

# Beyond Regulation, HTA and Negotiation: Patients as catalysers for affordable drug pricing in Canada

Patient Drug Summit  
Toronto, November, 15th,  
2016

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# Conflicts of interest

- Work in a governmental HTA agency for many years.
- Work as a consultant with different companies over the last 12 months. No active contract.
- Ongoing work with the Institute for Clinical and Economic Review in Boston.



## ***“Four Reasons Drugs Are Expensive, Of Which Two Are False”***

Reason 1: Cost of developing the drug **(False)**

Reason 2: Value for patients and families **(False)**

Reason 3: Power that follows from the rights to a legal monopoly **(True)**

Reason 4: Prizes - the R&D lottery is expensive to play, most games are a bust, and the rare wins take a long time to pay out **(True)**

**Drug prices are the result of market forces and patient groups are one of the forces.**

# The new buzzword: Value Assessment Frameworks

## Current Landscape: Value Assessment Frameworks

Thursday, March 31, 2016

Value assessment frameworks have the potential for considerable impact on patients, so there is a need to understand whether these frameworks have been developed with adequate rigor. By comparing and contrasting these frameworks, we can lay the groundwork for a dialogue about what elements should be included in a value framework, how those elements should be measured, and how a value assessment should be conducted and utilized.

This NPC paper, *Current Landscape: Value Assessment Frameworks*, builds on Neumann and Cohen's informative comparison of frameworks by carrying their assessment further and providing specific, detailed observations about the following frameworks:

- The American College of Cardiology and the American Heart Association (ACC-AHA) Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures
- The American Society of Clinical Oncology's (ASCO) Conceptual Framework to Assess the Value of Cancer Treatment Options
- The Institute for Clinical and Economic Review (ICER) Value Framework
- Memorial Sloan Kettering Cancer Center's DrugAbacus
- The National Comprehensive Cancer Network's (NCCN) Evidence Blocks.

### Current Landscape: Value Assessment Frameworks

Kimberly Westrich, MA  
Vice President, Health Services Research



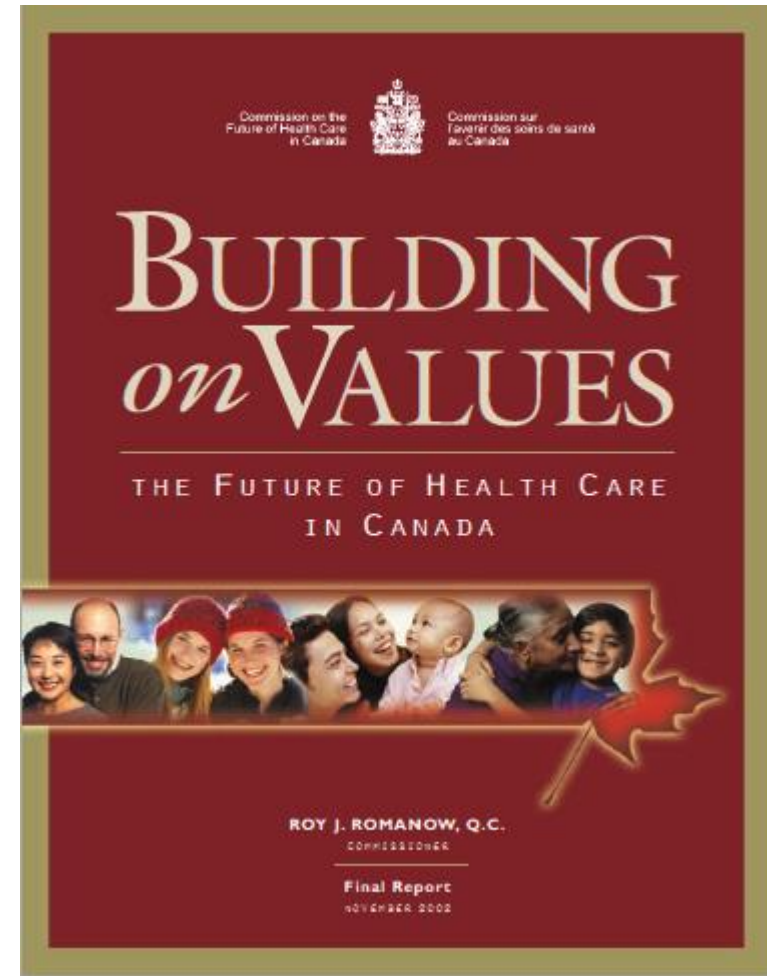
**Author:** Kimberly Westrich,  
**MAPages:** 14**Infographic:** [How Should Value in Health Care Be Assessed?](#)

