

STRATEGIC GUIDE

Steps for supply and demand actors to consider when innovating in the Silver Economy sector in Belgium, France, the Netherlands and the UK

Silver Economy Accelerating Strategies (SEAS) 2 Grow

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Executive Summary

This Strategic Guide is a tool to help companies and other organisations (e.g. housing, health and care providers and local authorities) be more efficient and successful in developing, commercialising, using, commissioning and/or purchasing innovative products and services that improve the quality of life and independence of elderly people, i.e. Silver Economy innovations. In this way, it aims to accelerate closing of the gap between a) unmet needs and demand, and b) supply of solutions that meet these needs and demand. The guidance is particularly pertinent to actors based in or targeting the Belgian, French, Dutch and UK markets. It complements and builds on a number of activities, reports and tools produced by the EU Interreg-funded SEAS 2 Grow project since 2016.

The Strategic Guide is structured in four parts:

- 1. An introduction to the Silver Economy and SEAS 2 Grow project
- 2. A step-by-step guide for supply actors
- 3. A step-by-step guide for demand actors
- 4. Case studies of companies receiving SEAS 2 Grow project support to progress towards cross-border market readiness.

The two step-by-step guides themselves comprise four chronological stages spanning the full lifecycle of an innovation and mapping onto industry-standard Technology Readiness Levels (TRL):

- 1. Concept & Design (TRL 1 3)
- 2. Prototype & Validation (TRL 4 6)
- 3. Market introduction (TRL 7 8)
- 4. Post-market (TRL 9)

Each step provides general information as well as information, tips and contacts, specific to Belgium, France, the Netherlands and the UK. The major lines of content of the step-by-step guides are summarised in the figure below (figure available enlarged on <u>page 10</u>).

Supply side: How to develop and commercialise an innovation? Page 11 • Validate the needs of end-users • Understand and analyse the market and industry ecosystem • Codevelop the user specification • Benchmark against competitors and assess Freedom to Operate • Identify target customers and route to market and assess willingness-to- pay • Identify marketing position • Demonstrate technical proof-of-concept, where necessary • Prepare initial business plan and seek funding	Concept & Design (TRL 1 – 3)	Demand side: How to identify and adopt solutions that meet your needs? Page 30 Recruit an Innovation Manager / team Identify and articulate needs Search for products and services meeting your needs Inform the market of your remaining needs Participate in co-creation sessions
Page 18		Page 32
 Build the prototype Gain approval to test the unregulated prototype Test the prototype in real-world conditions to refine its design and functions Protect your Intellectual Property / submit a patent Gain regulatory approval (CE mark) Adhere to additional national requirements 	Prototyping & Validation (TRL 4 – 6)	 Test prototypes Negotiate commercial basis of involvement, e.g. discounted early adopter fee, future sales channel, etc.
Page 21		Page 33
 Elaborate the business plan, including market expansion Develop the supply chain Increase reputation and brand awareness, including collecting evidence of real-world benefits (cost-saving, added quality-of-life potential) Enter the full market, including eligibility for reimbursement 	Market introduction TRL (7 – 8)	 Contribute to collection of evidence of real-world evidence of benefits, including cost-saving and added quality-of-life potential Influence go-to-market strategy Prepare for innovation implementation: training, monitoring
Page 29		Page 35
 Regulatory post-market surveillance Bring in more business, including via public tenders and preparing capacity Enter new markets 	Post-market (TRL 9)	 Cycle of appraisal of existing solutions and search for next-generation solutions

1) Glossary

Silver Economy	Sector focusing on providing the aged population with products or services that improve their quality of life and support their independence		
InnovationA new product that has the potential to bring significant improvement to the of life and/or independence of an elderly person.			
Supply actor	Companies developing and/or selling innovations		
Demand actor	 Individual, company or organisation using, commissioning or purchasing innovations, including: Housing, health and care providers Local authorities and other local government organisations Elderly people and their friends and family 		

2) Reading this Guide

Major purpose of this Guide: A tool to help supply and demand actors better manage innovation in the Belgian, French, Dutch and UK Silver Economies. In the case of <u>supply actors</u>, this Guide provides information that will help to increase and speed up the likelihood of developing and commercialising successful Silver Economy innovations. In the case of <u>demand actors</u>, this Guide provides information about how best to identify, adopt and benefit from innovations.

This Guide achieves this purpose by:

- Splitting the innovation lifecycle into 4 stages: 1. Concept & Design, 2. Prototype & Validation, 3. Market Introduction, 4. Post-market
- Providing general information about Silver Economy innovation, as well as content specific to each national market
- Providing useful tips, information and potential contacts at each innovation stage
- Presenting guidance for supply and demand actors separately.

This Strategic Guide focuses on <u>collective demand actors only</u> (housing, health and care providers, and local authorities and other local government organisation). For information about individuals as demand actors (individual elderly people and their friends and family, i.e. B2C business model), please consult other publications and resources from this project, namely the <u>Market Study</u> and <u>Route-to-market tool</u>.

Benefits to reading this Guide:

If you are a <u>supplier</u> of Silver Economy innovations, this Guide will help you understand how to:

- Validate the needs of end-users for your innovation
- Co-develop a fit-for-purpose and desirable solution
- Benchmark your innovation against the competition
- Identify target customers, routes to market and marketing position
- Calculate the business potential
- Prepare a business plan and win R&D grants and investment
- Protect your Intellectual Property
- Gain regulatory approval to market your product in the EU
- Collect evidence of the benefits (including cost-savings potential) of your innovation

- Strengthen your reputation and brand awareness amongst target customers
- Go to market, including building the supply chain (manufacturers, distributors, etc.)
- Generate business, including through public tenders and in new markets
- Grow the business, including sourcing high-quality employees

If you are a <u>consumer or purchaser</u> of Silver Economy innovations, this Guide will help you understand how to:

- Build up an effective innovation capability internally
- Identify and articulate your needs
- Search for products and solutions that meet your needs
- Inform the market of your remaining needs
- Build strategic partnerships to progress the development of an innovation (including in exchange for equity share or royalty payments)
- Contribute to innovation development, e.g. co-creation
- Evaluate how well an innovation meets your needs
- Build your reputation as an innovative, forward-thinking provider
- Influence the commercialisation of an innovation
- Monitor real-world performance of an innovation

How to read this Guide

The following 4 pages define and describe the Silver Economy and SEAS 2 Grow project – the project from which this Guide has emerged. Readers may then wish to jump to the section that is of most interest to them:

- <u>Supply actors</u> full innovation lifecycle beginning on page 11:
 - page 11 for suppliers of Concept & Design stage innovations
 - o page 18 for suppliers of Prototype & Validation stage innovations
 - o page 21 for suppliers of Market Introduction stage innovations
 - page 29 for suppliers of Post-market stage innovations
- <u>Demand actors</u> full innovation lifecycle beginning on page 30:
 - o page 30 for demand actors with interest in Concept & Design stage innovations
 - o page 32 for demand actors with interest in Prototype & Validation stage innovations
 - o page 33 for demand actors with interest in Market Introduction stage innovations
 - page 35 for demand actors with interest in Post-market stage innovations

These four stages of innovation map onto the Technology Readiness Level (TRL) metric in the following way:

TRL	Description	Stage in Guide	
1	Principles postulated and observed but no experimental proof available		
2	Concept and application have been formulated	1: Concept & Design	
3	First laboratory tests completed; proof of concept		
4	Built in a laboratory environment ("ugly prototype)	2: Prototype & Validation	
5	Tested in intended environment		
6	Tested in intended environment close to expected performance		
7	Operating in operational environment at pre-commercial stage	3: Market Introduction	
8	Manufacturing issues resolved		
9	Technology available for consumers	4: Post-market	

3) Introduction to the Silver Economy

It is well-known that ageing populations are creating significant challenges for European societies. But from these challenges come the opportunity and incentive for innovation and improvement, i.e. the Silver Economy.

a) What is the meaning of the term: "Silver Economy"?

The European Commission's 2015 paper <u>"Growing the European Silver Economy"</u> defines the Silver Economy as:

"The existing and emerging economic opportunities arising from the public and consumer expenditure related to population ageing and the specific needs of the population over 50."

It divides the ageing population into 3 groups: 1. active, 2. frail and 3. dependent.

b) Key sector indicators

The European Union (EU), and indeed the global, population is ageing. The following figures, which are taken from the report <u>"The Silver Economy"</u> by the European Commission, put into perspective the potential of the EU Silver Economy market, its key challenges and how it is structured.

i) Overall market statistics

The EU Silver Economy sustains / generates (2015 figures):					
199 million	€3.7 trillion	€4.2 trillion	78 million		
people aged 50+ (39% of total population)	of goods and services	of GDP	jobs		

By 2025, the Silver Economy is expected to contribute €5.7 trillion to Europe's economy. If ranked as a sovereign nation, the Silver Economy would be the third largest economy in the world, behind only the USA and China.



Figure 1: Distribution of Silver Economy private consumption expenditures in the EU, 2015

While the Silver Economy accounts for over 53% of all EU health and care expenditures, health accounts for only 5% of total private expenditures by this demographic. This may be because healthcare is mostly publicly funded in many EU countries.

ii) Noteworthy sectors

Market sizes of noteworthy Silver Economy sectors:				
Connected Health (mHealth, eHealth, telemedicine, wearables)	Robotics	Tourism & Leisure	Assistive Technology	
С, Ц			Ċ	
€200B by 2020 globally	€14M in EU in 2016, but growing rapidly	€110B globally	€15.5B globally by 2019	

c) EU policies

It is the responsibility of EU member states, not the EU, to take political steps towards tackling the challenges of an ageing population. The EU acts more as a catalyst, enabling and promoting support structures, initiatives, innovative solutions and strategic thinking. The European Commission's initiatives and actions around the Silver Economy fall into 3 main groups:

- promoting innovation focused on supporting ageing and independent living
- progressing towards prevention of ill-health and care needs of our elderly
- identifying solutions and tackling the challenges (economic, social, demographic, health) of an ageing population

Specific examples of these initiatives and actions include:

- Europe 2020 Strategy
- eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century
- European Year for Active Ageing and Solidarity between Generations 2012
- <u>Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME)</u>
- Health for Growth: 3rd EU health programme (2014-2020)
- <u>Horizon 2020</u>
- New European Commission project on Silver Economy
- European Lifelong Learning Programme
- Seventh Framework Programme (FP7) for Research and Technological Development (2007-2013)
- Health Strategy 2008-2013
- Innovative Medicines Initiative (IMI)
- Competitiveness and Innovation Framework Programme (CIP)
- European Employment Strategy
- Digital Agenda for Europe eHealth and Ageing (2014-2020)
- <u>European Disability Strategy 2010-2020</u>
- Active Ageing Index (AAI)
- European Innovation Partnership on Active and Healthy Ageing (EIP AHA)

4) SEAS 2 Grow project background

The Silver Economy Accelerating Strategies (SEAS) 2 Grow project (2016-2020) is an Interreg 2 Seas project partfunded by the European Regional Development Fund – a fund allocated by the EU. Its fundamental aim is to provide new tools, methods and services that accelerate the development, marketing and adoption of innovation in the Silver Economy in the 2 Seas area (see Figure 2). This shall be for the mutual benefit of all stakeholders in the Silver Economy, including companies, local authorities, housing, health and care institutions, and elderly people and their friends and family.



