on execution and engagement with stakeholders
- Application for reimbursement and coding

## Evidence For Decisions

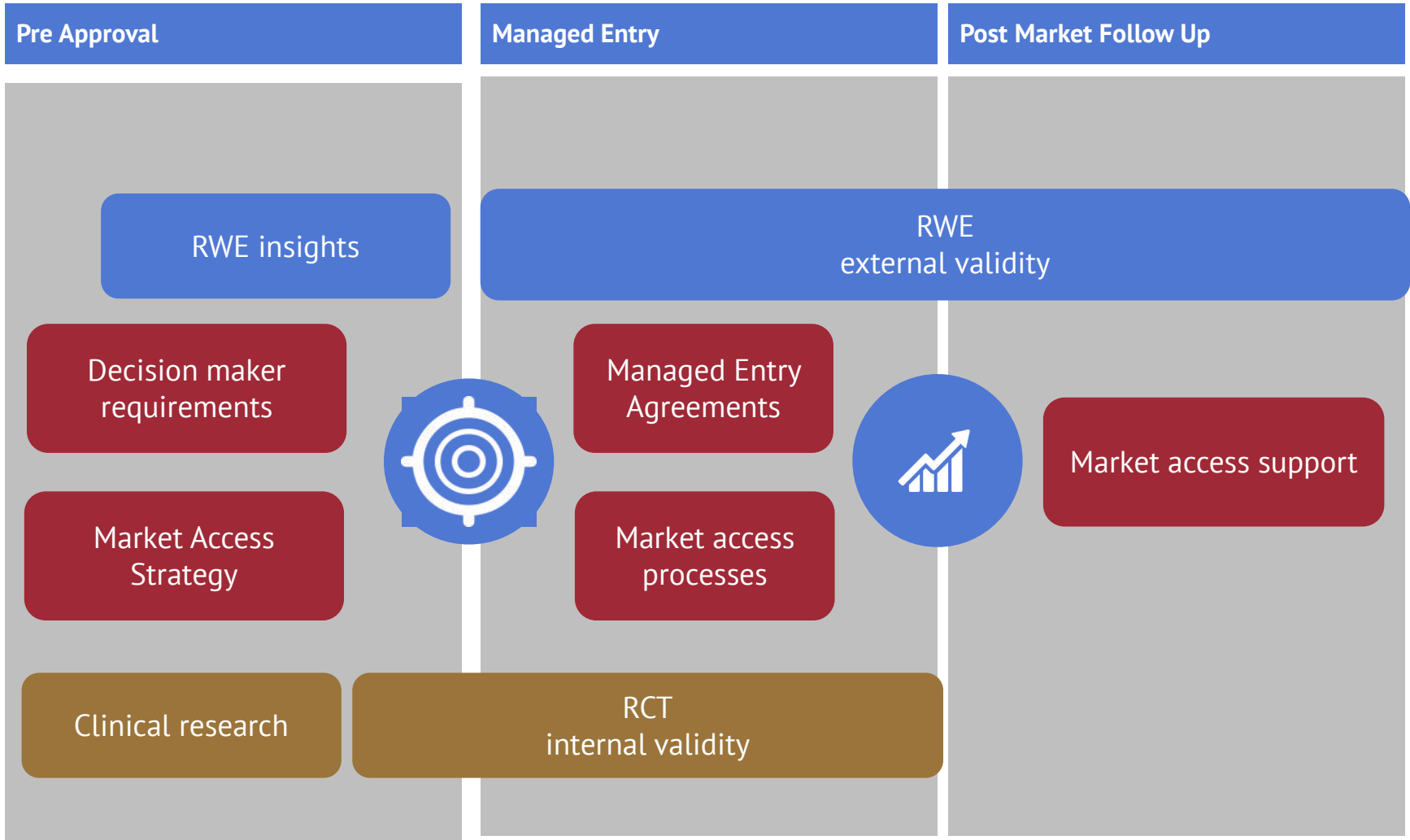
- Real World Evidence
  - European strategy
    - Leveraging both national as well as disease specific data sets.
  - Execution of RWE studies
- HEOR
  - Health Economic modelling
  - Systematic literature reviews
  - Sales tools (Ipad)



# STRATEGIC UNDERSTANDING AND PLANNING TO OPTIMIZE EVERY STEP IN THE PROCESS



# Evidence For Decisions

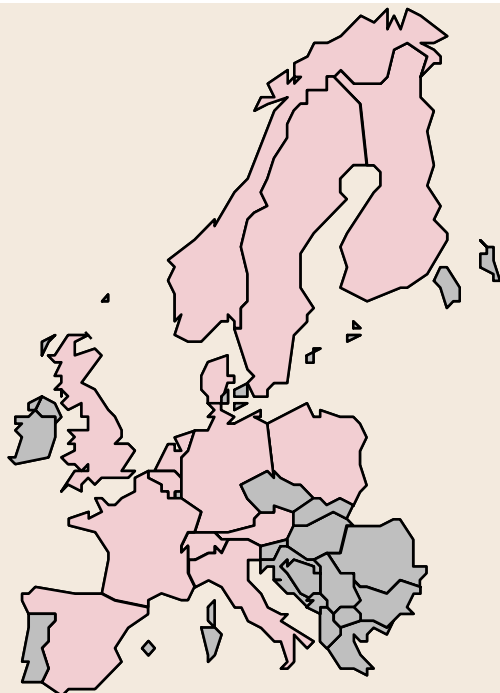


# Securing Market Access

## Analytical

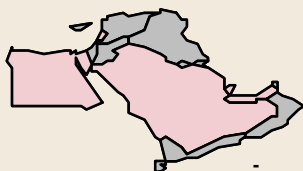
### Europe

- Austria
- Belgium
- Denmark
- Finland
- France
- Germany
- Italy
- Netherlands
- Norway
- Poland
- Spain
- Sweden
- Switzerland
- The United Kingdom



### Middle East

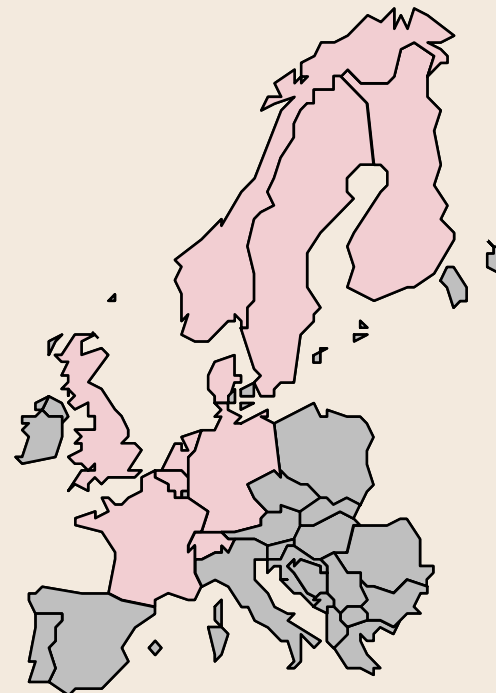
- Egypt
- Lebanon,
- Saudi Arabia
- United Arab Emirates



## Hands on

### Europe

- Belgium,
- Denmark
- France
- Germany
- Netherlands
- Norway
- Sweden
- Switzerland
- The United Kingdom

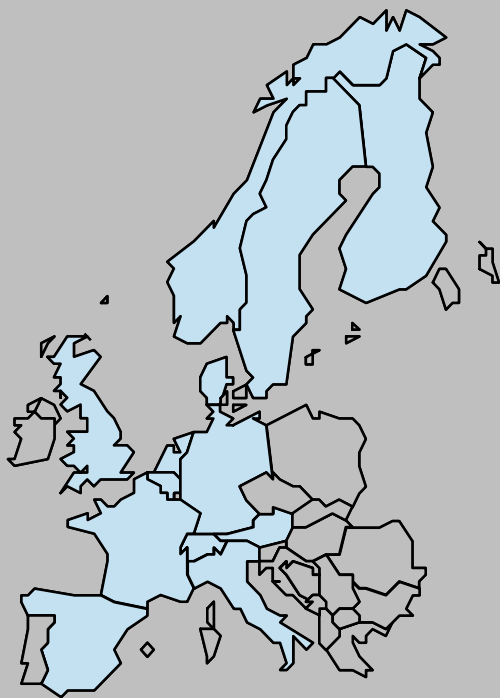


# Evidence For Decisions

## RWE Strategy and HE modelling

### Europe

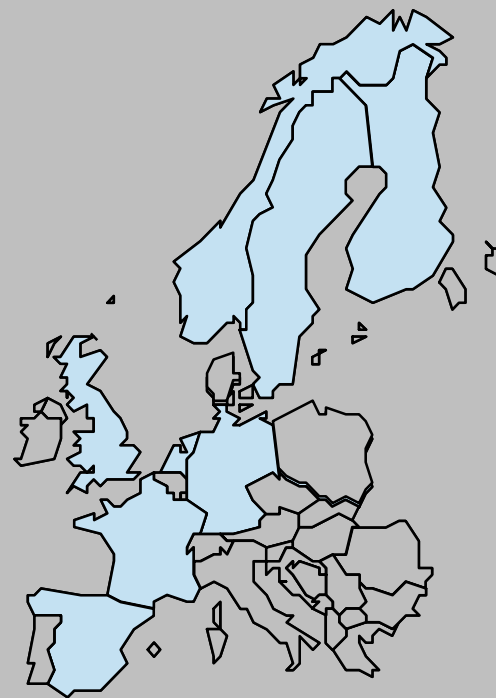
- Austria
- Belgium
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- Finland
- France
- Germany
- Italy
- Netherlands
- Norway
- Poland
- Spain
- Sweden
- Switzerland
- The United Kingdom



## RWE analysis

### Europe

- Finland
- France
- Germany
- Netherlands
- Norway
- Spain
- Sweden
- The United Kingdom



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1 Synergus RWE

## 2 Introduction

2.1 Terminology

2.2 Economic reality

2.3 Your customer determines the sales perspective

3 Funding and Reimbursement

4 Health care systems

5 Decision making

6 Conclusion

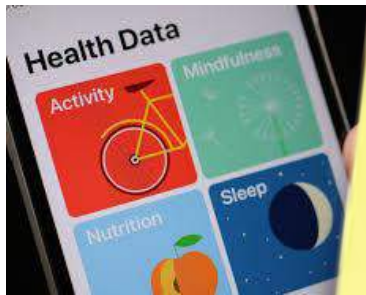


# Webinar introduction

- Target audience:
  - E-health companies with limited experience / understanding in market access from drugs and devices.
  - Market access professionals with experience in drugs or devices, but limited experience in e-health / diagnostics.
  
- Objective:
  - Understanding of the complex reality of market access for e-health and diagnostics
  
  - Foundation to understand consequent webinars:
    - Provide basic introduction to concepts that are essential to understand
      - Sign up for the webinar February 21<sup>st</sup> : HTA evaluation of e-health solutions
    - Provide guidance on where to focus your effort

## E-health has the ability to transform healthcare

**“When you look at most of the solutions, whether it’s devices, or things coming up out of Big Pharma, first and foremost, they are done to get the reimbursement [from an insurance provider]. Not thinking about what helps the patient. So if you don’t care about reimbursement, which we have the privilege of doing, that may even make the smartphone market look small.” – Tim Cook, Apple CEO\***



\* <https://www.cbinsights.com/research/apple-healthcare-strategy-apps/>

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- 1 Synergus RWE
- 2 **Introduction**
  - 2.1 **Terminology**
  - 2.2 Economic reality
  - 2.3 Your customer determines the sales perspective
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- 4 Health care systems
- 5 Decision making
- 6 Conclusion

# Existing payment mechanisms in health care

Doctors visit



Surgery



Device



Drug



Elderly care



Diagnostics (?)



Medical aid



Payment is linked to required resources / cost



Changes are based on disconnect in payment and required resources



DRG system is key-concept

Payment is based on value



Change is initiated by submission to evaluator (HTA)



Health Economics is key concept

# Where does e-health belong?

Doctors visit



Surgery



Drug



Device



Elderly care



Diagnostics (?)

