enabling new business

SWITZERLAND GLOBAL ENTERPRISE

EXPORTING MEDTECH AND DIGITAL HEALTH SOLUTIONS TO CANADA HOW TO MAKE IT WORK?

Webinar - Wednesday 21 February 2024

Welcome – Moderation

Etienne Gamache

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Swiss Business Hub Canada
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ABOUT S-GE

Switzerland Global Enterprise

The official Swiss consultancy, promotion and platform organization for export and investment promotion

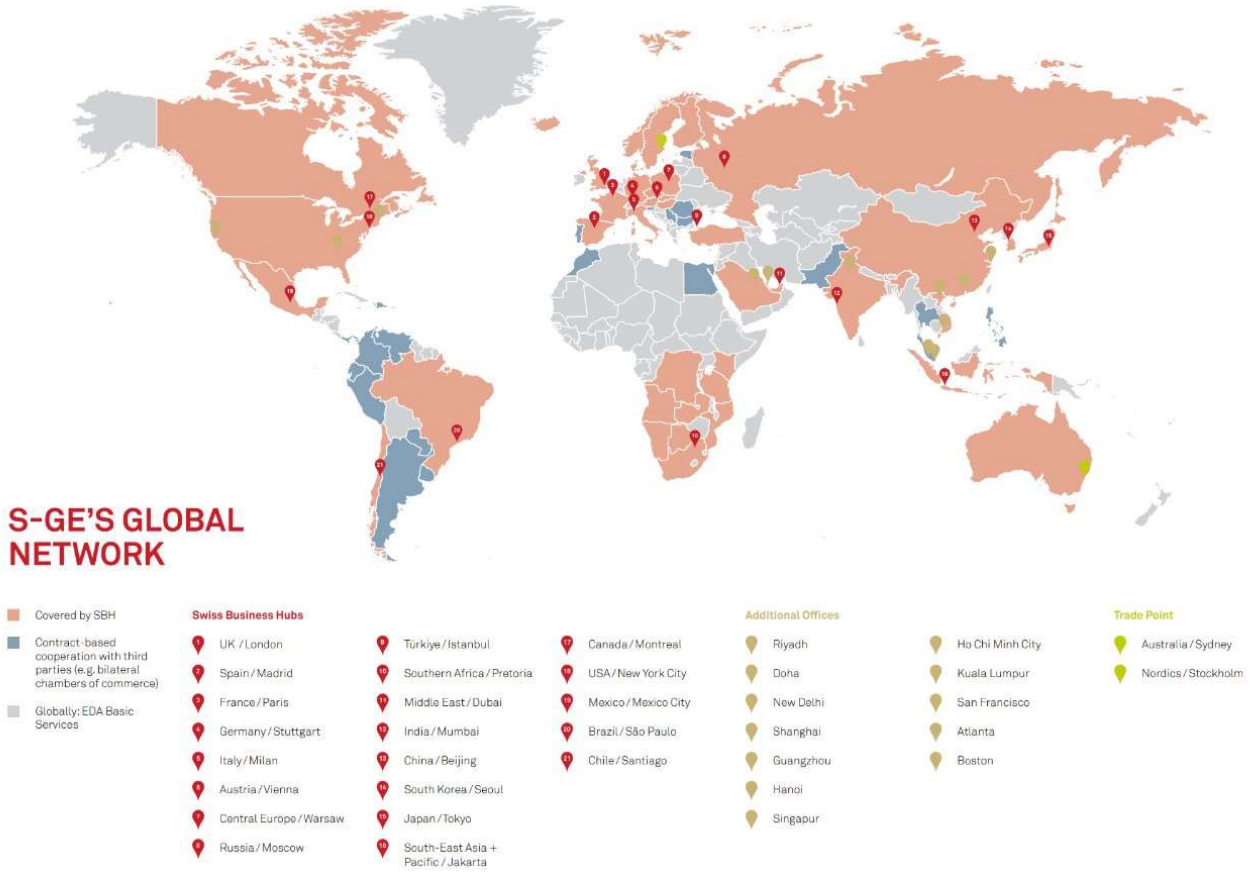
Together with our partners at home and abroad, we support Swiss SMEs in their international business and help innovative foreign companies with potential that are interested in settling in Switzerland. In this way, we create added value for our clients and prosperity for Switzerland.

At a glance

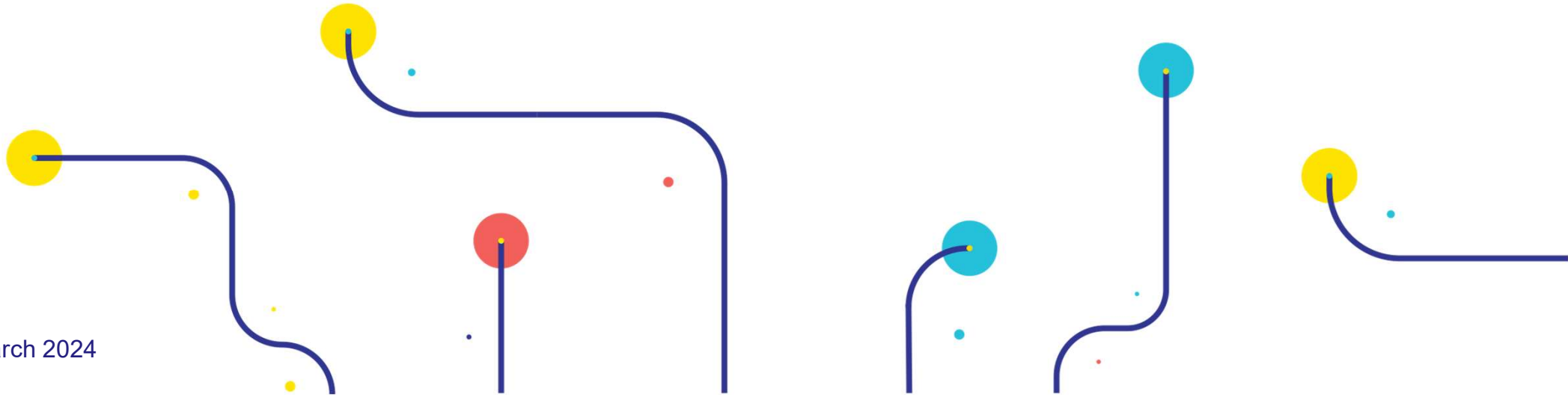
- Non-profit organization with over 2,000 members
- **Export promotion**: On behalf of the Confederation (SECO) since 1927
- **Investment promotion:** On behalf of SECO and all canton since 2008
- Swiss presence: Head office in Zurich, branch offices in Renens and Lugano
- Global presence: 26 shared global offices with the DFA, other markets via partner networks

There for customers worldwide - our global presence

Together with the Federal Department of Foreign Affairs (FDFA), we currently operate offices in 31 countries.
22 Swiss Business Hubs are located in important markets and regions. We also operate four Trade Points, smaller offices in further markets.



Swiss Healthcare Startups



March 2024

Contact details

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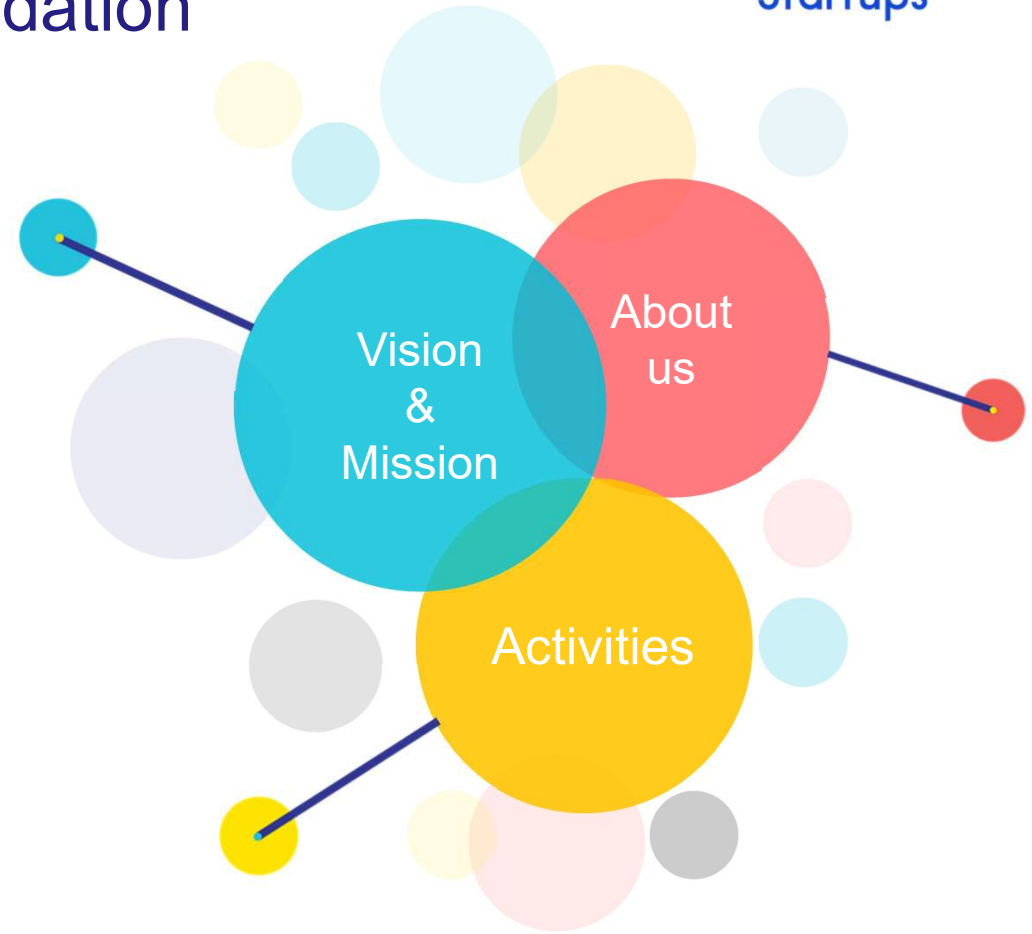
Swiss Healthcare Startups - Foundation

- non-profit organization
- founded in 2016
- by successful **entrepreneurs, managers, and influencers**
- **mission: supporting innovative healthcare startups** that aim to add value to the Swiss healthcare ecosystem & supporting health organizations in **driving open innovation**



SHS, a **nonprofit** organization supporting innovative Start-ups and corporates in the Swiss healthcare ecosystem

Swiss Healthcare Startups

Thought leader in Healthcare

Matchmaking / Networking

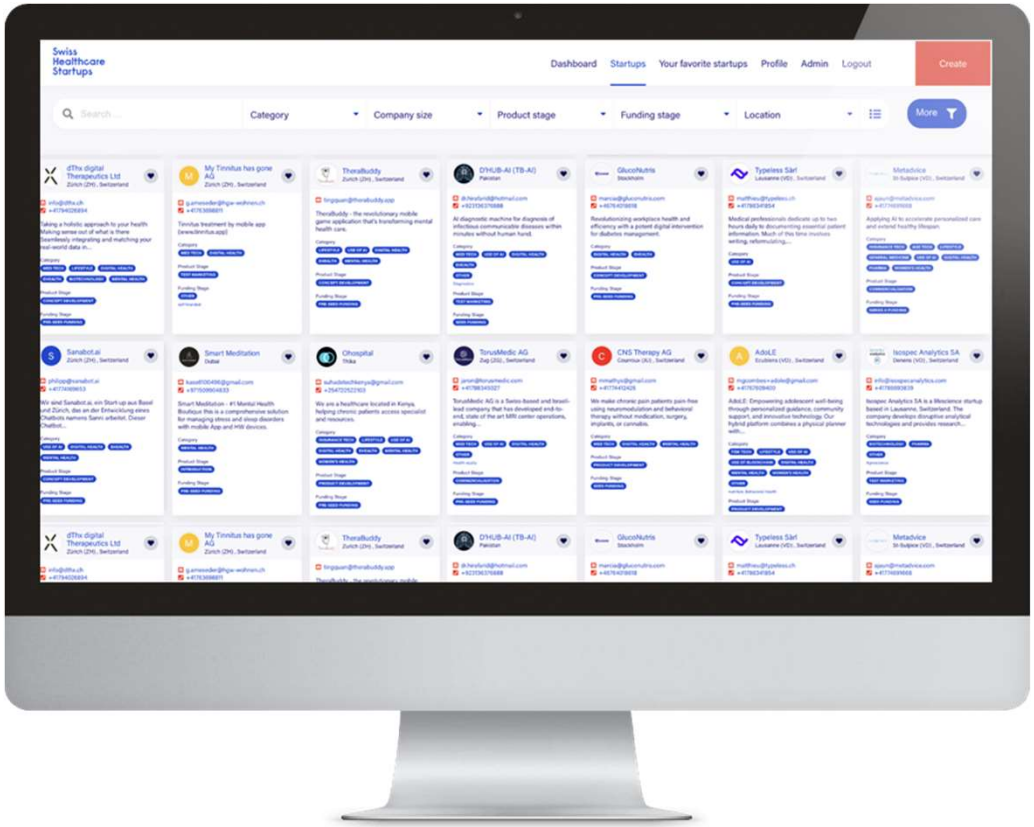
Education

Driving open innovation

Bridging the gap

Cortex – The SHS Database

- ★ **>680** Startup Members
- ★ **>100** new startup members during 2023 (screening & onboarding process)
- ★ **~ 85%** Swiss startups
- ★ **28** countries**, 5** continents
- ★ **Early** startups **to mature** scale-ups
- ★ Digital Health, MedTech, Age Tech, AI for Health, Use of Blockchain, BioTechnologies, Pharma, Mental Health, Insurance Tech, Women's Health…



Path *to Regulatory Approval for Medtech in Canada*

Me Louis-Paul Marin, eng., LL.B., LL.M.