[Download the PDF](#)

## A universe of values

- Societal values
  - Individual values
  - Values of groups
  - Value for money
  - Values of the health system
- 
- ..... **Values for patients**

Slide adapted from INESSS presentation at IMS|Brogan  
Pharmafocus 2012 meeting: Striking the Right Balance of  
Value for Money



**Institut national  
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**Québec**



## Synergy between evidence on patients' perspectives and patient participation

Slide from INESSS presentation at  
Rx&D Stakeholder Luncheon and  
Workshop, 2013 in Montreal

- « ..two distinct but complementary ways in which HTAs could be strengthened by taking account of patients' perspectives. First, we suggest a systematic approach to include **robust evidence on patients' perspectives** and in the second part, we outline different approaches that can be used to support **patient participation in the HTA process**.”
- “Robust evidence eliciting patients' perspectives can be obtained through **social science research that is well conducted, critically appraised and carefully reported**, either through meta-synthesis of existing studies or new primary research. “
- “In terms of **patient participation in the HTA process**, guidance exists for patient organizations to engage in an HTA process that allows evidence submission , but **there is no clear guidance for HTA agencies**. The HTAi Interest Group on Patient/Citizen Involvement in HTA will continue to provide material...”

Facey et al 2010. Patients' perspectives in health technology assessment: A route to robust evidence and fair deliberation <http://www.ncbi.nlm.nih.gov/pubmed/?term=20584364>

# Influence of patients perspectives on drug pricing:

## 1. Evidence on Patients' Perspectives

## 2. Patient Participation

1. Colorectal Cancer Association of Canada: Patient Values Project Framework allowing patient preferences to be quantitatively built into the evaluation process for cancer drugs using survey including discrete choice experiment and generic (EQ-5D) and disease-specific quality of life instruments (QLQ-C30+QLQ-CR38).
2. Participation in HTA processes and ???



# The origin of Health Technology Assessment

Request of the US Congress Senate Committee on Human Resources to OTA in 1974: « whether a **reasonable amount of justification** should be provided **before costly new medical technologies and procedures are put into general use** »

