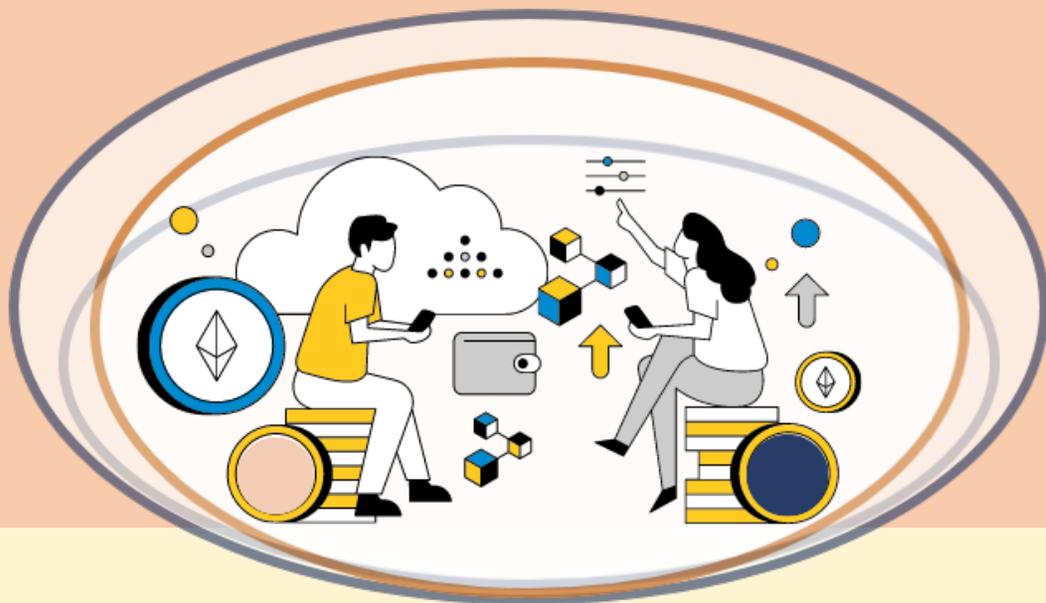


Responsible Innovation in Health Playbook

Lessons-learned and action points for health innovation stakeholders



January 2024

Helping innovators attend to the social, economic, and environmental impacts of their innovations and guiding innovation stakeholders to scale a responsible health innovation ecosystem.

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Introduction

Purpose of this playbook

Today, complex social, economic, and environmental forces affect our health and how we deliver healthcare in such a way that meeting clinical safety and efficacy standards when developing new innovations is no longer sufficient to protect patients.

Growing inequality and the climate crisis are forcing health innovation stakeholders to extend the long standing “do no harm” philosophy that has defined healthcare delivery.

Although health innovation stakeholders know how to meet well-established clinical safety and efficacy standards, they must often figure out on their own what the social, economic, and environmental impacts of their innovation are and how best to attend to them.

Because such impacts are multifaceted and greatly differ per innovation, finding proper guidance to identify and address them complicates the already laborious health innovation development process.

- ⇒ This playbook is here to help simplify this task and to empower health innovation stakeholders to not only “do no harm”, but to also “collectively do good.”
- ⇒ Because the production of health innovations is a highly collaborative process, the purpose of this playbook is to help entrepreneurs, innovation managers, healthcare managers, policymakers, and investors to collectively build a health innovation ecosystem that can generate responsible health innovations.

What is an innovation ecosystem?

An innovation ecosystem refers to:

- ▶ “The evolving set of actors, activities, artifacts, and the institutions and relations, including complementary and substitute relations that are important for the innovative performance of an actor or a population of actors”(4).
- ▶ “A set of actions designed to promote the development, and growth of social innovations, partly through improving interactions among actors”(5).

What you will learn

To build a more responsible ecosystem, stakeholders must share a common understanding of what is a responsible health innovation and what each stakeholder in the ecosystem must do to foster its development and use. In this playbook, you will learn:

- ✓ What is Responsible Innovation in Health (RIH);
- ✓ The foundations that support RIH;
- ✓ The challenges to build RIH;
- ✓ The lessons-learned about building an RIH ecosystem; and
- ✓ Action points for stakeholders to scale an RIH ecosystem.

Throughout the playbook, you will find examples and quotes from entrepreneurs and social finance experts sharing their experiences of producing a responsible health or social care innovation.

- ⇒ Because the research behind this playbook was conducted in Canada and Brazil, the lessons-learned and actions points can guide stakeholders in both developed and emerging economies to build a health innovation ecosystem that generates equitable and sustainable health innovations.



RIH: An innovation ecosystem in the making

What is Responsible Innovation in Health?

The [In Fieri research program](#) developed Responsible Innovation in Health (RIH) to help stakeholders design, commercialize, and use health innovations that are high quality and safe, as well as equitable, valuable, affordable, and environmentally friendly.

To develop a responsible health innovation, RIH invites stakeholders to work together to meet a set of ethical, economic, social, and environmental responsibility attributes (characteristics) when they design, finance, produce, use, and discard innovations that address health system challenges in an equitable and sustainable way (6).

To achieve its goal, RIH integrates five health innovation value domains that go beyond clinical safety and efficacy standards.



RIH **stakeholders** include all those involved in the development and use of a health or social care innovation, from the original idea that sparks the innovation to its disposal.

They can influence the pace and the direction of health innovations by bringing together complementary capacities and knowledge:

- ✓ **Healthcare professionals:** doctors, nurses, physiotherapists, social workers, etc.
- ✓ **Healthcare managers:** administrative personnel, mid-level managers, directors, etc.
- ✓ **Engineers:** biomedical, mechanical, computer, etc.
- ✓ **Designers:** industrial, user experience, digital interface, etc.
- ✓ **Entrepreneurs:** start-ups, small- and medium-sized enterprises, large enterprises, etc.
- ✓ **Leaders of intermediating platforms:** incubators, accelerators, innovation hubs, etc.
- ✓ **Policymakers:** health policy, innovation policy, economic policy, etc.
- ✓ **Investors:** impact, venture capital, angel investors, etc.
- ✓ **Patients and relatives:** care-receivers, informal caregivers, patient associations, etc.

What are the RIH attributes?

Each value domain of RIH sets a responsibility goal that is achieved through specific responsibility attributes.

An example of what a responsible health innovation can look like is summarized on the next page.