Figure 2: Interreg 2 Seas area (shaded in light blue), which comprises coastal areas of Belgium, France, England, and the Netherlands along the North Sea and the Channel.

Specific ways in which this fundamental project aim is being met include:

- By raising understanding of the market and regulations throughout the 2 Seas Region
- By fostering cross-border collaboration
- By bringing innovative solutions to market
- By helping companies develop abroad
- By closing the gap between Offer and Demand (collaboration between industry, start-ups, care institutions, local authorities, etc.) so that unmet needs are reduced or solved.

These objectives are being met through three main work packages:

Workpackage 1: Mapping the current Silver Economy Ecosystem in the 2 Seas area, and defining a Strategic Vision for this sector

Workpackage 2: Creating a **Cross-Border Accelerator** to co-create and test Silver Economy innovations in the 2 Seas area. The SEAS 2 Grow Accelerator, AgeTech, sources innovative projects in the 4 countries via dedicated calls for projects and helps them to develop with tailored living lab services and matchmaking

Workpackage 3: Designing and testing innovative **Funding and Financing Schemes** to support Silver Economy growth in the 2 Seas area, in particular related to the cross-border accelerator.

Together, SEAS 2 Grow is helping to create the market conditions and providing the resources and bespoke support for suppliers to enter the Silver Economy market and meet the needs of demand actors sooner and better.

Project partners span each country in the 2 Seas region:

- Belgium: LiCalab (living lab for innovations in living and care and coordinator)
- France: **Clubstersanté** (network of companies in the health sector promoting networking, mutualising and information sharing); **Eurasanté** (not-for-profit agency supporting technology transfer and business development of Life Sciences companies); La Vie Active (public-interest organization providing residential care services and supporting co-creation of innovations)
- England: Allia (not-for-profit organisation with expertise in property, enterprise support and business incubation centres); Anglia Ruskin University (academic institution with expertise in the technical, clinical, business and health and social care dimensions of Silver Economy innovations)
- The Netherlands: Smart Homes (expert centre in home automation and smart living); Care Innovation Center West-Brabant (living lab supporting businesses and organisations in the health, welfare and care sector by testing and validating their innovations with end users; tanteLouise (home care, assisted living, care, nursing and supplementary services provider).





a) Strategic Guide purpose

This Guide is a tool to help supply and demand actors better manage innovation in the Belgian, French, Dutch and UK Silver Economies. In the case of <u>supply actors</u>, this Guide provides information that will help to increase and speed up the likelihood of developing and commercialising successful Silver Economy innovations. In the case of <u>demand actors</u>, this Guide provides information about how best to identify, adopt and benefit from innovations.

This purpose is achieved by:

- Splitting the innovation lifecycle into 4 stages: 1. Concept & Design, 2. Prototype & Validation, 3. Market Introduction, 4. Post-market, which map onto TRL levels 1 3, 4 6, 7 8 and 9, respectively.
- Presenting guidance for supply and demand actors separately.

A summary of the topics covered, with the corresponding page of this Guide, is presented in Figure 4. Readers may wish to jump to the page of most interest to them.

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Page 29		Page 35
 Regulatory post-market surveillance Bring in more business, including via public tenders and preparing capacity Enter new markets 	Post-market (TRL 9)	 Cycle of appraisal of existing solutions and search for next-generation solutions

Figure 4: Themes covered within this Guide, separated by supply and demand actors and innovation stage of development (1. Concept & Design, 2. Prototype & Validation, 3. Market introduction, 4. Post-market).

5) Step-by-step Guide for Supply actors

a) Concept & design

The importance of the work conducted in progressing an "idea" into a business proposition should not be underestimated. This work needs to attract the necessary interest, commitment and perhaps even funding to enable physical development, i.e. to build a prototype in stage 2. As shown in Figure 5, "doing your homework" in these early months / years means you are less likely to waste significant time and money later on, for example, pursuing a market that cannot support reimbursement of your product or developing a feature that adds little value to your target end-users. Laying a strong foundation in this early stage will increase and speed up your likelihood for success in the market in future years.



Figure 5: Benefits of following the steps described below in the "<u>Concept & Design</u>" stage, before the prototype (Minimum Viable Product, MVP) is built.

i) Validate the needs of end-users

The first thing to do when you have an idea for an innovative product or service is check that it would actually be useful or desirable to some people, i.e. that it **meets a need** that they (may or may not realise that they) have. An innovation arising out of significant "demand pull" is more likely to be successful than one arising out of "supply push". This is because there is an already expectant market waiting to buy the innovation, if it does indeed prove to meet their needs; they do not need to be persuaded that they need it.

As a very first step, it is enough to **informally talk to lots of people** who you think might be your target endusers. You can likely access these people through existing family, friends, neighbourhood and recreation links. If you are concerned this might expose your idea, ask people to sign a short non-disclosure agreement (NDA). After informally speaking to about 20 people who you would consider your target end-users, you will have a better understanding of **how attractive your idea is** to them. If the informal feedback indicates that the idea is not as attractive as you were expecting, this may be because your thinking on the target end-user group is wrong, in which case you may wish to repeat this exercise. You might also wonder if your idea might be more attractive in a different cultural context, for example where family take more / less responsibility for caring for elderly family members¹. Ultimately, you will need to answer the question **"Are they willing to take the risk of investing more time and resources to explore your idea further?"**

ii) Understand and analyse the market and industry ecosystem

You should first gain a basic understanding of the market you wish to enter through **desktop research**. The SEAS 2 Grow <u>Market Study</u> and <u>Route-to-market tool</u> are good starting points to help you answer the following questions. They include links to external resources with more detail.

- Who are the Silver Economy stakeholders, and which **segment** do I consider to be my target end-users?
- What is the evidence that they have an unmet need and that my idea could meet this need?
- Where are these people **located**? At home, in nursing homes, in hospitals, etc.? What are the criteria or conditions that determine their location, e.g. total **wealth**, level of **autonomy**?
- What is the **size** of this segment? Is it growing or shrinking in number?
- Who are the actors surrounding these end-users? Which ones could have **motivations and means to be my customers**?
- What are the **exact mechanisms by which these customers could pay** for my product or service? Would it require my product or service to be listed on a nationally approved framework for reimbursement? Is there a single decision-maker for making these sorts of purchases, or will it involve bureaucracy?
- What is the supply chain supporting sales to these customers?
- What are the wider economic, social, environmental, cultural and/or political challenges which are influential in creating the opportunity, such as incoming regulations?
- What are the **networks and other points of access** to these end-users and customers?

A key message from the Market Study is there is less familiarity with the term "Silver Economy" in Belgium, Netherlands and UK compared to in France. **Only in France is there a formal and specific Silver Economy** set up by French government ministers to increase and aggregate fields of activities dedicated to adapting and proposing products and services for the elderly population.

It is unlikely that you will be able to find all the market information and answers you require on your own. The next step is to **become part of the industry ecosystem** so that you can attend industry events, access experts, and learn from your peers. Networks that you should consider joining in the four countries include (note that some are sector-specific, e.g. for food innovations only):

Health and Care	• <u>Eurasanté</u>	<u>Care for Innovations</u>	• <u>South East Health</u>
Network Kempen	<u>Clubster Santé</u>	Life Science and	Technologies
• <u>LifeTechValley/</u>	• <u>Silver Valley</u>	Health Cluster	<u>Alliance</u>
HappyAging	NHL cluster	Medical Delta	<u>MedilinkUK</u>
<u>Care Innovation</u>	• Picom	Health Valley	• <u>MedCity</u>
Cluster Aalst	Cluster Senior	Health Innovation	• <u>digitalhealth.London</u>
Blue Health		Park	• <u>TechUK</u>
Innovation Centre			

¹ To gain an understanding of these attitudes across OECD countries, please read: <u>"Help Wanted? Providing and Paying</u> for Long-Term Care: Chapter 3, The Impact of Caring on Family Carers" OECD 2011

VOKA Flemish Health	Healthy Ageing British Healthcare
	Network Trades Association
<u>Community</u>	
• <u>BEHealth</u>	<u>Netherlands</u>
<u>Community</u>	<u>ROMs</u> are regional
	development
	companies - one in
	each province.

Table 1: Networks for innovators to join

If you wish to receive extensive support, such as an objective appraisal of the market for your specific product or service idea, you may opt for **expert consultancy**. In addition to <u>AgeTech Accelerator</u>, which is run by the SEAS 2 Grow partners spanning all four countries, the following organisations can also offer this consultancy:

VOKA Flemish Health		• <u>Seijgraaf</u>	• <u>South East Health</u>
<u>Community</u>	• <u>KPMG</u>	 <u>Crefact</u> VLAIO 	<u>Technologies</u> Alliance

Table 2: Consultancies offering expert market research support

iii) Co-develop the user specification

You will now have a refined understanding of who your target end-users and customers could be. The next stage is to **validate their needs in a formal way**, via online market research, structured interviews and/or co-creation sessions. This might also involve actors surrounding or advocating for the end-user, such as nursing home managers, informal carers, charities, etc. The intelligence you gather in this needs validation exercise will lead into co-developing the user specification and defining the value proposition for your future product or service.