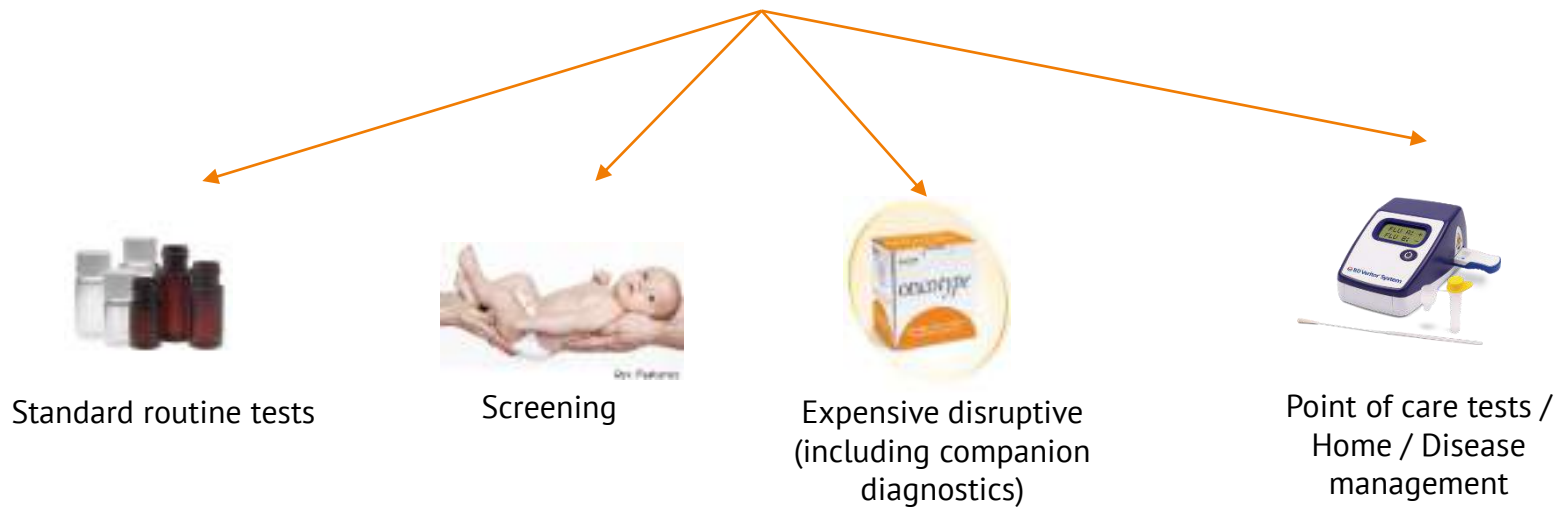


Medical aid



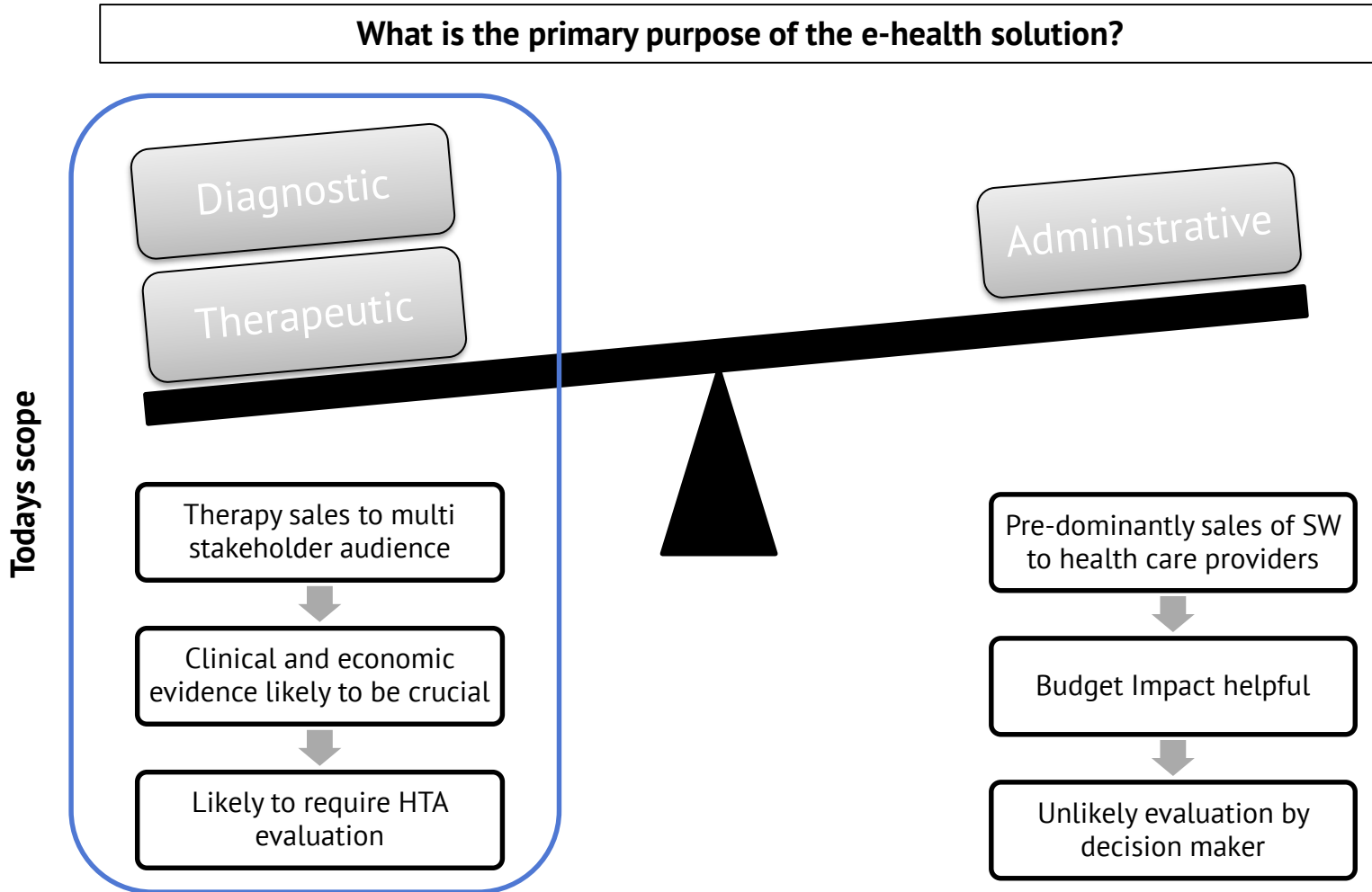
# Different type of diagnostics will raise different type of market access questions

## IVDs



Only a couple of countries in Europe has methods in place how to evaluate the value of IVD's connected to a reimbursement decision !?

# Defining e-health crucial to understand the market access challenge



# E-health and comparison to traditional funding / reimbursement scenarios

E-health dimension

Algorithms to provide decision support based on historical data

AI based interpretation of CT image

App to support behavioral change connecting with data from medical aid

App to provide customized training and support for knee and hip pain

Reimbursement based on cost



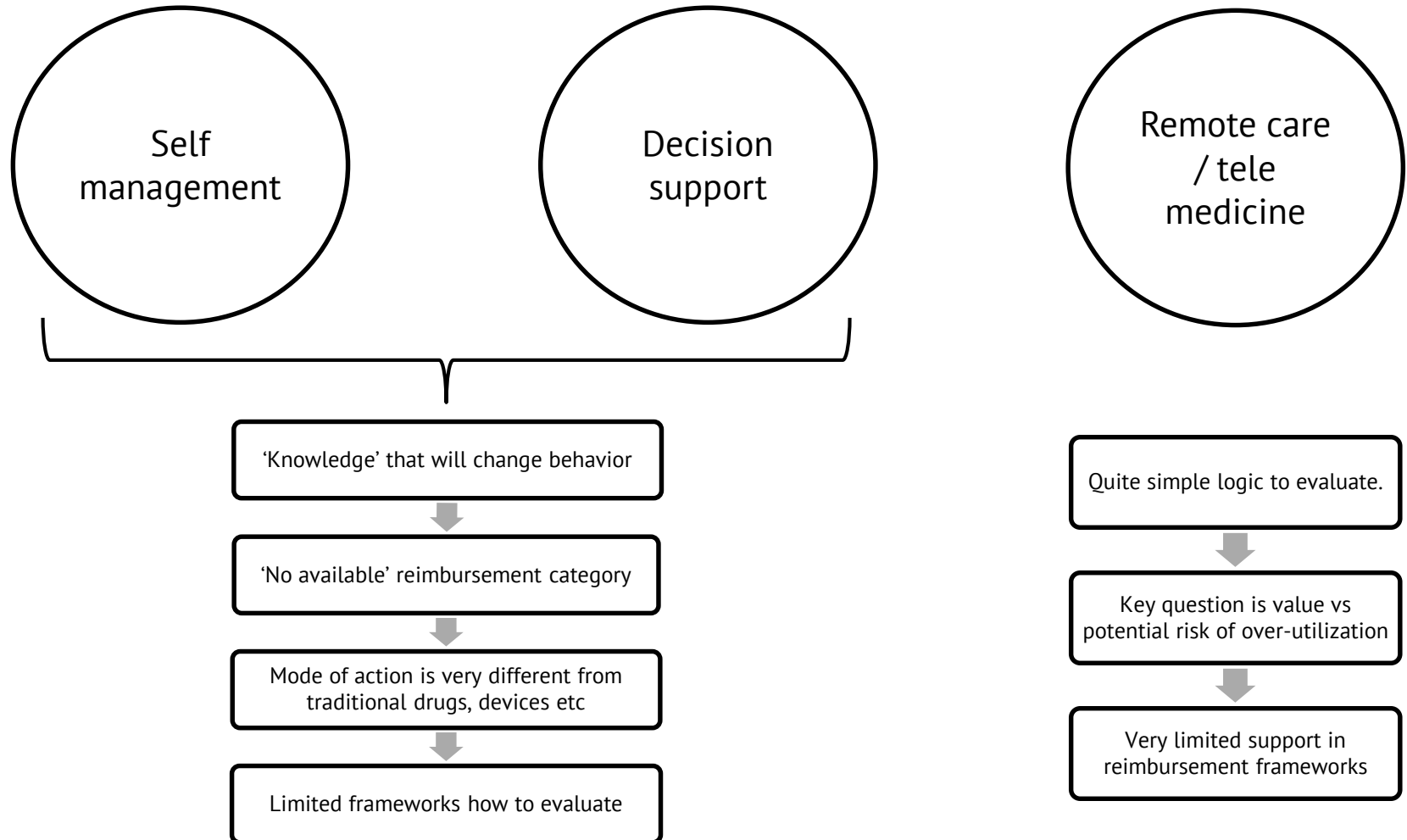
EHR



Investment budget



# What are the major themes in the e-health solutions (therapeutic / diagnostic) ?



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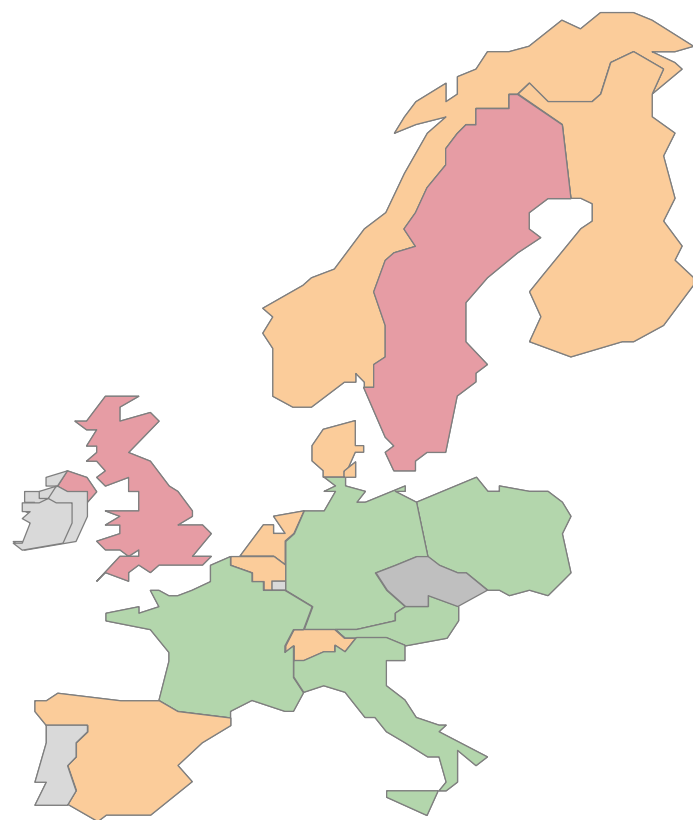
3 Funding and Reimbursement

4 Health care systems

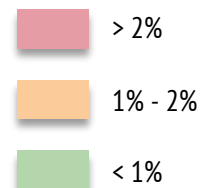
5 Decision making

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## Development of health care spending 2005-2015



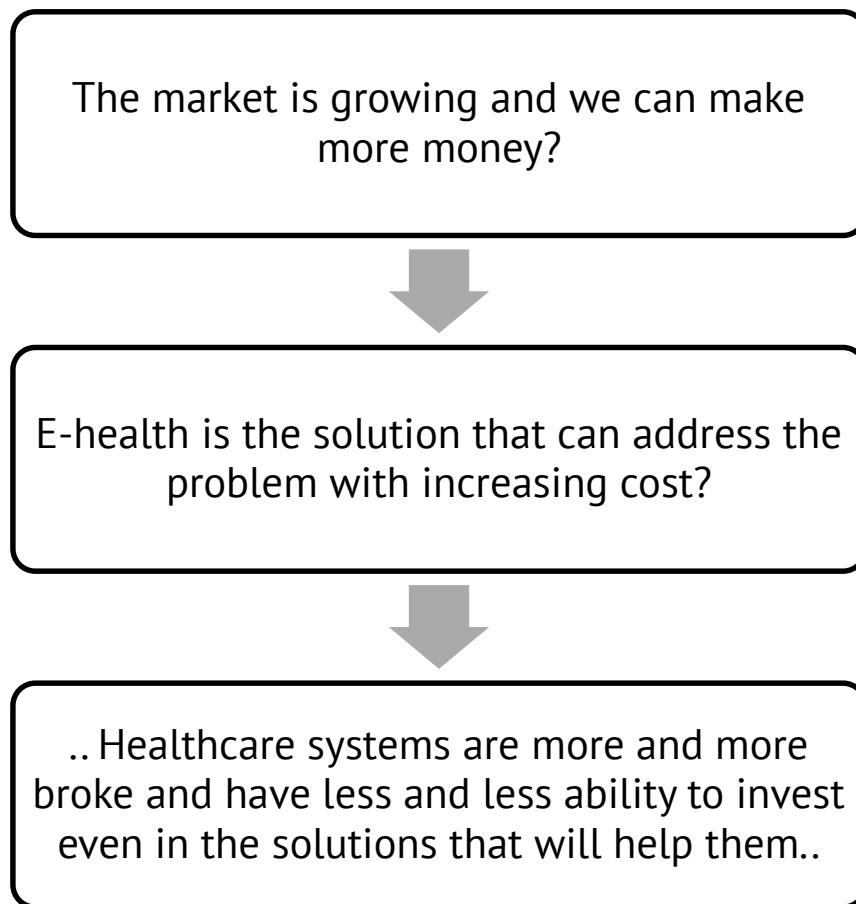
Annual increase in GDP expenditure on health care:



Country	Health care spending of GDP (2015)
Switzerland	11.5%
Germany	11.1%
Sweden	11.1%
France	11.0%
Netherlands	10.8%
Denmark	10.6%
Austria	10.4%
Belgium	10.1%
Norway	9.9%
United Kingdom	9.8%
Finland	9.6%
Italy	9.1%
Spain	9.0%
Poland	6.3%

The increased cost of health care across Europe has a significant impact on the introduction of new innovations.