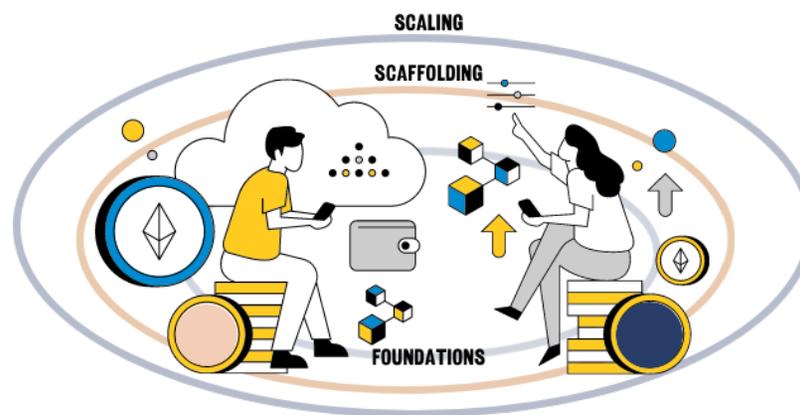
RIH value domains	Attributes
Population health value ⇒ Goal: meet collective needs	<ul style="list-style-type: none">○ Health relevance: addressing an important burden of disease○ Ethical, Legal, and Social Issues (ELSI): mitigating ethical, legal, and/or social issues○ Health inequalities: reducing health inequalities○ Human agency*: deciding and acting according to one's goals
Health system value ⇒ Goal: provide an appropriate response to system-level challenges	<ul style="list-style-type: none">○ Inclusiveness: fostering inclusive development processes○ Responsiveness: providing a dynamic solution to a system need○ Level and intensity of care: optimizing the level and intensity of care required○ Care-centric interoperability*: operating seamlessly within and across care settings
Economic value ⇒ Goal: deliver affordable high-quality products	<ul style="list-style-type: none">○ Frugality: delivering value to more people while using fewer resources
Organizational value ⇒ Goal: providing more value to society	<ul style="list-style-type: none">○ Business model: providing value to users, purchasers, and stakeholders○ Data governance*: managing data in a transparent and accountable way
Environmental value ⇒ Goal: reducing the environmental impact	<ul style="list-style-type: none">○ Eco-responsibility reducing the footprint throughout the lifecycle

*Applicable only to digital and AI-based innovations.

How is this playbook structured?

Inspired by the above definitions, this playbook invites health innovation stakeholders to work together to set up the processes and activities that can lead to more responsible health innovations. To guide stakeholders towards this common goal, the playbook is structured around the ecosystem metaphor.

It leads you through the RIH foundations, the challenges, the lessons-learned, and the action points that, taken together, will foster a new way of producing health and social care innovations.



An example of an innovation with 6 RIH attributes — An educational booklet that explains 160 cancer and treatment-related terms in a child-friendly and optimistic manner for pediatric patients and their caregivers (7).

Health relevance:

When we consider the types of diseases most prevalent in children, cancer ranks in the top quarter of all causes of death, injury or disability, or risk factors of the region where the intended users are located.

Inclusiveness:

Patients, parents, doctors, and nurses developed the booklet together. The doctors provided the technical explanation of the terms, the innovation team adapted the descriptions in child-friendly language, and healthcare professionals and end users reviewed the booklet.

Responsiveness:

As a patient-centered tool adapted to the specific needs of pediatric patients, the innovation addresses an important service delivery gap.

Level & intensity of care:

Because it is visually appealing for children, the booklet can be read at home, while healthcare professionals can use it in the hospital to explain the procedures when patients undergo treatment.

Business model:

The booklet is produced by a non-profit entity that adopts a pricing scheme based on the ability to pay. While the booklet can be purchased online by those who can afford it, it is also distributed for free to public healthcare facilities and patients.

Frugality:

The cost of production and use of the booklet are very low. The language and visual elements of the booklet are child friendly. The booklet is highly portable and fit for use in multiple clinical and non-clinical contexts.

Establishing RIH foundations



What are the foundations that support RIH?

With the growing popularity of the United Nations' Sustainable Development Goals (SDGs), innovation stakeholders have developed policy orientations, entrepreneurial approaches, and investment strategies that tackle grand societal challenges and generate positive social and environmental impacts.

These orientations, approaches, and strategies form the foundation blocks to build RIH and deliver equitable and sustainable health and social care innovations.

Policy orientations

The two innovation policy foundations of RIH are Mission-oriented innovation policies (MIPs) and Responsible Research and Innovation (RRI). Both are gaining traction in developed and emerging economies.

MIPs stimulate innovations that specifically target complex societal challenges, for example, reducing health inequalities within and among countries.

⇒ These policies set challenge-led missions that transcend the typical boundaries between economic development and societal well-being in order to tackle multi-dimensional problems (8).

As for RRI, its objective is to transform current innovation development pathways toward greater social, environmental, and economic responsibility (9). To make innovation development processes more responsible, RRI encourages stakeholders to:

- ✓ **Anticipate** the risks and unintended consequences of their innovation;
- ✓ **Reflect** on the values, biases, and social norms that shape their innovation;

- ✓ **Include** a variety of stakeholders when developing their innovation; and
- ✓ **Respond** swiftly to issues raised by the deployment and use of their innovation (10).

By bringing together the five health innovation value domains described above that go beyond clinical safety and efficacy standards —population health, health system, economic, organizational, and environmental— RIH transcends typical boundaries to tackle complex health and social care problems with innovations that bring more value to users and society (6).

With its 12 responsibility attributes, RIH helps stakeholders change the current innovation development pathway by setting tangible responsibility goals to achieve throughout the innovation's entire lifecycle (7).



Entrepreneurial approaches

Responsible value creation and **working with ecosystem resources** are two key entrepreneurial approaches that can support RIH.

Social entrepreneurs have made great headway in showing how responsible value can be created by innovating for the benefit of society through an efficient business logic.

By addressing the causes of a social or environmental problem, social entrepreneurs favor sustainable solutions, are accountable to innovation users, and collaborate with others throughout the innovation development process.

To generate responsible value, entrepreneurs require a sophisticated skillset that includes both ordinary capabilities and dynamic capabilities (11).

- ⇒ **Ordinary capabilities** are about “doing things right”. They are needed for operations, administration, and governance (personnel, facilities and equipment, processes, and routines, etc.).
- ⇒ **Dynamic capabilities** are about “doing the right things” at the right time. They are needed to better meet customer and organizational needs and to generate revenues.

To help entrepreneurs acquire this skillset, socially oriented incubators, and accelerators (I/As) play a key role by providing two types of resources:

- ⇒ **tangible resources**, which include workspace, equipment, and administrative services, and
- ⇒ **intangible resources**, which provide mentoring and networking.

Entrepreneurs need both kinds of resources, which must be adapted to their specific responsibility mission and entrepreneurial goals (12).

In addition to working with I/As, entrepreneurs must also **collaborate with health and social care systems** to ensure that their innovation is valuable for end users.

This can entail applying inclusive design methods with healthcare managers, clinicians, and patients to develop innovations that address a system-level challenge and strengthen caregivers' capacity to deliver care (13).

What are inclusive design methods?