President

February 21st, 2024

LOK
Amérique du Nord

Louis-Paul Marin

President + Founder

LOK North America Inc.

Roadmap

Answering the 5 “Whats”

- What type of health product?
- What are the S&E Requirements?
- What is the classification?
- What is the applicable regulatory process, if any?
- What is the required QMS certification, if any?

Path to Regulatory Approval in Canada?

YOUR PATH TO **COMPLIANCE**

LOK North America

What Type of Health Product?

First step… must be assessed from the get-go…

- Legal definitions lead to different interpretations
- Marketing claims must be aligned with regulatory claims

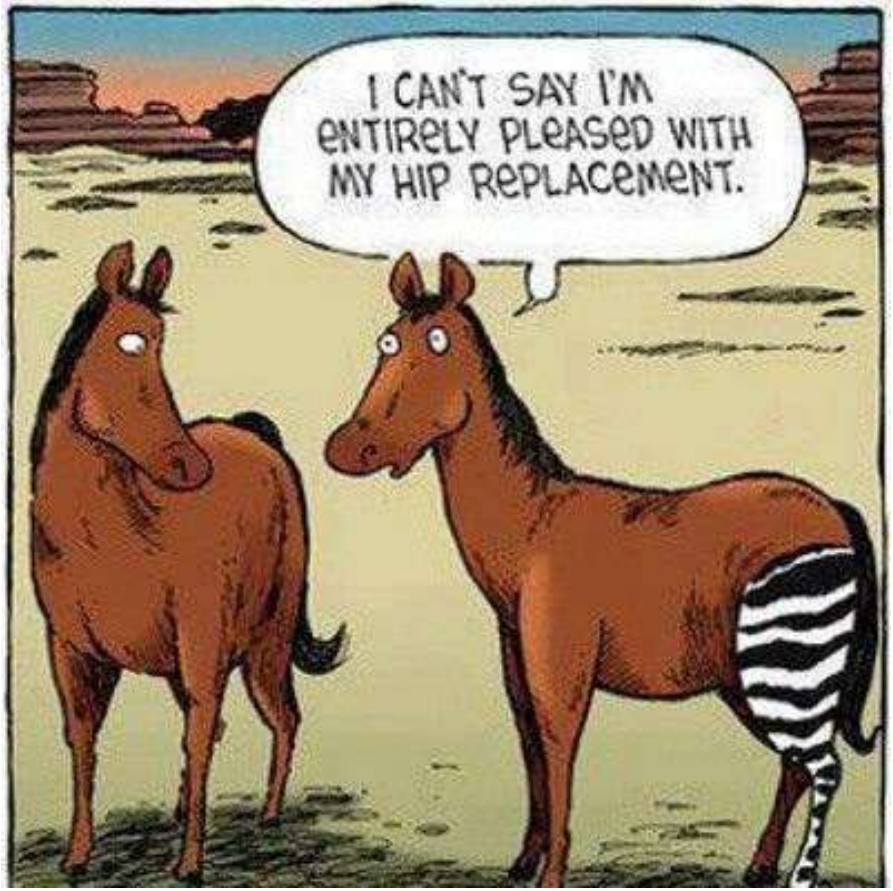
Common sense often does not prevail!

Drug or Device?

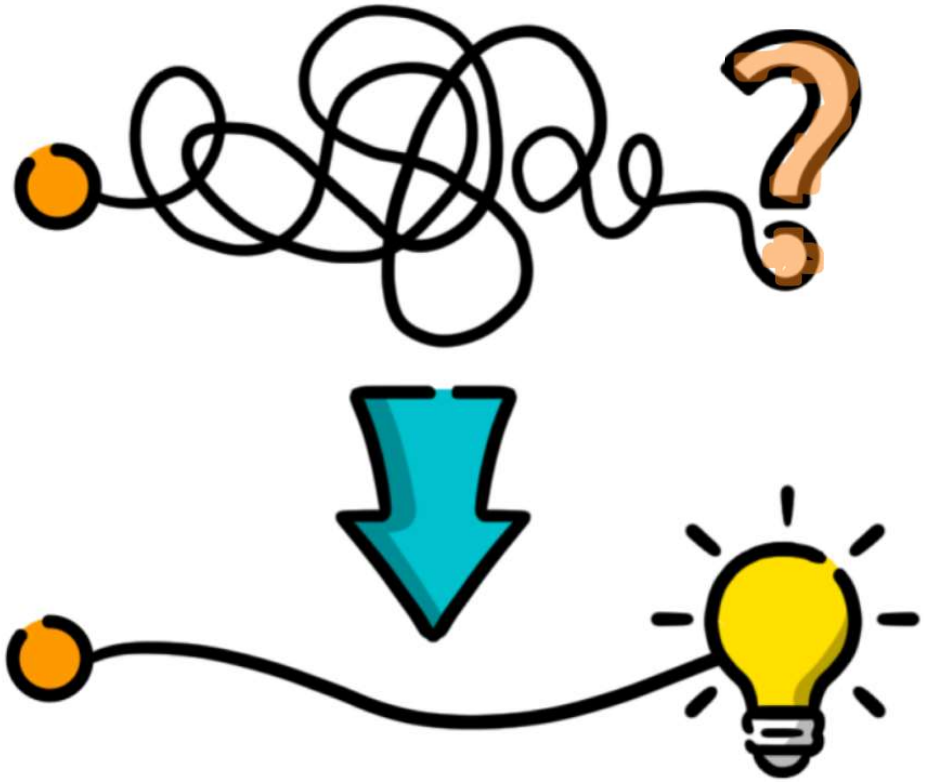
…it does not include such an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

Extract from the *Food and Drug Act*

Vet market...

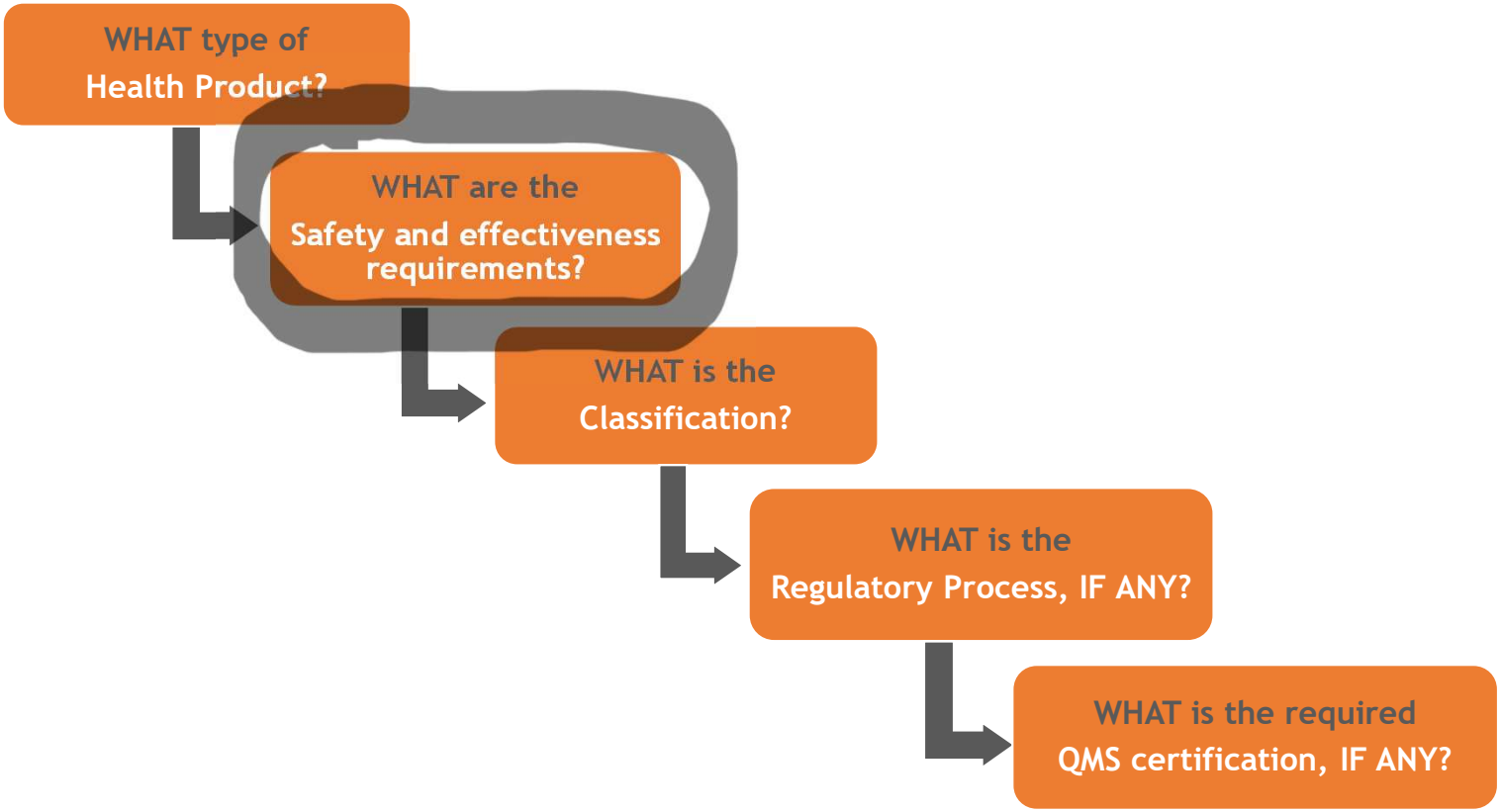


Safety and Effectiveness



Regulatory Path

Answering the 5 “Whats”

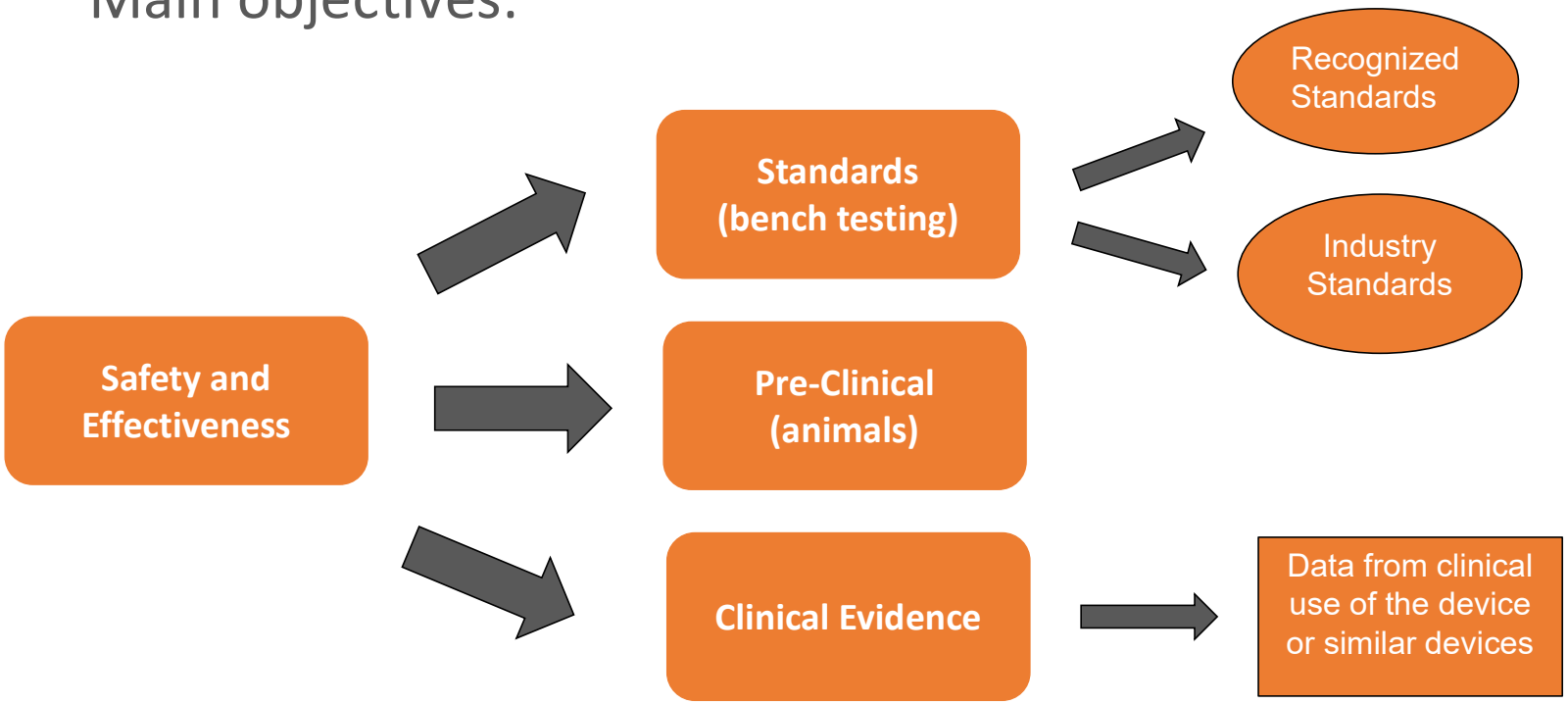


Class II, III and IV:
What must be typically demonstrated?