In addition to the <u>AgeTech Accelerator</u> team, here are notable organisations that can help you with co-creation activities in Belgium, France, the Netherlands and the UK. All of these organisations have access to these stakeholders and expertise and processes in **human-centred design methodologies**.

Living Labs:	<u>Clubster Santé</u>	<u>GezondeMening</u>	<u>Smart Living</u>
• <u>LiCalab</u>	• <u>Autonom'lab</u>	Zorgbelang	Accelerator
<u>Carelivinglabs</u>	• <u>27 Delvalle</u>	<u>Care Innovation</u>	• Design and Learning
Well-living lab	<u>CIU Santé</u>	<u>Center – House of</u>	Centre for Clinical
Patient organisations:	Medicen	Tomorrow	and Social
Flemish Patient	Forum LLSA	• <u>Smart Homes:</u>	Innovation
<u>platform</u>	Cluster AGHIR	<u>smartest house</u>	<u>VOICE</u>
Elderly organisations:		• <u>iZi-house:</u>	<u>Transform Ageing</u>
• <u>OKRA</u>		experience house	
• <u>Neos</u>			

Table 3: Living labs and other organisations that can arrange co-creation sessions, testing support and expert panels

Ultimately, you should use co-creation sessions as an opportunity to validate:

- a. What is the idea? Is it a product or a service, or both? Where does the concept start and end?
- b. Who are **the end-users and beneficiaries of the project?** What type of seniors? Age, level of autonomy, in residential or nursing homes or in care institution, etc.

- c. Which need is the product addressing? What type of product were the end-users initially looking for regarding this need?
- d. What is the main added value of the solution? What should the product/solution do, enable, or provide? What are the expectations regarding this product? Would end-users be willing to pay to receive this value, and if so, how much?
- e. What kind of gain would the product enable? (Social, economic, etc.)
- f. How much change does this solution require for end-users to adopt it? What kind of training would be required to use the solution?

These co-creation sessions may also provide intelligence on business aspects such as competitors, financial model, routes to market and legal and regulatory constraints. These should be the topics that you focus on next.

iv) Benchmark against competitors and assess Freedom to Operate

It is always important to **know what your competition is**, and so it is a good idea to create a structured competitor database and perform an analysis that is **continually kept up-to-date**. You might be able to find some competitors by searching for specific keywords on the <u>SEAS 2 Grow Map</u>. Other resources available in each country to help you compile this database are provided below. **Only in France is there a publicly available directory dedicated to Silver Economy products and services** (<u>SilverEco directory</u>).

 None specific to the Silver Economy, but general information of specific sectors can be found <u>here</u>. 	 <u>SilverEco directory</u> <u>Innovation Santé</u> <u>Autonomie</u> <u>SolaInn</u> <u>Solutions Bien Viellir</u> 	 <u>Zorginnovatie</u> <u>national platform</u> <u>Villans</u> <u>Hulpmiddelenwijzer</u> <u>Thuisleefgids</u> <u>Huis van Morgen</u> 	 Office of Life Science's Strengths & Opportunities report and databases Living Made Easy assisted living products comparison site Telecare Services Association Directory

Table 4: Resources for conducting a competitor search

You should **also consider indirect competitors**, i.e. solutions that look very different but perhaps still compete with or undermine the functions and value proposition that your future product or service could offer. An example could be that you wish to develop a technology for diagnosing a disease. An indirect competitor here could be a vaccine that stops people from developing the disease in the first place.

Your competitor search should consider solutions **still in development as well as already on the market**. This might mean searching the academic literature e.g. using Google Scholar[©]. If you do find solutions in development, you might wish to consider the pros and cons of partnership with their developers, as this might allow you to reach market sooner or stronger, albeit in exchange for relinquishing future income.

If you do find directly competitive solutions, it does not necessarily mean that you should abandon your idea. In fact, having competitors can be a good thing; people can be afraid or hesitant of brand-new innovations, and this may be more acute if your innovation is the only one available. Being the "First Mover", i.e. the first to get to market, has downsides as well as upsides. It is not unusual to observe "Fast Followers" overtaking First Movers. The important thing is to understand your **Freedom to Operate**.

You may wish to contract a Patent Attorney to perform a **comprehensive patent search** for you. This will give you the reassurance that you will be free to market your product or service in your target markets in the future. If you decide to perform the patent search yourself, you run the risk of missing an important patent. Nevertheless, all the information you require to perform your own global patent search is publicly available at sites such as <u>Espacenet</u> and <u>Patentscope</u>. The national databases are <u>BE National Patent Register</u> (Belgium), <u>French Patent Database</u> (France), <u>NL Patent Register</u> (Netherlands), <u>Ipsum</u> (UK).

If you do find directly competitive solutions but freedom to operate, you should **gather as much intelligence about your competitors as possible**, so that when you are all in the market, you can persuade potential customers that they should choose your solution instead of competitor solutions. Alternatively, you might decide to target a slightly different customer and end-user base (see "<u>Marketing position</u>" section later), or even a completely different market (perhaps a market that your competitors would face a lot of resistance to enter).

v) Identify target customers and route to market and assess willingness to pay

You will by now, have an understanding about who the customers for your product or service might be. Your customers may be the same as your end-users, or different. If your customers are different from your end-users, e.g. if your product would be bought by a local authority (customer) and prescribed to eligible elderly persons (end-users), it is important that you speak to them, perhaps at **co-creation sessions involving a wide range of stakeholders**. Other stakeholders that should attend are people who might be part of the **supply and value chains, such as prescribers, distributors, resellers, etc.** (see Figure 11). The SEAS 2 Grow Market Study and Route-to-market tool should help you understand the routes to market existing in Belgium, France, the Netherlands and the UK, and therefore which stakeholders you should invite to attend the co-creation session. Detail on these routes is available in the "Enter the market, including eligibility for reimbursement" section.

The purpose of these extended co-creation sessions is to **understand the commercial risks** for your product or service idea. When you know the risks, you can take steps to reduce the likelihood or impact of them occurring during the "Prototype & Validation" stage, e.g. by developing the product so that it falls within a certain categorisation eligible for reimbursement, or simplifying the product so that it can be manufactured at a price the target customers are able and willing to pay. This should help to avoid the situation faced by French start-up Vigilio, which developed the "Vigi'Fall" fall detection system as part of a large European Commission Horizon2020 project. This start-up did not succeed in fully entering the market because its target customers (nursing homes) were facing reduction in budgets by their funders and so could not afford to buy the product.

vi) Marketing position

The way you market your product or service will be **determined by characteristics of your target end-users**. It may seem premature to decide marketing position now, but it will make it easier to recruit people for real-world testing in the "<u>Prototype & Validation</u>" stage, because you can **communicate with them effectively**.

There are four ways to market a product to be used by elderly people:



Figure 6: Options for marketing products and services for use by the elderly.

- 1. Products which are designed for the elderly and with a clear marketing targeting elderly, sometimes with the word "senior" or "ageing" in the name of the product. For instance, "Senioriales" in France, which are residences dedicated to the elderly.
- 2. Products developed specifically for elderly people but can be acquired and used by other consumers even if they are younger. For instance, Oxo, which sells kitchen tools that are easy to use for the elderly but also for everybody.
- 3. Products not developed for the elderly, with no marketing targeting them, but which can be used by all including seniors. Such as cars, e.g. Renault.
- 4. **Products initially not developed specifically for the elderly, but with a marketing targeting the older consumer**. For instance Actimel yoghurts.

Market position number 1 can be risky, because only those elderly who have accepted their status would buy such products. Another option is to focus not on the elderly but on their children or other informal caregivers. **Intergenerational marketing** is often an efficient way to sell products that will be useful for the elderly.

Figure 7: Four ways to market a Silver Economy innovation

vii) Demonstrate technical proof-of-concept

Just as the desktop market research, competitor analysis and co-creation sessions have helped to clarify your commercial risks, you should also use the "<u>Concept & Design</u>" stage to ensure you fully understand the **technical risks you face in trying to develop your product or service idea**. At the very least, you will want evidence that your product or service idea could potentially be manufactured and provide the functions described in the user specification. Ways in which you might assess the technical feasibility include performing a **literature search**, **running experiments using or combining third-party technologies**, and **developing and testing the fundamental programming code or electrical or mechanical mechanism** (but not to the full extent of a prototype or even of a minimally viable product). You can perform a literature review yourself, e.g. using Google Scholar©, or you can contract a specialist firm, such as <u>Crystallise</u> in the UK.

Where specialist equipment or expertise is required, you may need to collaborate with, for example, an **academic institution**. A good way to identify academic collaborators is to identify the authors of any relevant published materials, such as peer-reviewed journal papers (again perhaps by using Google Scholar[©]). You can then search for their contact details on their institution's website.

viii) Prepare initial business plan and seek funding

It is important that all the work that has been carried out during the "<u>Concept & Design</u>" stage is recorded. This will prevent resource being wasted repeating the same research multiple times. It will also provide the content for a business plan – a necessary document when it comes to raising funds to finance the "<u>Prototyping & Validation</u>" stage, which may incur significant cost. The minimum contents of a business plan include:

• Description of unmet need

- Technology overview
 - Plain summary (for public release)
 - o Detailed summary, including any science and existing evidence
 - Description of the innovative / novel step(s)
 - o Expected benefits
 - o Competitor analysis
- Business opportunity
 - o Market description and customer and end-user segmentation
 - Value proposition and value chain
 - Sales and marketing plan
 - Operating plan (partnerships, supply chain actors, dependencies e.g. licenses)

R&D Roadmap

- Mid- and long-term objectives: where are you aiming?
- Short-term objectives
- o Full short-term workplan with Gantt chart
- Funding arrangements
- Delivery team details
- Register of commercial, technical and managerial risks.

Compiling **all the risks** in one document will allow you to make the informed decision about whether you wish to take the next step to developing your idea or not.