The **Inclusiveness** attribute of RIH invites innovation teams to work with a variety of relevant stakeholders during the design, development, and pilot stages of an innovation by using highly engaging and accountable methods for a meaningful participation.

What is a system-level challenge?

The **Responsiveness** attribute of RIH invites stakeholders to develop an innovation that provides a dynamic solution to a health system need that is documented as being important in the region where the intended users are located.

How to strengthen care delivery capacity?

The **Level and intensity of care** attribute of RIH aims to strengthen the health system's capacity to deliver care in a sustainable manner by empowering patients, informal caregivers, and primary care professionals to deliver effective and safe care.

Investment strategies

Alongside social entrepreneurship objectives, skillsets, and resources, **social finance (SF)** can also support RIH. SF integrates social and/or environmental goals into financial decision-making by investing in projects that address important societal issues such as poverty, inequality, and climate change.

The term SF is often used interchangeably with the terms 'impact investing' and 'social impact investment.' It follows the three waves of responsibility:

- ▶ 1960s-1980s: Socially responsible investing and microfinance;
- ▶ 1990s: Corporate Social Responsibility (CSR); and
- ▶ 2000s: Impact investing and Environmental, Social, and Governance (ESG)(14).

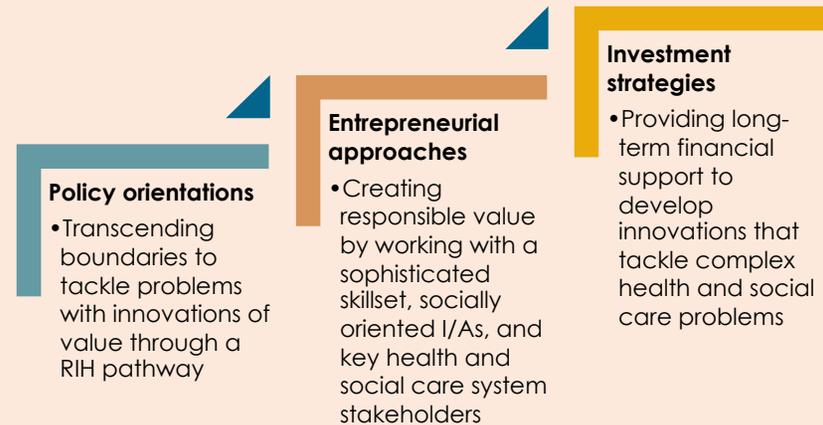
By applying financing instruments, tools, and strategies to generate economic, social, and/or environmental value, SF can offer the long-term financial support that impact-driven organizations need to develop responsible innovations.

There are 2 types of impact investors:

- ⇒ **Impact first:** investors primarily aim to generate positive benefits to society and the environment with a floor for financial returns;
- ⇒ **Financial first:** investors primarily "seek to optimize financial returns with a floor for social or environmental impact" (14).

How do these foundations support RIH?

Taken together, these policy orientations, entrepreneurial approaches, and investment strategies help to establish a new breed of innovation, one that deliberately provides a valuable solution to an important health or social care problem in a collaborative and responsible manner.



Upholding a responsible mission:

“We don’t see our social impact as a by-product of what we do, it is what we do.

Our value system is embedded in every facet of our strategic planning, our execution, our outcome measures, that philosophy is vertically integrated in our company. It’s the benchmark.

So, if it doesn’t respond to that fundamental why, we simply just don’t do it.”

Scaling responsive production processes:

“We have to switch over to other forms of investment and sources of revenue.

And so this hybrid model will be very important to our long-term success and ability to scale.”

Building nimble organizational capacity:

“We focused a lot on human resources. We hired a HR director because we didn’t have a HR department before, like many other small businesses.

So we decided to invest in our workers and to have someone with the skills to lead new HR projects.

We wanted to create a good working environment for everyone.”

Struggling toward financial sustainability:

“We have to find financial sustainability so that we rely less on volunteers.

We need full-time staff who can really make things happen because the management of volunteers is very difficult.”

Fulfilling ethical, legal, and regulatory responsibilities:

“It’s tough dealing with international regulations and cultural differences.

We found that different parts of the world where we go to implement our innovation have different ways of doing things. Even though everyone is producing prosthetics, they all have different skillsets.

Part of the challenge is to prove the efficacy of what we’re doing.”

Juggling with misaligned funding sources:

“We started a major fundraising effort with our institutional partners, companies with which we have had contact, and individual donors.

We hired a fundraising consultant to build a financial sustainability plan.

This was a learning process, moving from a project-only organization to one with a long-term, properly supported vision.”

The **COVID-19 pandemic** further exacerbated many business model challenges, especially organizational and financial challenges. For example, entrepreneurs had to adapt to lagging staff motivation, high turnover rates, and disrupted supply chains. Their revenues both decreased and increased as they responded to new opportunities, such as grants for COVID-19 research and innovation, as well as to investors asking for more value in use accountability (16).

Challenges to work with ecosystem resources

Two key resources within the health innovation ecosystem are incubators/accelerators (I/As) and health and social care systems.

While they provide essential knowledge, opportunities, and resources to develop and implement an innovation, entrepreneurs faced challenges when working with these resources and trying to obtain what they needed to advance their responsible innovation projects.

I/As often (12):

- ⇒ Lacked the expertise required to help entrepreneurs navigate the health sector where they must meet regulatory requirements, obtain research ethics, provide evidence, and often involve third-party payers and patients.
- ⇒ Had a poor understanding of innovations that aim to generate positive societal impacts.
- ⇒ Had a traditional market approach to innovation that prioritized profitability and intellectual property over health and societal impacts.

Entrepreneurs also found that the health and social care systems they were working with often had (13):

- ⇒ A hierarchical governance and a physician-centered culture that predetermined with whom they could work. This in turn limited their capacity to engage with diverse stakeholders, which in turn influenced the types of needs they could address and the innovations they could develop.

Working with A/Is — Looking for the right match

"It wasn't from lack of trying. I signed up for everything and most of them denied us because we were an NGO. They said, 'No, no... it has to be a startup.'"

"I tried to join incubators, but they didn't see the economic potential, so I got rejected pretty quickly. Our enterprise is too young."

Working with A/Is — Benefiting from the right match

"The incubator we work with is highly connected to other social ventures and social funding programs and they put the social change above the business model.

With the program you learn that you need each of them to make it work, but they focus on making you drive your social mission first and foremost.

That's really important because other incubators are more like 'What's your business plan? What's your revenue model?' and that's a turnoff."

Working with health and social care systems

"In our enterprise we see everyone as the same, without much hierarchy, but in the health field, there's a lot of hierarchy. You know, the doctor owns the information. So, we must be careful.

We validated our innovation with the doctors, the nurses, the technicians, plus a very important team, which is the cleaning team. They sanitize the hospital. We asked them "what is more difficult to clean?"