Medical Device Licence
Review to evaluate the safety and effectiveness of all devices

Fundamental Requirements

Main objectives:

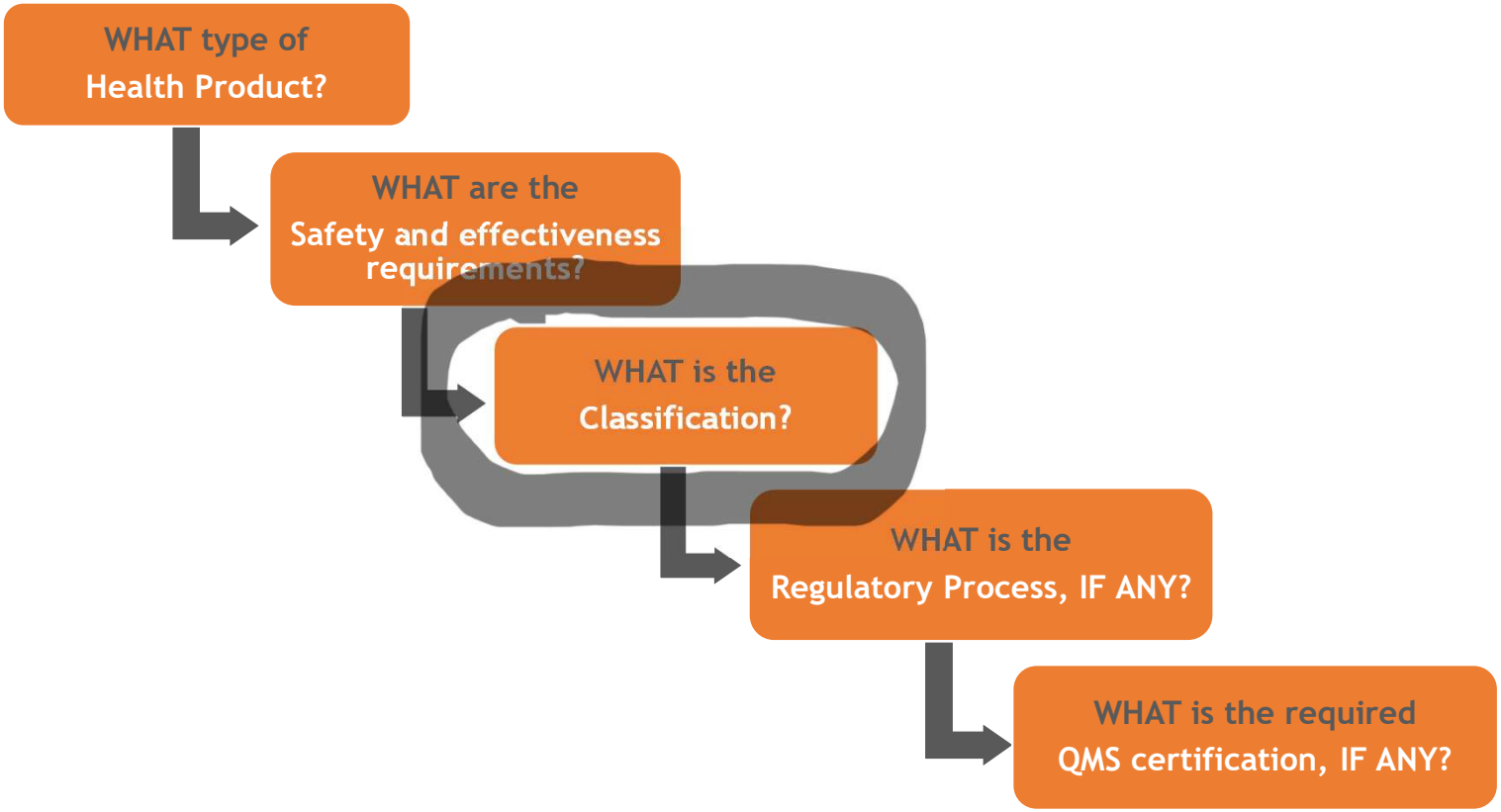


Risk Management

Risk Classification

Regulatory Path

Answering the 5 “Whats”



Risk Classification

The classification system is based on a series of factors, notably:

- how long the device is intended to be in continuous use;
- the duration of contact in or on the affected body part;
- whether or not the device is invasive or requires surgical intervention;
- whether the device is an active or non-active implantable.

Device Classification

Determining Device Class

A Rule-based System

Medical Specialty Panels

Device Class

Risk Classification

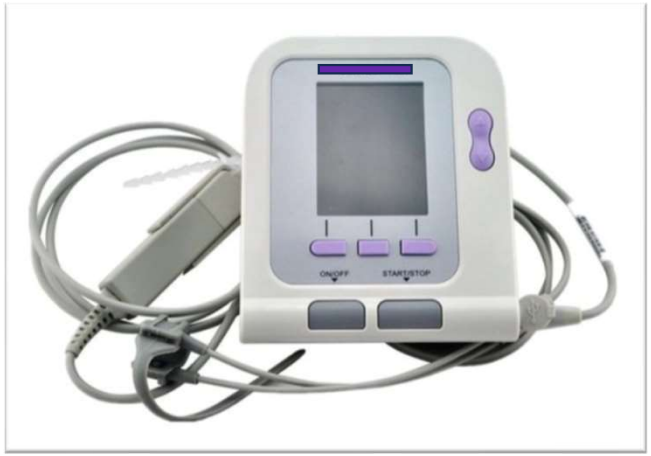
Rule 10(1):

- active diagnostic devices
- that supply energy for the purpose of imaging or monitoring physiological processes…

→ as Class II

Risk Classification

Rule 10 (2): if **erroneous readings could result in immediate danger…**



→ **as Class III**

Risk Classification

CLASS IV

CLASS III

CLASS II

CLASS I

CLASS III

CLASS IIb

CLASS IIa

CLASS I

CLASS III

CLASS II

CLASS I

Increased Risk =
Increased Requirements

Risk Classification

CLASS I

- ✓ Force-measuring platform
- ✓ Manual, adjustable hospital bed
- ✓ Mechanical wheelchair
- ✓ Hand Splint

CLASS II

- ✓ Digital dental imaging system
- ✓ Powered toothbrush
- ✓ Long term, portable ECG recorder
- ✓ Laryngoscope

Risk Classification

CLASS III

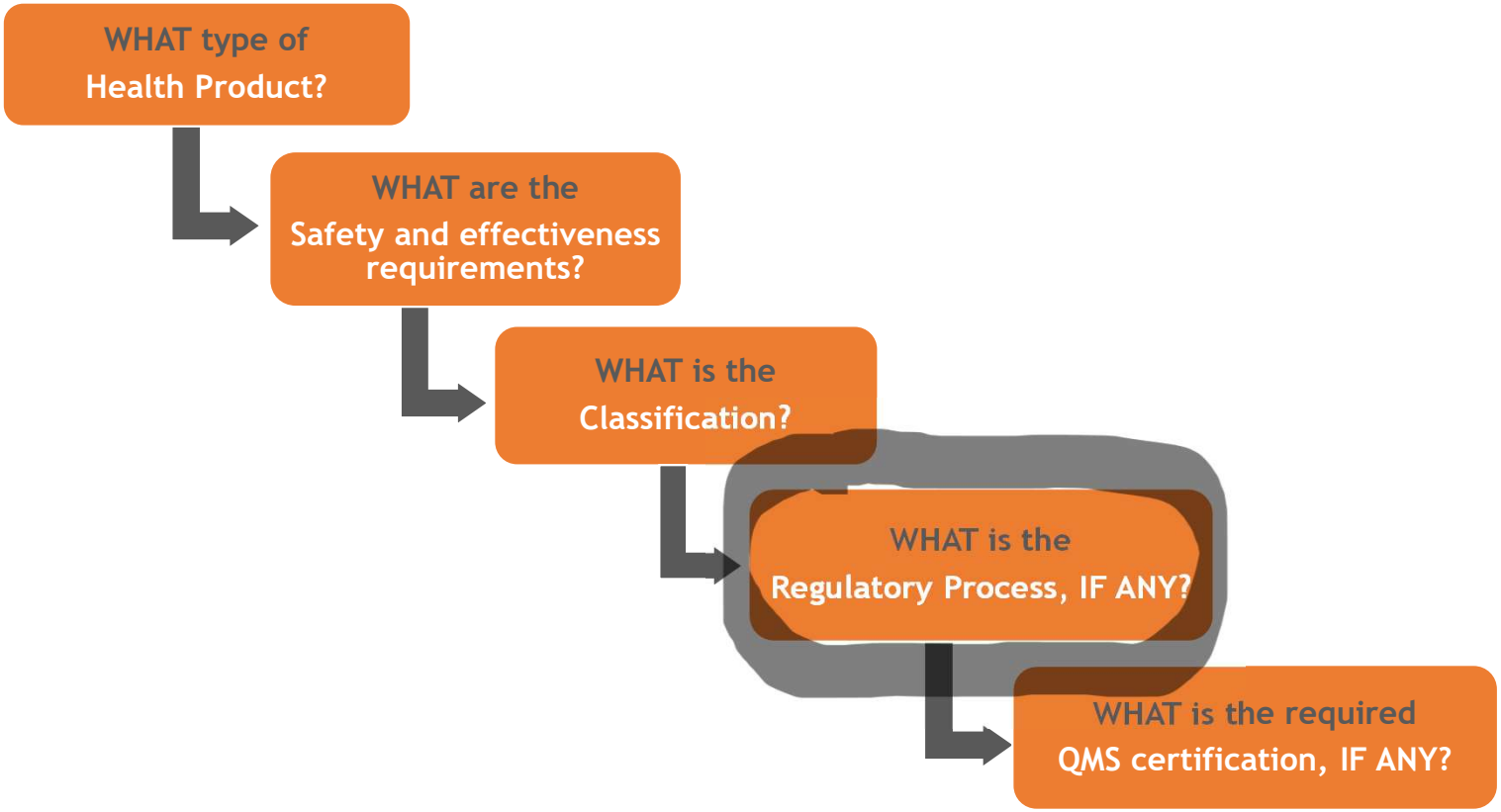
- ✓ Dental Implants
- ✓ Glucometers
- ✓ Neonatal Incubators
- ✓ Hyperbaric chambers

