FORUM
ÉVALUATION ET TECHNOLOGIES *INNOVANTES*

BETTER INNOVATION THROUGH ASSESSMENT

Participant Guide

QUÉBEC
3.12.2013

INESSS
LE SAVOIR PREND FORME

Québec

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Institut national d’excellence en santé et en services sociaux

Head Office
2535, boulevard Laurier,
5th floor
Québec (Québec) G1V 4M3

Montréal Office
2021, avenue Union,
Suite 10.083
Montréal (Québec) H3A 2S9

Phone: 418-643-1339
Email: inesss@inesss.qc.ca

An electronic version of this document is available on the INESSS website at *inesss.qc.ca.*

Authors
Geneviève Plamondon, in collaboration with Reiner Banken, Lise-Ann Davignon, Diane Guilbault and Dima Samaha

Editor
Véronique Baril

Graphic Designer
Magali Bérubé

Bibliographic verification
Denis Santerre

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Health Innovation Week partner
Carl Viel, President and CEO, Québec International

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Alain Boisvert, Vice-President, Market Access and Public Affairs, Bristol-Myers Squibb (BMS)
Diane Côté, President and CEO, MEDTEQ, a consortium for industrial research
Vincent Dumez, Director, Bureau de l'expertise patient partenaire, Université de Montréal
Louise Lavergne, President and CEO, Institut de réadaptation en déficience physique de Québec
Marc Rhainds, Medical and Scientific Co-Manager of Health technology Assessment (ETMIS) activities, CHU de Québec

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Christian Bellemare, Coordinator, Health Technology Assessment Unit, CHUS Hôtel-Dieu
Sylvie Bouchard, Director, Follow-up and optimal use, INESSS
Pierre Dagenais, Director, Quality and Method Support, INESSS
Kim Furlong, Director, Federal Government Affairs, Amgen
Benoit Larose, Vice President, MEDEC, Québec
France Mignault, Director, Government Affairs, Janssen, Québec
Gilles Pineau, Coordinator, Oncology Assessment Unit, INESSS

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Stéphane P. Ahern, internist-intensivist, Hôpital Maisonneuve-Rosemont and Chair of the Comité scientifique d'évaluation des médicaments aux fins d'inscription (CSEMI), INESSS
Dan Cooper, Senior Scientific Advisor, Pharmacoeconomics, Direction scientifique de l'inscription, INESSS
Michelle Laflamme, President and CEO, Emovi
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Marc Osborne, Director, Government Relations and Health Policy, Oncology, Hoffmann-La Roche
Sophie Rochon, Senior Manager, Patient Access and Health Policy, Québec, Pfizer
Jean Rousseau, Director, Health System Solutions business unit, Covidien
Éric St-Gelais, Research and Innovation Coordination and Orientation Advisor, Ministère de la Santé et des Services sociaux (MSSS)

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15:45 **Refreshment break**

16:00 **Panel 2 – Différents acteurs, différentes perspectives… des solutions en synergie ?**
(Different stakeholders, different perspectives… finding solutions in synergy?)
Luc Castonguay, Assistant Deputy Minister, Direction générale de la planification, de la performance et de la qualité, MSSS
Paul Lirette, President, GlaxoSmithKline Canada
Teresa Mattarelli, Vice-President and General Manager, Covidien Canada
Juan Roberto Iglesias, President and CEO, INESSS

16:45 **Closing conference: "Évaluer pour mieux innover… place à l'action"**
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Véronique Déry, Chief Scientist, INESSS

17:05 **Speech by Dr. Réjean Hébert, Québec Minister of Health and Social Services and Minister responsible for Seniors**

17:30 **Cocktail**

A WORD FROM THE PRESIDENT

Ladies and Gentlemen,

I am very proud to welcome you to the inaugural INESSS HTA and Innovative Technologies Forum.

I am thrilled by the amount of participation in this event and the involvement of Québec International, which allowed us to unite stakeholders from the field of assessment, the world of research and the health care network, as well as patients, users and the medical device and pharmaceutical industries.

This Forum is one of the many projects that INESSS has launched with its partners. Following several months of fruitful discussions, the time has come to share with a larger audience these reflections aimed at improving our health and social care system, and making it more efficient.

For INESSS, this event marks a turning point in support on the often difficult journey of passing from thought to action.

We firmly believe that these discussions between stakeholders committed to finding solutions will lead to concrete results that will be beneficial for all Quebecers.

Have an excellent day!