So, inside our enterprise, it's not so hard to deal with, but you're kind of breaking up a way of talking to the patient. So sometimes there's still a little...ego."

Challenges to respond to supply and demand side policies

Supply side policies “are government attempts to increase productivity and increase efficiency in the economy” while demand side policies aim “to increase aggregate demand” for innovations (17).

For example, typical supply side policies “include improved education and training” or “improved infrastructure,” while typical demand side policies entail “cutting taxes” or “increasing government spending” (18).

Entrepreneurs explained how current innovation policies often acted as obstacles for organizations developing responsible health innovations. They reported that (8):

- ⇒ Policy instruments better supported **technology-led innovations** than **societal challenge-led innovations**.
- ⇒ Early-stage business requirements did not align with the capacity of all responsibility-oriented organizational forms, such as a non-profit or hybrid model.
- ⇒ A lack of policy directionality held back societal challenge-led innovations.
- ⇒ Market-approval and physician incentives have a greater impact on technology-led solutions.

What are technology-led innovations?

They are innovations primarily designed to address techno-economic challenges. For example: improving productivity or achieving innovation-based growth (1).

What are societal challenge-led innovations?

They are innovations that aim to address social and environmental challenges. For example: socioeconomic inequality and environmental sustainability (1).

Supply side policies

“There are governmental programs that help us to absorb some of the R&D costs. But what’s missing is the political will to support businesses who chose to be environmentally sustainable because we’re still being considered like any other manufacturing business even though we aim to be eco-friendly. We’re lowering our overall costs, but that requires a lot of big investments in manufacturing technology and we’re not being supported like we should. The government wants manufacturing businesses to be more competitive and more automated, but the impact of sustainable development goes a lot further than just selling the product at a lower cost.”

Demand side policies

“For physicians in Canada, their model really depends on whether they can bill for it. If they can bill for it or better yet, their nurse can bill for it, while they don’t even do it, then it works for them.

Our innovation is so simple, it can be administered by anybody. It has to be reviewed by the physician, but it doesn’t have to be performed by the physician.”

Challenges to invest in responsible health innovations

Here are six challenges that compromise SF's capacity to support the production of responsible health innovations (14):

- ⇒ Many SF investors lack a clear understanding of the responsible innovation concept.
- ⇒ SF investors tend to provide more support to impactful projects led by ventures in their late stage of development. This is problematic because many failures occur during the early stages of innovation when securing financial resources is particularly difficult.
- ⇒ SF's **multi-criteria decision-making process** may make it difficult for an entrepreneur to comply with all the requirements.
- ⇒ The SF market is relatively small, representing only 2% of all assets managed globally.
- ⇒ There are sizeable challenges related to **illiquid** impact investments, complex **exiting strategies**, and measuring the effects of impact investment.
- ⇒ Non-profit organizations struggle to access SF resources because of a lack of knowledge about SF and because their investment scale may not correspond to a typical SF portfolio.

An example of multi-criteria decision-making:

"We look at whom their employees are and how they treat them, we look at who the board of directors is, and how that's inclusive and diverse.

We look at what their supply chain or procurement practices are in terms of how they obtain their goods.

We look at what the product and service is that the company is providing and look to see the benefits that it may have on communities.

And finally, we look at who their actual customers, clients, users are in hopes that they are also benefiting from the product or service.

We consider all the above in addition to what value we might bring as investors before making an investment decision."

What are illiquid investments?

"Illiquid refers to the state of a stock, bond, or other assets that cannot easily and readily be sold or exchanged for cash without a substantial loss in value" (2).

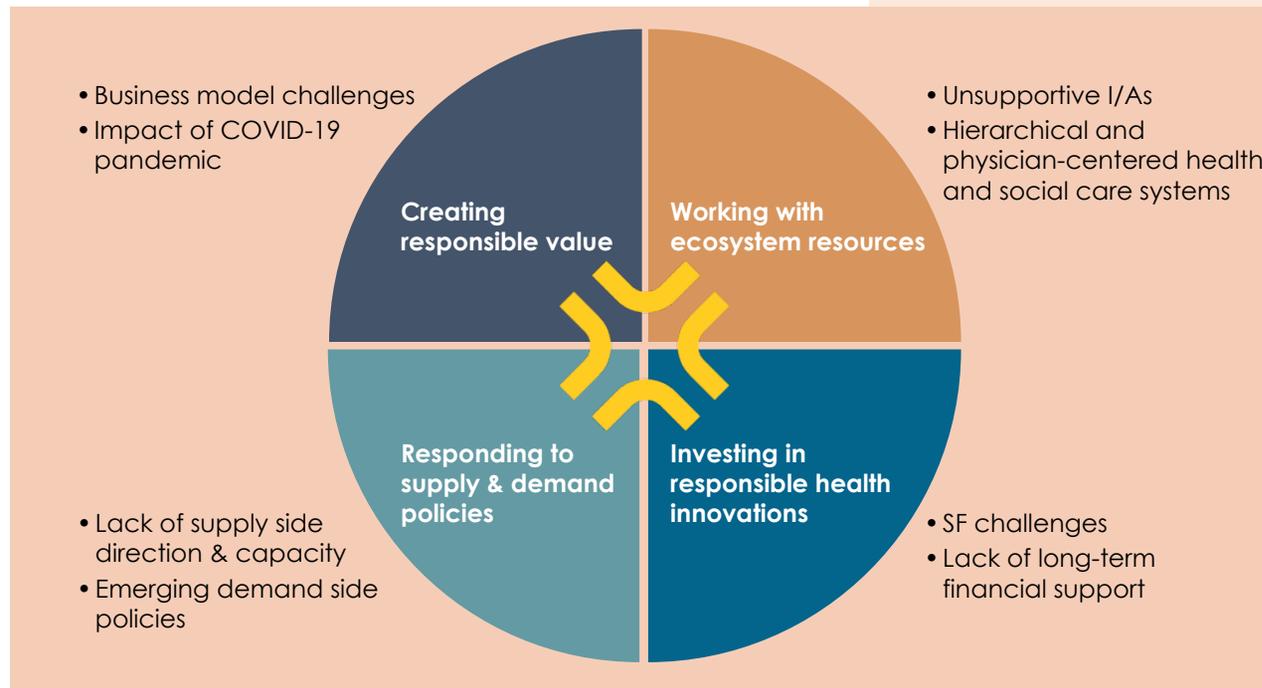
What is an exit strategy?

An exit strategy is "a plan that a founder or owner of a business makes to sell their company, or share in a company, to other investors or other firms (3).

Such strategies may include Initial public offerings (IPOs), acquisitions, and management buyouts. It can be applied to make a profit—when the business is making money, or limit losses, when it is struggling.