CLASS IV

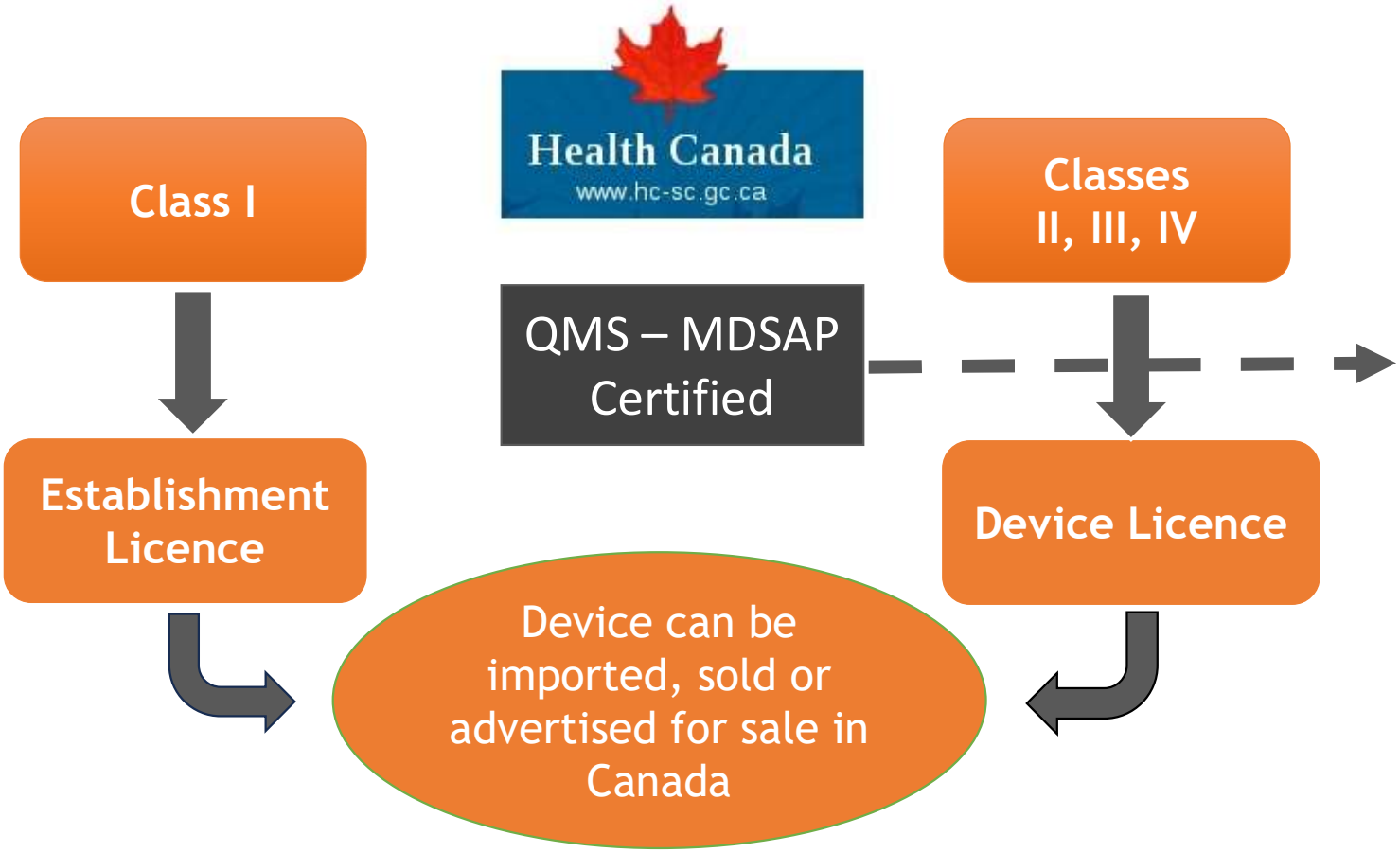
- ✓ Intracranial pressure monitoring
- ✓ Artificial heart
- ✓ Intra-aortic valvuloplasty balloon catheter
- ✓ Bone graft

Regulatory Path

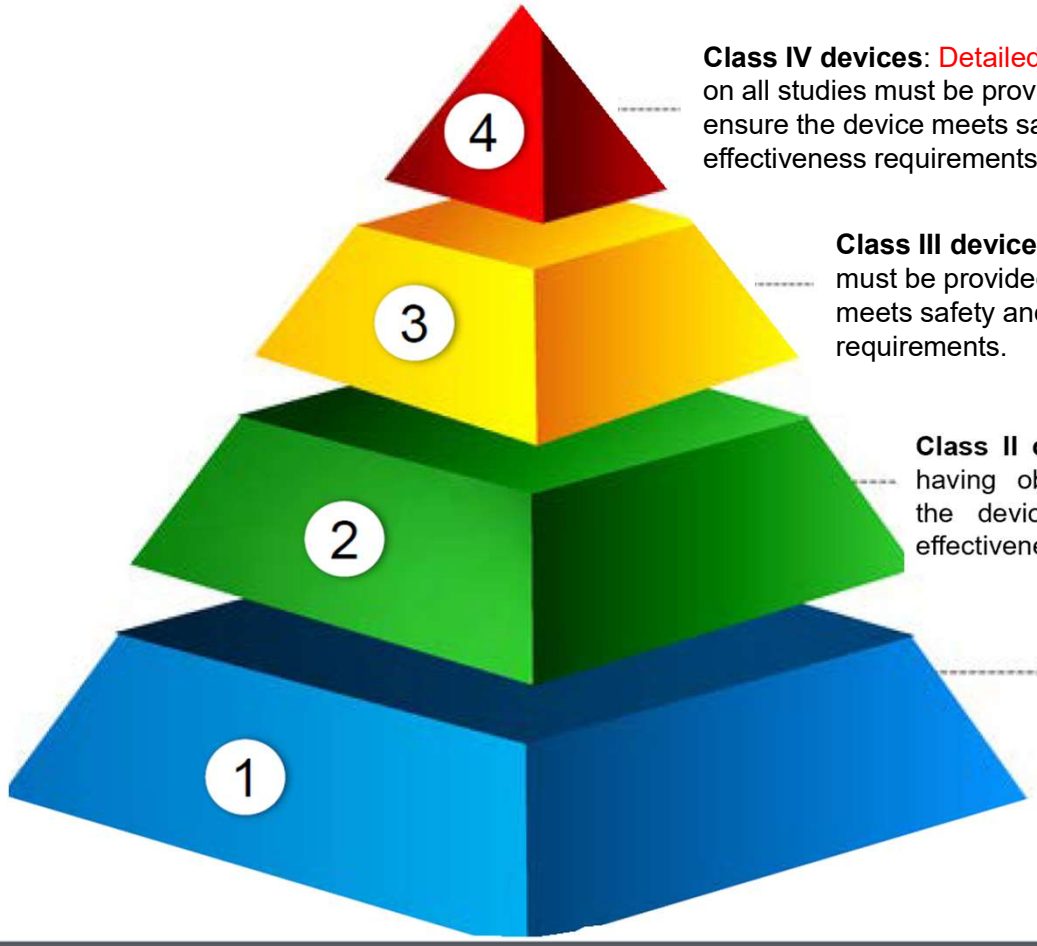
Answering the 5 “Whats”



Regulatory Process



Risk Classification



Class IV devices: Detailed information on all studies must be provided to ensure the device meets safety and effectiveness requirements.

Class III devices: Summary of all studies must be provided to ensure the device meets safety and effectiveness requirements.

Class II devices: Attestation to having objective evidence that the device meets safety and effectiveness requirements.

Class I devices: Not subject to any regulatory review; but an establishment license is required.

Regulatory Process

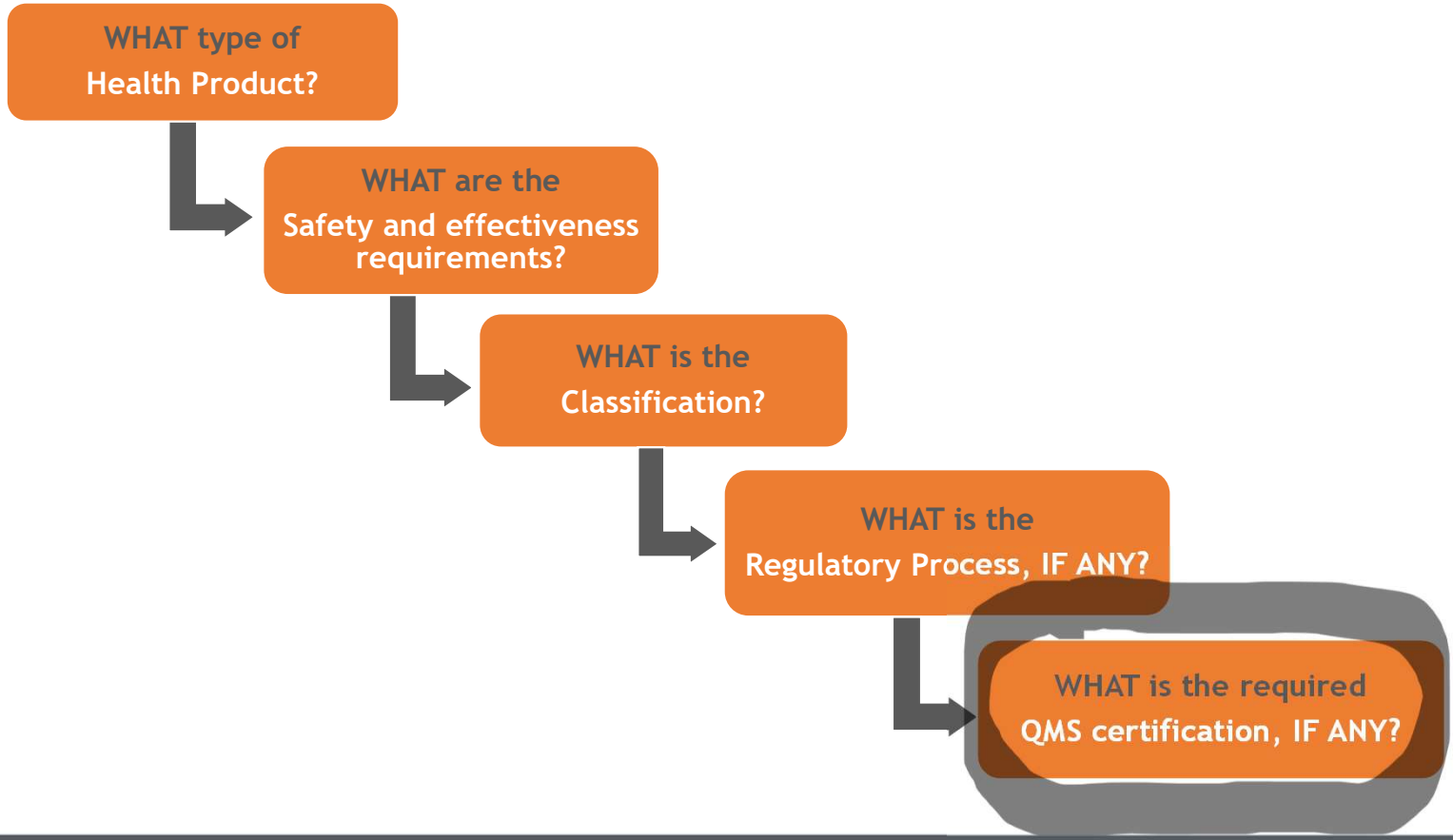
- Access through other processes:

  - Investigational testing involving human subjects may be performed in Canada. Requirements for devices used for investigational testing on human subjects are set out in Part III.

  - For emergency use or if conventional therapies have failed, are unavailable or are unsuitable, Health Canada may authorize a health care professional's access to the device through its Special Access Program. Requirements for devices that are custom-made or imported or sold for special access are set out in Part II.

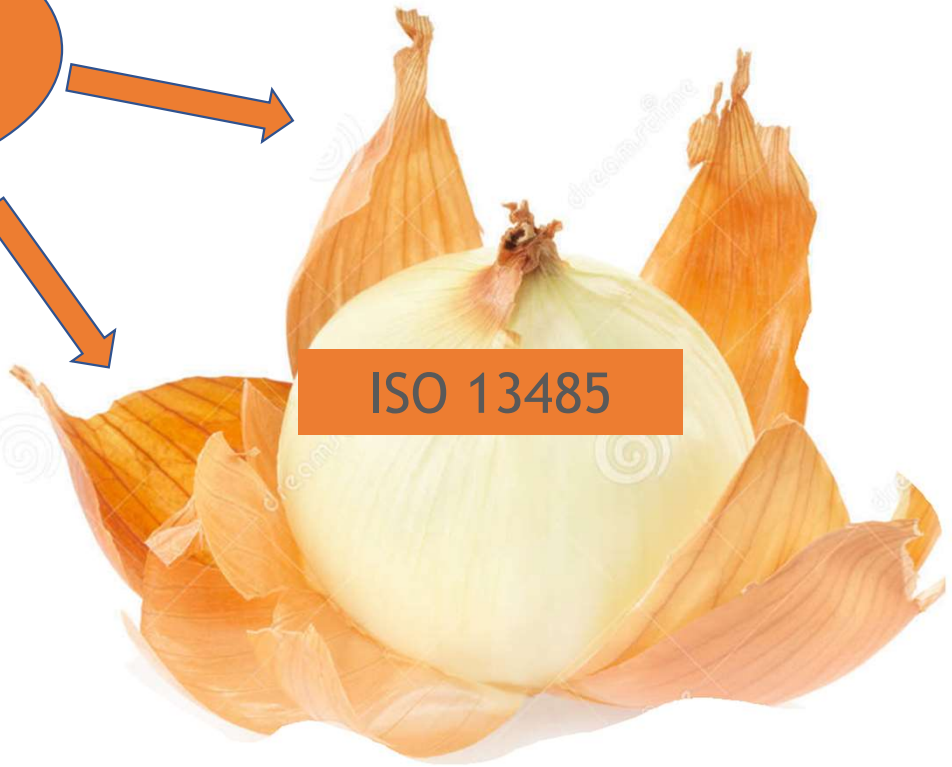
Regulatory Path

Answering the 5 “Whats”



ISO 13485:2016 vs MDR?

Regulatory requirements for the application of quality management systems



Medical Device Single Audit Program

(MDSAP)

MDSAP

- MDSAP eliminates the need for four separate regulatory audits :
  - Better use of human and financial resources
  - Reduced time required for regulatory audits

- MDSAP allows the usage of authorized third parties:
  - More flexibility and better planning for the audits
  - To build relationships with auditing organizations.

- MDSAP uses One Audit Model:
  - Uniformity of the requirements
  - Better predictability of the audits' outcomes.

MDSAP

In addition to Canada, the participating countries are:

- Australia (TGA);
- Brazil (ANVISA);
- Japan (MHLW); and
- USA (FDA).