President and CEO

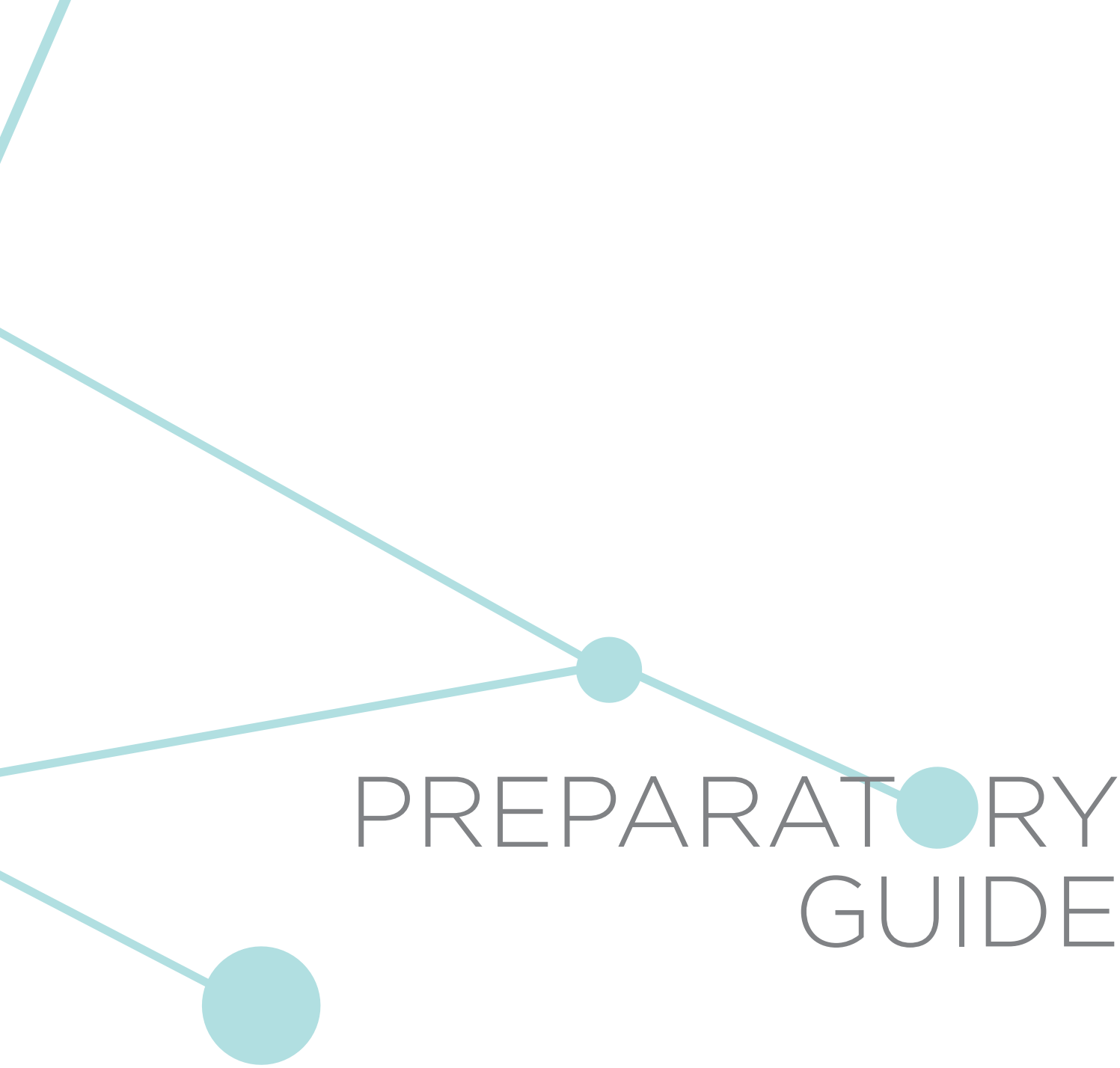
Juan Roberto Iglesias, M.D., M. Sc.

BACKGROUND

A source of hope for many Quebecers, health innovation is an emerging topic that many people are passionate about and that presents a challenge to the sustainability of the health system as well as for the principle of fairness the system is based on. Through its mission, INESSS is directly involved in innovative technologies, but it cannot fulfill its role without the contribution of concerned stakeholders. It is with this in mind that the Institut assembled an advisory committee on HTA and innovative technologies, and over the past year, committee members have combined their efforts to come to a common understanding of the challenges of introducing innovative technologies and to identify possible solutions to optimize innovation assessment strategies. This work has led to the inaugural HTA and Innovative Technologies Forum – "Better Innovation Through Assessment," which invites patients and technology users, government actors, clinicians, researchers and healthcare managers, together with representatives from the pharmaceutical, biomedical and information technology industries, to join the discussion.

Objectives of the HTA and Innovative Technologies Forum

- Present the work of the advisory committee on HTA and innovative technologies.
- Discuss with a larger audience the various challenges addressed by the advisory committee, and encourage greater dialogue with different stakeholders.
- Discuss the challenges associated with assessment and the role of assessment over the lifespan of technology.
- Find, together, possible solutions to better assess innovative technologies together, and use assessment to better integrate them.
- Explain the concepts and processes related to assessment, and increase dialogue about them.
- Identify new challenges to be addressed by the advisory committee.
- Create a summary of guiding principles to be used to assess initiatives presented at the Québec International forum the next day. These guiding principles will pertain to demonstrating added value and to the key stages of assessment.



PREPARATORY GUIDE

FACTS AND FIGURES

Innovative technologies, whether pertaining to drug products or non-pharmaceutical technologies, are the result of decades of life science research and inspire hope and trust in millions of Quebecers. Their introduction and their use in the health system has contributed to earlier diagnosis of diseases, improved prognoses and more efficient and safer patient management. While the merit of health technologies is no doubt recognized, there remains significant challenges associated with them, and assessment is becoming an increasingly essential step for addressing these concerns.

Between 1996 and 2012, the number of ***outpatient surgeries*** in Québec **increased by 38%**—a concrete result of innovative technologies.

[MSSS, 2013]

Childhood ***cancer survival rates*** have climbed from **71 to 82%** in the past 30 years, which can be ascribed to several factors including better diagnostic procedures, the development of multi-modal therapies and the centralization of care and support services.