How do these challenges affect RIH?

These four types of challenges create obstacles for the establishment of an RIH ecosystem, as entrepreneurs and their organizations must deploy considerable time, energy, and resources to set up and sustain the key components of their responsible innovation and business model.



Scaffolding RIH into the ecosystem



What are the lessons-learned about building an RIH ecosystem?

Our analyses of entrepreneurs' and SF investors' experiences led to four key lessons-learned to tackle the challenges and scaffold an RIH ecosystem.

Lesson 1: Creating responsible value

As the table below indicates, entrepreneurs found a solution and specific adaptation measures for each of the business model challenges they faced while seeking to address the impact of the COVID-19 pandemic (15, 16). They also consolidated 3 types of capabilities, which are key to responsible value creation.

Challenge	Solution	Adaptation measure
Defining a responsible entrepreneurial identity	An inclusive responsible innovation development process that includes at an early-stage value network stakeholders possessing responsibility-oriented assets	<ul style="list-style-type: none"> ○ Question how COVID-related market opportunities affect entrepreneurial identity ○ Reorient the capital-intensive growth model towards a more sustainable one ○ Take advantage of the hybrid nature of the organization to provide solutions with greater societal impacts
Upholding a responsible mission	A prospective mapping of value network stakeholders' complementary assets, followed by continuous (re)alignment toward the pursuit of a socially compelling mission	<ul style="list-style-type: none"> ○ Build team capacity and align employees with the organization's mission, vision, and values ○ Refocus activities to cope with solutions misaligned with the mission ○ Develop new solutions to anticipate target achievement
Building a nimble organizational capacity	Identification of key organizational resources to produce and improve the responsible innovation and of responsible third parties' capacities to complement the value chain	<ul style="list-style-type: none"> ○ Hire new staff members, obtain support from incubators/accelerators, and develop in-house training to increase technical and business capacities ○ Focus on human resources management to deal with internal conflicts and employees being exhausted or stressed ○ Establish new collaborations to obtain complimentary expertise
Scaling responsive production processes	Identification of responsible third parties that can contribute to, and help scale responsively the value chain	<ul style="list-style-type: none"> ○ Implement safety procedures to mitigate contamination risks in the workplace ○ Bring changes to the supply chain to address shortages and rising production costs ○ Establish new collaborations to deal with fluctuating demand

Challenge	Solution	Adaptation measure
Struggling toward financial sustainability	A model linking targeted beneficiaries and potential purchasers to the expected social and/or environmental value creation activities, with the aim of identifying partners for value sharing activities	<ul style="list-style-type: none"> ○ Expand into new markets to diversify revenue sources ○ Provide new products and services to meet changes in demand and urgent needs of beneficiaries ○ Tap on e-commerce as an alternative to traditional, disrupted sales channels
Juggling misaligned funding sources	Identification of funding sources dedicated to societal challenges and the planning of social and/or environmental value creation activities around the model defined above	<ul style="list-style-type: none"> ○ Implement a blended-finance approach to access and balance public and private funding sources ○ Use internal resources to fund research and development activities ○ Mobilize external and in-house expertise to improve fundraising opportunities
Fulfilling ethical, legal, and regulatory responsibilities	Identification of organizations and institutions within the value network that can share knowledge and capacities to reflect on, and help address ethical, legal, and regulatory responsibilities	<ul style="list-style-type: none"> ○ Adapt to additional time-consuming ethical, legal, and social requirements ○ Integrate new requirements into the value proposition to increase competitive advantage
Accounting for value in use	A strategy embedded into the responsible innovation to gather with users and communicate the economic and/or environmental value created through value sharing activities	<ul style="list-style-type: none"> ○ Align targets and impact measures of achievements to respond to investor requirements ○ Integrate impact into commercial proposals and strategic planning ○ Establish new collaborations to better document impact



To help solve the business model challenges and further boost their RIH entrepreneurial skillsets entrepreneurs require **ordinary, dynamic, and socially oriented capabilities** (19).

Ordinary capabilities enable entrepreneurs to:

- ✓ recruit skilled human resources and tap on external sources of knowledge;
- ✓ gain access to proper facilities and/or equipment;
- ✓ implement successful innovation development processes;
- ✓ ensure administrative coordination.

Example of ordinary capabilities — A diagnostic test for thyroid cancer

"We always work with people who are willing to share the risk with us. I'm a scientist, I'm not a business administrator. So, we have support from an incubator who teaches us cash flow management, accounting, all that involves the day-to-day of the business itself.

When an investor comes in, we get help to assemble material so that we can show that we have the capacity to execute a project, to bring all this knowledge that we need to structure it as a business."

Dynamic capabilities enable entrepreneurs to:

- ✓ sense health and social care needs;
- ✓ seize opportunities to innovate, secure financial resources, and establish collaborations;
- ✓ regularly transform the organization as it develops and grows over time.

Example of dynamic capabilities — Cooking tools made of iron ingots to reduce iron deficiency

"The initial idea was we would sell the product in Cambodia, door to door, in villages, at a very low price. We had a sales team, we had done market research, we had a mascot, a jingle, training materials, etc. And though we think people loved it, we couldn't convince them to pay money for it.

We learned that there was a lack of trust because there were so many health interventions in Cambodia, and it failed miserably. So, we started talking to other people and got advice from NGOs who had lots of experience and we decided that this probably wasn't the way forward.

Instead, we moved towards a partnership model where we sell the product in bulk to non-profits or other agencies for them to distribute as part of their existing nutrition and health programs where they already have success, and already have trust in the community. And that proved to be much more successful.

We also worked very hard to become a certified benefit corporation, or B-Corp, and that commitment to achieving our social mission is not only built into the company structure, but also into our by-laws: both the board of directors and the shareholders have to sign on that social commitment."

Socially oriented capabilities enable entrepreneurs to:

- ✓ consolidate the dynamic capabilities needed to tackle societal challenges; and
- ✓ develop a stakeholder-centered business model.

Example of socially oriented capabilities — An intervention to improve waste pickers' safety and living conditions by offering direct services to pickers and an app that connects them to clients and indicates the economic value of various recyclable materials

"As a graffiti artist, I first painted walls and then started to paint the carts of waste pickers to amplify their voice. I wrote on their carts 'I do more for the environment than the environment minister,' because the waste pickers actually do a public service by collecting waste and they are not paid to do so.

So, I started painting their carts and then I saw that it's not that simple, that we had to do a lot more. For example, their carts often needed to be fixed and this really improved their working conditions. That turned into a project that was no longer just me as an artist, but 300 volunteers helping to fix carts on a day in 2012, and then it never stopped.

When I founded the organization, our goal was to make the waste pickers visible. We explained that they worked invisibly, no one noticed them. But when you see that 90% of what is effectively recycled in Brazil passes through their hands, you say: "Oops, wait, their work is not insignificant." Then our purpose as an organization changed.