Take Away of Take Away Messages!

- Regulatory claims must be carefully worded
- Establishing the fundamental requirements is key…
- Risk Assessment is key – even at the very early stage of development
- Investigational testing is not always required for approval
- QA management: MDSAP Certification is mandatory in Canada for class II-IV medical devices (ways to work around…)
- Can't avoid the regulatory affairs folks…

Regulatory Yours!

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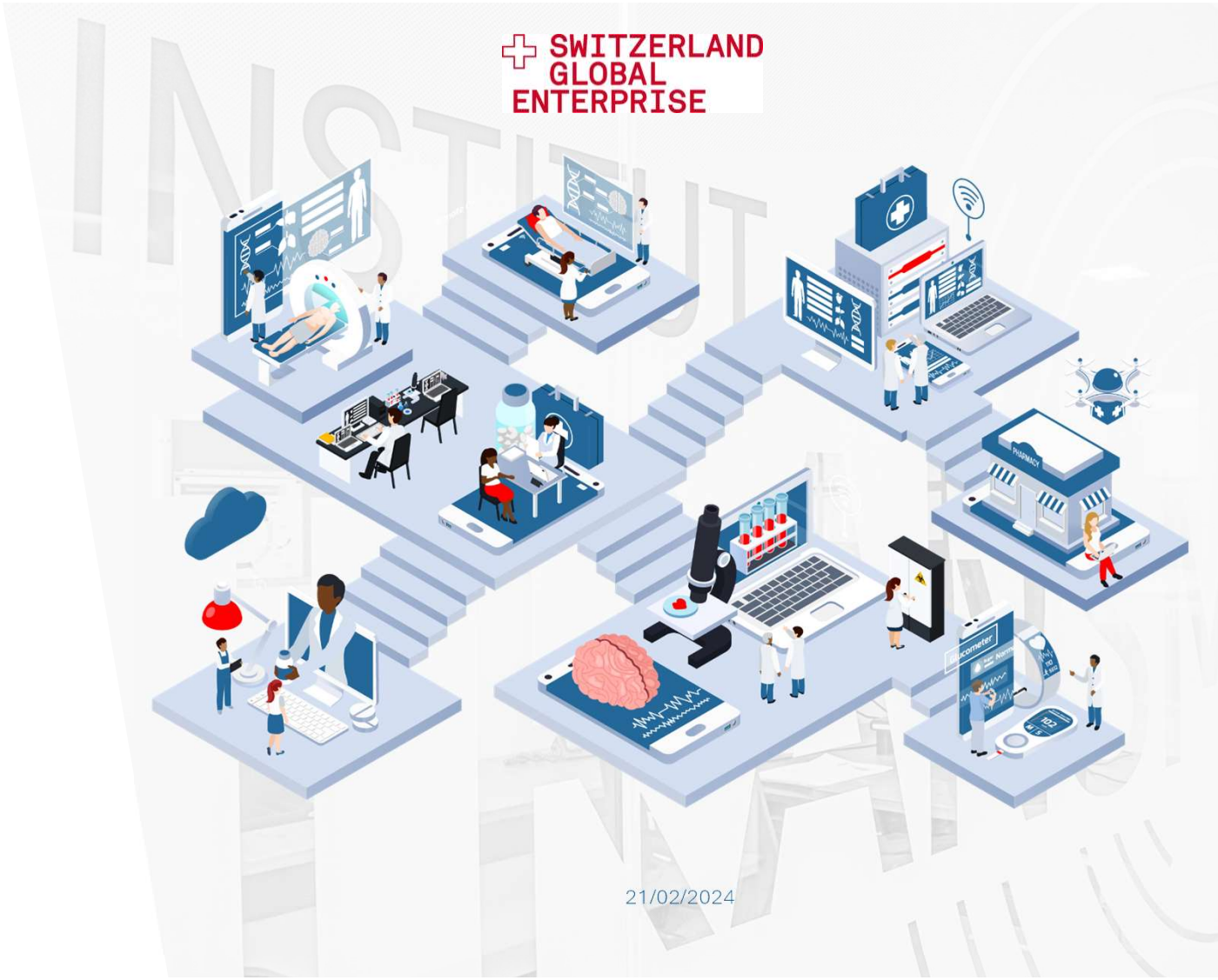
INSTITUT TRANSMEDTECH MONTRÉAL LIVING LAB

Exporting MedTech and Digital Health Solutions to Canada. How to make it work?

Dr. Marie-Pierre FAURE
Director Innovation & Living Lab, TransMedTech

Malick Deme, Senior Manager, Deloitte



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Why Canada?

$7.8B Market value

8th Medtech market worldwide

+2K Medtech companies

35K Employees in medtech

Québec, a territory dedicated to MedTech

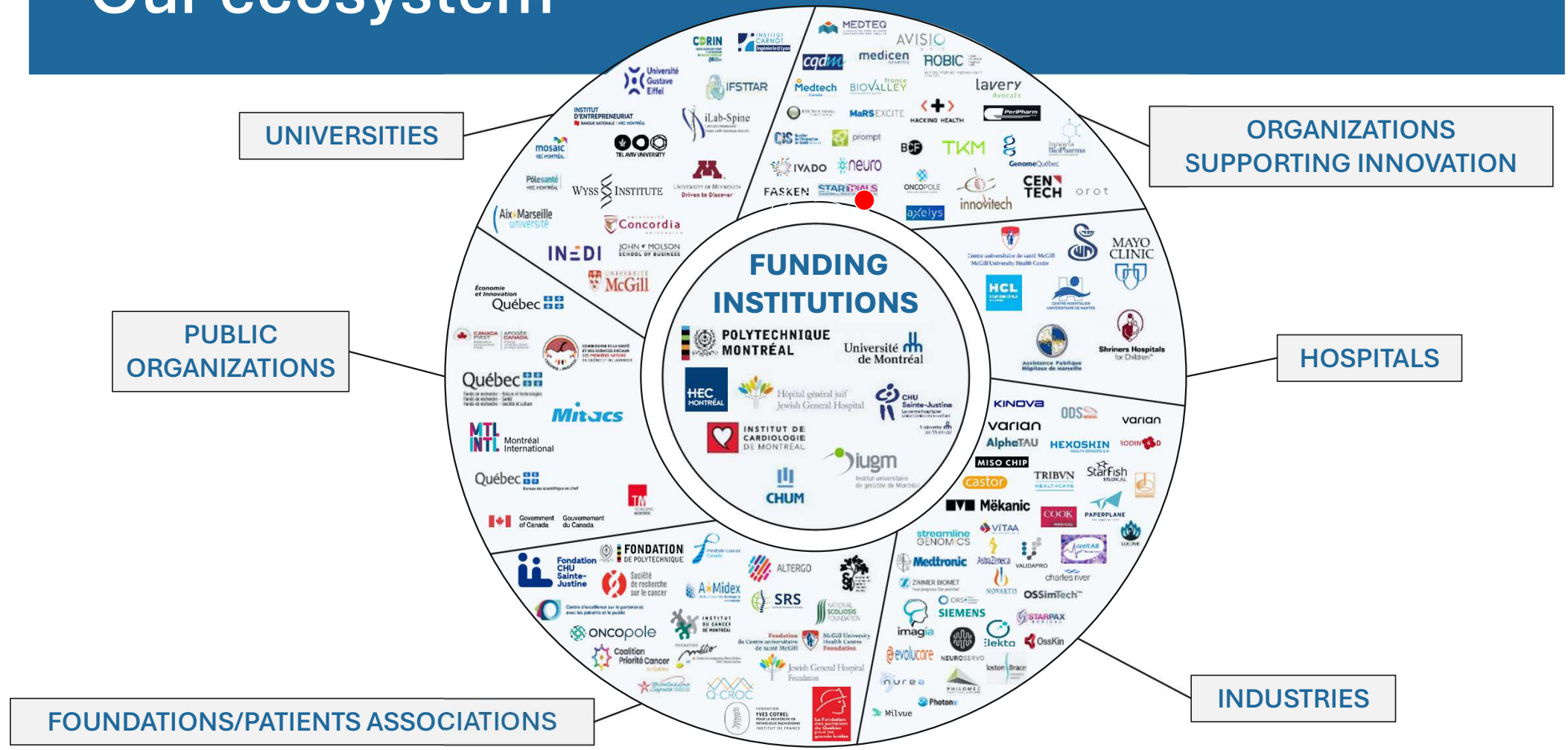
+150 Research centers

180 Multinational subsidiaries

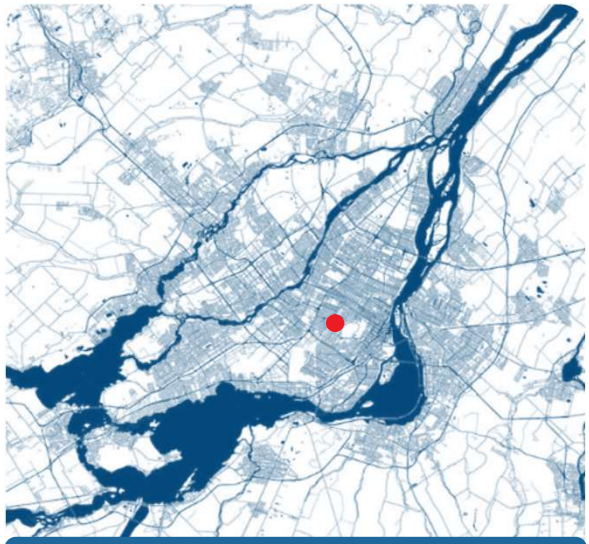
650 Organizations

30K Students

Our ecosystem



At the centre of the action



Montréal

CHU Sainte-Justine
Mother and child hospital

TransMedTech Institute

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TransMedTech Institute

Vision

To be a **hub** of **impactful medical technology innovation** and **added value** for **population health** and **socio-economic development**.

Misson

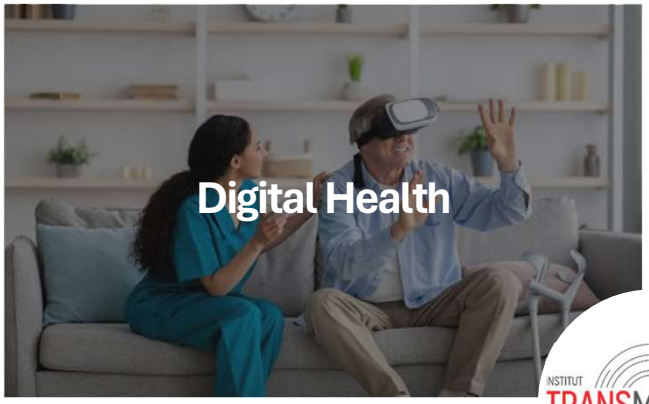
Support innovation in health technologies that meet the needs of the community, in order **to facilitate** and **catalyze their development and implementation**

Train the next generation of medical technology leaders and **support the industry** and innovation community

Mobilize knowledge and **lead a vibrant and dynamic environment** that promotes innovation and the adoption of solutions

Priority Innovation Sectors

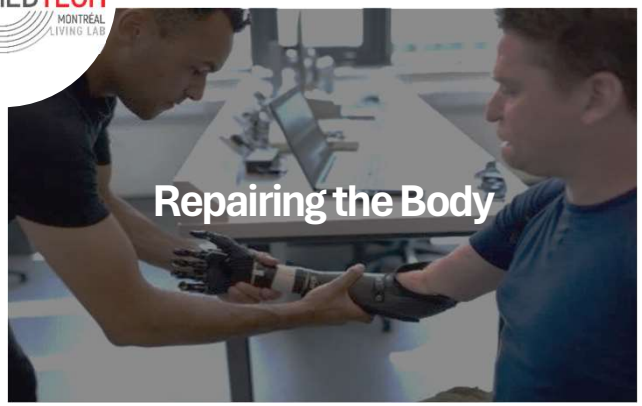
Digital health
Telehealth
Hospital-at-home
Telerehabilitation
Virtual Reality



Robotics and Minimally Invasive Surgery
Interventional Imaging
Simulation
Targeted Therapies