[PHAC, 2012; CCS, 2008]

Approximately **500,000 Quebecers** carry or have a ***rare disease*** (RQMO); **20,000 die** from ***cancer*** each year (CCS); and nearly **30% suffer** from a ***chronic disease.***

[Cazale et Dumitru, 2008]

Drug spending represents nearly **9% of health expenditures** (and 35% of RAMQ's budget), whereas ***medical supplies*** account for approximately **4%.**

[Dubeau et al., 2010]

Personalized medicine, or stratified medicine, makes it possible to target patients that respond positively to an administered treatment. According to the WHO, this could help ensure that limited health care resources are used more efficiently.

[WHO, 2013]

The resources requirement linked to acquiring non-pharmaceutical technologies results in reduced budgetary capacity for other services (staff, number of beds).

[McGregor, 2009]

In 2010, the increase in drug spending in Canada was not related to rising drug prices, but rather other factors such as an aging population, a greater incidence of health problems that require drug therapy and new physician prescribing practices.

[PMPRB, 2011]

The average budget impact of seven anticancer drugs included on the lists of medication in 2011 is estimated at **$35.1 million** annually to treat **1,500 patients.**

[INESSS, 2012]

THE IMPORTANCE OF HTA

AN OVERVIEW OF INESSS

MISSION

INESSS's mission is to support the health and social services network in the pursuit of clinical excellence and the efficient use of resources, by mobilizing knowledge and stakeholders.

VISION

INESSS blends the perspectives of the health and social services network partners, and acts as a catalyst for excellence in public health and social services.

INESSS PRODUCER

Scientific production by INESSS, in collaboration with standing scientific committees, focuses on four areas: evaluating drugs for inclusion on the lists of medication, studies and analyses, health and social services follow-up and optimal use, and quality and method support. In addition, three dedicated units work in cardiology, oncology and traumatology.

INESSS- PARTNER

INESSS supports its health and social services network partners, particularly with regard to methodology development and knowledge transfer projects, as well as through support and collaboration activities.

Advisory committee on HTA and innovative technologies

This committee, which is composed of a variety of health innovation stakeholder representatives and presided over by INESSS, aims to promote a common understanding of the challenges of introducing innovative technologies to the health system and to identify possible solutions to ensure consistency in doing so, for the benefit of users.

Advisory panel

Representatives from health network **user** and **patient** committees as well as associations of **professionals** and institutions help to define priority challenges to address.

Community of practice on health technology and intervention assessment

Québec has an abundance of expertise in technology assessment. Ten **organizations that produce HTA** share their work, experience, methodologies and challenges as part of the community of practice.

MSSS

INESSS works in close collaboration with **MSSS** in the interest of promoting the implementation of its notices and guides, among other things.

Industry

INESSS has permanent bridging mechanisms with representatives from the **pharmaceutical and medical technology industries**.

National and international organizations

INESSS is a member of various **international networks and initiatives**, which enable it to stay abreast of developments in technology assessment. Some examples include Pan-Canadian Collaboration on health technology assessment, the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment international (HTAi), the Guidelines International Network (G-I-N) and EuroScan.

DEFINING TO REACH A BETTER UNDERSTANDING

Health technology

Any intervention that can be used to promote health; to prevent, to diagnose or treat an acute or chronic illness, or for rehabilitation.

As part of the advisory committee's work, the definition has been restricted to include all material technologies directly linked to the delivery of care and services.

Drug products include substances or compounds that are reported to have curative or preventive properties against human diseases, such as ibuprofen or a chemotherapeutic agent. Non-pharmaceutical material technologies include equipment, devices, instruments, implants or other agents whose principal function is not accomplished by pharmaceutical means, such as a medical imaging device, an insulin pump or a blood screening test.

Innovation

All stages of a process that includes developing ideas, transforming them into products or practices, and using them in the health system. Innovation is characterized by the added value it offers compared to what is currently used.

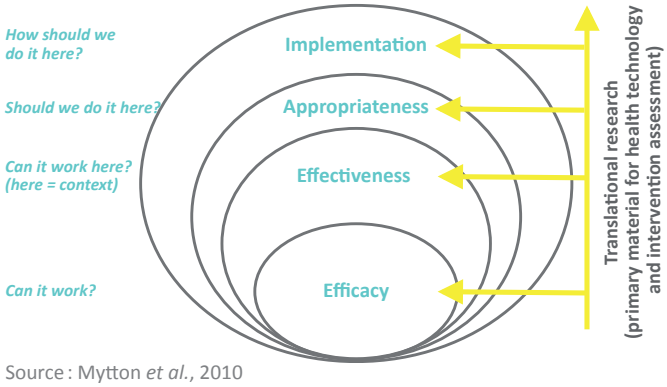
Innovative technologies

Innovative technologies are said to be incremental when they improve upon existing technologies, and disruptive when they are completely different from anything currently available and significantly change the way care is delivered.