Today we fight for the recognition of and payment for the services they provide. For example, I was in the junkyard today and a waste picker had recently cut himself; another had a leg problem; and another a vision problem. And, in fact, sometimes these physical and mental challenges make it difficult for them to be on the labor market.

They become waste pickers because it's one of the few things that they can do.

Before, we used to organize big events where I'd join waste pickers in a region. Then, we began to work on a format where each person can help a waste picker. So, if a waste picker needs glasses, then let's see if we can get some glasses. We also fight for the payment of their service because they are not paid for the waste collection service, public cleaning, and transportation.

If they were paid, they would have a better standard of living and fewer health problems. They themselves would buy their own safety materials, or even have health insurance. A lot of waste pickers are homeless. If they were paid for their services, they wouldn't be living on the street.

So, this is the point where we changed our intervention."

Lesson 2: Working with ecosystem resources

Based on the experiences of entrepreneurs working with I/As and health and social care systems to produce responsible health innovations, we now know that:

- ⇒ While traditional I/As frequently support for-profit organizations and socially oriented I/As frequently support non-profits, socially oriented I/As are as efficient as traditional ones (12).
- ⇒ I/As supported non-profits only at the late-stage of venture maturity when survival rates are lower, while for-profits were supported at earlier stages when the rate of failure is lower (12).
- ⇒ Power relations within the health and social care system affect the diversity of stakeholders (managers, providers, patients, caregivers) with whom entrepreneurs may work (13).
- ⇒ The needs and problems brought to the attention of entrepreneurs depend upon who contributes to the design process, which in turn influences who will benefit from the use the innovation (13).

Lesson 3: Responding to supply and demand side policies

To respond to supply and demand side policies, we have learned that (8):

- ⇒ Public health and social care systems must demand the innovations they need, and policies must support this demand as a legitimate lever for health innovations.

Lesson 4: Investing in responsible health innovations

Our research shows that the SF community has the ability and skills to invest in responsible health innovations as key SF principles clearly align with the 5 RIH value domains (14).

See the **figure on the next page** to learn about these important SF principles.

Example of working with I/As

"In 2018, we worked with a social business accelerator, in 2019 we had 2 programs for impact businesses, and we now work with an acceleration program focused on NGOs.

We like it because new knowledge comes to us from people who are always in contact with social organizations, who have similar challenges."

Example of working with health care systems

"We often discussed with physicians to clearly identify the problem. For example, we wanted to replace antibiotics, and when discussing with physicians, we realized that it would be very difficult to change habits and protocols.

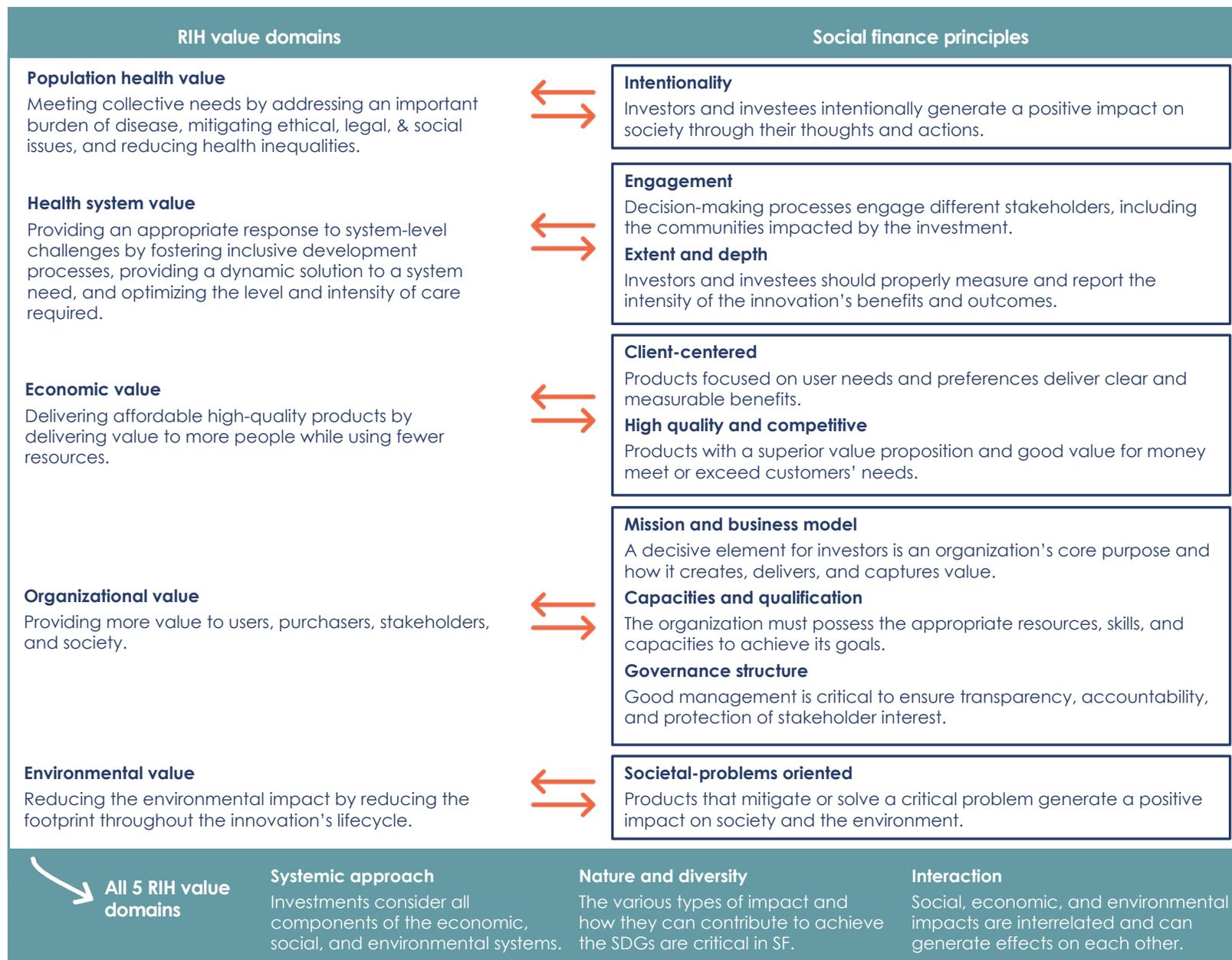
There was very little chance that physicians would put the lives of their patients at risk; they will always be very conservative in their treatments. So, it definitely shapes what we do."

Example of responding to supply and demand side policies

"A national prevention strategy on dementia has now passed. For us, the recognition of the issue and a concrete plan to move forward has opened a lot more access to funding.