If your business plan is particularly persuasive and the risks for you to get to market sufficiently low, you may be able to raise **Angel investment**. Resources that you can help identify Angel Investors are:

- All regions
 - o Angel Investment Network
 - <u>Angel List</u>
- Belgium
 - o Business Angels Network Vlaanderen
- France
 - o Start Up Fundraising in France report from Business France
- Netherlands
 - o <u>Start Up Amsterdam's Investor Database</u>
 - o <u>The State of the Dutch Tech Startup & VC Landscape</u> report
- UK
- o <u>UK Business Angels Association</u> member directory

For most innovators in the "<u>Concept & Design</u>" stage, the usual response from Angel Investors will be to return once a prototype has at least been tested. It is likely that you are too early for crowdfunding also. You may therefore have to rely on **private funds** (including of friends and family) and **grants**. <u>Table 5</u> presents some grants available to innovators in the four countries. Few of these are specific to the Silver Economy, however. Some are thematic, and so the innovator must wait until a competition along a relevant theme is launched.

"Zorginnovatieruimte	<u>SE Innovation Fund</u>	• <u>Amsterdam</u>	Most public-sector
Vlaanderen" was a	<u>Silver Surfer</u> from	Economic Board	grants are
programme focussed	Eurasanté	<u>Utrecht Economic</u>	advertised on the
on 65+ that ran from		<u>Board</u>	gov.uk website
2013 – 2016		<u>SlimmerLeven 2020</u>	• Key funders are:
Flanders Care 2.0			o <u>Innovate UK</u>
sometimes has			o <u>Small Business</u>
grants available			<u>Research</u>
• The Belgian			<u>Initiative</u>
provinces sometimes			o <u>National Institute</u>
provide impulse			<u>for Health</u>
funding			<u>Research</u>

Table 5: Relevant grants

EU sources of grant funding to consider are <u>SME Instrument</u> from Horizon 2020 and <u>Active Assisted Living</u> <u>Programme</u>.

b) Prototype & Validation

i) Build the prototype

You are now ready to build the prototype. This prototype should be a **minimum viable product** with only main functionalities and constructed to allow **agile development**, i.e. to be rapidly modified as user feedback is gathered. One way to achieve this is to have modular design, so only one module needs to be modified at once. Building the prototype consistent with **Quality Management Systems** for future CE marking (the "technical documentation" mentioned in the "<u>Gain regulatory approval (CE mark)</u>" section), will save you time later on.

It is a good idea to gain end-user feedback in parallel with building the prototype, i.e. in an iterative fashion. For products that will require CE marking, this co-creation needs to be **carefully controlled so that it does not endanger the tester**. The next section describes the ways to gain approval and a license to fully test an unregulated product. Until that time, you might still be able to collect some useful feedback. For example, you could ask target end-users about **how it looks**, and you could also **demonstrate or simulate demonstrating using the prototype** to gain their feedback on its functional form.

ii) Gain approval to test an unregulated prototype

In order to test an unregulated product in the EU, **dispensation from EU-wide CE marking law** (see later section on "<u>Gain regulatory approval (CE mark)</u>") and Ethics approval may be required. If it is required, strict adherence to a **nationally stipulated process by national certified bodies** is required.

In Belgium, you need approval from a Medical ethical committee. The 25 committees are listed <u>here</u> . Some of these committees have separate clinical trial centres where you can receive support to fill in your application.
Readers are recommended to seek advice on this matter from one of the French organisations listed in <u>Table 3</u> .
In the Netherlands, the kind of permission you need depends on the product, the impact and the risks involved. To obtain permission, you need to go to one of the 23 certified Medische Etische Commissies (METCs). You can find more information from <u>CCMO</u> .
In the UK, you should first check whether your testing classifies as research. The Health Research Authority (HRA) provides a useful <u>tool</u> to do this. If it is considered as research, you next need to determine if approval from a NHS Research Ethics Committee (REC) is required. There is another <u>tool</u> to help you with this. If you do require ethical approval, you will need to complete and submit an IRAS application form and necessary trial documentation to the HRA. The 15 <u>Clinical Research</u> <u>Networks</u> can help you with this. A list of all the RECs and their meeting schedule is available <u>here</u> .
For medical devices, Notice of No Objection is also required from the <u>Medicines and Healthcare</u> <u>products Regulatory Agency</u> (MHRA). There is a fee for this application (which consists of the same IRAS application form and supporting documents as the Ethics Committee).

Table 6: Process for gaining approval to test unregulated products

iii) Test the prototype in real-world conditions

Allowing end-users to test the prototype under real-world conditions will reveal:

- If the original target end-user groups are the right ones
- If the product really **answers the users' needs**
- The time needed for end-users to **adapt / get used** to the product

- Whether some functionalities should be added, deleted or changed
- How else the prototype can be improved.

It will also give you the opportunity to gather information and testimonials from the testers and to start to talk with the potential future buyers where the testing is taking place.

The living lab organizations listed in <u>Table 3</u>, as well as the <u>AgeTech Accelerator</u> spanning Belgium, France, the Netherlands and the UK, can help you deliver **successful and useful real-world tests**. Some questions you (and the living lab) will need to consider before experimentation starts include:

- Who are the **target groups** and how do we **involve them** in the tests?
- What is the optimal **test duration**? (several weeks are often needed)
- What are the features that are still **open to change / cannot change** anymore?
- What are the features to be **tested**?
- How do we capture this feedback / data?
- What is the **threshold** that we should set to indicate that the test was a success? (and to inform a GO decision on go-to-market)

These questions will help identify the **best methodology** for generating the desirable feedback and data. The methodology will then inform the **mechanisms for collecting the feedback and data**. Again the living labs listed in <u>Table 3</u> and some of the networks listed in <u>Table 1</u> can help with this. They may also be able to provide a **panel manager experienced in running objective tests with elderly people in an efficient way**.

iv) Protect your Intellectual Property / submit a patent

By this time, you will have accumulated significant Intellectual Property (IP) that needs to be protected. If applicable, the best way to do this is to **file a patent**. A patent for an invention is granted by a government to the inventor, giving the inventor the right to stop others, for a limited period, from making, using or selling the invention without their permission. The invention becomes the property of the inventor which can be bought, sold, rented or hired. Patents are territorial rights: UK patents will only give the holder rights in the UK and rights to stop others from importing the patented products into the UK, for example.

If you do not protect your IP, you run the risk of:

- Somebody else protecting it, excluding your company from the market or requiring you to pay a licensing fee to enter the market
- Competitors taking advantage of your IP. If a larger company goes to market with your IP, they may take advantage of economies of scale to produce the product more cheaply and invest much more in marketing and advertising than you can, reducing the chances that you have success the market.
- Finding it difficult to license, sell or transfer your IP, meaning you lose out on important revenue.

Filing a patent usually requires the help of a **Patent Attorney**. In addition to the Patent Attorney fee there is an upfront filing fee as well as long-term maintenance fees. The exact cost will depend on for how long you wish to patent the IP, and in how many countries. The following links will help you find a patent attorney:

- Office de la Propriété Intellectuelle (Belgium)
- <u>CNCPI</u> (France)
- <u>De Orde van Octrooigemachtigden</u> (Netherlands)
- <u>Chartered Institute of Patent Attorneys</u> (UK)

Not all forms of IP can be patented. Other ways to protect IP include through **trademark** (for a fee but not requiring the services of a Patent Attorney), to **copyright** (free), and to ask for people and other companies to sign an **NDA** before you disclose any commercially sensitive information to them (free).

v) Gain regulatory approval (CE mark)

The step that usually progresses an innovation from the "<u>Prototype & Validation</u>" stage to the "<u>Market</u> <u>Introduction</u>" stage is gaining **EU and national regulatory approval**. CE marking products allows them to be sold throughout the European Economic Area (34 countries and 500 million consumers). The mark signifies that the product has been **assessed to meet safety, health, and environmental protection requirements**.

The SEAS 2 Grow <u>Route-to-market tool</u> is an interactive tool that will help you understand whether your product requires a CE mark, and if it does, whether it requires Medical Device accreditation too (and as what "Class" of medical device). A summary of this information is provided below.

For most products, **self-certification by the manufacturer** is sufficient. The manufacturer needs to carry out six mandatory steps:

- a. Identify the applicable directive(s) and harmonized for the product type
- b. Verify product specific requirements
- c. Identify whether an independent conformity assessment (by a notified body) is necessary
- d. Test the product and check its conformity (this varies depending on the product type)
- e. Draw up and keep available the required technical documentation that allows the conformity of the product with the requirements of the relevant directive to be assessed at any time it is sold in the EEA
- f. Affix the <u>CE marking</u> and draw up the <u>EU Declaration of Conformity</u> to declare responsibility for the conformity to the relevant directive

For a manufacturer to legally place a **medical device on the European market**, the requirements of <u>Medical</u> <u>Devices Directive 93/42/EEC</u> must be met. The definition of a Medical Device (Article 1(2) (a)) is:

"Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

For medical devices that are sterile and/or have a measuring function (i.e. Class II and above), **third-party certification by a Notified Body is required**. A list of the certified authorities in Europe is available <u>here</u>. More information is available on the European Commission's <u>general information webpages on Medical Devices</u>.

ii) Additional national requirements

EU members can set additional requirements of suppliers in order to enter their market. A good example of this are requirements related to **health data handling and storage** for innovations that require access to or processing of these data (in addition to the EU-wide <u>General Data Protection Regulation</u> (GDPR) requirements).

France

Figure 8 presents the process for suppliers to comply with the French health data hosting laws.



Figure 8: Process for suppliers to adhere to French health data hosting laws

In summary, health data in France need to be hosted by a <u>certified health data-hosting provider</u> according to French health data storage rules. More information on this topic in France is available from <u>ASIP Santé</u> and <u>CNIL</u>.

UK

In contrast, in the UK, suppliers should be compliant with <u>Health and Social Care Network</u> (HSCN) standards and integrate with additional, non-specific security controls.