Health technology assessment

The systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. *[INESSS et al., 2011]*

Health technology assessment to support decision-making

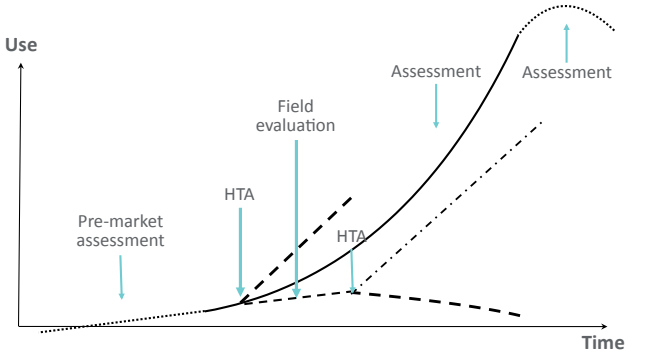


Source : Mytton *et al.*, 2010

ECOSYSTEM OF INNOVATIVE TECHNOLOGIES IN QUÉBEC

The lifecycle of innovative technologies

HTA and innovative technologies



Research and development	Experimental technologies	Innovative technologies	General use	Replacement

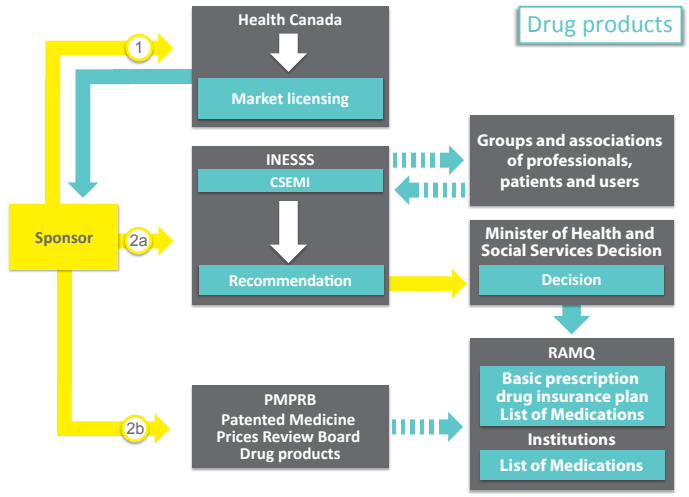
Different pathways

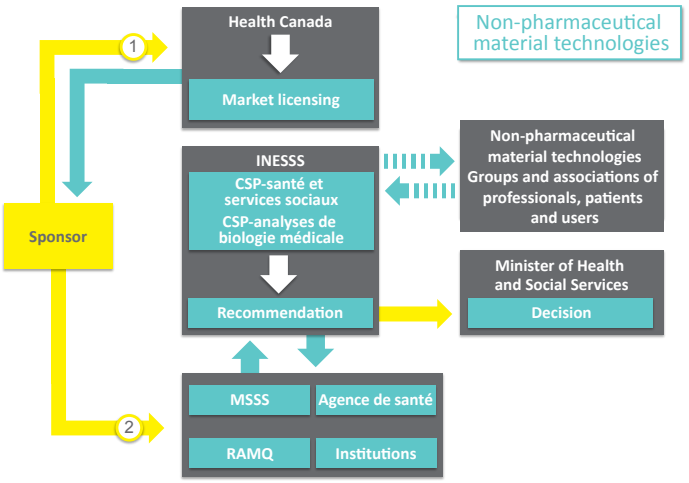
The assessment of drug products and non-pharmaceutical technologies begins with the review process by Health Canada, during which time, safety and efficacy are assessed with the intent to authorize the product for sale in Canada. Following this, the steps differ depending on the type of technology.

The assessment of drugs for inclusion on the list of medications is one of INESSS's responsibilities. Assessments are based on five criteria set out in the Act: the therapeutic value, the reasonableness of the price charged, the cost-effectiveness ratio of the medication, as well as the consequences and the advisability of registering the drug product with regard to the health care system. Demonstrating therapeutic value is a prerequisite to the other four criteria and assessments are part of a deliberative process involving clinicians, researchers, ethicists, pharmacoeconomists and citizens. At the end of the deliberation, INESSS submits its recommendations to the Minister of Health and Social Services, who is responsible for making the final decision on whether the drug product will be included on the list.

Non-pharmaceutical material technologies are not assessed systematically; INESSS assesses a product when a request is filed by one of the organizations authorized to do so, specifically public and parapublic Québec organizations, professional orders and patients' associations. The request will therefore determine the criteria and scope of the assessments, and the extent of the recommendations arising from it.

Applications to modify or add to the Répertoire québécois et système de mesure des procédures de biologie médicale are assessed by INESSS science professionals and by members of the Comité scientifique permanent des analyses de biologie médicale, a standing committee on medical biology tests. The committee is composed of physicians and biochemists specialized in different areas of laboratory medicine, and external experts also collaborate. This scientific committee has been tasked to assess INESSS evidence on clinical benefit, clinical validity, analytical validity, costs and various issues (including economic, organisational and ethical), and to issue recommendations pertaining to the acceptance/refusal of new tests to the INESSS CEO for use by the Minister of Health and Social Services.





Adapted from *Center for Innovation in Regulatory Science (CIRS)*

ONE WORLD, DISTINCT ROLES

Research and development

Fundamental and applied research

The research and development process, carried out by the industry as well as academic and clinical institutions, leads to the creation and refinement of innovative technologies and is often performed in cooperation with these different groups.

Assessment

Health Canada

This is the federal agency in charge of regulating and approving drug products and non-pharmaceutical technologies for sale in Canada. To do this, it assesses the safety and efficacy of technologies.

INESSS

INESSS assesses all drug products for inclusion on the list of medications and some non-pharmaceutical technologies for Québec.

Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board is an independent organization whose mission is to ensure that patented drug products are sold at a reasonable price in Canada.

UETMIS

Health technology assessment units assess non-pharmaceutical technologies as well as interventions, and are located in university institutes. The assessments they produce meet the needs of the institutions they are located in, and are therefore local or regional in scope.

Decision implementation

Ministère de la Santé et des Services sociaux

The conclusions of assessments made by INESSS are submitted to the Minister, who is responsible for making the final decisions regarding the implementation of technologies.