It has also allowed some of our partners who are less on the medical side of things to better understand the race that the country is in to deal with the cost of individuals with dementia.

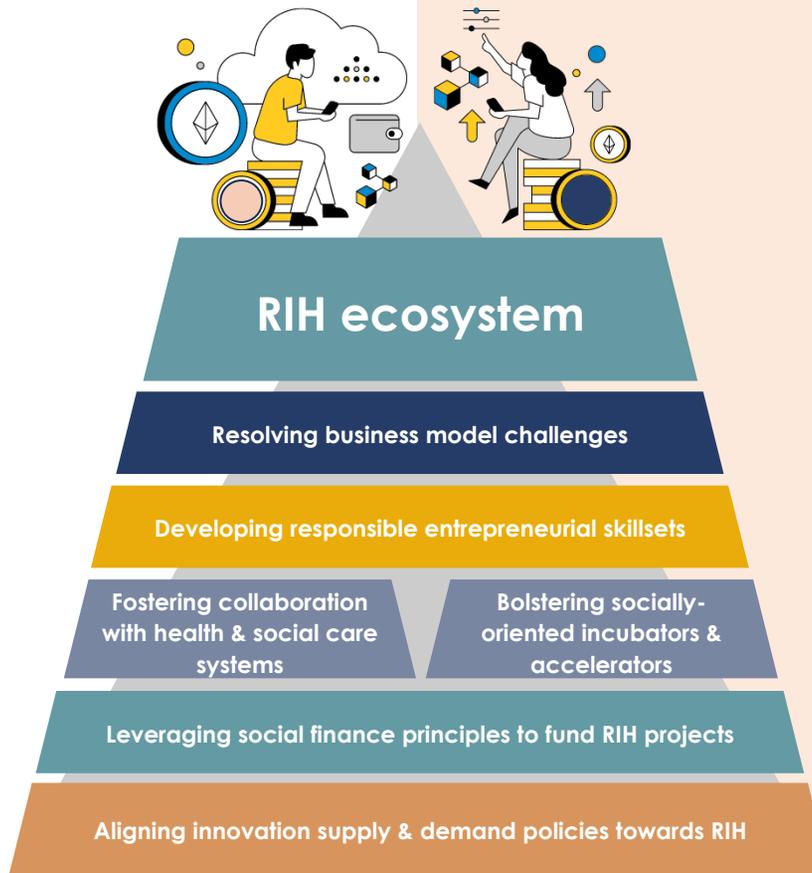
So, the government support is fairly impactful in helping us to better explain our mission around dementia."



How do these lessons scaffold RIH?

As we can see in the figure below, each lesson-learned to solve business model challenges, to identify skillsets, to work with I/As and health and social care systems, to respond to supply and demand policies, and to invest in responsible health innovations provides key elements to scaffold an RIH ecosystem.

The following section details each of these elements with action points and worksheets that will equip different health innovation stakeholders to scale the RIH ecosystem.



Scaling an RIH ecosystem



What are the action points to scale an RIH ecosystem?

This final section provides key action points and worksheets for health innovation stakeholders to scale an RIH ecosystem that can deliver responsible health innovations.

Resolving business model challenges

Entrepreneurs can resolve business model challenges by (15):

- ⇒ Obtaining support that is adapted to the value proposition, organizational capacities, and contributions to responsible value networks.
- ⇒ Considering responsibility throughout multiple stages, from the initial design of the value proposition and its business model to the mapping activities, resources, and capabilities that will be needed in both the short- and long-term.
- ⇒ Considering the business model challenges through a multilevel approach:

Individual level: analyzing entrepreneurial strengths and weaknesses and realigning business model components to uphold a responsible value creation mission;

Organizational level: promoting a supportive work environment for staff, implementing inclusive organizational processes to foster a shared culture of responsibility, and realigning organizational activities towards responsible value creation;

Network level: adopting a collaborative mindset to obtain the knowledge, resources, and collaborations needed to produce and scale responsible health innovations.



REFLECT



DISCUSS



DO



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Worksheet

- How might you resolve your business model challenges at the individual, organizational, and/or network levels to create responsible value?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.

Developing responsible entrepreneurial skillsets

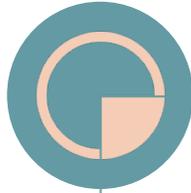
Entrepreneurs, innovation managers, investors, and policymakers can contribute to the development of responsible entrepreneurial skillsets by (19)

Entrepreneurs



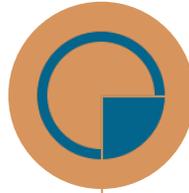
Complementing technical skills with socially oriented skills to be able to apply inclusive design processes and develop a stakeholder-centered business model.

Managers



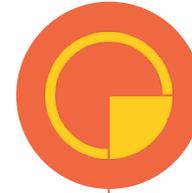
Supporting technical and socially oriented skill complementarity at the team-level.

Investors



Avoiding a traditional narrow focus and supporting entrepreneurs to obtain the diverse skills needed to achieve both economic and social impact goals.

Policymakers



Adapting policy instruments to help scale the skillsets needed for responsible value creation.



REFLECT



DISCUSS



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Worksheet

- How might you develop a responsible entrepreneurial skillset to include ordinary, dynamic, and socially oriented capabilities?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.

Fostering collaboration with and within health and social care systems

Healthcare managers can support inclusive design processes, increase responsiveness to system-level challenges, and adjust the level and intensity of care required by an innovation in the following ways (13).

Support inclusive design processes by:

- ✓ fostering onsite interactions between innovators, clinicians, researchers, all categories of healthcare managers, patients, caregivers, and citizens;
- ✓ providing all user groups with the time, space, and means to articulate the problems to be addressed by the innovation;
- ✓ mitigating the power relations that impede inclusive design processes;
- ✓ developing appropriate protocols to meaningfully engage with vulnerable patients or caregivers in design processes.

Increase responsiveness to system-level challenges by:

- ✓ relying on data to clarify the importance of challenges in terms of demography, epidemiology, human resources, service delivery, knowledge, and governance;
- ✓ creating a unique point of entry for innovators where they can be referred to relevant interfacing teams and obtain support;
- ✓ assembling interdisciplinary teams to explore with innovators “what the demand is” without “killing” novel ideas too quickly;

Adjust the level and intensity of care required by an innovation by:

- ✓ identifying general practitioners' and community care providers' obstacles to attend to patients' needs;
- ✓ identifying how innovations may easily integrate patient pathways and clinical workflows;
- ✓ anticipating how care practices at all levels may be affected by an innovation;
- ✓ measuring the health and well-being benefits deriving from innovation-based activities that purposefully integrate groups with particular needs.



REFLECT



DISCUSS



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Worksheet

- How might you collaborate with health and social care system actors to: 1) work with everyone who should be in on the project; 2) find a relevant solution to an important need; and 3) target the right users?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.