## How do we interpret the increasing spending in health care?



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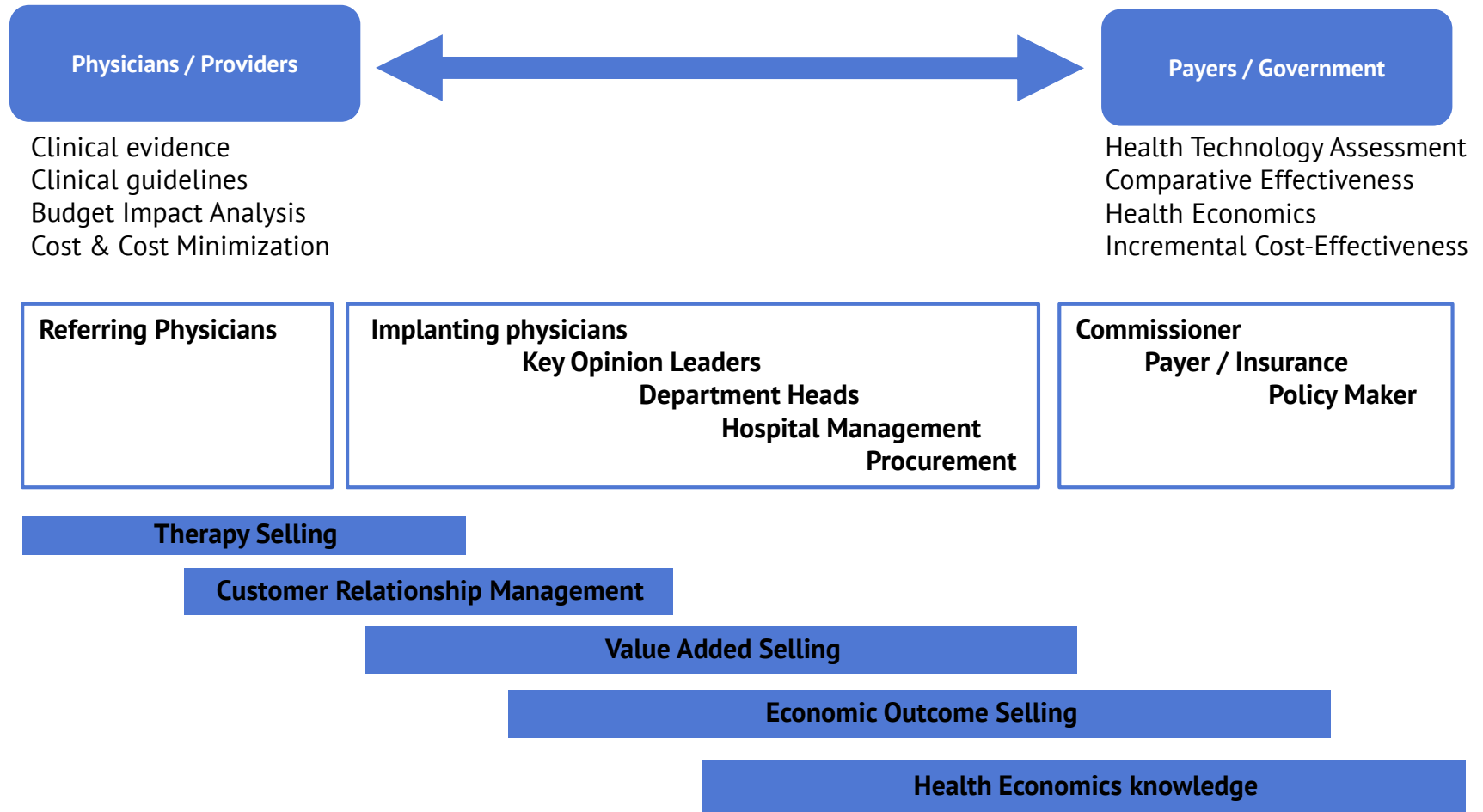
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# Therapy Development & Reimbursement

## A multi-disciplinary approach



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## Reimbursement vs funding

### Reimbursement

- The mechanism to pay for intervention
- The most common mechanisms include diagnosis-related groups (DRGs), fee for service, and global budget
- Reimbursement represents “mechanics” of payment, which often might be artificial, especially for novel procedures with no established specific reimbursement
- In most countries there is no correlation between the existence of a reimbursement mechanism and the willingness to pay for the intervention
- Countries differ in requirements for changes in the reimbursement system. Some don't have any evidence requirements, some have very high requirements

### Funding / Commissioning

- The way to define which interventions are covered and which are not; willingness to pay for procedure
- In most countries the decision to fund or commission the extent of use of an intervention is not clearly defined
- In most countries multiple stakeholders are involved in funding decisions, including the ministry of health or other defined commissioners and health technology assessment bodies
- The common theme among these organizations is the informed decision based on evidence and economical implications

**Reimbursement and funding represent two different challenges**



# Examples

- A medical aid has a tariff/reimbursement defined for use.



- Payer / commissioner do not see the value of using the medical aid and consequently do not fund the use of the technology.
  - The reimbursement does not matter. It is only a price – tag.

- There are budgets available at both national and at hospitals to fund for the use of solutions which do not fit in the standard ways.
  - Typically limited in time and limited budget available.
  - Can be very valuable as a starting point, but be aware of the limitations.
- If a solution is able to demonstrate a cost-saving within the budget of the potential buyer, there is no need to worry about funding or reimbursement. This is obviously the best scenario.

It is crucial to understand the short and long term solution for reimbursement and funding /commissioning as this may be the most critical parameter for the success.

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- 2 Introduction
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# Financing of healthcare systems

There are three types of healthcare systems and in general two are used in Europe with each country still having their own particularities.

## The Beveridge 'public' model

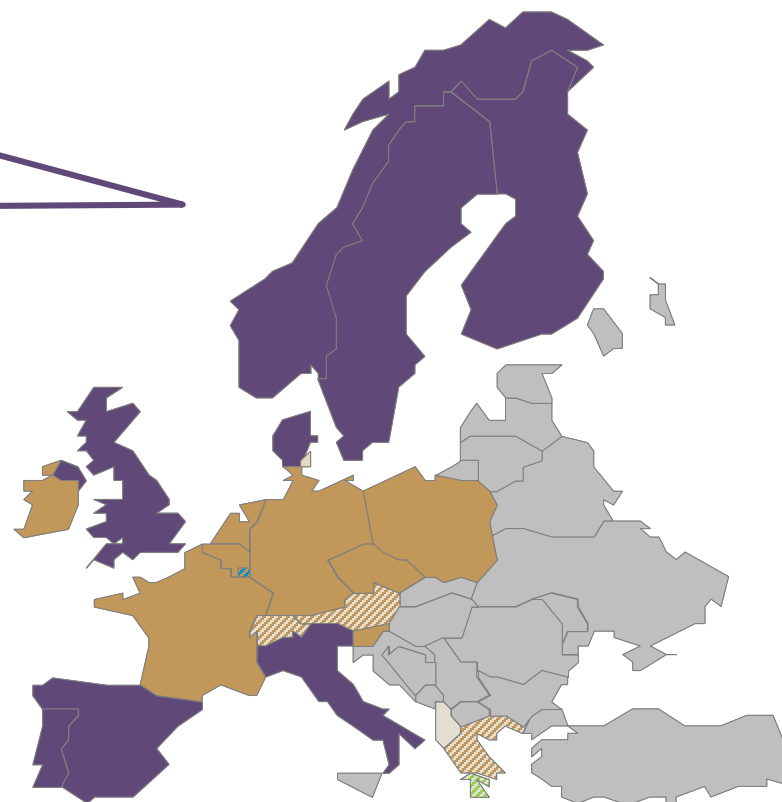
- Funding is **based** mainly on **taxation** characterized by a **centrally organized** National Health Service - services are provided mainly by public health providers e.g. hospitals, community doctors.
- **Healthcare budgets compete** with other spending priorities.

## The Bismarck 'mixed' model

- Funded mainly by a premium-financed social / **mandatory insurance**
- This model results in a mix of private and public providers, and allows **more flexible spending on healthcare**

## The 'private' insurance model

- Funding of the system is based on **premiums, paid** into private insurance companies
- In this system, the **funding is predominantly private**, with the exception of social care
- The great majority of the **providers** in this model belong to the **private sector**.



# How are health interventions reimbursed? How is it possible to change the system?

## Centralized - Strict reimbursement/HTA barrier for introduction of new devices / procedures

- A centralized decision-making process that includes HTA when establishing the reimbursement of a new procedure/device.
- High level of clinical evidence is required and economic evidence might be required
- Alignment of Key Opinion Leaders and payers is important
- Device/procedure can't be used prior to obtaining permission

## Centralized - Reimbursement barrier for the introduction of new devices/procedures

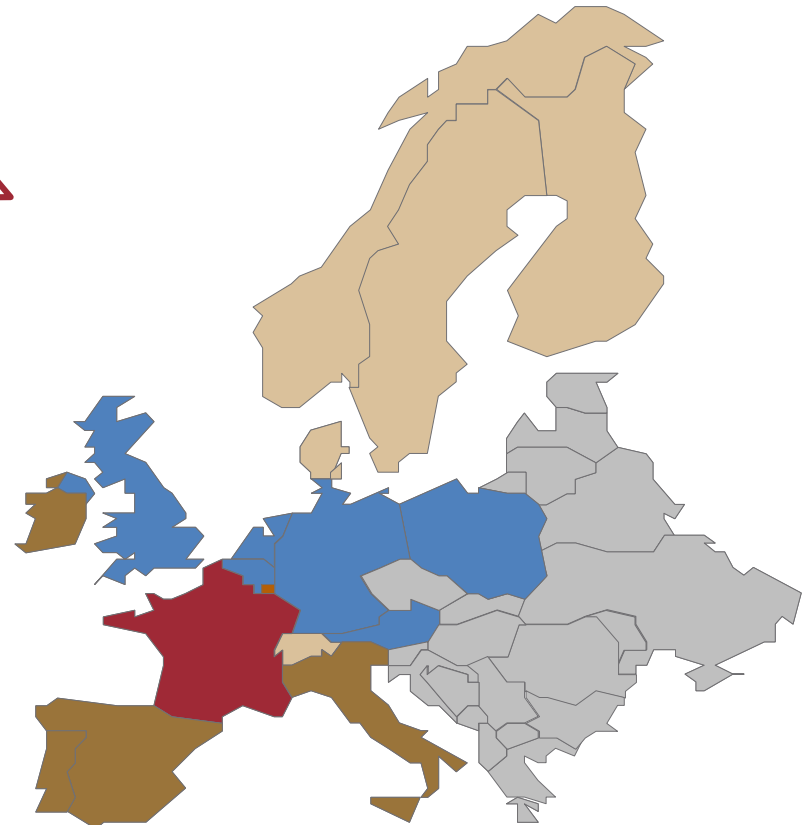
- A centralized decision-making process that includes HTA when establishing the reimbursement of a new procedure/device.
- High level of clinical evidence is required and economic evidence might be required
- Alignment of Key Opinion Leaders and payers is important
- Device/procedure can be used to limited extend prior to obtaining permission

## Centralized - Gradual change of DRG system

- Changes are introduced via the DRG system
- No evidence requirements from the DRG system
- Economic evidence is usually not required
- Adoption by clinicians is a key to create an inclusion

## Decentralized - Decision about introduction of new procedure/device is made locally

- Clinicians are key players
- Hospital administration influences the adoption of technology
- Hospital-based HTA can be common