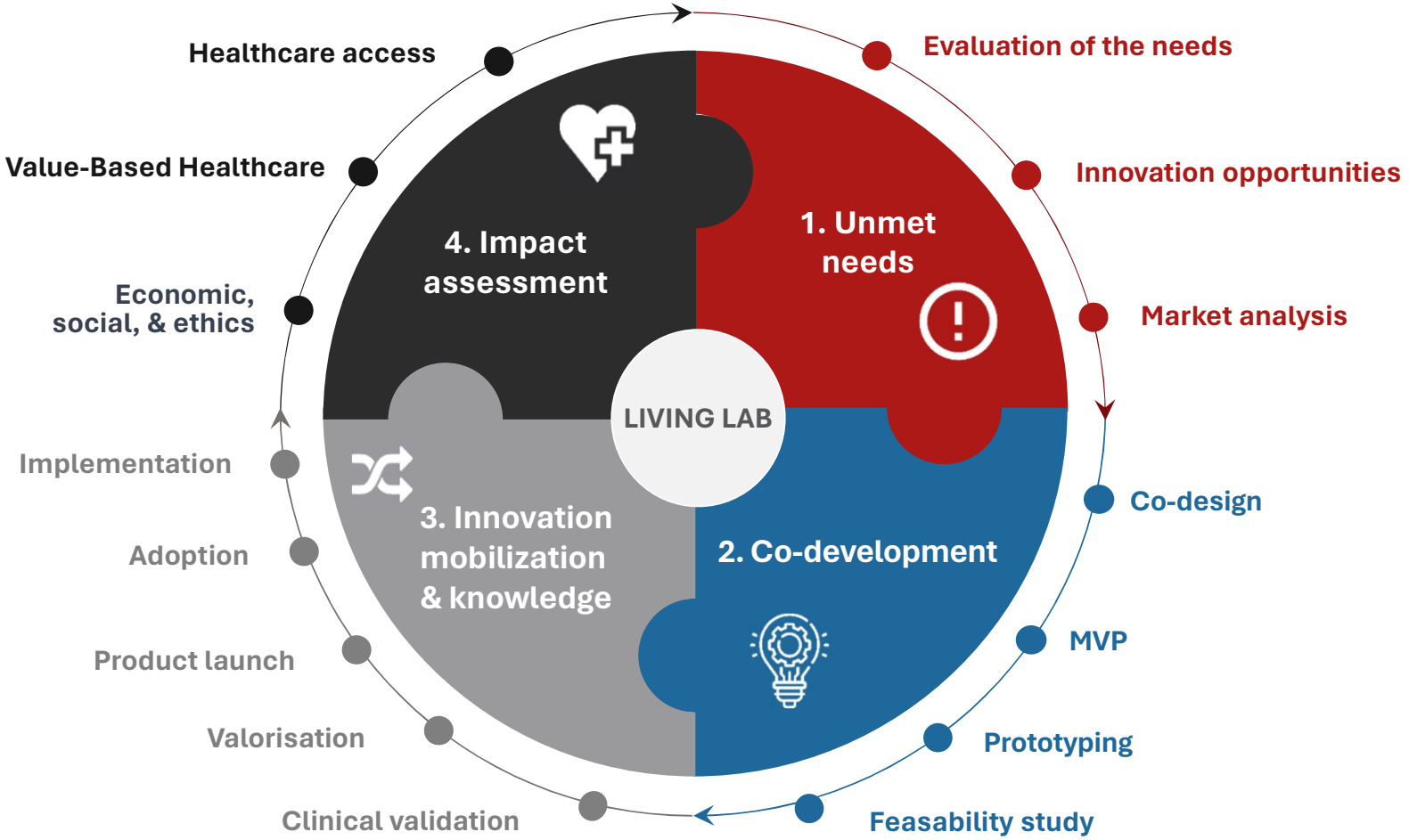
INSTITUT TRANSMEDTECH MONTRÉAL LIVING LAB

Decision Support and Therapeutic Follow-up
Diagnostic Tools and Imaging Biomarkers
Digital Pathology



Artificial Organs, Regenerative Medicine, 3D Bioprinting
Implants and Biomaterials
Neuroprosthetics, Intelligent Orthotics
Sports Medicine Technologies

TransMedTech Method™



ISO 13485
Quality Management Systems
Medical devices
Requirements for regulatory purposes

The Medtech Innovation Lab program

Integrated innovation management program in healthcare providing high-value services including support and coordination for the development and commercialization of medtech innovations along with the community and innovators in real-world settings.

The program aims to optimize the innovation and commercialization cycles of companies with the support of key actors of the ecosystem based on a living lab approach.

Main high value services offered:

- **Capacity building and access to specialized resources/expertise** (e.g., key opinion leaders, infrastructures and technological platforms, highly qualified personnel);
- **Project management and coordination** in real-world settings (e.g., process alignment, referencing and support for scientific validation and technical & commercial maturation, monitoring, networking with key actors of the healthcare sector, project monitoring)
- **Strategic planning** (e.g., scientific and economic benchmark and comprehensive analysis of the environment, design of innovative business models, distinctive value propositions and financing strategies, regulatory guidance)
- **Professional development** (e.g., training programs for managers and leaders in the healthcare technology sector, coaching and mentoring activities)

Supporting companies setting up in Québec

VIRTUALISURG

Smart Biotic

Milvue

mypl

AlphaTAU

INSTITUT TRANSMEDTECH MONTRÉAL LIVING LAB

Thank you!
Any questions?

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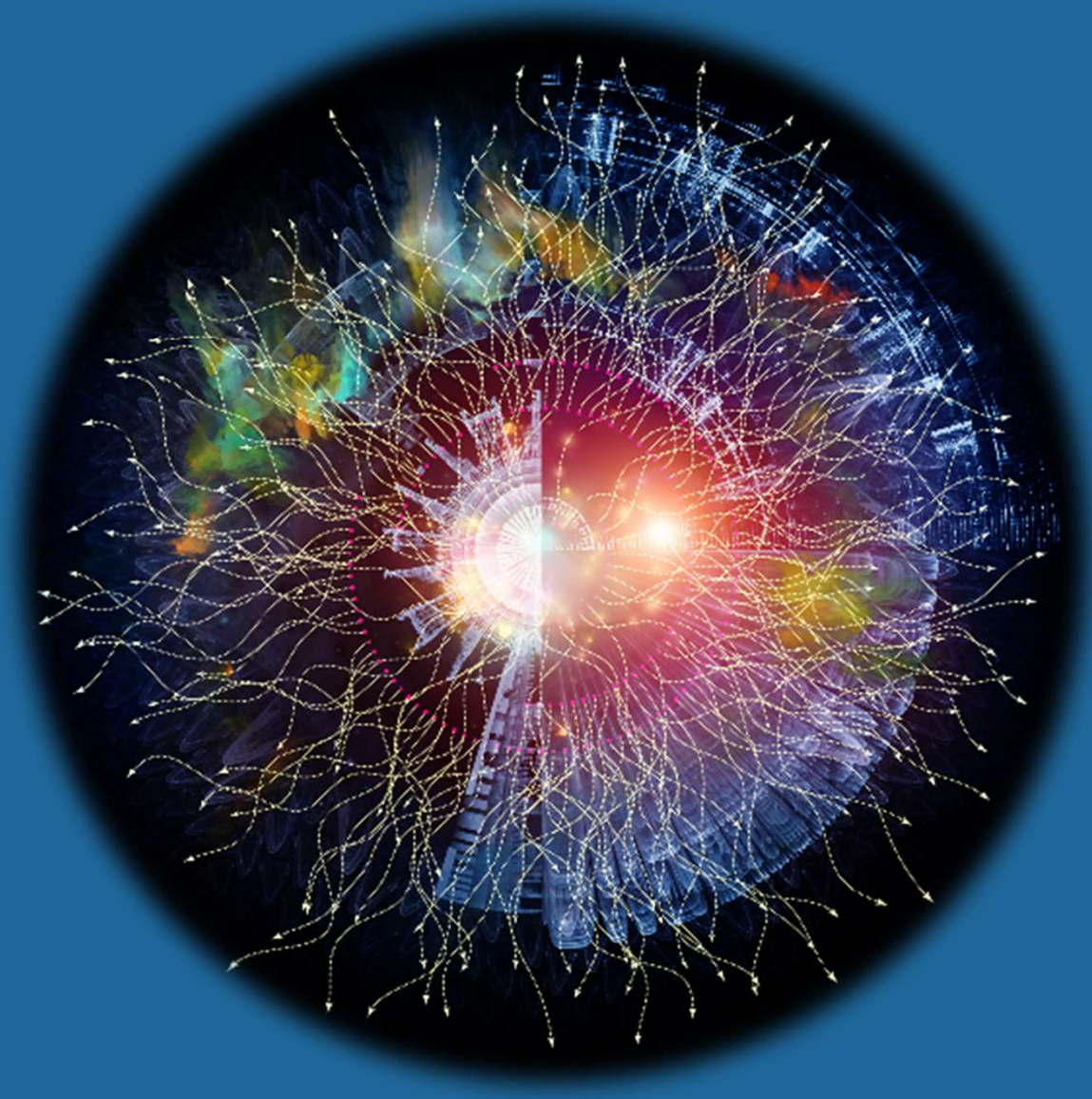
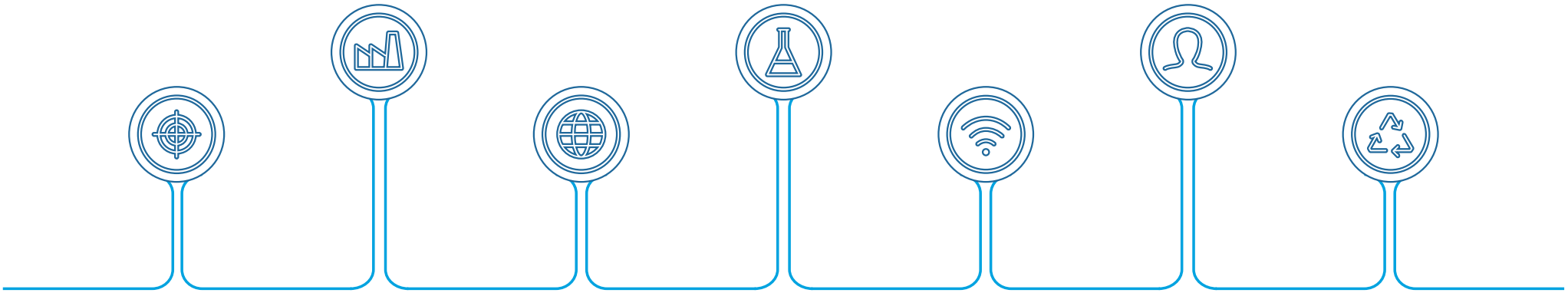
Deloitte

Government Incentives available in Quebec & Canada



Main Triggers for government funding



- ✓Export
- ✓New markets

- ✓Startup
- ✓Investment capital

- ✓Enlargement/ Expansion
- ✓New production
- ✓Increase productivity

- ✓Innovation
- ✓R&D
- ✓New products
- ✓Collaboration with experts

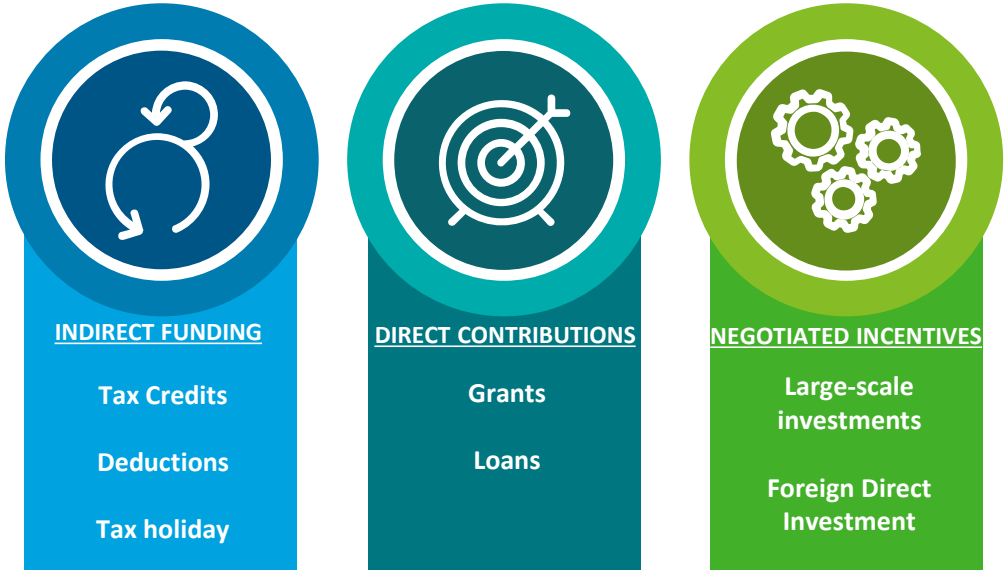
- ✓Implementation of new technologies
- ✓AI
- ✓Cyber-security

- ✓Job creation
- ✓Training
- ✓inclusion initiatives with diverse groups
- ✓student hiring initiatives

- ✓Energy efficiency
- ✓Reduction of greenhouse gas (GHG) emissions
- ✓Protect natural resources