Healthcare network

Healthcare agencies and institutions decide to implement some non-pharmaceutical technologies, and the INESSS or UETMIS assessments are available to support these choices.

Decision use

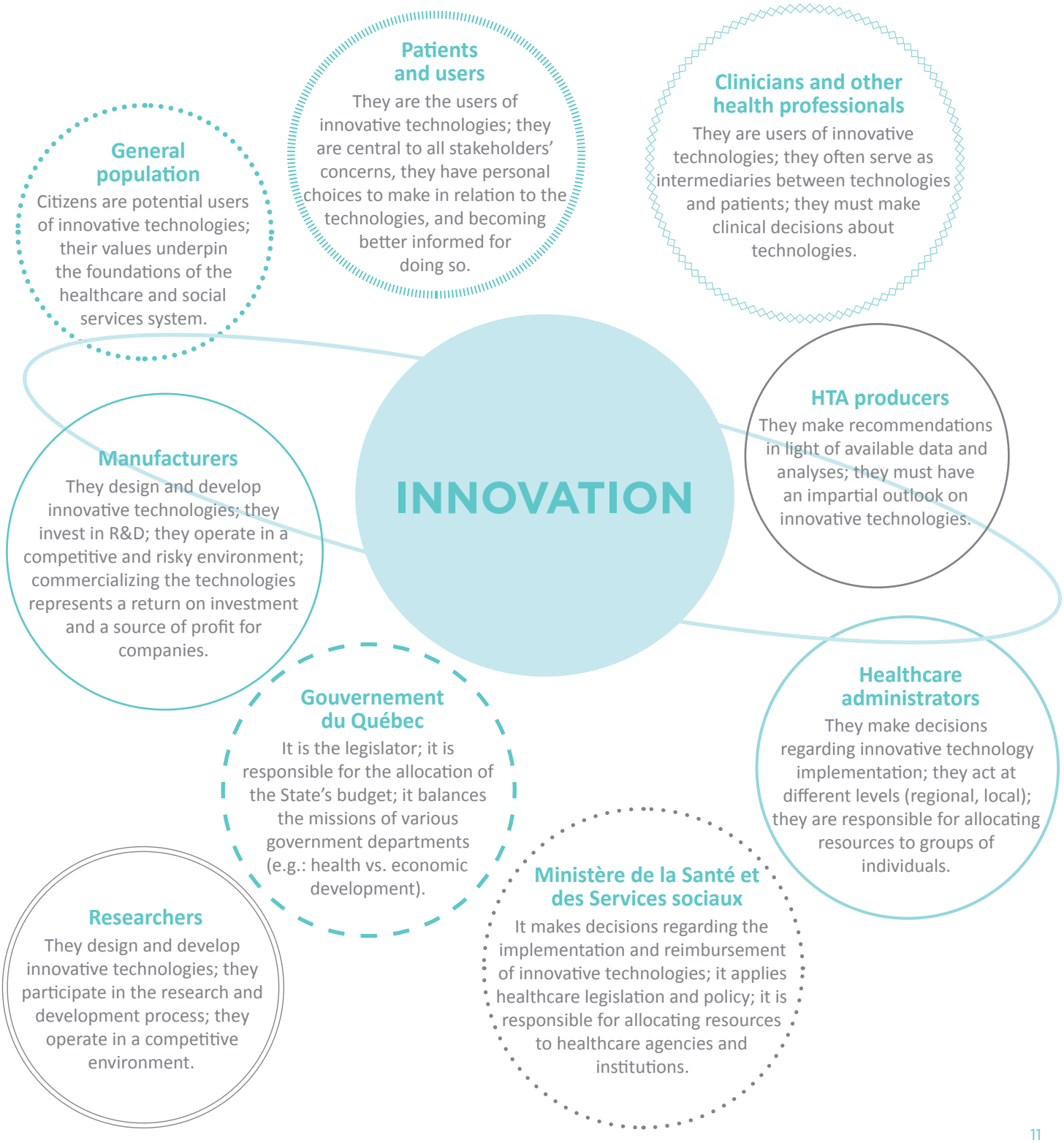
Healthcare network

The widespread use of technologies, once they are established in the network's organizations, depends on multiple clinical and personal decisions (clinicians and their patients make the decision to use one technology over another).

Funding

The funding method varies depending on the technology, the context and the environment where it is implemented as well as on insurance coverage. The RAMQ, the MSSS, private insurers, patients and users, healthcare institutions and institutions' private foundations are all possible sources of funding.

These organizations involved in the life cycle of innovative technologies are made up of groups of individuals, termed here "healthcare system stakeholders." Given their place in the world of innovative technologies, these stakeholders each have their own different perspectives and concerns, therefore they have different relations to innovation.



INNOVATIVE TECHNOLOGIES: PARTICULARITIES AND CHALLENGES

WHAT IS ADDED VALUE? ARE WE TALKING ABOUT VALUE OR VALUES?

Central value of innovation

With patients central to their concerns, all stakeholders work towards the common goal of improving users' health and life quality. Clinical benefit is therefore recognized as the first criterion for defining the value of innovative technologies, as well as the prerequisite condition for other elements to be considered.