# Different reasons in different countries for decision making.

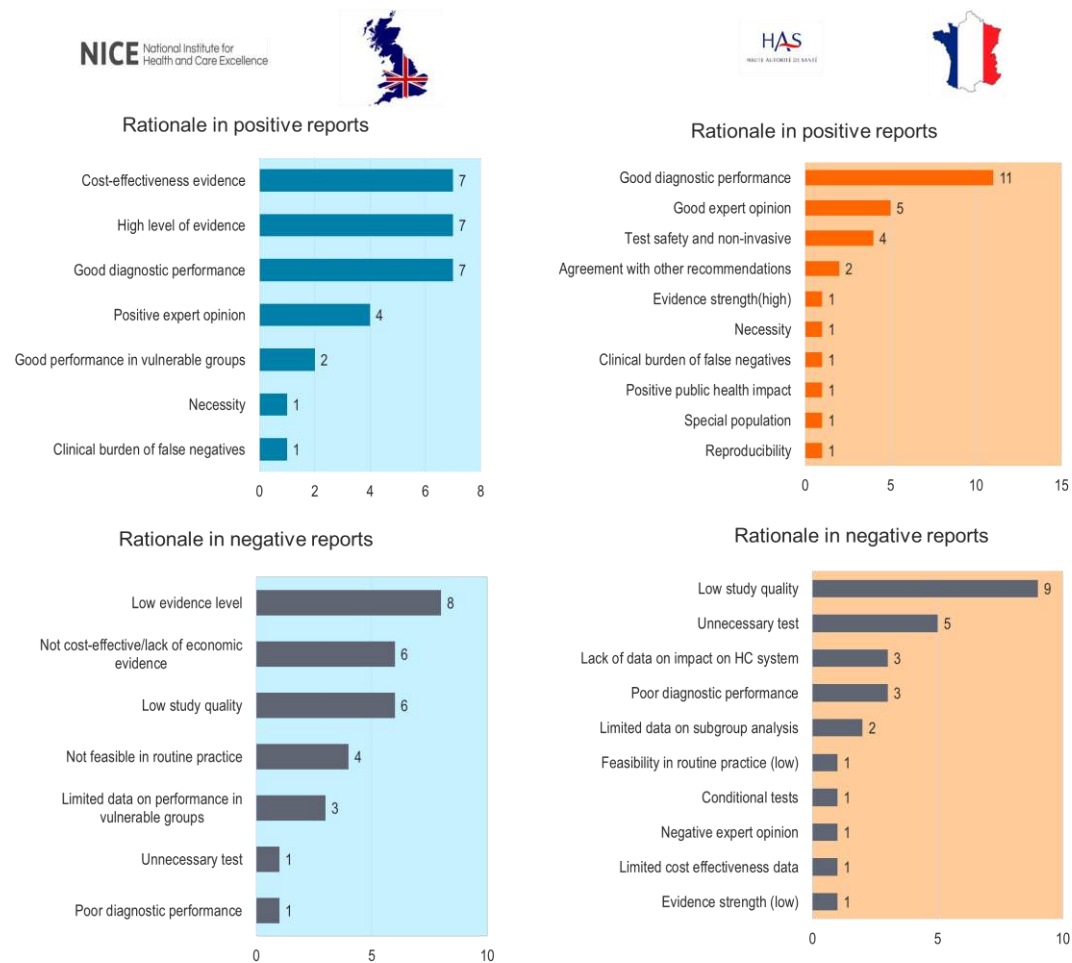


Figure 3. Rationale for positive and negative recommendations

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**5 Decicision making**

5.1 DRG system

5.2 HTA evaluation

5.3 Comparative Efectivness - Health Economics

5.3.1 Quality of Life

5.3.2 Target indication

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# Ways to make decision about funding / reimbursement

Doctors visit



Surgery



Device



Drug



Elderly care



Diagnostics (?)



Medical aid



Payment is linked to required resources / cost



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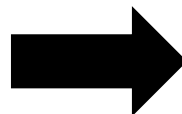


## How does DRG relate to e-health?

- Some e-health solutions will be in a setting where they preferably would be placed in a DRG reimbursement.
- It is important to have a high-level understanding of this method in order to understand why it is not applicable.

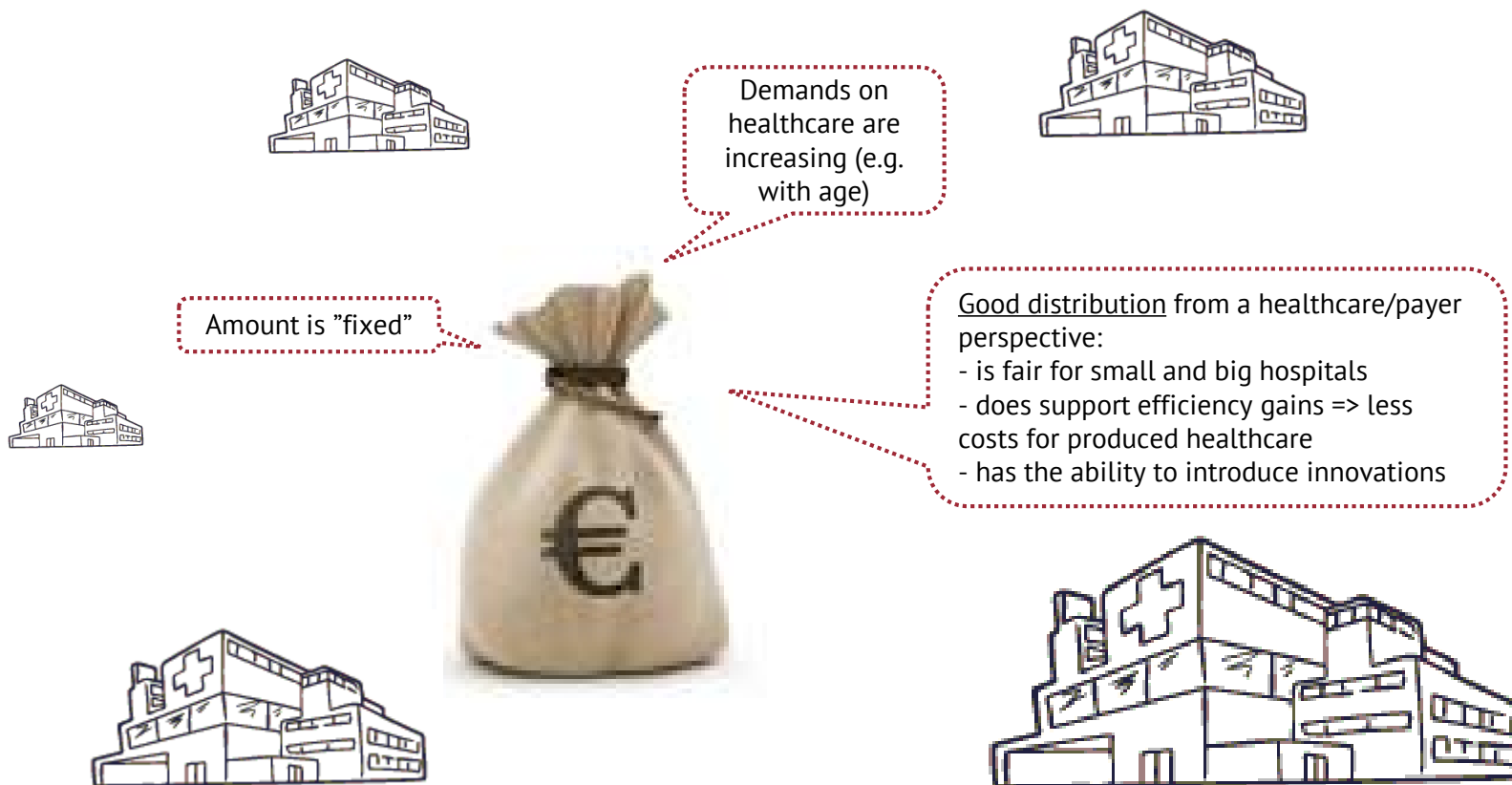
## Payment mechanisms in healthcare services

- Global budget
  - Fixed budget for providers
  - Possible slow adjustments to changes in volumes/costs
- Fee-for-service (FFS)
  - Retrospective reimbursement
  - Each service reimbursed with a fee – reflecting costs/efforts/specialization required
  - May encouraged excessive services and unnecessary / inappropriate care
- Pay-for-performance (P4P)
  - Attempt to link payment to quality
- **Diagnosis-related group system (DRG system)**
  - Linking of reimbursement to the expected extent of care required by single cases/admissions
  - Overtreatment, readmissions



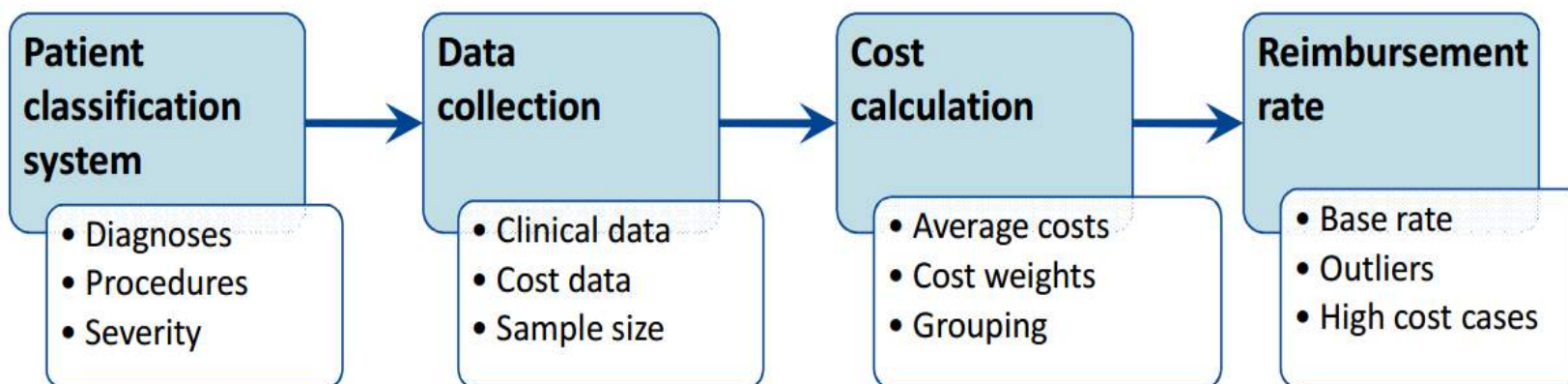
Health care provider can use the money as they wish. No formal process to be included. Good opportunity if the budget is available ..

# DRG – A system to distribute healthcare funds

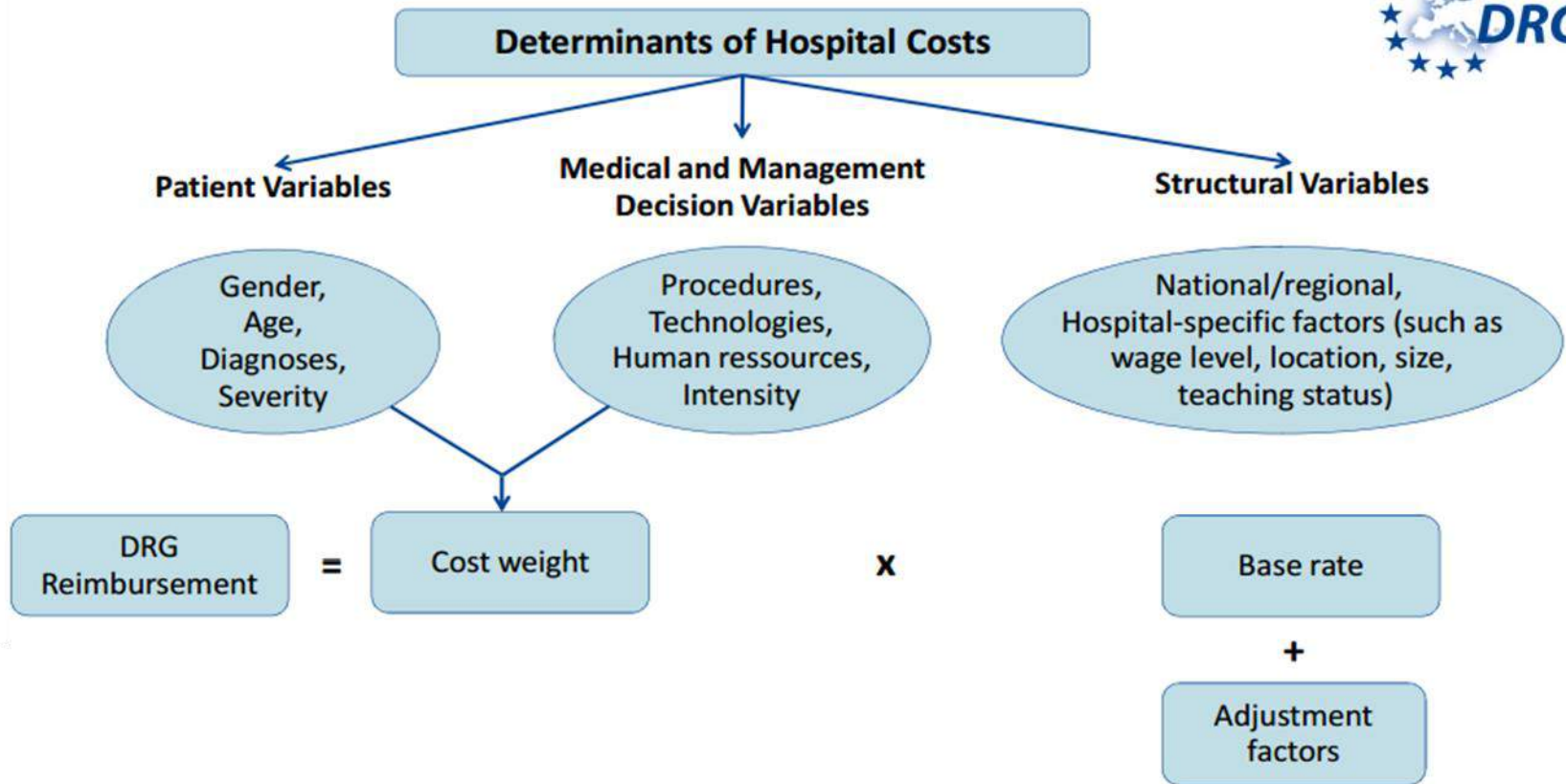


The core function of a DRG system does not have **any evaluation of the 'value'** of the procedures being provided. It is intended to provide a fair model to distribute money.