Tax Incentives and Grants

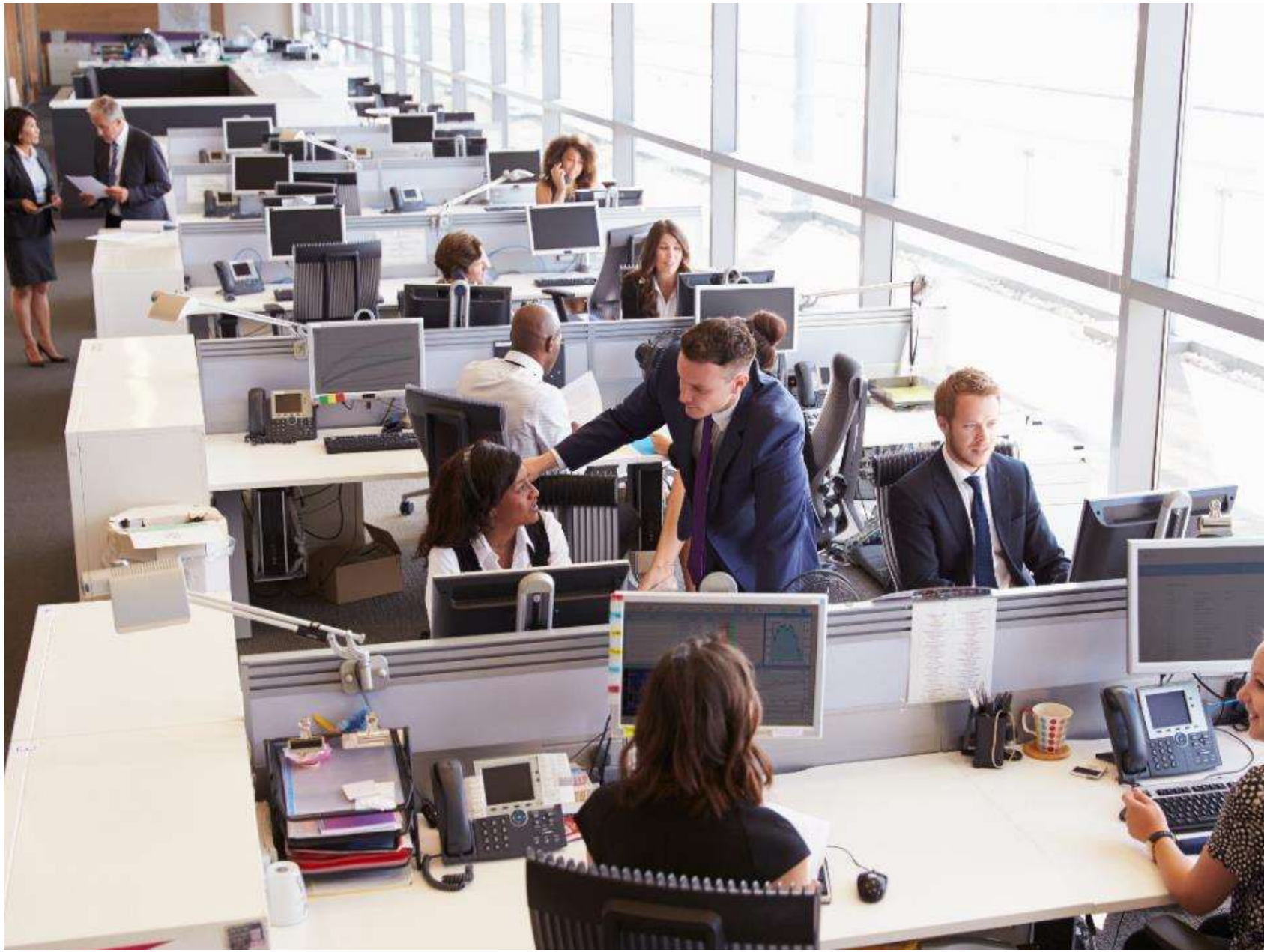
- Dynamic calls for projects
- Dependent on federal and provincial budgets
- More than $6 billion in government financial assistance available to Canadian organizations



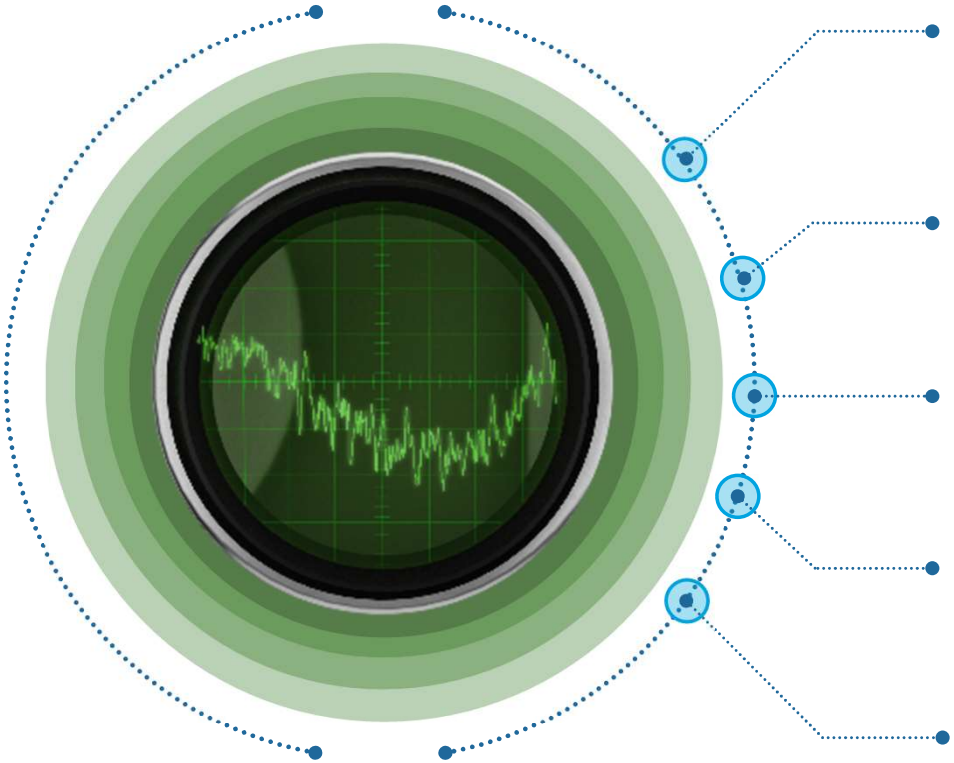
Possible interaction between these three types of incentives

Stacking government assistance rules to observe

Scientific Research & Experimental Development (SR&ED)



Scientific Research & Experimental Development (SR&ED)



SR&ED
Systematic investigation or research of a scientific or technological nature, carried out by means of experimentation or analysis.

Pure Research
Work undertaken for the advancement of science with no practical application in sight.

Applied research
Work undertaken for the advancement of science with a practical application in sight.

Experimental development
Work undertaken in the interest of technological progress for the creation of new materials, devices, products or processes or for the improvement, however slight, of existing ones.

Oriented work
The field of engineering, design, operations research, mathematical analysis, computer programming, data collection, testing, and psychological research.

Scientific Research & Experimental Development (SR&ED)

Calculation of the SR&ED tax credit

Fédéral		
Eligible	**Tax credit rate**	**Eligible Expenses**
CCPC	35% on the first eligible expenses of $3M	Wages - 100%
	15% of surplus	Subcontractor- 80%
		Overhead (proxy method) - 55%
Others	15%	Materials - 100%

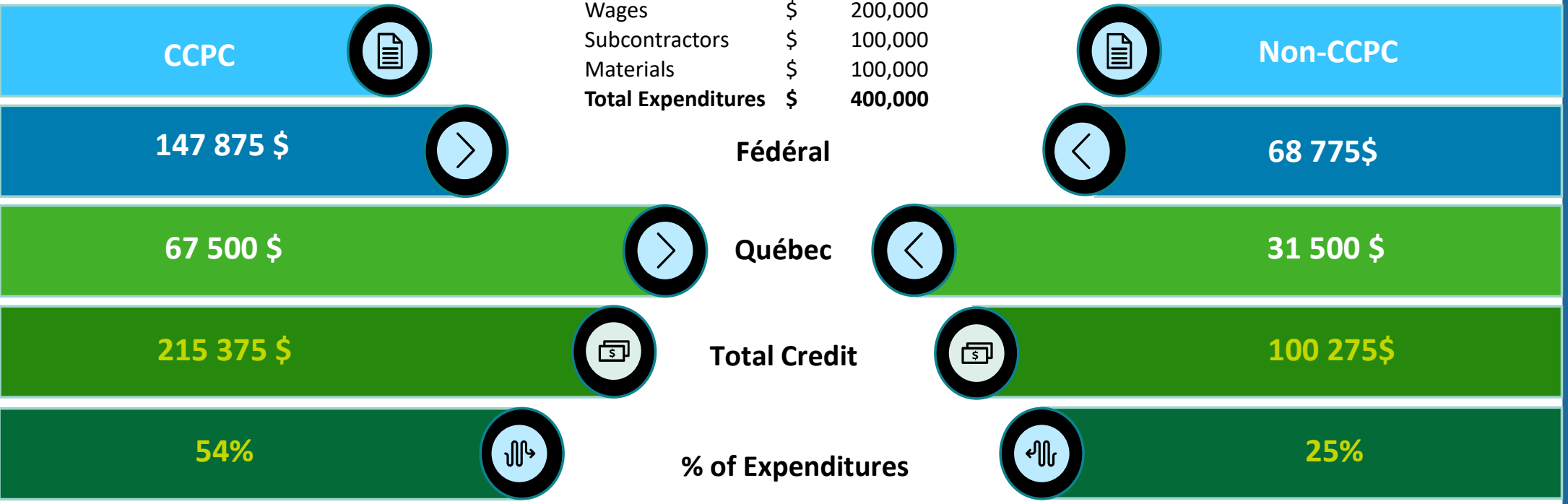
Québec		
Eligible	**Tax credit rate**	**Eligible Expenses**
CCPC	30% on the first eligible expenses of $3M	Wages - 100%
	14% of surplus	Subcontractor - 50% *
Others	14%	Overhead- NA
		Materials - NA

* In order for subcontractors to be eligible in Quebec, they must be contractors who have an establishment in Quebec.
** For Quebec, there is an exclusion threshold on the first $50,000 on eligible expenses if the corporations' assets are less than $50 million.
*** The exclusion threshold increases to $225,000 if the corporation's assets exceed $75 million.

Scientific Research & Experimental Development (SR&ED)

SR&ED tax credit comparison CCPC vs. Non-CCPC

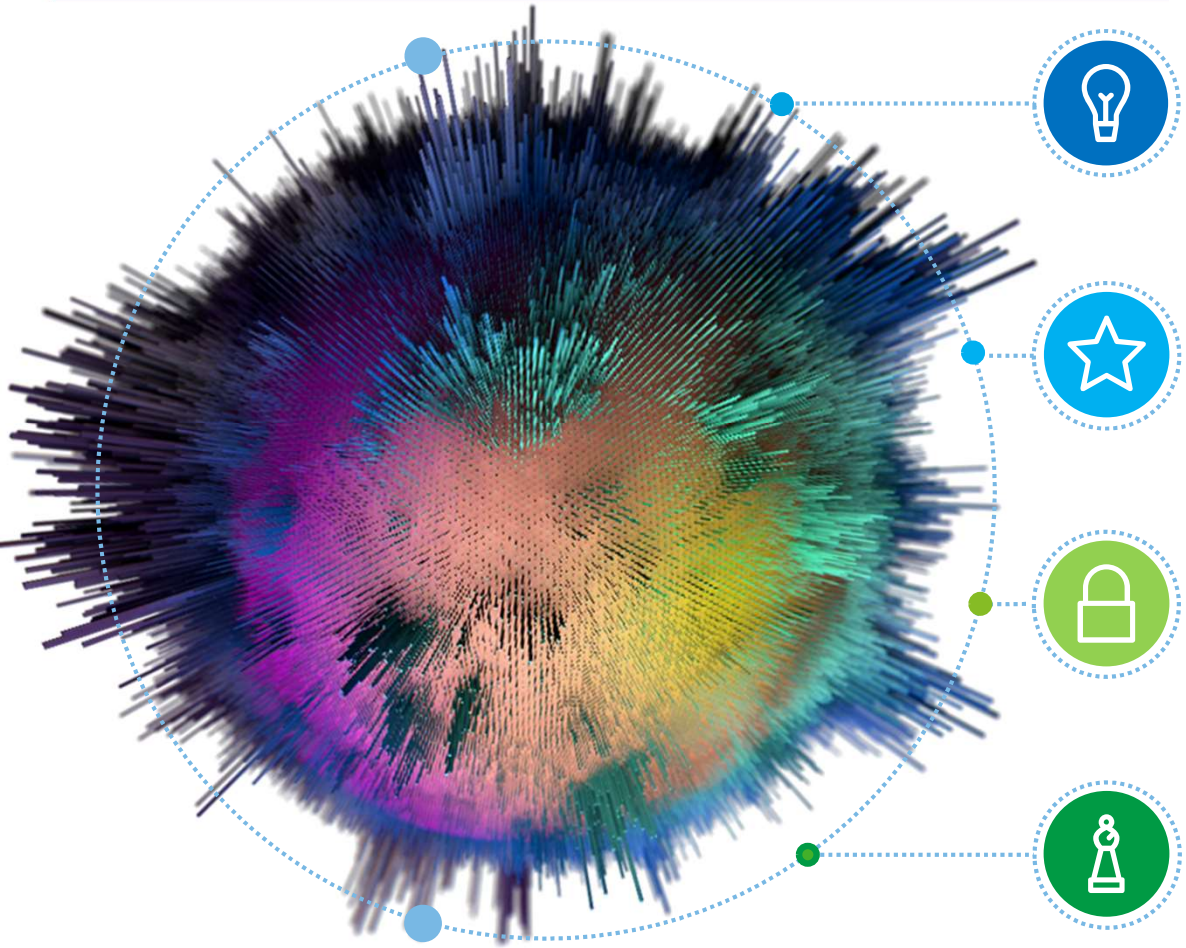
EXPENDITURES		
Wages	$	200,000
Subcontractors	$	100,000
Materials	$	100,000
Total Expenditures	**$**	**400,000**



*The calculated percentage is for this specific scenario and may vary depending on the expenses incurred.