**Decisions based on  
needs expressed by  
physicians**

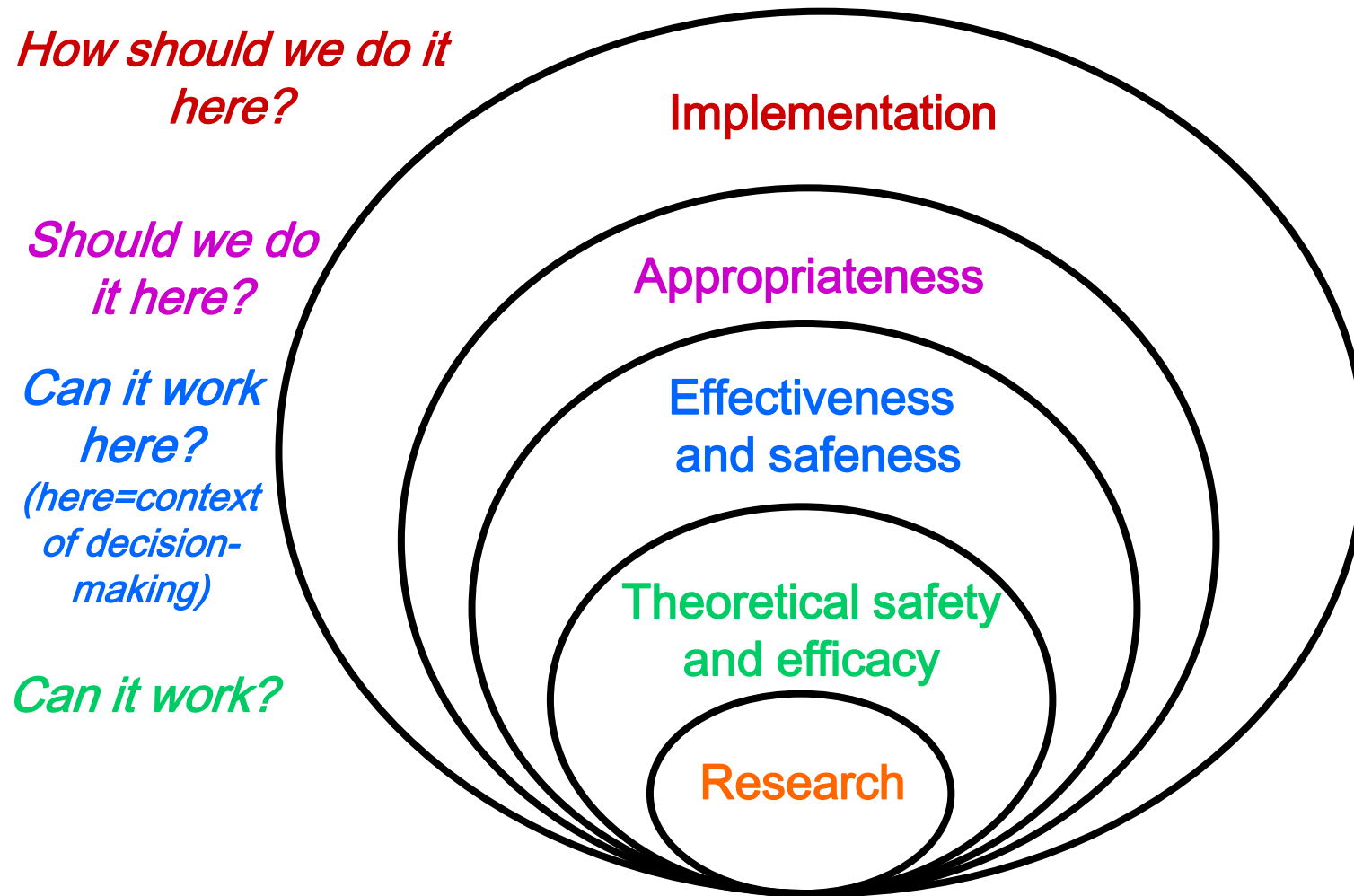


**Decisions based on (informed by)  
a formal and transparent assessment  
of the evidence**





# Reasoning in HTA



- HTA depends on available primary studies.
- HTA must deal with uncertainties in knowledge.
- HTA can be a hurdle or an enabler for innovations.

*The real value of NICE is in the collective judgement of a balanced group of experienced people*

Sir Michael Rawlins (2009) NICE decision-making. Br J Clin Pharmacol; 70:3

A decorative pattern of overlapping blue triangles and parallelograms in various shades of blue, located at the bottom of the slide.

# Beyond Regulation, HTA and Negotiation

1. Health Canada cannot diminish drug prices.
2. PMBRB's tools are very limited concerning the typical new drugs with high price tags.
3. HTA and related processes provide pharmaco-economic information to inform decision-making.
4. PCPA can lower prices, but often not to the extent needed for enabling coverage.
5. Industry is using the market mechanisms that allow the current evolution in pricing.
6. Innovative mechanisms are needed for enabling innovative drug development and market access.
7. Lowering development time and development cost may enable significantly decreased drug prices.



# Examples of introduction with evidence development in Canada

- Health Canada: NOC with conditions, renewal of regulatory framework, international involvement on adaptive pathways
- INESSS work with Advisory committee on HTA and innovative technologies 2012-2015
- Specific initiatives such as around drugs for Alzheimers disease in BC
- Evidence-Building Program at Cancer Care Ontario
- Others ?