# Components of DRG System



# Diagnosis Related Groups



# What is included in the DRG tariff



**Admission**

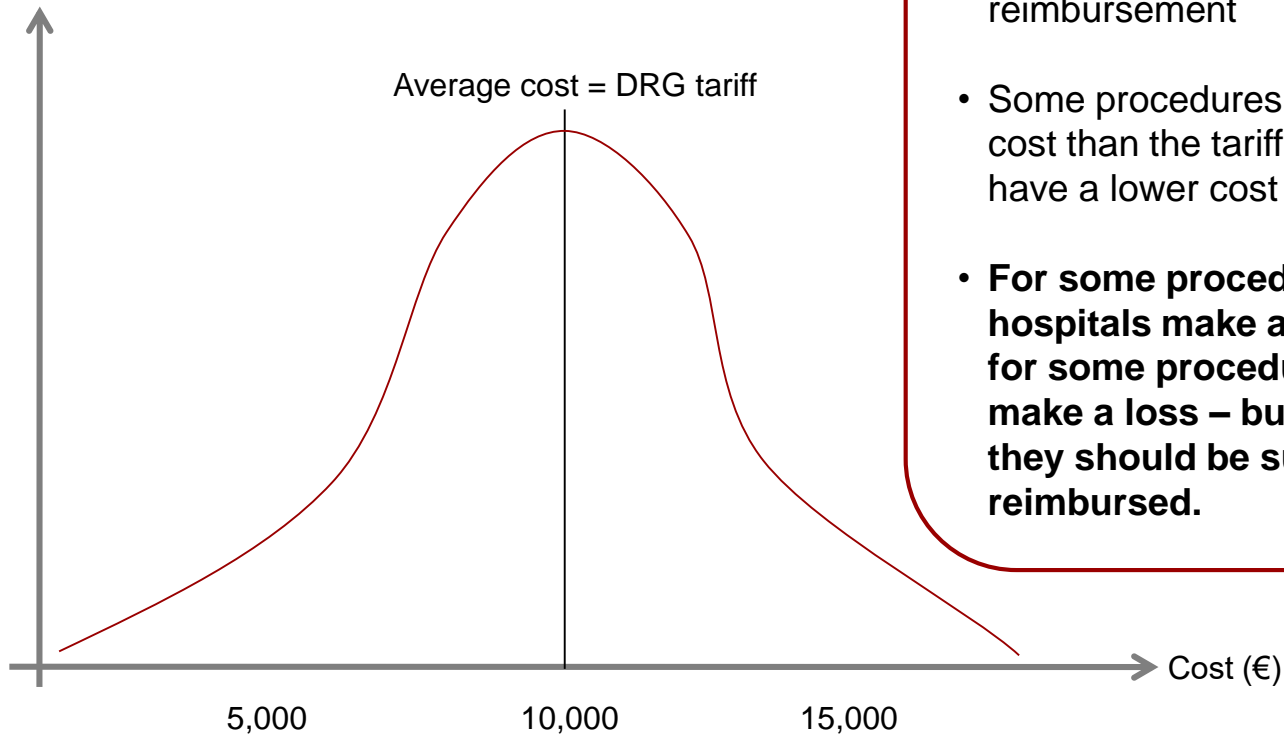
**Discharge**

Staff  
Facilities  
Drugs  
Diagnostics  
Ward  
etc  
Implants

**DRG's include the average cost for all expenses from a patient from admission to discharge.**

# DRG tariffs are not intended to cover the cost of each individual procedure but should suffice on average

% of procedures within DRG



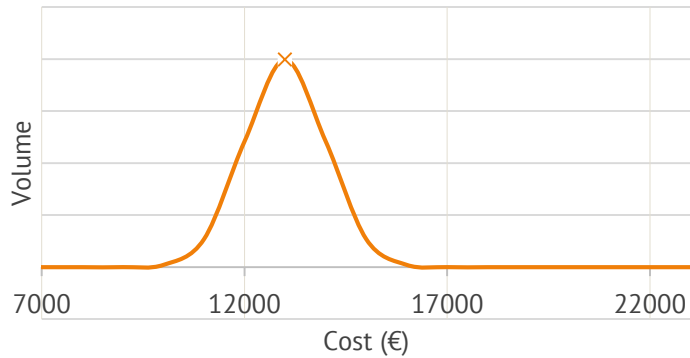
Note: Conceptual illustration

- On average, DRGs are intended to provide sufficient reimbursement
- Some procedures have a higher cost than the tariff, while some have a lower cost
- **For some procedures the hospitals make a profit and for some procedures they make a loss – but on average they should be sufficiently reimbursed.**

# Sufficient volume and cost discrepancy make a DRG change necessary

## A change of coding is required to distinguish different interventions

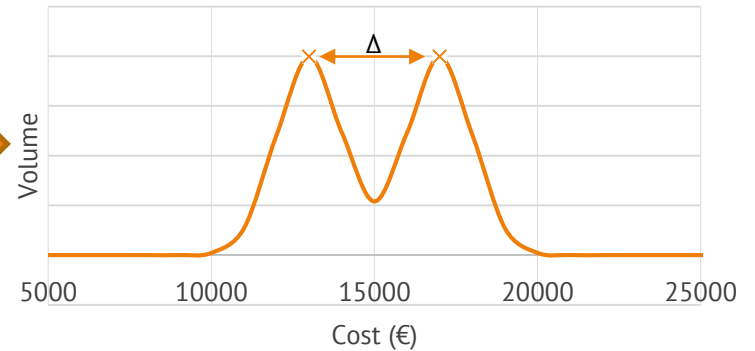
DRG cost distribution of traditional procedure



Introduction of new technology

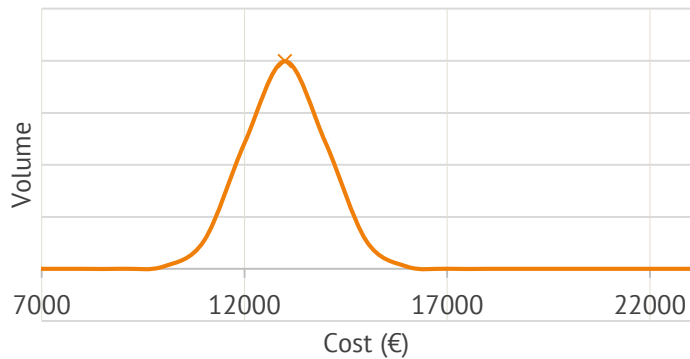


DRG cost distribution of traditional and more expensive innovative procedure

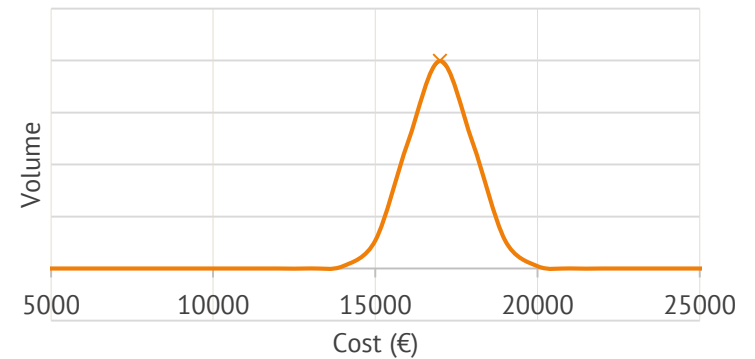


New DRG /  
DRG split

New DRG for traditional procedure



New DRG for innovative procedure





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5.3.1 Quality of Life

5.3.2 Target indication

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# Making decisions what to buy and how to determine the value of different alternatives?

Which fruit should I buy?



How many should I buy /  
can I afford?



How should I  
compare the value  
/ determine the  
price?



# The evaluation framework



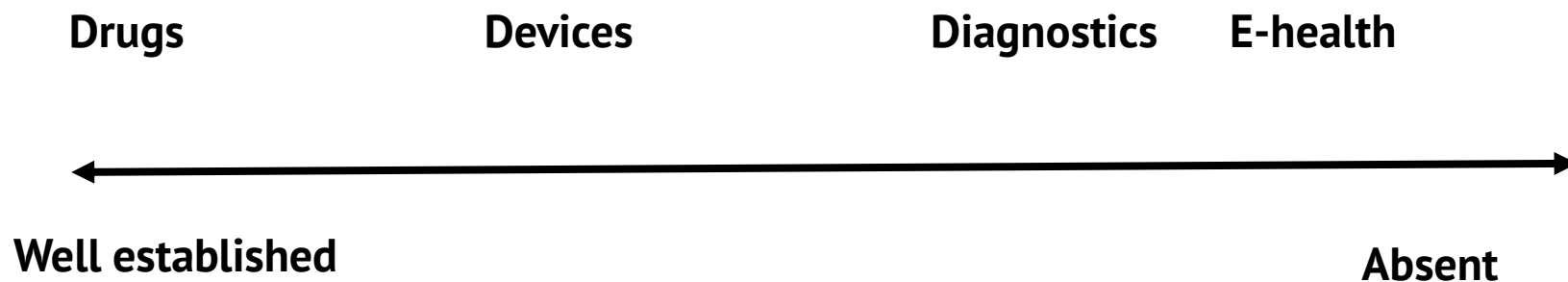
**Health  
Technology  
Assessment  
(HTA)**



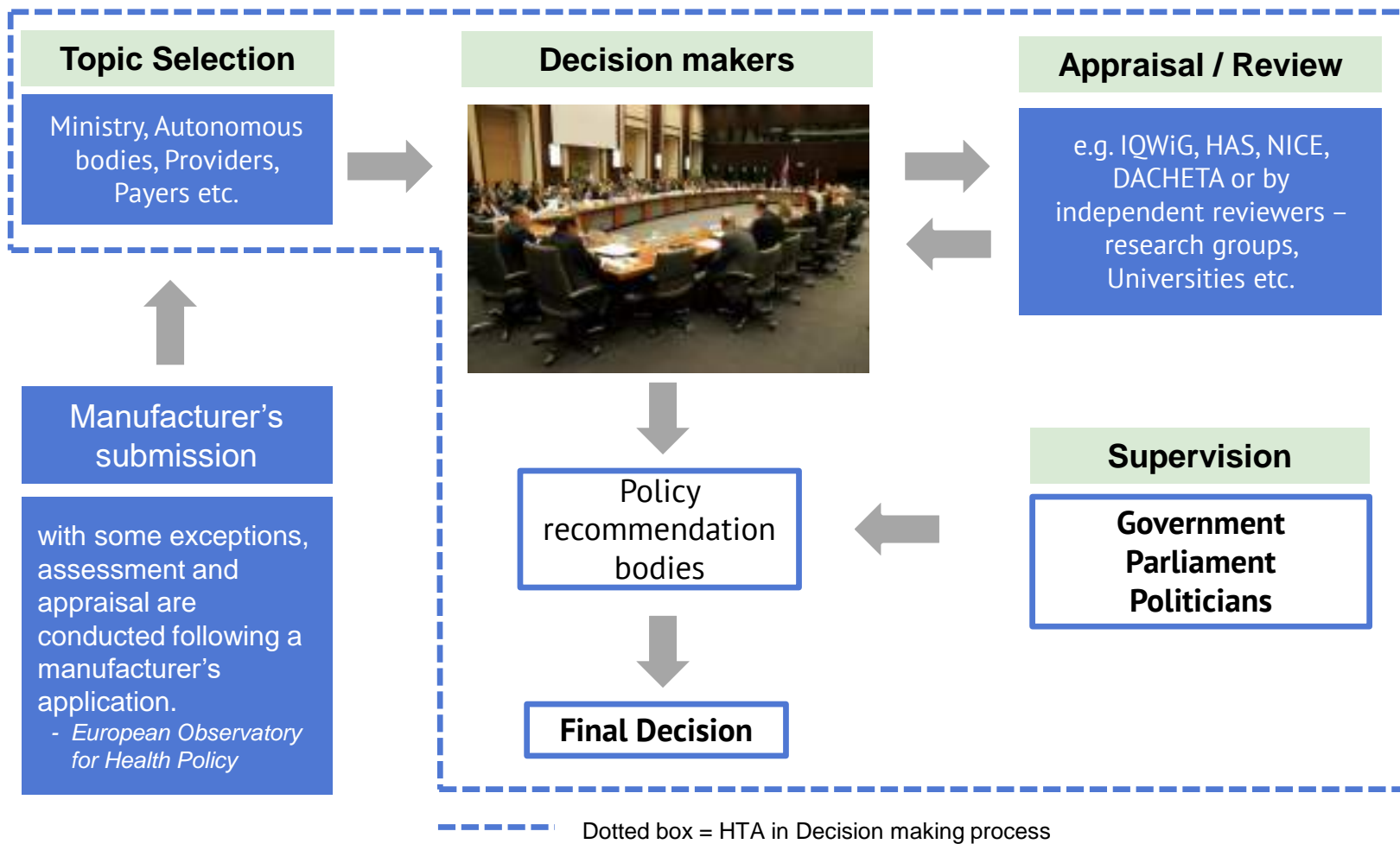
How does the use of the new solution impact cost and outcomes compared to current treatment over a longer period of time.