NON TAX INCENTIVES & GRANTS

Non-Tax Incentives and Grants



Dynamic environment

Periodically, government agencies announce programs/calls for projects that open and close quickly.

Based on government priorities

Program trends and priorities depend on federal and provincial budgets.

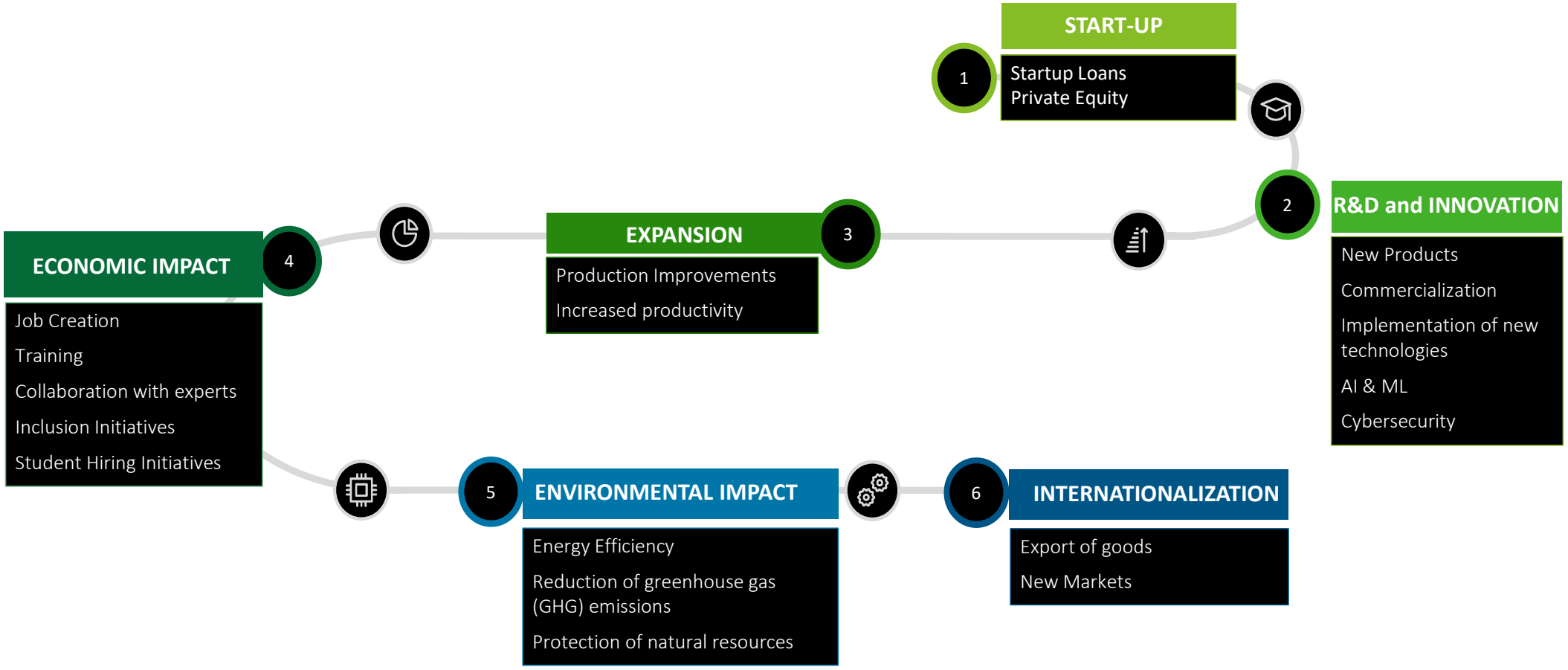
With processes in place

The grant must be complementary to your funding model and must include a minimum amount of funding that has already been secured.

Targets specific investments

Government financial assistance is generally available for specific types of investments.

Non-Tax Incentives and Grants



Non-Tax Incentives and Grants

Exemples – Innovation

Two funding streams:

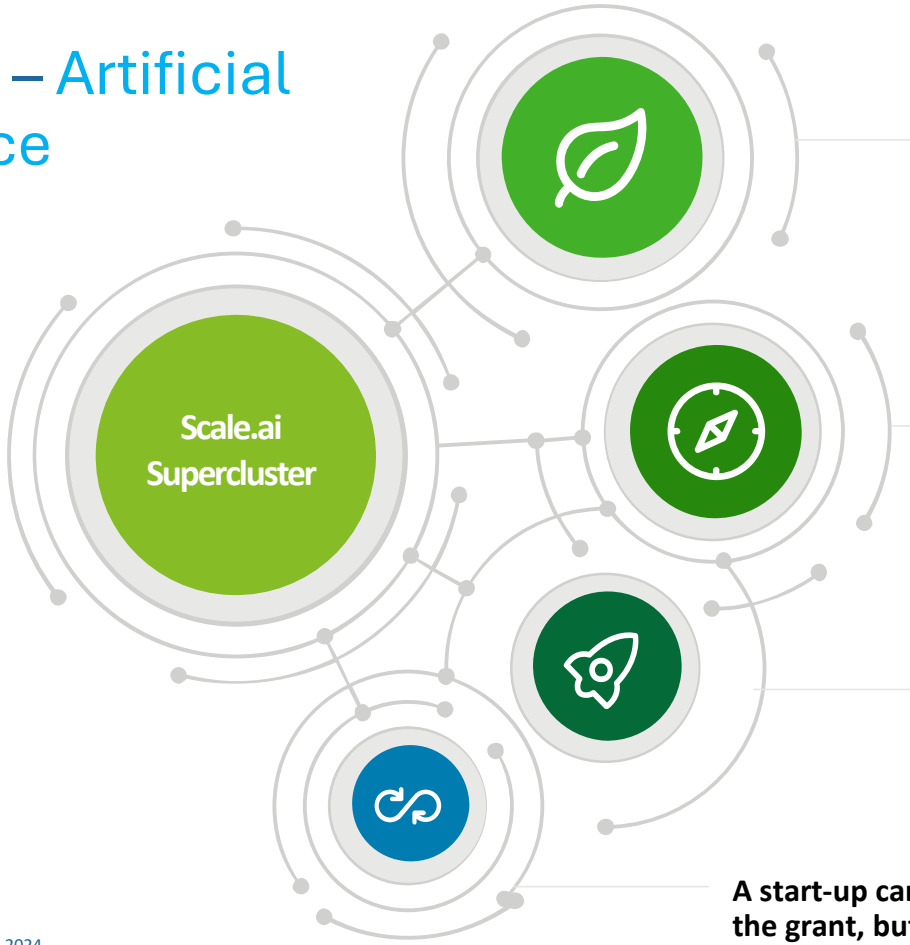
- **Accelerated Review Process (ARP), up to $50K per project,**
- **Mid-size, up to $10M per project.**

80% of project-related technical assistance (direct labour).

50% of Canadian subcontractor costs related to the project.

Non-Tax Incentives and Grants

Examples – Artificial Intelligence



Collaborative AI projects that contribute to the adoption of AI in supply chains and the commercialization of AI-based products.

Up to 40% (no maximum amount) on AI projects with a typical duration of 12 to 18 months.

85% of the first $100K of personalized training in the field (personalized digital intelligence programs).

A start-up can be a partner in a project and benefit from the grant, but it is the established company that must apply.

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Examples – Expansion & Export

CanExport – Innovation Stream

50% of eligible expenses, up to a maximum of $50K per project.

Maximum budget of 100,000.

Max stack: 75%.

Marketing and Export Support Program (PSCE) Stream 1

50% of eligible expenses, up to a maximum of 250K per company.

Max stack: 85%.

Capital Synergy

Tax measure to promote business networking and synergy between Québec companies.

An eligible investor will benefit from a 30% non-refundable tax credit, not exceeding $750,000.

SME Impulse

Financing in the form of convertible loan

Impulsion PME's investment may not exceed 50% of the total financial package, the rest must be financed by the investors.

The minimum investment amount will be $250,000, and the maximum amount will be $750,000.

Deloitte capabilities and experience

Deloitte. Insights

FEATURE

A new view on market access and reimbursement

Launching innovative biopharma in China

David Xie and Xiaofeng Li

Market Access Strategy

- Global pricing research
- Analysis of reimbursement schemes
- Market strategy assessment

Cost-Effectiveness Studies

- Cost-Utility Analysis
- Cost-Benefit Analysis
- Cost-Consequence Analysis

Deloitte. Access Economics

Cost effectiveness of continuous positive airway pressure for obstructive sleep apnoea

Sleep Health Foundation

October 2018

Value Assessment of Health Technologies

- Therapeutic value
- Economic value
- Impact on healthcare system and society

Burden of disease studies

- Economic impact of treatment strategies
- Health resource utilization

Deloitte.

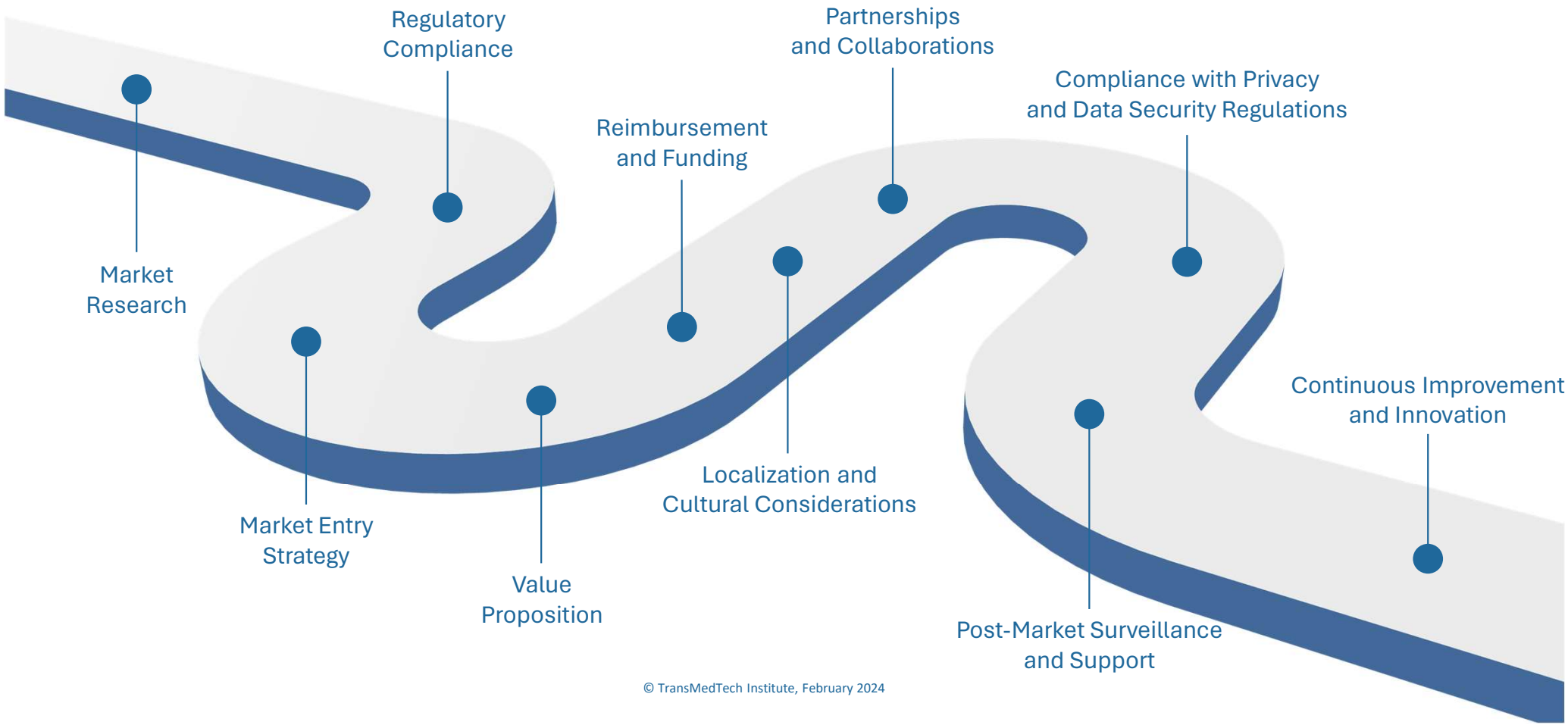
Changing the chronic kidney disease landscape: The economic benefits of early detection and treatment

Kidney Health Australia

February 2023

Deloitte Access Economics

Soft landing, a typical trajectory



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