HSCN is the interoperable data network to be used by health and care providers, supporting data sharing and therefore integration of health and care services. Although HSCN features enhanced security monitoring, it should not be considered "secure". Where patient or sensitive data needs to be exchanged it must be encrypted in transit and the way in which this is done is not specified. Ultimately, the risks surrounding data protection lie with the health and care organisations – it is up to them to employ their own adequate security controls.

c) Market introduction

You may already be able to sell a small number of units to some **Early Adopters**, such as stakeholders who tested your product or service in the "<u>Prototype & Validation</u>" stage. To reach the **market at large**, however, there is more work to do. In fact, the period between CE marking and significant sales can be long, as indicated by the grey "Reimbursement approval" arrow in Figure 9 (specific to the Australian context but a useful case in point).



Figure 9: Time to bring a regulated medical device to full market (grey arrow). Image courtesy of MTP Connect.

i) Elaborate the business plan

You should have prepared an initial business plan during the "<u>Concept & Design</u>" stage; the contents of the plan are described in the "<u>Prepare initial business plan and seek funding</u>" section. This plan will require updating and elaboration to:

- Ensure your **go-to-market plan** (GTM plan) is up-to-date and comprehensive (see Figure 10), including:
 - Plans to build and activate the supply chain that supports you to manufacture, sell, distribute, maintain and support the innovation in real-world use (covered more in the "<u>Develop the supply</u> <u>chain</u>" section).
 - Plans to fill remaining gaps in **internal capacity** (sales team, customer service, relationships manager, post-market regulatory manager, etc.)
 - Plans to apply to be entered onto a **reimbursement framework** (if you are aiming for your product to be available to end-users subsidised by the public sector or an insurance policy covered more in the "Enter the market, including eligibility for reimbursement" section).
- Strengthen your reputation and awareness of your brand / innovation amongst your target end-users and customers (covered more in the "Increase reputation and brand awareness, including collecting evidence of real-world benefits" section). An important outcome of evidence gathering is understanding what value the innovation creates for customers, helping to inform what the pricing strategy should be (both value and format, e.g. one-off fee, annual subscription or pay-per-use).
- Reassure yourself that you have sufficient funds to be able to prepare for and deliver sales before and after revenue begins, i.e. a full **profit / loss balance forecast**, incorporating your pricing strategy.

A complete business plan is the minimum requirement for seeking private investment. Please see "<u>Prepare initial</u> <u>business plan and seek funding</u>" for resources that can help you find an Angel investor.



Figure 10: The elements of a complete go-to-market strategy. Image courtesy of <u>Sketch Bubble</u>.

ii) Develop the supply chain

Figure 11 presents the actors of a full generic supply chain. A supplier should have a good understanding of all the actors that will feature in their supply chain, and build and nurture these relationships. Suppliers can encompass one or more of these roles. For example, a supplier may distribute its products directly, or via an industry specialist distributor. They may choose to have an internal sales and marketing team or outsource this work to an external, specialist sales and marketing provider. In addition, they may offer a service layer to support

their products, e.g. customer services, product installation and maintenance, or they might outsource this too. Stand-alone products may not require a service layer at all.



Figure 11: Generic supply chain actors. Image courtesy of <u>Manufacturing and Technology Enterprise Centre</u>.

The organisations listed in <u>Table 1</u> and <u>Table 2</u>, as well as the <u>AgeTech Accelerator</u>, will be able to advise on major distributors in the four countries. For example, in the **Netherlands**, the main distributors of care tools are:

- Medipoint
- <u>Vegro</u>
- Medicura
- <u>Welzorg</u>
- <u>Vitility</u>

Except for Welzorg and Vitility, all of these distributors have shops and webshops where you can buy, rent or borrow tools and get advice. Welzorg also gives advice about necessary adjustments to standard products.

In the **UK**, many of the members in the <u>Telecare Services Association Directory</u> fulfil the dual role of supplier of their own products and services as well as distributor of other suppliers' products. <u>Tunstall</u> is one such company, and it has 70% capture of the UK telecare market.

iii) Increase reputation and brand awareness, including collecting evidence of real-world benefits

Key to driving sales is having a solid reputation in target markets. Ways to achieve this include:

- Having industry-standard certifications and labels
- Running robust trials to **demonstrate the benefits and outcomes** unlocked by the product or service, reported in and peer-reviewed journal publications
- Gaining approval from national health and care regulators and technology appraisal bodies
- Having persuasive marketing materials and an effective marketing campaign
- Having a renowned "Product Champion", e.g. a widely published and influential geriatrician
- Networking and speaking at trade fairs and conferences
- Publishing thought-pieces in industry magazines, etc.

Industry-standard certifications and labels

In **France**, <u>Afnor</u> is the national organization for standardization. The AFNOR certification "<u>Tested and approved by a panel of Elderly people</u>" implies the product is fit for use. To receive this certification, the product must have been demonstrated at home and analysed by a team of experts, ergonomists and occupational therapists and finally evaluated against the main criteria for purchase.



Figure 12: Afnor certificate

In the **UK**, some customers, such as many local authorities, require suppliers of technologies for the care sector (i.e. non-medical devices) to have a <u>Quality Standards Framework</u> certificate and regular audit.

Trial evidence

You may find that **prospective customers request more evidence** of the potential benefits and outcomes they could expect from using your product or service than you collected in the prototype real-world tests (see "<u>Test</u> <u>the prototype in real-world conditions</u>" section). This may require you to run a carefully controlled trial with the help of trial design methodologists, statisticians, health economists, etc. These experts can help you identify the **optimal study design** (blind / non-blind randomised control trial, longitudinal case-control study, or observational study), and calculate the necessary **study duration**, **sample sizes**, **evaluation points**, etc. to ensure the trial generates the statistically significant results you require. Collecting **quantitative data** and answers to questions derived from an **established methodology**, such as the EQ-5D metric system for measuring quality of life, will strengthen your conclusions. Collecting **qualitative data** will allow you to properly interpret the quantitative results and ensure a human-centric focus prevails.

The living labs listed in <u>Table 3</u>, some of the networks listed in <u>Table 1</u> and the <u>AgeTech Accelerator</u> will be able to signpost you to experts. In the **UK**, the 10 <u>Research Design Services</u> provide free trial design support, and the 15 <u>Clinical Research Networks</u> and the 26 <u>Clinical Trials Units</u> may be able to support running of trials. <u>JB Medical</u> offers specialist medical statistics and health economics support to health and care innovation companies.

Assuming positive trial results, you should publicise them as widely as possible. An excellent way is to publish them in a **peer-reviewed journal paper**. This will raise the credibility of your company and innovation, which should improve sales. Journals to consider include (with impact factors in brackets, where available): <u>Journal of Telemedicine and Telecare</u> (3.046), <u>DIGITAL HEALTH</u>, <u>BMJ Innovations</u>, <u>Journal of Gerontology and Geriatric Research</u> (0.92), <u>Journal of Aging and Health</u> (2.168), <u>Quality on Ageing and Older Adults</u> (0.64).

Appraisals and approvals

In Belgium, <u>FAGG</u> is the federal agency for Medicines and Health Products, which supervises approvals of medical devices that are released on the Belgian market.
In France, there is one certified body empowered to evaluate the requirements of a Medical Device before it enters the French market: <u>LNE G-Med</u>
Readers are recommended to seek advice on this matter from one of the Dutch organisations listed in <u>Table 1</u> or <u>Table 2</u> .
In the UK, medical devices released onto the market are monitored by the <u>Medicines and Healthcare</u> <u>products Regulatory Agency</u> (MHRA). They do not publish guidance about specific products, however. This is the responsibility of <u>National Institute for Health and Care Excellence</u> (NICE), which is fulfilled through three work streams: 1. Medical technologies guidance, 2. Diagnostics guidance, and 3. Medtech innovation briefings. Their purpose is to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies. They include a description of the technology, how it is used, its potential role in the treatment pathway, a review of relevant published evidence and the likely costs of using the technologies. These publications conclude with a recommendation about the extent to which health and care providers should use the innovation. A determinant of this recommendation is the cost-effectiveness (see Figure 13). Anyone can request a medical device be considered for one of three workstreams, but there is a competitive selection process, i.e. only devices supported by the highest quality trials may be selected. NICE has recently published <u>guidance</u> on the evidence required for the NHS to take up digital health solutions.



Figure 13: Cost-effectiveness plane: The occasions when NICE will and will not recommend an innovation.

iv) Enter the full market, including eligibility for reimbursement

The process for getting a product or service onto a **framework that enables commissioners, health and care providers and consumers to be reimbursed for their expenditure** differs between countries, as highlighted by Figure 14. The exact process will depend on the mechanism by which healthcare is funded (e.g. via insurance or free-at-the-point of use) and the type of product or service. For example, some countries reimburse e-health products and services but others do not.



Figure 14: Comparison of time (in months) to gain reimbursement approval in different countries, including in France and the UK. "Patient Access to Medical Devices — A Comparison of U.S. and European Review Processes" Basu et al. (2012)

The SEAS 2 Grow <u>Market Study</u> and <u>Route-to-market tool</u> are good starting points for understanding when and how reimbursement may be available in the four countries. A summary is provided below.

Belgium

<u>(Health)Care</u>: Today, the vast majority of the Belgian population have access to healthcare. To make use of the available medical services, the citizen must meet certain conditions and take the necessary steps to complete **health insurance**. The nationally established fee schedule describes more than 8,000 services that are covered by this compulsory health insurance.

<u>B2C</u>: Reimbursement of care products and services can only (partly) be obtained when these products/services are on the <u>NIDHI list</u> (published by RIZIV).

<u>B2B</u>: Residential care centers, sheltered homes and psychiatric care centers are also reimbursed for products/services on the <u>NIDHI list</u> via sickness funds granted through a third payer scheme. This funding,

among other things, takes in account the number of staff needed to meet the needs of the clients. In the care for elderly, the funding is explicitly linked to their care-dependency level.