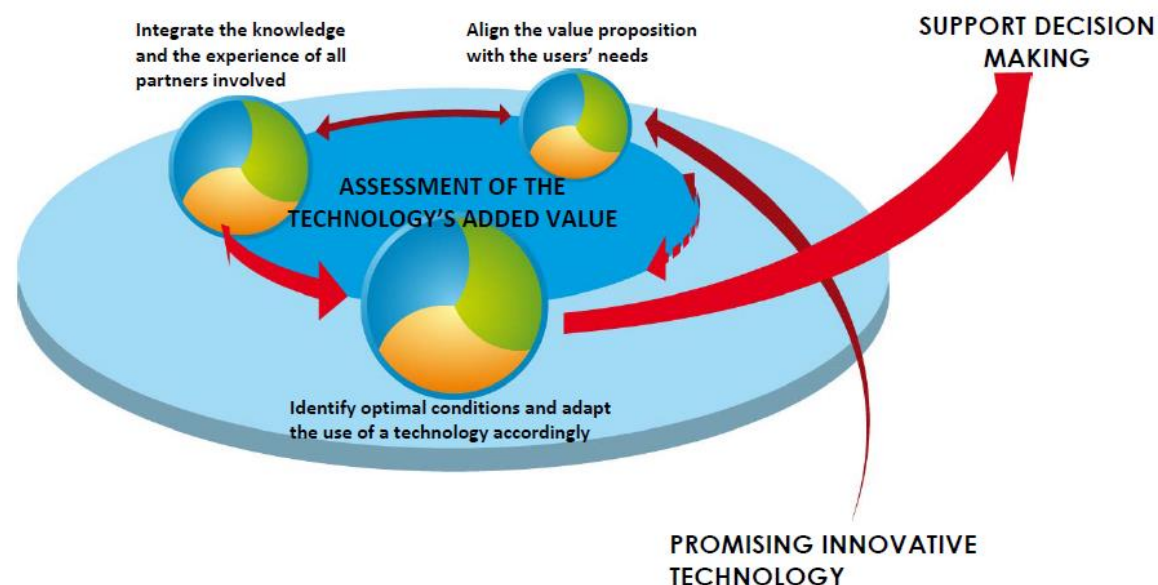


# Progressive field evaluation

Slide from INESSS work with the Advisory committee on HTA and innovative technologies 2012-2015  
<http://www.inesss.qc.ca/en/networks-and-partnerships/bridging-mechanisms/advisory-committee-on-hta-and-innovative-technologies.html>

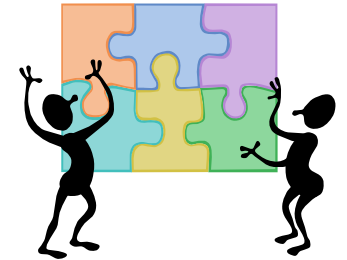
## Objectives:

- Align the value proposal of an innovative technology with the needs of the users
- Integrate the knowledge and the experience of the partners involved
- Identify optimal conditions and adapt the use of a technology accordingly
- Collect information about the effectiveness of a technology, as well as contextual and organizational elements relevant to decision makers



# Necessary conditions for dynamic HTA systems linked to collaborative, patient-centered evidence-development pathways

1. Developing the vision
2. Developing Trust (probably the biggest challenge)
3. Methods and infrastructure:
  - a) innovative trial designs, ex randomized register trials;
  - b) information systems based on Big Data, Open Data and Linked Data
  - c) processes based on Living Lab style approaches



# Role for Patient Organisations, ...especially in Canada

1. Developing the Vision and Political will in the fragmented Canadian Health Care landscape
2. Advocacy across the provinces and on the federal level
3. Patient organisation acting as catalysers between the economic, scientific, administrative and political perspectives







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# Additional Slides

2016-12-23



# Values for assessing medications at INESSS

7. In exercising the functions described in paragraph 8 of section 5, the institute must **first assess the therapeutic value of a medication**. If this is not established to its satisfaction, the institute sends a notice to that effect to the Minister.