## Status of established evaluation frameworks connected to reimbursement



# HTA – In EU Decision Making Model



# What Health Technology Assessment organisations (HTA) Look for?

What HTA Authorities Look for?



Budget Impact

Clinical / Therapeutic Value

Cost effectiveness

Available Alternatives

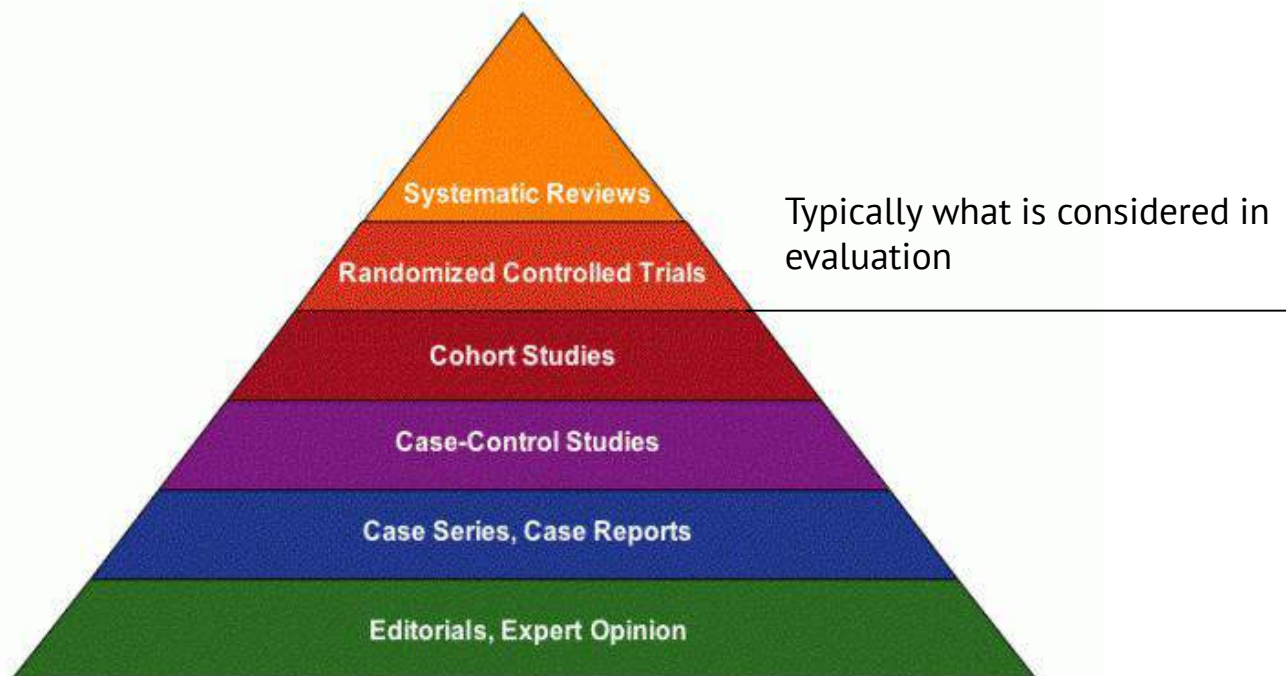
Public Health Impact



All based on high-level published evidence

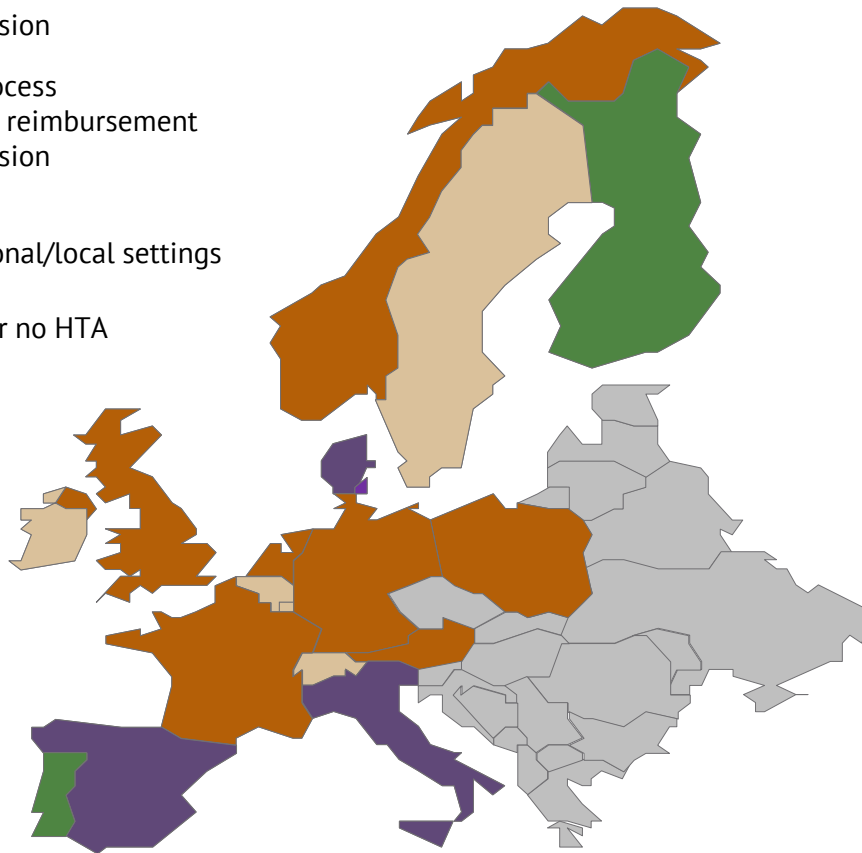
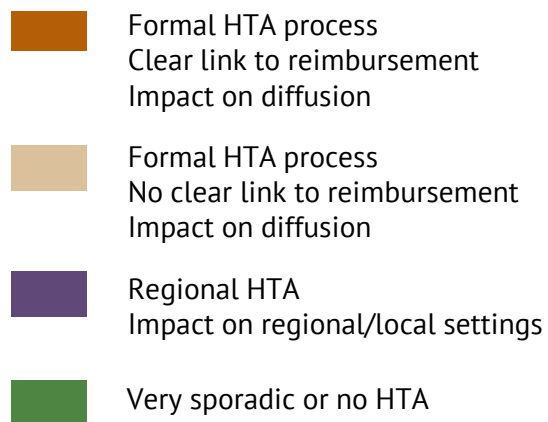
- Hard outcomes:
- Mortality
  - Quality of Life
  - Economic impact

# Hierarchy of Evidence



In most HTA frameworks there is no or limited recognition of the value of Real World Evidence. This may however be a significant opportunity for e-health solutions.

## Differences in HTA processes around Europe (Medical devices)



### Key messages

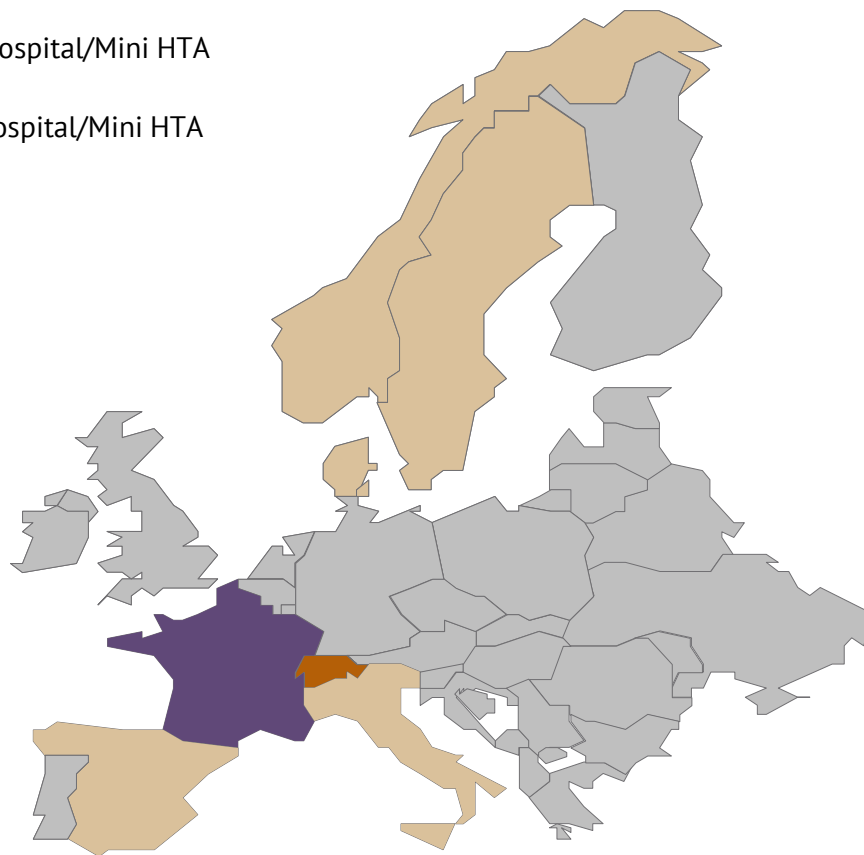
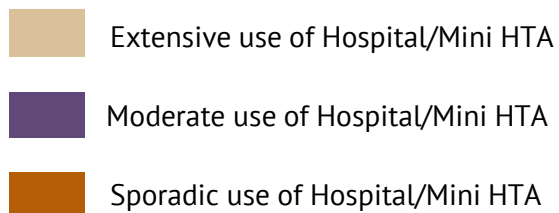
- Only in several European countries health technology assessment is connected to reimbursement system
- In majority health technology assessment carries only advisory role

\* Very sporadic in-patient, formal HTA process with clear link to reimbursement and diffusion in out-patient sector. In process to implement HTA for assessment of innovations in hospital settings.

\*\* All innovative products may require national or mini-HTA



# Hospital/mini-health technology assessment use in Europe



## Key messages

- Nordic countries and France have established practice of mini-health technology assessment
- Italy and Spain has also relatively developed network of hospital HTAs

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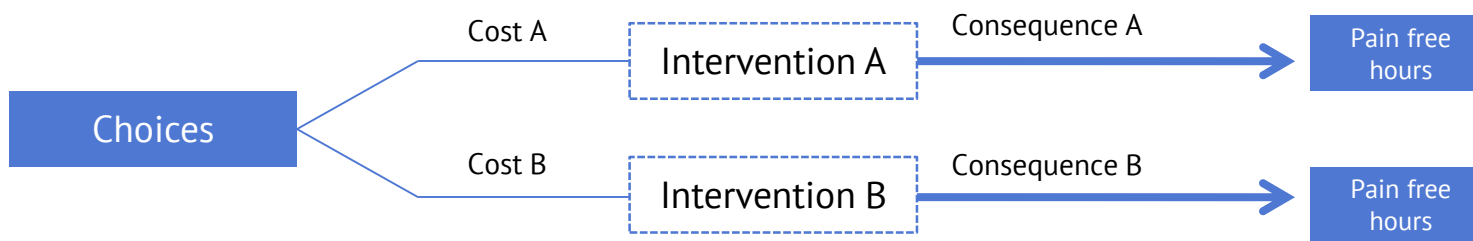
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# Comparative effectiveness – The foundation for assessments

“ The comparative analysis of alternative courses of action in terms of both their costs and consequences in order to assist policy decisions” (Drummond et al)

Always comparative analysis

Comparison of both costs and Consequences

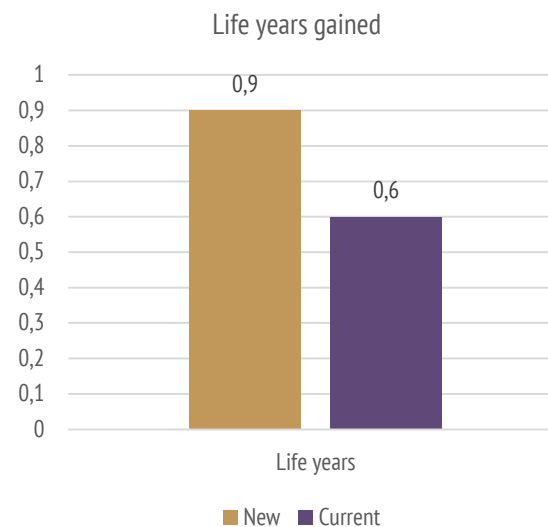
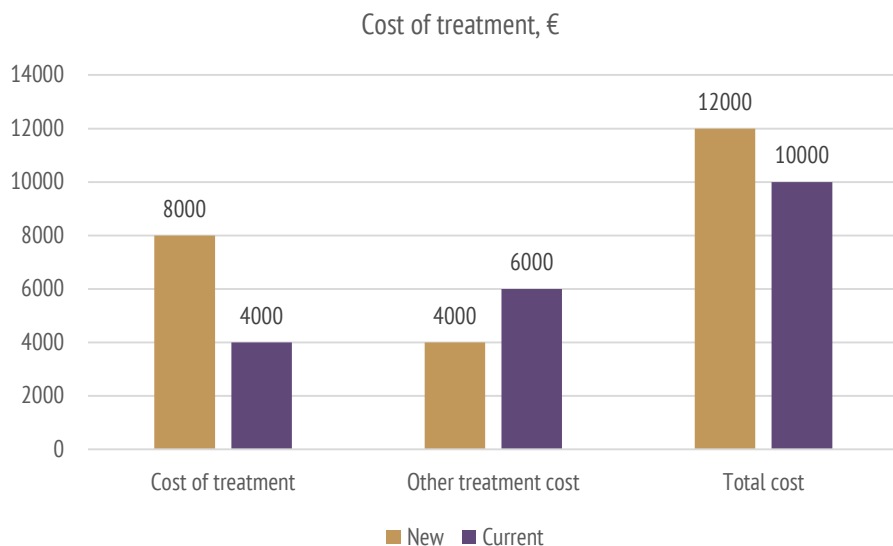