<u>Elderly aids</u>: This is a B2C market enabled through **direct sales** to the end consumers, offline as well as online. For the following aids required by elderly people with high dependency needs but remaining in their own home, (part) reimbursement from the sickness and care fund is possible:

- Mobility aids: see <u>NIHDI list</u>
- Personal alarm systems
- Aids for disabled persons: reimbursement is organised by VAPH

Across Flanders there are several **home care shops** operated by the different sickness funds, where elderly people can come into contact with all these types of aids. They can **buy the aids directly or they can rent them** for a certain period of time. These home care shops include:

- <u>https://www.cm.be/diensten-en-voordelen/thuiszorg/materiaal/thuiszorgwinkel.jsp</u>
- https://www.thuiszorgwinkel.be/nl
- <u>http://www.devoorzorg.be/antwerpen/voordelen-advies/dienstverlening/personen-met-handicap/zorg-ondersteuning/Pages/hulpmiddelen.aspx</u>
- <u>http://www.partena-gezondheidshop.be/nl</u>
- <u>https://www.oz.be/gezondheid/oz-shop/onze-winkels</u>
- <u>http://www.lmzorgshop.be/</u>

Household and equipment products, and food products: This is also typically a B2C market and the business model can be either **buy or lease**.

France

<u>Business to Consumer (B2C) products</u>: After CE marking (and Medical Device approval, if necessary), you can ask for reimbursement of your product by **French Social Security**. To be granted, you have to provide a product or a service that is defined as giving a **certain level of services** (SA). This will require consultation with the following organisations, as per the processes presented in <u>Figure 15</u>, <u>Figure 5</u> and <u>Figure 16</u>. Once complete, your product will appear on the <u>List of Produits et Prestation Remboursable</u> (LPPR). This enables consumers to have partial or total reimbursement by the French Social Security.





- <u>CEESP</u>
- ANSM

• <u>CNEDIMTS</u> (Commission nationale d'évaluation des dispositifs médicaux et technologies de santé), which is in charge of medical devices' evaluation for getting reimbursement by the French Social Security

• <u>ANSM</u>: French regulation authority on Drugs & Medical Devices. The agency has 3 main roles: Evaluation, Expertise and Decision (Market authorization approval)

Ministry of Health

Figure 15: Process for gaining reimbursement for B2C products in France



Figure 16: Process for ascertaining level of services provided by a Medical Device, and therefore its eligibility for reimbursement

<u>Business to nursing homes (specific form of B2B) products:</u> If nursing homes are your target customers (because your product is targeting dependent elderly persons or nursing homes directly (daily tools for nursing home staff for instance)), having your product on the LPPR will not help you to sell it, because the French Social Security does not reimburse French nursing homes.

In a nursing home budget, three components are included:

- Care and medical support: for instance nursing staff
- Dependency: for instance incontinence changes, mobility aids, caregiver staff
- Hosting people: everything related to the rent of a room for the elderly person

Departments pay for every expense related to dependency of the elderly person in a nursing home, and by Health Regional Agencies for every expense related to care. The elderly individual pays the hosting expense.

Three types of nursing homes exist in France:

- Public nursing homes, linked to a city or a local government
- Private nursing homes groups non for profit
- Private nursing homes groups for profit

Depending on the type of nursing home, the route-to-market and marketing should be different.

Netherlands

There are **five routes leading to having paying customers** for your innovation in the Netherlands.

- 1. The consumer route
- 2. The care provider route
- 3. The insurance route
- 4. The municipal route
- 5. The national government route.

<u>1. Consumer route</u>: This route has the advantage that you will spend less time, money and energy on persuading different stakeholders, as you can **focus directly on the people who have to use your product**. On the other hand, you are entirely responsible for the financing, promotion and distribution of your product.

This route is expected to become more logical in future years, as **consumers are having to self-finance their care** more and more. It is a particularly popular route for applications that focus on **'wellness', health management or that provide convenience and comfort**, i.e. marketing that does not stigmatize elderly users.

<u>2. Care provider route</u>: This route is preferable if you have developed an application that offers **immediate** (financial) benefits for a healthcare provider. For example, when care provision becomes more efficient, a competitive advantage will occur, thus, a healthcare provider could be interested to purchase your product.

<u>3. Insurance route</u>: In the Netherlands, you first have to know if the health insurance companies will reimburse the care that is delivered to patients with the help of your innovation. Healthcare providers cannot simply declare their activities resulting from your innovation to a health insurer, as this does not fit within the rules of the government. This implies that you have to **convince a health insurer** to make special agreements about this. <u>This website</u> provides information on the sorts of products and services that insurance companies may reimburse.

<u>4. Municipal route</u>: Since 2015, local municipalities in the Netherlands have been given additional tasks in the area of care procurement. They purchase for their residents all care that falls under the Social Support Act (WMO) and the Long-term Care Act (e.g. domestic help, counseling and care and daytime activities). A municipality therefore pays for care products or services that it delivers directly or through a care provider to its residents. This route is particularly suitable if your innovation contributes to more self-reliance of clients, support of informal care and lower costs for municipalities.

<u>5. National government route</u>: This is the route you need to follow if your innovation leads to **new care that is not (yet) offered or reimbursed**. For example, because the nature or the effect of the care changes, or because care can now be provided which was not possible before. In order to successfully market your innovation, it is important that your innovation has a place in the financing and funding of health care.

You can find more information about the different routes to market <u>here</u>.

UK

There are **four payers** for a product or service for the elderly in the UK:

<u>1. Local Authority</u>: For individuals assessed as having substantial or severe care needs and also having less than £23,250 in savings, the **local authority may pay for all or some of their care** (here "care" excludes "healthcare"), including any useful products (such as monitoring systems, handrails, telecare alarms). Depending on the set-up of the authority and the cognitive level of the individual, the product or service may be selected by:

- Traditional: A local authority occupational therapist selects the products and services from those offered by the authority's chosen supplier(s). The supplier(s) is usually a distributor of care products that won a tender to provide these products on behalf of the local authority for roughly 5 years.
- **Personal budget**: The individual is given a certain allowance with which to choose care products and services. The local authority purchases / pays for these products and services on behalf of the individual.
- **Direct payment**: The individual is given a sum of money to spend on care products and services of their choosing (but agreed by the local authority). The individual makes the purchases directly.

Some local authorities (but increasingly few) also provide care and housing services themselves, and thus could purchase products and services for its own consumption directly or via a procurement process.

<u>2. NHS</u>: **Healthcare is free at the point of use** in the UK (paid for through standard taxes). There are three levels at which the NHS can purchase a product or service: local (i.e. at the individual hospital, GP surgery or Clinical Commissioning Group level), regional (i.e. the NHS Procurement Hubs), and national (i.e. national frameworks and <u>NHS Supply Chain</u> directory). The advantage of getting onto a **national framework** or onto the NHS Supply Chain is that new customers do not need to launch a formal procurement in order to access your product – they

can simply just buy it. The <u>Innovation and Technology Payment</u> (ITP) programme is a recent and competitive programme that **fast-tracks novel innovations** meeting specific needs / themes onto these frameworks.

<u>3. Private health, care and housing providers</u>: Clients / patients eligible for publicly funded health and care will receive products and services funded by the local authority or NHS as described above. If the private health, care or housing provider wishes to purchase additional products or services for their clients / patients or for themselves (e.g. tools for their staff), they will make a direct purchase e.g. online or via a distributor or retailer.

<u>4. Private citizens</u>: Individuals who do not meet the needs and means thresholds for support from the local authority, who wish to access a product or service that the NHS does not offer to them, or that simply wish to purchase a product or service that they desire, can do so **directly** (online or via a retailer).

d) Post-market

i) Regulatory post-market surveillance

Suppliers of CE-marked products, and especially medical devices, have a duty to **continually monitor their real-world use** (regulatory post-market surveillance) according to approved Quality Management Systems. They must report **unprecedented safety and adverse events** to the national authority empowered to do so, such as <u>FAGG</u> in Belgium and the <u>Medicines and Healthcare products Regulatory Agency</u> in the UK. When this happens, these bodies can order the supplier to stop supplying their product and to recall distributed products.

ii) Bring in more business, including via public tenders

If you are successful in being added to a national framework for reimbursement, there is a good chance that you will receive a good volume of business. But this is a passive way to receive business.

Suppliers on a framework, as well as those not on a framework, can also **proactively seek business by responding to public-sector tenders**. As a business registered in the EU, you have the right to **compete for public-sector contracts in other EU countries**. EU law sets minimum harmonised rules that apply to tenders above a certain value (see <u>thresholds</u>). <u>TED</u> is the site for tenders to be advertised at the European level. The national equivalents are: <u>PublicProcurement.be</u> (Belgium), <u>BOAMP</u> (France), <u>tenderned</u> (Netherlands), <u>Contracts Finder</u> (England). A simple online search will reveal the sites that advertise private-sector tender opportunities. Unlike the public-sector tender sites, these sites tend to run on a membership fee model.

It is important that your company and supply chain has **capacity and capability to deliver** on high business volume, so you do not disappoint customers. There is obviously a **risk** to this, as you could expend significant resource moving to larger premises, recruiting more staff and manufacturing many units of your product in anticipation of a large sale, which then does not emerge. The profit/loss balances you created in the "<u>Market</u> <u>Introduction</u>" stage will inform how much risk your company (including investors, shareholders, etc.) can take. Run a scenario analysis on these profit/loss balances so you can understand the worst, expected and best cases.

<u>Employees</u>: In **France**, the recognition and awareness of the Silver Economy sector may make it easier to recruit high-quality staff. For example, the Silver Economy is included in University curricula, e.g. Science Po Paris with its Executive Master's Degree on Silver Economy.

iii) Enter new markets

You will want to maximise the return for all the hard work you put into developing your product or service and getting it to market. This may mean you need to enter new sectors or markets, which, in the case of a radically different market (because of different culture, different balance of public/private service provision, different regulatory requirements, etc.) might require cycling back to the "<u>Concept & Design</u>" stage and progressing through the stages once again.