If the institute considers that the therapeutic value of a medication has been established, it sends its recommendation to the Minister after assessing

- (1) the **reasonableness of the price** charged;
- (2) the **cost-effectiveness** ratio of the medication;
- (3) the **impact** that entering the medication on the list will have on the **health of the general public** and on the other **components of the health and social services system**;

Slide from INESSS presentation at IMS|Brogan  
Pharmafocus 2012 meeting: Striking the Right  
Balance of Value for Money

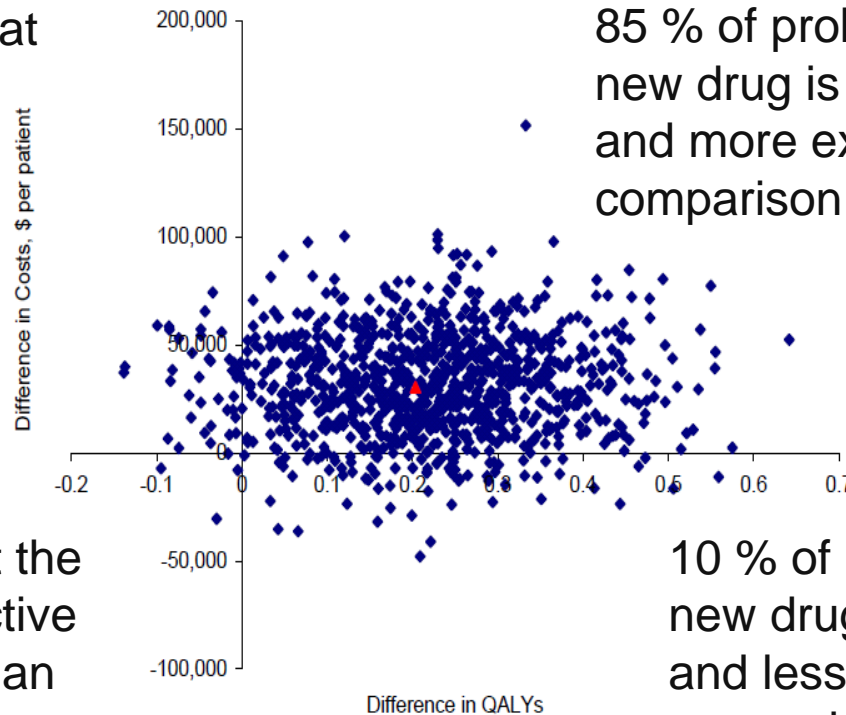
# Uncertainties: The crux in decision-making

(A real world example of Uncertainties about benefits and costs through probabilistic sensitivity analysis)

*Each point represents a possible ratio (simulation)*

4 % of probability that the new drug is less effective and more expensive than comparison

1 % of probability that the new drug is less effective and less expensive than comparison



85 % of probability that the new drug is more effective and more expensive than comparison

10 % of probability that the new drug is more effective and less expensive than comparison

\*Base-case value represented by filled triangle.

# Modelling: A Consumer Perspective view

Reprod Health Matters. 2000 May;8(15):113-6.

## **A consumer trip into the world of the DALY calculations: an Alice-in-Wonderland experience.**

Bastian H<sup>1</sup>.

### Author information

### **Abstract**

For a consumer advocate, entering the world of the disability-adjusted life years (DALYs) calculations was a surreal experience. What began with the noble aim of working out how to overcome the tyranny of death as the only way of 'measuring' health, has led to an exercise where people weigh the relative value of health conditions without death as a feature. However, life-threatening diseases, if they no longer carry the threat of death, are no longer themselves. These valuations of 'altered health states' then, can become absurd. While data often fail to measure real life very well, and distort as well as illuminate, the ranking of disease in this way is particularly problematic. It has been said to disadvantage the poor, the very young and very old, and women. It privileges short-term interventions over prevention and long-term strategies. Can this really improve decision-making about resource allocation in health?

## Another view on modelling...

***“Computer models are no different from fashion models...  
seductive, unreliable, easily corrupted and they lead  
sensible people to make fools of themselves.”***

Antony Jay and Jonathan Lynn . *Yes, Prime Minister*. Satirical British sitcom 1986 to 1988.  
<http://ow.ly/EuNQG>

# How is the progressive field evaluation different from other approaches?

**Evolving nature:** the process fosters the adaptation of the use of the technology according to the users' "real" needs