A common feature of different types of values

The value an actor places on a given technology is not always the same. Whether it's social, economic, organizational or related to the technology's capacity to address needs, it is dependent on other elements. It can vary according to the ways a technology is meant to be used or to the subgroups it is designed for (e.g., a technology can be the only treatment option for one group of patients, but one possibility among several for another group). The value placed on a technology can also change over time. The extent of the benefits associated with an innovation compared to other available technologies differs depending on its life cycle and depends on whether the technology is in a period of growth, maturity or decline. Although it is virtually impossible to predict it, this variability in how the value of innovative technologies is defined must be recognized and represents a challenge in the assessment of innovative technologies.

Other elements of the added value of innovation

Since they each have a different perspective, the stakeholders involved in the innovative technologies ecosystem naturally consider different elements when defining innovation's value. Therefore, not every element of value has the same importance for every stakeholder.

Meeting health needs

Innovative technologies are designed to meet the population's health needs. Different stakeholders do not give the same importance to each type of need, which directly influences the value they place on related technologies. Some innovations meet unmet needs by allowing the treatment of diseases for which no treatment exists, while others improve patient management (e.g., in terms of efficiency or safety). Some technologies are designed to meet needs related to life-threatening conditions, while others improve quality of life in patients with chronic diseases. Patients, users and their families also have global preferences and needs that go beyond those related to the disease, and the value of a technology can also be determined in light of how it meets such non-clinical needs.

The social value

Probably the issue that elicits the most passionate reactions, social value refers to the desire to help those who are the most vulnerable. Since innovative technologies are often new treatment options, they represent hope and additional possibilities. The social value of innovation is supported by ethical arguments such as fairness, justice and solidarity, and is particularly defended in end-of-life situations and cases of serious illness. The ethical elements then tend to promote patient access to therapies with larger uncertainty or risk components, which would generally not be accepted in other contexts. However, individual needs are constantly weighed against social ethics, where the concept of fairness in the allocation of resources within the population becomes particularly important. One cannot ignore the fact that resources granted to a small group of people can no longer be allocated elsewhere, where they might have contributed to the improvement of collective welfare (as, for example, the implementation of a public health program or the addition of a family physician to a community).

The organizational value

The value of an innovation depends on the particular context in which it is implemented and can vary according to organizational environments. In a given institution, this value can, for example, take the form of a greater range of services provided and even be associated with staff retention linked

to the acquisition of advanced equipment, and thus weigh heavily in the decision process. Some innovations also have the potential to significantly change the care delivery—for example, the use of a technology that would shorten a post-surgery recovery time, allowing patients to been seen in an outpatient setting for follow-ups. Such technology would certainly bring changes, but the added value placed upon it by an institution would depend on the organization's vision as well as its ability to support these changes.

Economic value

The value of innovation can also be assessed from an economic perspective. Innovative technologies are the result of a long process of research and development, during which large sums are invested. Marketing the product is the final step, as well as the moment when manufacturers can expect a return on their investment (which is the fuel for their next research projects). Meanwhile, return on investment is also a concern for decision makers who want the costs associated to an innovation to translate into substantive health outcomes for patients. Since these costs cause significant financial strain and represent a challenge to the sustainability of Québec's healthcare system, the value of technologies can also be considered in light of their opportunity cost (everything else that could have been done with resources that were allocated to a given technology), as well as their budgetary implications. Finally, some stakeholders place value on the economic development that results from research and development, and suggest that innovative technologies should also be promoted as tools for economic prosperity.

UNCERTAINTY

By definition, innovation is synonymous with novelty. The newness of innovative technologies implies that limited number of studies have been conducted (research and development phases are expensive, and conducting numerous studies is difficult). A limited amount of evidence is therefore available, which implies a certain degree of uncertainty around the various elements that need to be assessed, such as technologies' therapeutic and quality-of-life aspects (e.g., long-term effects, adverse effects), economic factors (e.g., costs associated with use or implementation) and organizational effects, as well as the wider effects arising from common use (e.g., shifting care from hospitals to the home).