6) Step-by-step Guide for Demand actors

More and more, housing, health and care providers and local authorities are recognising the benefits that innovative service provision can bring, both for their clients / residents / patients and to them directly. An obvious benefit is **satisfaction and fulfilment of duty** in providing enhanced services that improve the health, wellbeing and quality of life of service users. Of particular interest to non-profit-making providers struggling to deliver services within budget and profit-making providers, is potential to also **improve financial standing** by:

- Justifying increases in fees (through better regulator ratings, client / resident / patient satisfaction testimonials, and outcome/performance statistics).
- Attracting more business (again through better regulator ratings, client / resident / patient satisfaction testimonials, and outcome/performance statistics)
- **Reducing disruptive client / resident / patient churn** (through improved client / resident / patient satisfaction)
- Optimising staff and other resources
- Improving ability to **attract and retain high-quality staff** (due to them feeling empowered and having tools to support their work)
- Reducing insurance bills (through improved outcome/performance statistics)

Moreover, investing time, energy and resources in the R&D process can be also offset by the creation of an **entirely new revenue stream** for demand actors.

a) Concept & design

i) Recruit an Innovation Manager / team

Housing, health and care providers and local authorities have increasing awareness of the need to dedicate **continuous resource to innovation**, instead of only when there is a critical need for it. Generally, the resource that is most efficient and effective for this purpose is dedicated innovation personnel - either a **single Innovation Manager or a small team of staff** with complementary expertise and skills (spanning innovation identification, end-user needs (e.g. health or care provider background), external relationship management, internal relationship management, trials and testing and evaluation and appraisal).

It should be easy for suppliers to **make contact** with these individuals. An alternative to advertising individual's email addresses is to create a single contact form on the organisation's website.

Importantly, there should be an internal process defined for how these enquiries are managed and progressed.

It is noteworthy that the recognition and awareness of the Silver Economy sector may make it easier to recruit high-quality staff for these roles in **France** than in other countries. For example, the Silver Economy is included in University curricula, e.g. Science Po Paris with its Executive Master's Degree on Silver Economy.

ii) Identify and articulate your needs

At the very least, service providers should have a robust policy for **collecting**, **reviewing and actioning on complaints and unsolicited feedback**. Better still is to **proactively solicit feedback**, not only from service endusers, but also from their friends and family and provider staff. Some providers achieve this by sending out **surveys** at regular timepoints. Asking survey respondents to give quantitative answers and to answer questions derived from an established and rigourous methodology, such as the EQ-5D metric system for measuring quality of life, will provide you with baseline data to properly assess the value that an innovation that you are testing in the future brings. An alterative format for sourcing ideas is to run an **Innovation Day** to which all stakeholders are personally invited to attend for brainstorming and other co-creation activities. A good approach to reviewing all the raw evidence of needs is to group them into a **small set of themes**. This will require you to diagnose what the fundamental need driving each feedback or complaint is. This can be challenging as the way a need is expressed will depend on by whom it was expressed – service end-users, family members and employees may all describe the same need but from very different perspectives.

Identifying the fundamental themes will instruct you how to articulate the fundamental capability / functionality / value that a solution will need to provide, i.e. the **solution specification**. Without a good idea of what you are looking for, you are less likely to find it. The solution specification should include a list of **criteria** against which you can assess the "fit" of products and services that you come across in your search for the optimal solution.

The consultancies and living labs listed in <u>Table 2</u> and <u>Table 3</u>, as well as the <u>AgeTech Accelerator</u> spanning Belgium, France, the Netherlands and the UK, can help you with every step described in this section.

iii) Search for products and services meeting your needs

As a first step, demand actors should search the **websites and resources** listed in <u>Table 4</u> to identify what solutions meeting their articulated specification already exist on the market in the four countries.

Another good way to identify products and services already on the market is to attend and network at **trade fairs and conferences**. Notable local events with a Silver Economy (or similar) focus are:

- <u>Health & Care</u> (Belgium)
- <u>Reva</u> (Belgium)
- <u>Silver Expo</u> (France)
- <u>Health Plus Care</u> (UK)
- <u>The Care Show</u> (UK)

The networks and living labs listed in <u>Table 1</u> and <u>Table 3</u>, plus the <u>AgeTech Accelerator</u>, may also "matchmake" you with specific innovations. In the UK, support could also come from <u>United Kingdom Homecare Association</u>, <u>National Care Association</u> and local organisations such as <u>Surrey Care Association</u>.

Even if you have not yet been able to develop a clear solution specification, it is a good idea to reach out to the living labs to become an **expert panel member**. This will give you the opportunity to be exposed to innovations generally (particularly innovations under development) on a regular basis. Better understanding what the technological possibilities are can help inspire what the solution specification should be.

iv) Inform the market of your remaining needs

If you are unable to identify an already developed or in-development solution that meets your solution specification, you should inform the market. This should happen as soon as possible as co-development of fit-for-purpose solutions takes time.

You can inform the market in the following ways:

- Posting a Pre-intention letter or organising a Pre-Commercial Procurement: Public-sector organisations can post these letters and launch procurement on <u>TED</u> (European level), <u>PublicProcurement.be</u> (Belgium), <u>BOAMP</u> (France), <u>tenderned</u> (Netherlands), <u>Contracts Finder</u> (UK). A simple online search will reveal tendering sites open to private-sector organisations.
- **Speaking at conferences and other events:** The events listed in the "<u>Search for products and services</u> meeting your needs" section welcome expressions of interest from demand actors to be speakers.
- **Developing strategic and collaborative relationships with intermediaries**: The clusters, economic development agencies, chambers of commerce, incubators, grant-funders listed in <u>Table 1</u>, <u>Table 3</u> and <u>Table 6</u> can help disseminate your requirements, run collaborative innovation days, incorporate your requirements into grant-funded competitions, etc.

v) Participate in co-creation sessions

For products and services in "<u>Concept & Design</u>" stage – either because you have identified them at this early stage in their development or because you could not find an existing solution that meets your needs – the chances for the solution to meet your exact needs will be greater if you are **closely involved in its R&D from the start**. At this early stage, there may not be a prototype available. Nevertheless, co-creation activities involving the full spectrum of stakeholders (service end-users and their family and friends, service provider staff and managers, as well as the technologists) can already begin in order to **refine the user specification and value proposition** that informs what the prototype should do and look like. Taking "ownership" of this co-creator role and recognising its value will set a precedent with the innovator of the value that you bring to this work (see "<u>Negotiate a commercial basis of involvement</u>" section for a discussion of the options for you to generate a return for your important involvement).



Co Creation requires customers to actively participate in the process.

Figure 17: The benefits of co-creation. Courtesy of Antwerp Management School "Sales and co-creation" slides.

The living labs listed in <u>Table 3</u> and the <u>AgeTech Accelerator</u> can ensure the views from each stakeholder are heard and considered during co-creation activities. They can also help to draw up the roadmap for developing and testing the prototype in the next stage.

b) Prototype & Validation

i) Test prototypes

Co-creation should continue throughout prototype building. This will maximise the likelihood that the future prototype genuinely meets your needs.

It is important to **protect those individuals contributing to co-creation from harm that might arise out of physically testing a prototype**. This is particularly important for products that will eventually require a CE mark (including as a medical device). The process to follow to gain a license / approvals / dispensation to physically test unregulated products is described in the "<u>Gain approval to test an unregulated product</u>" section. Until such time, co-creation should be limited to visual inspection and demonstrations by the innovating company.

It is a good idea to have an **internal procedure** for assessing which prototypes to test under real-life conditions. This is important because real-life testing can require **significant time, energy and resources** (staff, change management, IT infrastructure, etc). The ways you can financially offset this contribution are described in the "<u>Negotiate commercial basis of involvement</u>" section.

Your procedure should prompt you to answer the following questions:

- How well does the product address our fundamental needs / meet our solution specification?
- What have we learnt from testing similar products / ideas in the past that might be relevant?
- What is our level of **confidence in this supplier**? How well do we know them? How well have our interactions with them been? Has the **company already received some awards** for the product? Has the product **already been tested by other organizations** and what are the results?
- What **wider changes** are required to real-world test (and fully implement this innovation in the future) e.g. IT infrastructure, staff training, approvals from service end-users and their family? Could any of these **barriers be insurmountable** or too disruptive to be worthwhile?
- What is the supplier's **timeline** for releasing this product onto the market? Can we wait that long?
- What will / could be the **financial model** of the product? Will it be affordable for us?
- What other **evidence or reassurances** do we require to make a decision about whether to purchase the fully developed product in the future (e.g. improvement in staff satisfaction or service end-user quality of life)? How can we **design** our real-world testing to generate this evidence / reassurances?

The living labs listed in <u>Table 3</u> can help you with this assessment and any subsequent testing. With their support, you stand to benefit from their expertise and ready materials e.g. evaluation grids, increasing the chances that the tests meet your objectives and increasing their efficiency. Additionally, it creates an **independent** "**middleman**" who can work towards satisfaction of all parties.

ii) Negotiate commercial basis of involvement

Testing a prototype can disrupt the day-to-day business of a demand actor. It can also result in co-development of Intellectual Property. Unless you **negotiate a return for your involvement** in the co-development work, you may feel that your input is not being fairly rewarded. After all, this work may result in a product that meets your immediate needs, but that could be eclipsed by the profits that the supply actor receives when they go to market with a product that you had a significant role in developing.

There are five options of commercial arrangements that you might consider:

1. **Immediate payment** to offset some or all of the resources invested in co-creation and testing. Ultimately these monies might come from a public-sector grant, such as the ones listed in <u>Table 6</u>.

2. Negotiating a **discounted fee** on the future purchase of the market-ready product.

3. Negotiating **equity** in the supplier company.

4. Negotiating **royalty terms** on future sales.

5. Establishing yourself **in the supply chain**, for example as a sales channel, taking a share of the profits from sales that you make to your clients / residents / patients or others.

The latter 3 options mean that you take on some supply actor responsibilities – a phenomenon growing in popularity as demand actors struggle to remain financially viable by remaining a traditional demand actor.

c) Market introduction

i) Contribute to collection of evidence of real-world evidence of benefits

Before deciding to purchase a product or service, you should **feel sufficiently reassured that, its adoption will deliver a successful outcome** for you. In fact, your Board of Directors may demand this evidence before they

agree to the purchase. If you were involved in the "<u>Prototype & Validation</u>" stage you may already have this reassurance. If not, it is a good idea to run a "pilot" now that the product or service is available on the market.