Comparison\* = 
$$\frac{\text{Cost B} - \text{Cost A}}{\text{Effect B} - \text{Effect A}}$$
 **Incremental Cost Effectiveness Ratio (ICER)**

ICER should be below the Willingness-To-Pay of each payer (e.g. in UK it is 30,000 £ / QALY)

\*Assuming B as a new intervention having more costs and effects

# Basic concept of economic evaluation



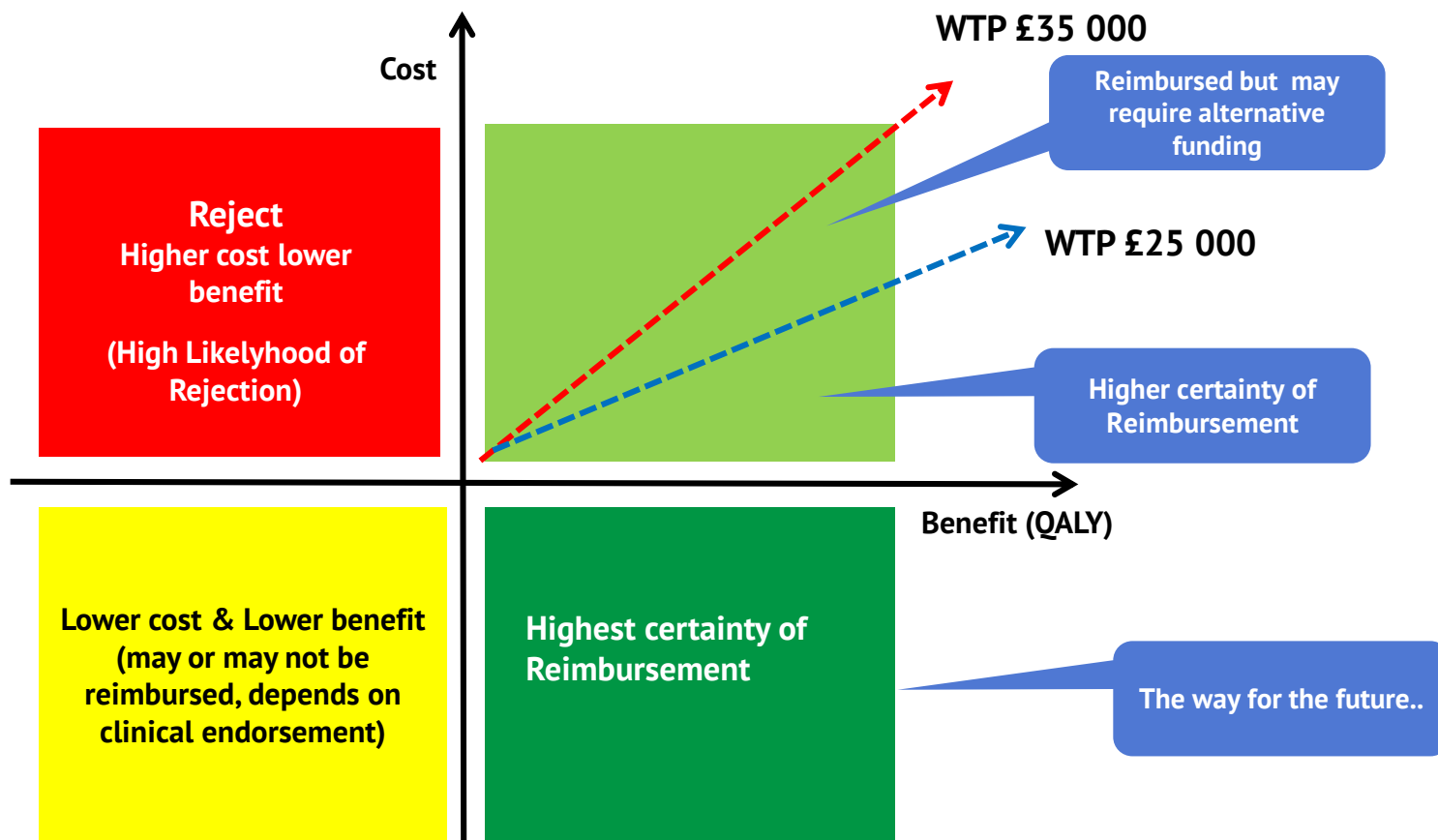
Incremental cost-effectiveness ratio

$$\frac{\text{Cost (new)} - \text{Cost (current)}}{\text{Life years (new)} - \text{Life years (current)}} = \frac{12,000 - 10,000}{0,9 - 0,6} = 6,666 \text{ euro per one additional life year gained}$$

## Key messages

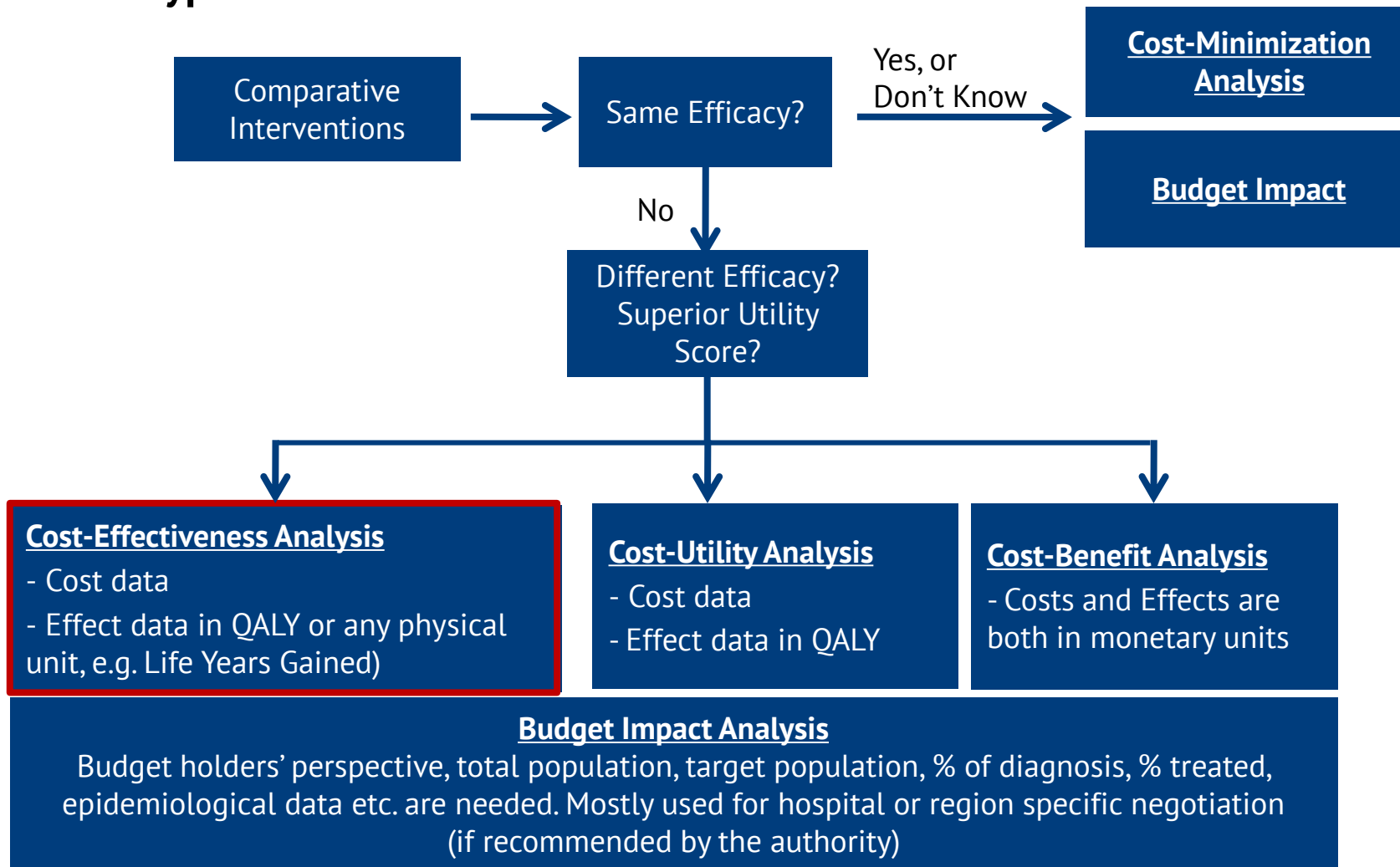
- Economic analysis includes comparative analysis of clinical and economic consequences of two treatment methods
- Results of cost-effectiveness analysis are presented in the form of increment cost-effectiveness ratio. It shows how much extra society shall pay for one additional year of health (quality-adjusted)

# Reimbursement Potential: Which Quadrant?



WTP = Willingness To Pay or Cost Effectiveness Threshold (e.g. In UK £25 000 – £35 000)

## Different types of economic models



# Agenda

1	Synergus RWE
2	Introduction
3	Funding and Reimbursement
4	Health care systems
<b>5</b>	<b>Decision making</b>
5.1	DRG system
5.2	HTA evaluation
<b>5.3</b>	<b>Comparative Effectiveness - Health Economics</b>
5.3.1	Quality of Life
5.3.2	Target indication
6	Conclusion

# Quality of Life



- ❑ Quality of life is the subjective feeling (by patient) about a defined health state. This feeling needs to be elicited from the patient
- ❑ The feeling of well-being needs to be quantitatively converted as a score
- ❑ Quality of Life can be generic or disease specific
- ❑ QoL score can be elicited as preference-based or non preference-based

Today my Quality of Life is 0.74





# Quality of Life Value : Methods of Elicitation\*

<ul style="list-style-type: none"> <li>▪ Generic QoL</li> <li>▪ Disease Specific QoL</li> </ul>	<ul style="list-style-type: none"> <li>• Preference-based QoL</li> <li>• Non preference-based QoL</li> </ul>	<p>Combination</p> <ul style="list-style-type: none"> <li>• Generic preference based</li> <li>• Disease specific preference based</li> </ul>
<p>Generic Questions</p>	<p>Disease specific questions</p>	<p>Preference based questions</p>
<ol style="list-style-type: none"> <li>1. How are you today?</li> <li>2. Do you have any <b>problem</b> to work?</li> <li>3. Do you have any <b>problem</b> to sleep?</li> </ol>	<ol style="list-style-type: none"> <li>1. Did you feel <b>pain</b> in your <b>ankle joint</b> in the last 12 hours?</li> <li>2. How severe was the <b>Pain</b> if you rank it on a scale of 1-5 where 5 is worst?</li> </ol>	<p>Which life you prefer between –</p> <ol style="list-style-type: none"> <li>1. Additional 20 years of life with 50% mobility – or</li> <li>2. Additional 14 years of life with 100% mobility?</li> </ol>

**In Europe the preference-based method is recommended by most of the evaluation authorities**

\*Simplified example

# Quality of Life Measurement

Disease-specific

The best suited for detecting small changes in disease-related quality of life. Acknowledged by clinical community. Can't be directly used in economic evaluations. Additional studies are required. Example: Kansas City Cardiomyopathy Questionnaire for heart failure area

Health profile

Multi-dimensional health profile provides information about different aspects of life, such as mobility, pain, cognitive functioning etc. Health profile data may allow comparison with other diseases and treatments. Example: SF-36. SF-36 may be used in economic evaluations

Preference measures

Patients preferences for the condition is collected. Example: EQ-5D, SF-6D, Health Utility Index. Generic measures are the preferred tools for economic evaluations

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# Indirect Measurement of Preferences – EQ-5D

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today

1 → **Mobility**  
I have no problems in walking about   
I have some problems in walking about   
I am confined to bed

2 → **Self-Care**  
I have no problems with self-care   
I have some problems washing or dressing myself   
I am unable to wash or dress myself

3 → **Usual Activities** (e.g. work, study, housework, family or leisure activities)  
I have no problems with performing my usual activities   
I have some problems with performing my usual activities   
I am unable to perform my usual activities

4 → **Pain/Discomfort**  
I have no pain or discomfort   
I have moderate pain or discomfort   
I have extreme pain or discomfort

5 → **Anxiety/Depression**  
I am not anxious or depressed   
I am moderately anxious or depressed   
I am extremely anxious or depressed

Source: adapted from the EuroQol Group: [www.euroqol.org](http://www.euroqol.org)

- EQ-5D is the method of choice in most CUAs
- Simple and well suited questionnaire for self-completion by participants
- EQ-5D is the preferred HRQoL measurement for NICE
- EQ-5D-5L version is available which allows greater sensitivity