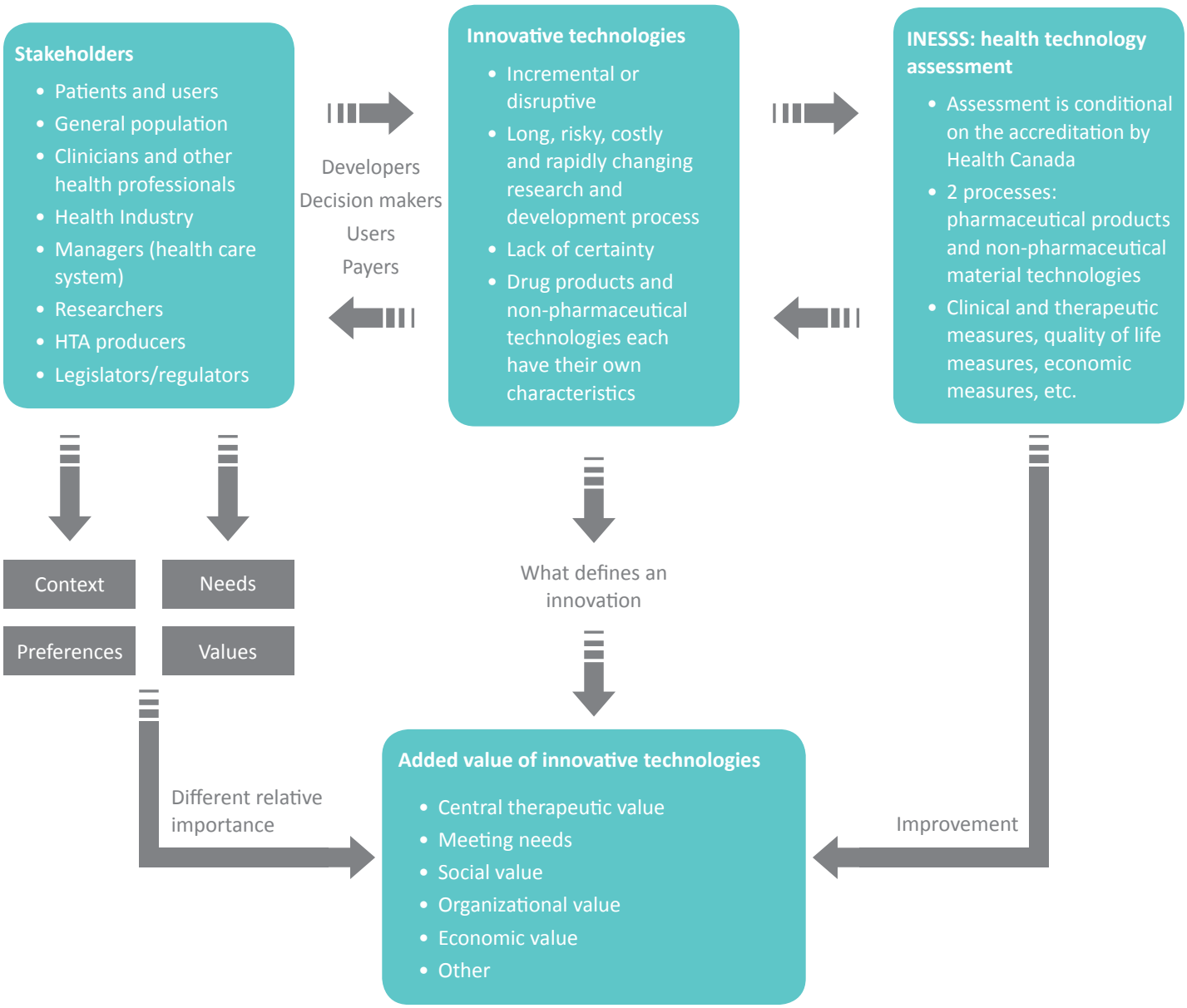
This uncertainty is inherent to innovative technologies, and the benefits that can reasonably be expected from a current version of a technology but that cannot be demonstrated convincingly, can be labelled as promises *[Henshall and Schuller, 2013]*. In addition to the expected benefits, innovative potential also resides in a technology's refinement over time or from its use in a situation that was not initially foreseen, as has been the case for aspirin. A technology's potential can also be seen in the "domino effect" resulting from research and development, as Pritchard *[2001]* remarks: "Frequently, one innovation leads to another by yielding new knowledge and opening up new, sometimes unexpected, avenues of research and learning, which can result in further new medicines in future".

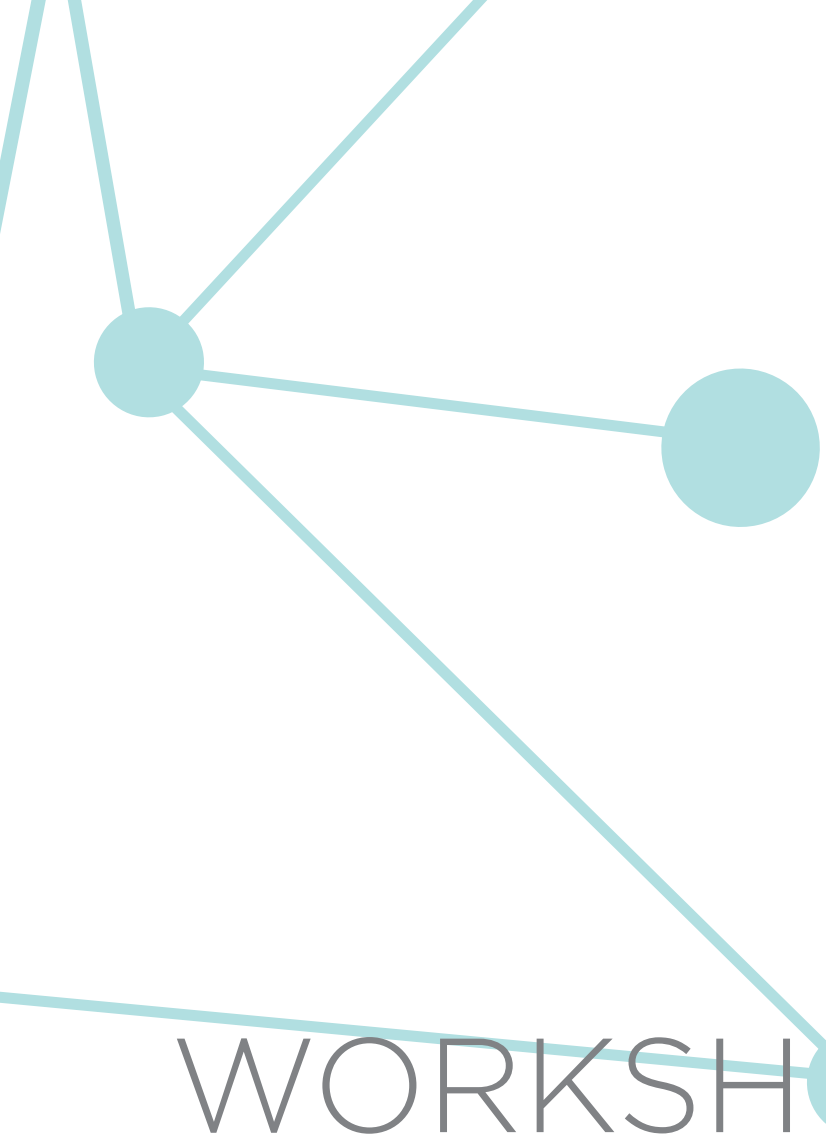
DRUG PRODUCTS AND NON-PHARMACEUTICAL MATERIAL TECHNOLOGIES: SIMILAR YET DIFFERENT

Drug products and non-pharmaceutical material technologies are similar but differ with regards to their characteristics and in their history from their beginnings as an idea to their widespread use. These differences have an influence on research and development, assessment, decision making, adoption and implementation.