Another reason why you may consider running a trial is because a supplier has requested you to do so. Their motivation is to collect evidence of the benefits of their innovation to support their marketing claims and build their reputation. Even if you were not explicitly seeking this type of product or service, you may still consider running the trial, especially if it is in exchange for a commercial arrangement (see "<u>Negotiate commercial basis</u> <u>of involvement</u>" section). Other reasons to run such a trial centre on using it as an opportunity to **raise your organisation's reputation** as an innovative, forward-thinking organisation, helping you to:

- Distinguish yourself from your service provider competitors, allowing you to justify increasing your fees and attracting more business
- Improve your ability to attract and retain high-quality staff, due to them feeling empowered in a new line of work
- Become acquainted with products and solutions that help uncover needs that you did not realise you had, and an already-tested solution.

Other than not requiring a special license / approvals / dispensation to run this pilot, as the product will now be CE marked (perhaps as a medical device), the guidance in the "Prototype & Validation" stage to do with setting up, running and evaluating real-world tests still applies. For formal clinical trials, the supplier sponsoring the trial should consult the guidance given in "Increase reputation and brand awareness, including collection evidence of real-world benefits" supplier section of this Guide.

Regardless of the trial results, it may be in your interests to **publicise them as widely as possible**. This is because it is evidence of your interest and ability to run these kinds of trials. An excellent way to do this is to publish the trial results in **peer-reviewed journal paper**. To pre-empt issues with the supplier in cases where the trial results are negative, agreement should be reached with the supplier about your freedom to publish work during partnership negotiations (i.e. before you agree to run the trial).

ii) Influence go-to-market strategy

If you have negotiated a royalty-based or equity-based commercial agreement or supply chain role with the supplier (see "<u>Negotiate commercial basis of involvement</u>" section), you will be keen to influence the supplier's go-to-market strategy so that it **maximises your return potential**. Ultimately, it will be up to the supplier to develop the full go-to-market strategy (see "<u>Elaborate the business plan</u>" section). However, you can offer the very valuable customer's perspective to this endeavour.

iii) Prepare for innovation implementation

If, in-principle, go-ahead has been granted for your organisation to purchase an innovative product or service, a **favourable basis of purchase** should be negotiated. For innovations recently brought to market, you may be in a strong position to negotiate a **discounted fee** or other benefit in order to make an "Early Adopter" purchase that grows the supplier's small customer list. You should run a scenario analysis on your **financial forecasts** to understand the impact that different scenarios of purchase would have for you, for example one-off fee compared to annual fee or pay-per-usage.

In the case that you have negotiated a **supply chain role** for yourself (see "<u>Negotiate commercial basis of</u> <u>involvement</u>" section), and this is a new role for you, you will need to establish some or all of the following **internal capabilities**: stockholding and ordering, sales, distribution, installation, monitoring, customer support and maintenance and repair. Clear delineation of where your role begins and end, and where the roles of other actors in the supply chain begin and end (see Figure 11), should be formally recorded and agreed.

Humans are generally "comfort creatures" who prefer familiarity. Innovations, by definition cause change, and this change can present both expected and unexpected challenges, particularly at the start. It is therefore critical

that stakeholders receive **sufficient support to adopt and use the new product or service**. If this support is not provided or insufficient, you risk poor uptake of and satisfaction with the innovation, meaning the money you invested to make the purchase was a waste. Saving on implementation costs may be "false economy". You should instead aim to ensure your organisation **gains maximum benefit** from your investment.

Challenges with implementation that may occur include:

- Training staff, such as digital skills in the case of apps or software or how to operate mechanical products
- Upgrading, extending and interfacing with existing IT infrastructure
- Integrating the innovation into care pathways and other established processes
- Fear of / reluctance to use the innovation, particularly digital innovations

Some of these challenges can be pre-empted or overcome by:

- Providing **one-to-one monitoring** support to staff and service end-users for an extended period of time. A key objective of this monitoring is to remind the staff / service end-user of the desired purpose of the innovation – how it should help or benefit them. Sometimes these benefits are not direct or obvious.
- Providing a user support "hotline" that users can call in real-time when they require assistance
- Creating materials that support easy innovation use, particularly in the context of a procedure or care pathway, such as **"How to ..." leaflets** with step-by-step instructions and **product guides** and distributing them in popular places, e.g. staff rooms.
- Selecting hardware based on whether any physical locations suffer from poor Wi-Fi / 3-4G internet connectivity, or adding internet signal boosters.
- Not discontinuing existing infrastructure / solutions until confidence in the new infrastructure / solution is high (allowing return to the legacy infrastructure / solution if the new one fails).

d) Post-market

i) Cycle of appraisal of existing solutions and search for next-generation solutions

As shown in <u>Figure 18</u>, innovation is continuous – it does not end at implementation. Your innovation manager or team should establish a cycle of continuous appraisal of the implemented innovation, and benchmarking against new and emerging innovations. Your existing suppliers should support you with this endeavour, for example by providing access to data with which you can evaluate use of the innovation. Equipped with this intelligence, they can be in a position to **negotiate more favourable terms** for any ongoing costs of implemented innovations, or to return to the "<u>Concept & Design</u>" stage to co-develop the **next-generation solution**.



Figure 18: The continuous benchmarking cycle.

7) Case Studies

a) MoveUp

MoveUP is a Belgian solution providing personalised coaching after hip or knee prosthesis surgery. It allows rehabilitation to take place from the patient's home, at their pace, with only a tablet and internet connection.

The company needed to develop a **new go-to-market strategy** in order to enter the French market:

- **Revenue model**: In Belgium, patients are accustomed to contributing towards the costs of physiotherapy sessions. There is therefore willingness to pay for follow-up after surgery (including moveUP) in general. In France, physiotherapy sessions are 100% reimbursed for most patients. This means there is little incentive for them to adopt MoveUP at the moment; it would need to be reimbursed by the French Social Security to have a chance to be widely used by patients in France.
- **Stakeholder Management**: In Belgium, the mutuality has mostly a role of intermediary for the payments made by the national health insurance. However, in France the mutuality has, generally, a broader offering of insurance services, and there is more competition between mutualities. Therefore, the mutuality in France is a more significant stakeholder for MoveUP to engage with than in Belgium.
- **Data Management compliance**: In France, personal health data must be hosted on servers physically located on French territory, with services from a certified hosting company (HADS). This law is unique to France and MoveUp must collaborate with a French HADS in order to be compliant.
- **E-Health acceptance**: In Belgium, the government only starts to consider and evaluate potential e-health solutions when they are already on the market. In France, the government has already created a national framework specific to e-Health and has regular on-going innovative projects. For instance, teleconsultation is already accepted in France. Therefore, there are opportunities for MoveUP to integrate into an existing remote-care service legislation in France, unlike in Belgium.

b) Sensara

Sensara is a monitoring system that allows elderly people living alone to feel safe in their own home. In emergencies, Sensara alerts the proper authorities with a simple push on a button. Sensara offers solutions to private individuals without care, municipalities, elderly with care and nursing homes. For loved ones, it is a reassurance to know how the elderly person is doing when he or she is home alone. The family, friends or informal caregiver will worry less and thus experience less stress.

SEAS 2 Grow offered Sensara **live-testing** (with individuals aged 60-88) and **business modelling sessions** in the UK, Belgium and France. This resulted in the following learning and outcomes:

• **Contacts and potential future business:** Sensara was put in touch with a nursing home organisation in Belgium where they have started testing the products. The nursing home has decided to purchase the system if the testing generates positive results. This organisation has 25 locations and around 2500 beds, so it could be a significant customer for Sensara.

In the UK, a number of companies and local authorities were interested in arranging a meeting with Sensara, and these leads are now being followed up.

Sensara also initiated new contacts and co-operation with a Dutch health care organisation and a Dutch municipality, so the domestic market has improved for them as well.

• **Knowledge:** Sensara has gained knowledge about foreign healthcare market and its possibilities. Sensara is using this end-user feedback to improve its product. A key conclusion for Sensara from all of this support is the UK market is particularly interested in its product, willing to pay more for it and were particularly receptive to its design and functionalities.

c) Kintell

Overview of the innovation

Kintell is a smart health system that helps people develop and maintain healthy habits which improve their wellbeing and lifestyle. Using sensor-based technology and a simple user interface the user can set a personalized programme of reminders, which help them keep on track with important activities such as taking medication and regular exercise. The system also includes voice-activated features, an emergency key to alert carers if the user has a fall or other incident in the home, a nightlight and intercom and an alarm clock that reschedules the days programme if the snooze button is pressed.

The innovation's value proposition

Falls and frailty are two of ageing's most common problems and both of these can be managed and the risk reduced by good health and lifestyle habits. Kintell uses 'nudge theory', a principle of behavioural science, to improve adherence to good health and lifestyle routines at the same time as allowing an individual's 'care circle' to keep up to date with their loved one's wellbeing.

Impact of services provided by Seas 2 Grow AgeTech Accelerator programme

Kintell has been involved in a co-creation session in the UK where several older people attended along with one of their grown-up children. The feedback from the session helped Kintell benefit from a greater understanding of their target market and as a consequence they have been able to adapt and strengthen the design of the Kintell product and its core value proposition. A further co-creation session has been organized in the Netherlands for January 2019.

In terms of contacts, Kintell have been introduced to a professional designer who specializes in user insights and user-driven innovation and met further new contacts via invitations to the Seas 2 Grow conference in Brussels; and also an invitation to a workshop focused on housing design for the older population. Kintell have also been name-checked in several news pieces on the AgeTech Accelerator website and via social media leading to an increased awareness and interest in the Kintell product.

Quotes from the Kintell co-creation session

"My son and I thought the session was very stimulating. It's great that companies want to hear from us and understand our perspective when they are designing products. We also enjoyed meeting the other participants and learning from their experiences." Mrs P, age 79, UK

"I attended a co-creation session organised by AgeTech UK. We were a small group of older people and a couple of their middle-aged children. I found it to be a mutual support group which first shared their common challenges experienced with ageing. It was an opportunity for the people who run AgeTech UK to "pick our brains" and to use the new knowledge and insights we supplied to help guide the development of innovations for people like us as we get older. It proved to be a fruitful session of intergenerational cross-fertilisation with the possibility of good and fulfilling outcomes in future developments." Mr W, age 78, UK