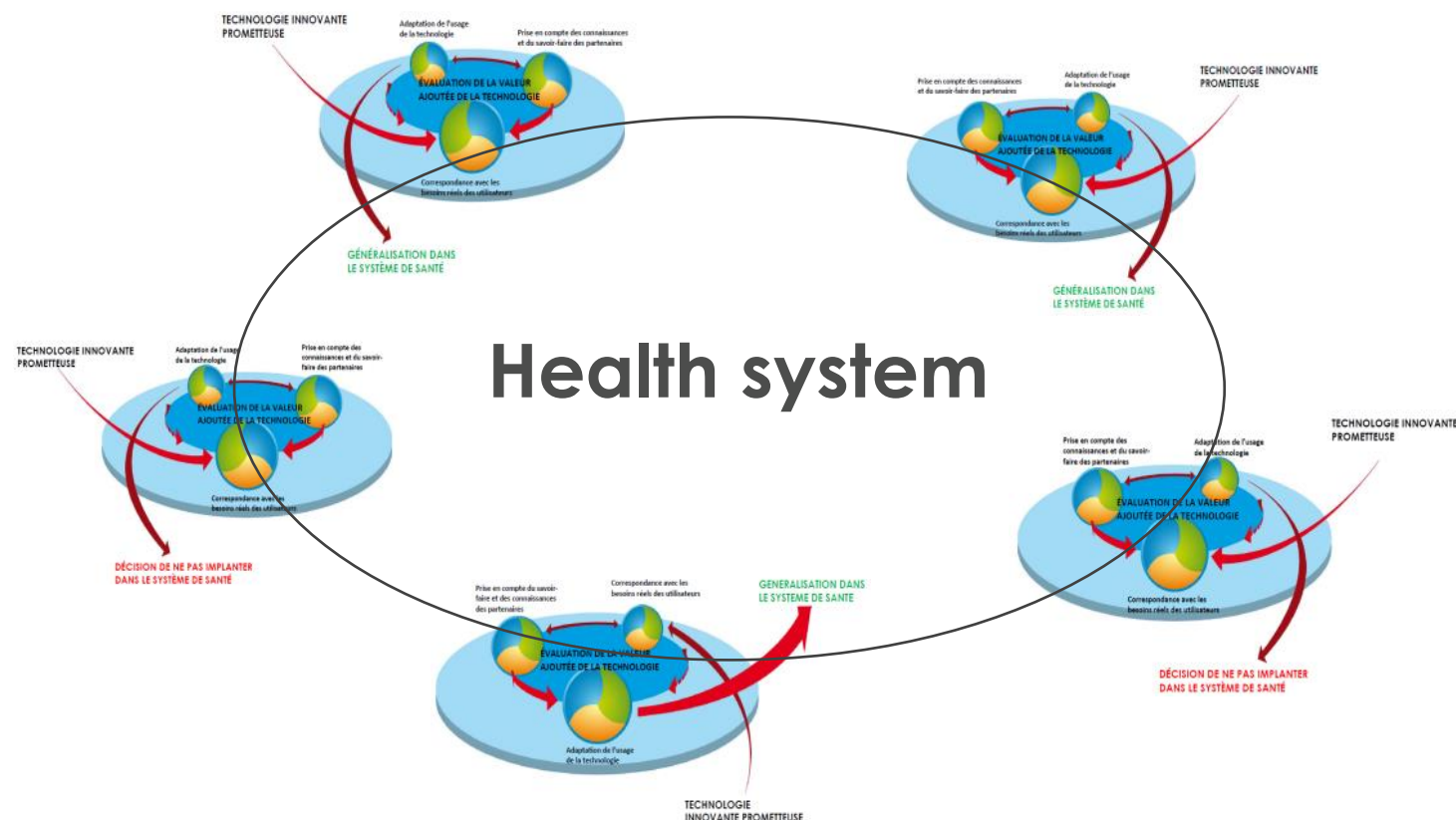
**Co-responsibility:** activities are influenced by all partners and the decision making (within the project) is shared

**Co-production:** knowledge is generated through the participation and the commitment of all partners

**Transparency:** the information is public (open data), the rules are clear and known (innovation protocol) and the processes are open



# Towards a learning health system



## Challenges for pharmaceuticals

- Defining the role and place of progressive field evaluations in relation to the life cycle of drug development and use
- Cohabitation between an open collaborative approach with the rules and practice of regulation and market access
- Trust between the health system, industry and patients
- Links to other innovative initiatives such as adaptive licensing and IMI Get Real