	Differences Drug products	Non-pharmaceutical technologies	**Consequences**
Purpose	Relief and intervention	Diagnosis, relief and intervention	It can be difficult to distinguish between the consequences of an earlier or more precise diagnosis and the effects of the subsequent therapy; determining the value of the diagnosis technique therefore poses a challenge.
Method of use	Used directly by users	Often performed by an operator (e.g., stent placement by a surgeon)	The performance of a technology depends not only on its characteristics, but also on how it is used, whereas the effectiveness of drug products is generally not affected by the person administering them. The learning curve associated with using a non-pharmaceutical technology must therefore be considered along with potential training needs for users.
Length of use	Known and relatively short length	Length is not necessarily known; it may be multiple years (e.g., prosthetic hip) and technologies may be reusable (e.g., medical imaging device)	The identification of the benefits of non-pharmaceutical technologies that have a long length of use or multiple uses are less obvious, and such technologies may require maintenance over time.
Research and development	Randomized clinical studies are the gold standard.	These studies are often impossible to conduct because the requirement of blindness cannot be met or because certain factors make randomization impossible (e.g., implants, rare illnesses).	This impacts the quantity and quality of the data produced during the research and development phases. In cases where randomized clinical trials for non-pharmaceutical technologies are possible, the learning curve needs to be taken into account. Indeed, comparing between a new technology and a current one could measure the level of experience of the operator rather than the effectiveness of the technologies themselves.
Regulatory requirements	All new drug products must have primary data and must go through certification and assessment in order to be listed.	May be assessed based on existing data from other manufacturers or previous versions of the product. Only the certification process is mandatory.	Drug manufacturers must all meet the same requirements, but manufacturers that develop incremental non-pharmaceutical technologies do not have to make the same investments related to the production of clinical data as those who design disruptive innovations. This can have significant effects on the market and on the life cycle of technologies (much shorter for non-pharmaceutical technologies than for drug products).

INNOVATIVE TECHNOLOGIES AT A GLANCE





WORKSHOPS' AND PANELS' GUIDE

WORKSHOP AND PANEL 1

HTA AND INNOVATIVE TECHNOLOGIES – CHALLENGES

How do we adapt assessment to the context and dynamic of innovation?

How do we deal with the uncertainty and lack of evidence surrounding innovative technologies in the HTA process?

How do we encourage access to innovative technologies given budgetary constraints?

How can we address the difficulty of measuring the value of innovative technologies in the HTA process?

How can HTA be a tool to increase the value of innovative technologies?

How can we appropriately recognize the perspectives, roles and responsibilities of all stakeholders?

How can we integrate HTA into different stages of technology life cycles?

How can we enhance assessment within the innovation process and get different stakeholders to understand and favor it?

How do we align the requirements of the different assessment and regulatory bodies ?

Panel 1 – Different stakeholders, different perspectives… common issues?
Workshop 1 – Debating, organizing and prioritizing

WORKSHOP AND PANEL 1

WORKSHOP AND PANEL 2

HTA AND INNOVATIVE TECHNOLOGIES – POSSIBLE SOLUTIONS

Would field evaluation and coverage with evidence development contribute to a better demonstration of the added value of innovative technologies?

Would it be realistic to consider a longitudinal continuous HTA process instead of a one-time assessment?

Would promoting information systems increase the quantity and quality of data available for HTAs?

Could greater collaboration early in the process between the reviewers and the sponsors contribution to the innovation process?

Could disinvestment be a means of fostering innovative technologies ?

Would greater collaboration between the different stakeholders set the stage for an effective partnership throughout the lifecycle of a technology?

Could enhanced collaboration between Health Canada and INESSS, in the area of drugs for rare diseases for instance, allow for better evidence development?

Workshop 2 – Debating, proposing and innovating

Panel discussion 2 – Different stakeholders, different perspectives… finding solutions in synergy?

WORKSHOP AND PANEL 2

THANK YOU!

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Members of the HTA and Innovative Technologies Advisory Committee for their significant contribution to current discussions

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INESSS
Carole Chamberland, Scientific Advisor, Pharmacoeconomics
Jayson Gallant, Scientific Advisor, Pharmacotherapy
Lolita Haddad, Administrative Assistant
André Jean, Ethics Senior Advisor
Jonathan Moreau, Communications Advisor
Catherine Safianyk, UETMIS Relations Coordinator
Hélène St-Hilaire, Administrative Assistant

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inesss.qc.ca
inesss@inesss.qc.ca

Head office
2535, boulevard Laurier, 5th floor
Québec (Québec) G1V 4M3
Phone : 418 643-1339

Montréal Office
2021, avenue Union, Suite 10.083
Montréal (Québec) H3A 2S9
Phone : 514 873-2563

Institut national d'excellence en santé et en services sociaux
Québec