# Agenda

1 Synergus RWE

2 Introduction

3 Funding and Reimbursement

4 Health care systems

**5 Decicson making**

5.1 DRG system

5.2 HTA evaluation

**5.3 Comparative Efectivness - Health Economics**

5.3.1 Quality of Life

**5.3.2 Target indication**

6 Conclusion

## **Balancing financial impact is critical for decision-makers in the case of expensive innovations**

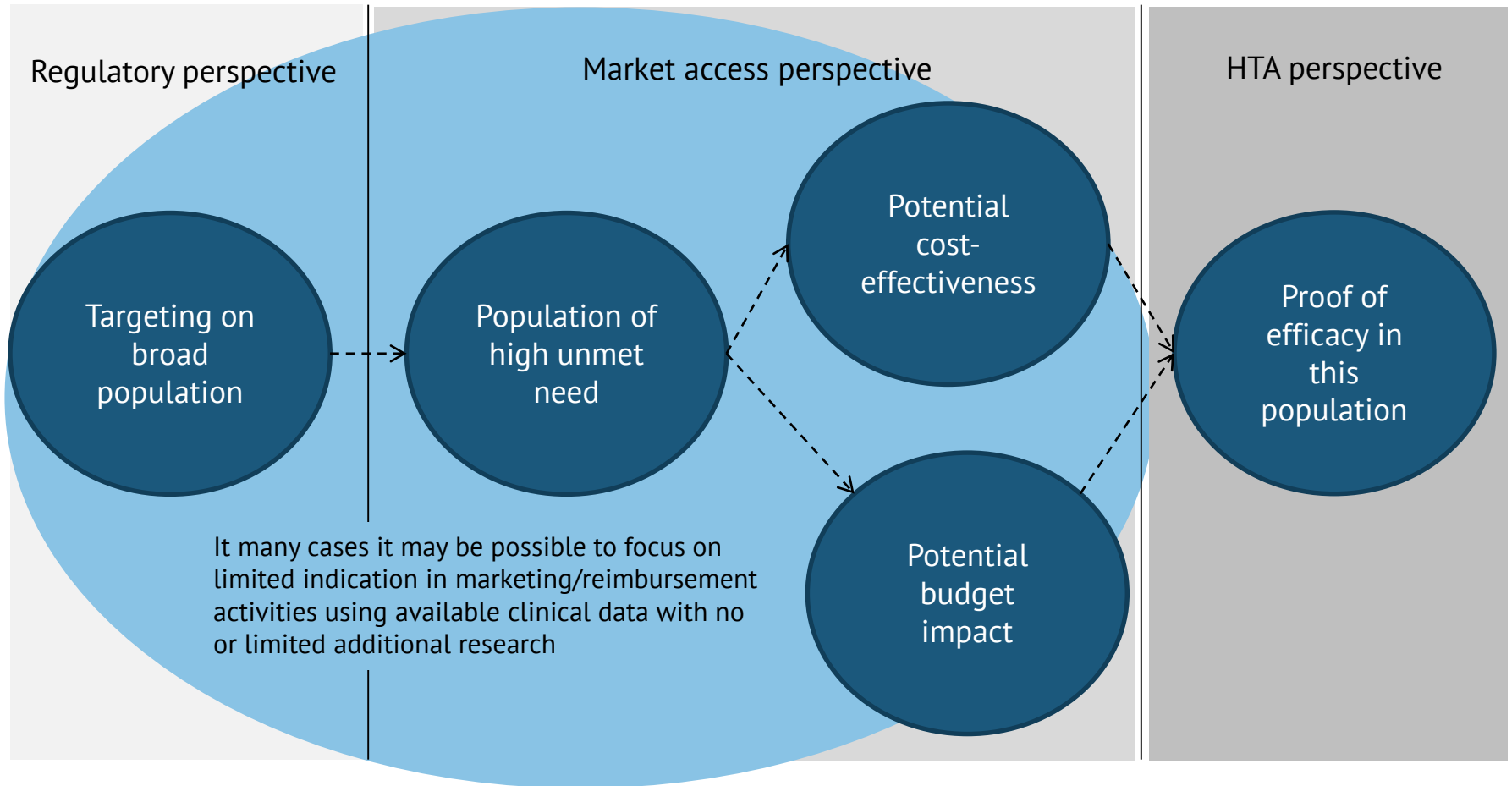


**vs.**

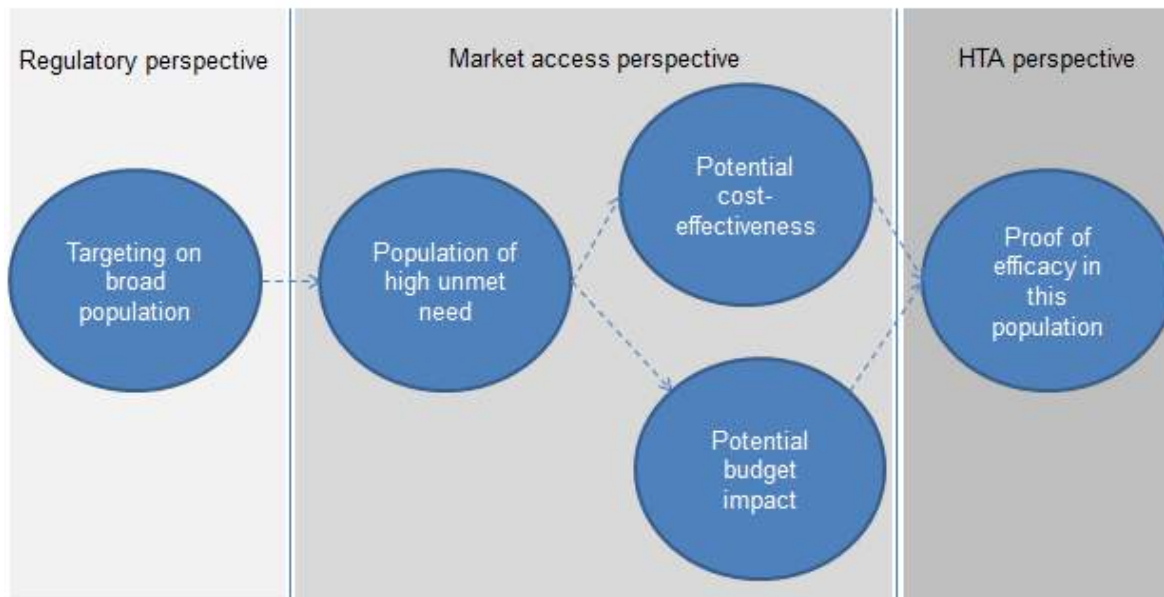


**It is critical to inform decision-makers about budget impact and it is better to have a modest and even innocent proposition**

# Changing mindset: moving from regulatory to reimbursement perspective

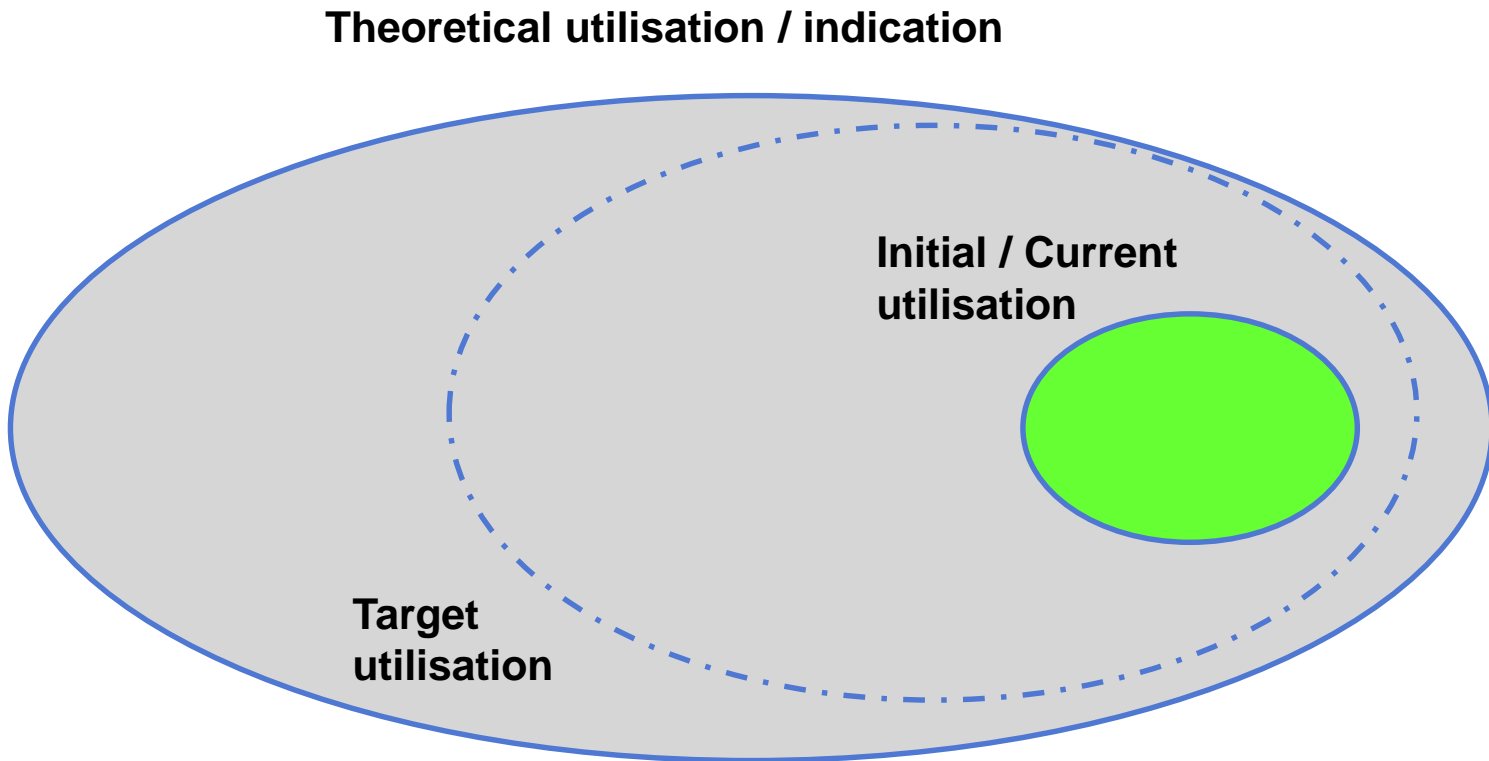


## Several questions for discussion



- When device may be more valuable in specific population?
- How to identify patient sub-groups with the highest unmet need?
- How to adjust clinical and market access strategy?
  - Clinical research
  - Economic evaluations

# What is your target indication

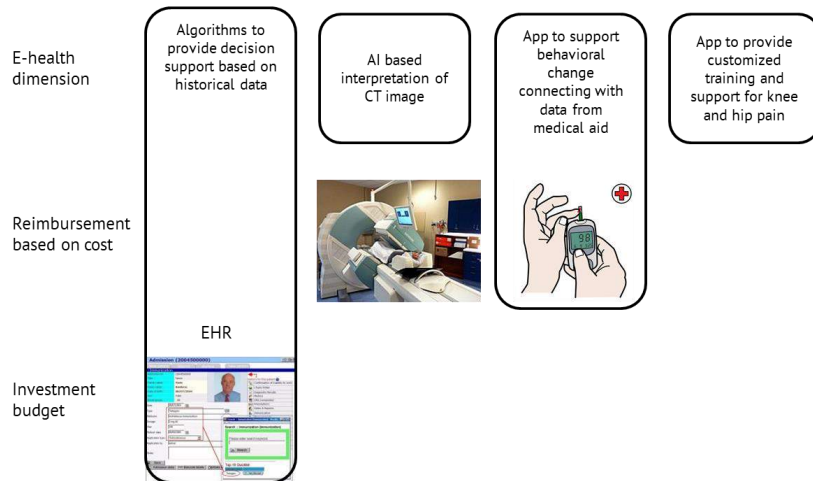




# Agenda

- 1 Synergus RWE
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- 5 Decicision making
- 6 Conclusion**

# Replacing the term e-health (therapeutic / diagnostic..) with Disease Management Tools?



- The assessment of the e-health solutions will be based on the impact it has on the disease in terms of:
  - Cost for health care
  - Clinical outcomes
  - Patient related outcomes
- It will be assessed as a tool to improve the management of the disease.
- Using the term Disease Management Tools helps to create clarity of how this is different then administrative solutions in e-health and also help you as a company to have the right perspective of what you are trying to accomplish.
- Disease Management Tool

# Conclusion

Many ways to find money..

- There are many ways to find the money for the use of your solution. Try the easy ways first.

Limitations in reimbursement systems may 'kill' your plan!

- There are many (stupid) limitations in current reimbursement systems that may prevent your commercial plan. Be aware!

Know the long term strategy

- Make sure you understand the long-term strategy to establish reimbursement. Many of the processes takes a long time.

Understand your target indication

- Understand what the comparative treatment is for your solution and for which patients your solution can provide relevant value.

Develop clinical and economical evidence

- Decision makers will require evidence to make decision. Make sure to develop both clinical and economical evidence for the value for your therapy.

## Coming webinars

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Topic	Date	Speaker
• <b>Funding and reimbursement of E-health in France</b>	31 Jan	Michel Verhasselt
• <b>HTA evaluation of e-health solutions</b>	21 Feb	Dr Kristian Kidholm
• <b>Funding and reimbursement of E-health in Germany</b>	28 Feb	Dr Thomas Seeger
• <b>Developing an RWE strategy. Part 1: Defining the variables and outcomes of interest</b>	07 Mar	Mattias Kyhlstedt
• <b>Funding and reimbursement of E-health in The Netherlands</b>	28 Mar	Wim Meijer

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**Thank you for listening!**

**Let us know if we can be of any support.**

**Contact for questions: [mattias.kyhlstedt@synergusrwe.com](mailto:mattias.kyhlstedt@synergusrwe.com)**

**[CLICK HERE TO SEE THE FULL WEBINAR](#)**