Bolstering socially oriented incubators/accelerators

To strengthen the capacity of I/As to support responsible health innovations that aim to generate positive social impacts, I/A managers and policymakers can (12):

I/A managers



Adopt mechanisms to assess I/A performance and adapt to the needs of start-ups producing RIH.

Pay special attention to non-profit ventures as they face different challenges but hold a great potential to produce innovative solutions to complex societal challenges.

Policymakers



Revisit health innovation strategies to foster investments in I/As that can account for the intensity, duration, and impacts of the support they bring to RIH-oriented ventures.

Aligning innovation supply and demand side policies towards RIH

Policymakers can develop a comprehensive mission-oriented policy approach to RIH by aligning health priorities with innovation-led economic development. Action points include (8):

- ⇒ Identifying the misalignments between health innovation steering and absorbing policies and determining which instruments reinforce health inequalities or stimulate the oversupply of low-value innovations.
- ⇒ Working with public and private actors to consolidate a clear alignment for RIH.
- ⇒ Orchestrating efforts across governance levels to develop an integrated vision for RIH accompanied by performance indicators.
- ⇒ Making explicit the way risks and rewards of innovation are shared between public and private sectors.



REFLECT



DISCUSS



DO



SHARE

Worksheet

- How might you bolster the capacity of socially oriented I/As to properly support RIH entrepreneurs and organizations?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.



REFLECT



DISCUSS



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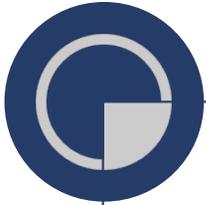
Worksheet

- How might you better align innovation supply and demand policies to support the RIH ecosystem?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.

Leveraging social finance

Finally, entrepreneurs, investors, and policymakers can leverage social finance to properly fund and support RIH-oriented projects in the following ways:

Entrepreneurs



Improve your financial literacy.

Identify SF investors aligned with your practices and purposes and who can effectively help you address the challenges faced by organizations developing RIH.

Investors



Address the shortage of investment-ready deals that offer financial returns and social impact.

Address the challenges in measuring the effect of impact investments.

Policymakers



Facilitate SF by using a range of policy instruments, including:

- Infrastructure projects
- Regulations
- Supportive legislation
- Credit guarantees
- Tax credits
- Direct provision of seed capital.



REFLECT



DISCUSS



DO



SHARE

Worksheet

- How might you help to leverage social finance tools and mechanisms that can offer the long-term financial support RIH projects require?
- Who might be other key stakeholders to involve in discussing this issue?
- Identify key insights from your discussions and transform them into action points.
- Collaborate with other ecosystem stakeholders to implement your best ideas.

Conclusion



This playbook summarized the key lessons we learned through interviews with SF experts and our 4-year research on 16 SMEs in Brazil and Canada. These enterprises succeeded in producing health and social care innovations with key elements of responsibility.

We encourage readers who would like to follow their footpath and contribute to build a health innovation ecosystem that generates equitable and sustainable health innovations to consult the following resources:

RIH tools to get you started

Responsible Innovation in Health: Concepts and tools for sustainable impact

This short [book](#) provides the tools for health innovation stakeholders to work with the RIH attributes throughout the innovation's lifecycle, and includes:

- ✓ A design-thinking tool
- ✓ A design brief
- ✓ A design and management toolbox

Advocacy for Responsible Innovation in Health

This [illustrated booklet](#) briefly explains what is RIH for innovation ecosystem stakeholders and shares inspiring real world examples.

The RIH Assessment Tool

This [Tool](#) (and its [user guide](#)) assesses the degree of responsibility of a health or social care innovation using the 9 RIH attributes. It is a tool for people who possess research skills and can retrieve and critically read scientific literature.

Responsible D/AI Solutions Tool

This [Tool](#) is an adaptation of the RIH Assessment Tool to assess the degree of responsibility of digital health or social care innovations that operate with or without artificial intelligence (AI). The tool includes the 9 RIH attributes as well as 5 attributes that specifically target the responsibility issues raised by digital and AI solutions in health.

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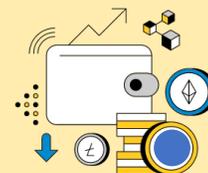
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The research behind this playbook



This playbook shares the results of two studies. The first is a 4-year case study conducted with 16 SMEs producing health and social care innovations in Ontario, Quebec, and Sao Paulo State (Brazil). The study aimed to better understand why and how innovative SMEs that possess responsibility characteristics can develop responsible health innovations.

Description of the innovations produced by the 16 SMEs

Patient and caregiver tools

- ✓ Dementia-friendly illustrated books and app
- ✓ Online community to support informal caregivers that provides content and referrals
- ✓ Web-based directory of buildings accessible to people with reduced mobility
- ✓ Illustrated books clarifying complex terms and treatments for children with cancer

Diagnostic and research tools

- ✓ Platform producing high-quality, low-cost eco-responsible antibodies (using chicken eggs)
- ✓ High-quality affordable diagnostic test for indeterminate thyroid nodules
- ✓ Affordable portable smartphone device to support non-mydriatic eye fundus examinations
- ✓ Affordable tablet-based solution that makes hearing tests more accessible

Mobile care

- ✓ Mobile care units for patients living in underserved areas

The second study was conducted with 15 social finance investors from Quebec, Ontario, and Sao Paulo State. The aim of the study was to better understand what criteria these investors use to select impact-oriented projects, how they define an impactful project, and what principles they consider important in social finance.

Multidimensional interventions

- ✓ Sustainable lighting solutions made of plastic bottles, solar panels, and LED lamps
- ✓ Multidimensional intervention to improve safety and economic conditions of waste pickers

Technical aids

- ✓ Affordable hearing aids using rechargeable batteries and solar-powered charger
- ✓ Cloud-based platform and 3D printing of affordable assistive devices for children
- ✓ Robotics and digital components that control a wheelchair through users' facial expression

Nutritional supplement

- ✓ Cooking tool made of cast iron that dissolves in boiling water to reduce iron deficiency

Sustainable drug packaging

- ✓ Set of eco-friendly pharmaceutical packaging solutions for distributors and retailers

About the authors

Pascale Lehoux completed a bachelor's degree in Industrial Design, a PhD in Public Health (Université de Montréal), and postdoctoral studies in Science & Technology Dynamics (University of Amsterdam).

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She was awarded the 30th anniversary medal of the Canadian Agency for Drugs and Technologies in Health (CADTH) and the 2022 Peggy Leatt Award from the University of Toronto for her achievements in developing transformative health system evidence.

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Her multidisciplinary background has led her to conduct a broad scope of research and consultancy projects in education, international development, gender, physical activity, and mental health in Africa, Southeast Asia, and Canada.

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