

Early development and evaluation of technological devices

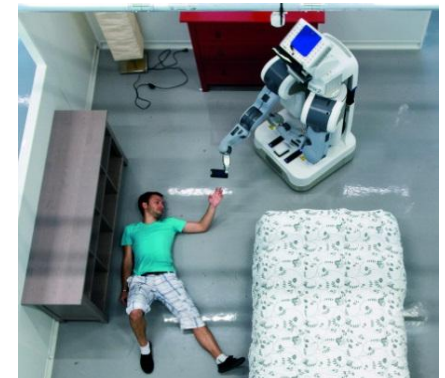
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Background

Commercial market of aging care remains poorly developed since introduction of low-technology devices decades ago

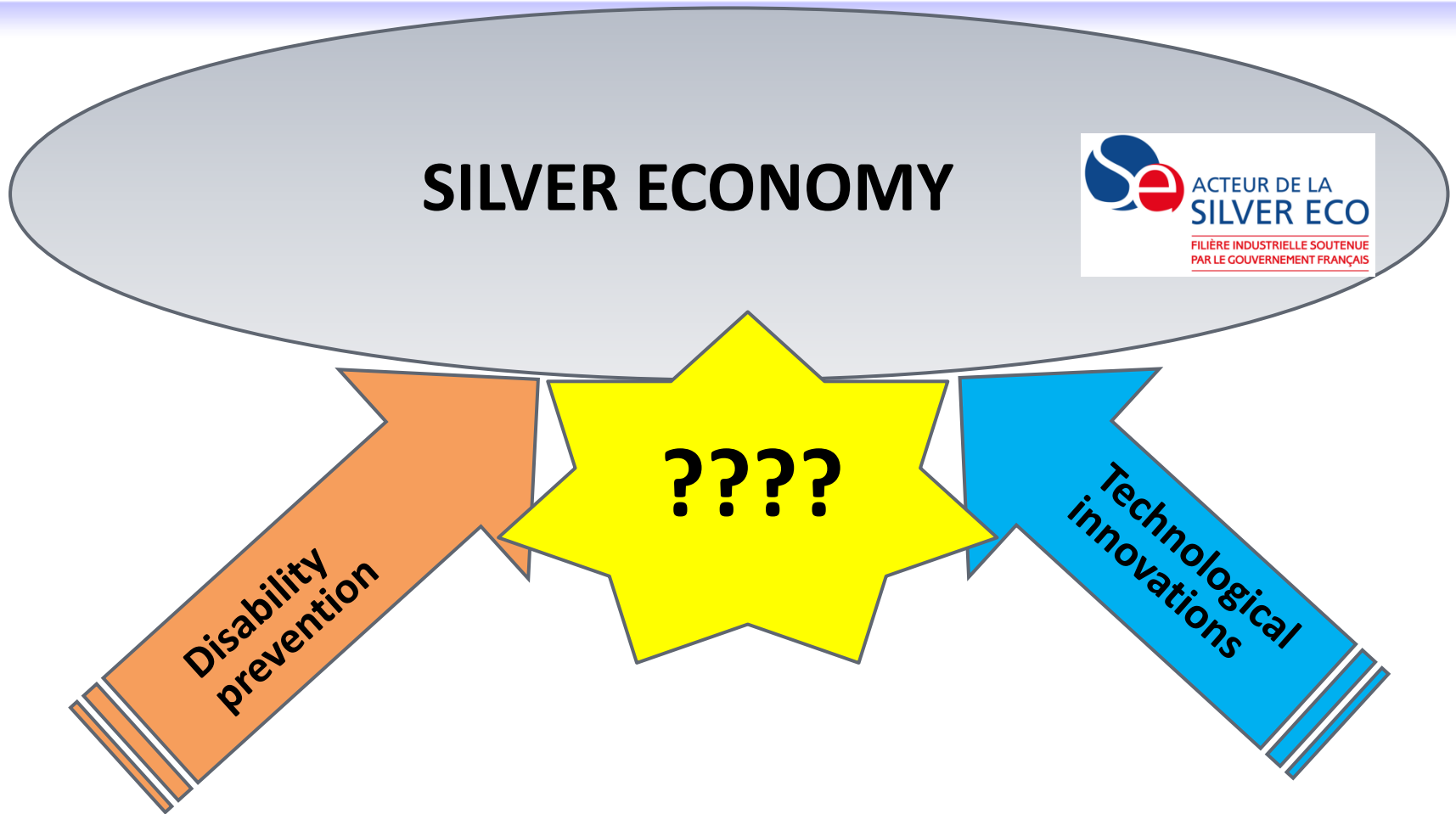
1. A lack of early multidimensional reflexion during technology development (leading to irrelevant tools)
2. A lack of evaluation (e.g. Cochrane « Smart Homes »)

This deficiency is due to the confrontation of two worlds:

- technology = not yet well versed in the field of healthy aging intervention = **techno-push strategy**
- medical = **mainly uses the linear pharmaceutical drug development model**



Background



- We need to develop more relevant devices = « **techno-pull strategy** »
- Many methods are proposed for multidimensional evaluation of health technologies, **they do not address the early development and evaluation processes**

Where to start?

Not with the technologies but from what we need !!

Software

Connected Medical device software
 -Failure alert
 -Maintenance reminders

Feed-back software
 -Performance indicators presentation

Motivational coaching software
 -Nutrition
 -Physic exercise
 -Therapeutic education

Socio-cultural software
 -Transport
 -Culture
 -Shopping, home delivery

Social network
 -Family and relative
 -Social caregivers coordination

Home computer = Touch-pad
 - Patient interface
 - Data collection
 - Pre-treatment

Internet secured transmission to database

MD computer = Dash-board
 -Frailty indicators trends
 -Medical relevant events
 -Intervention adherence
 -Alerts

Hardware

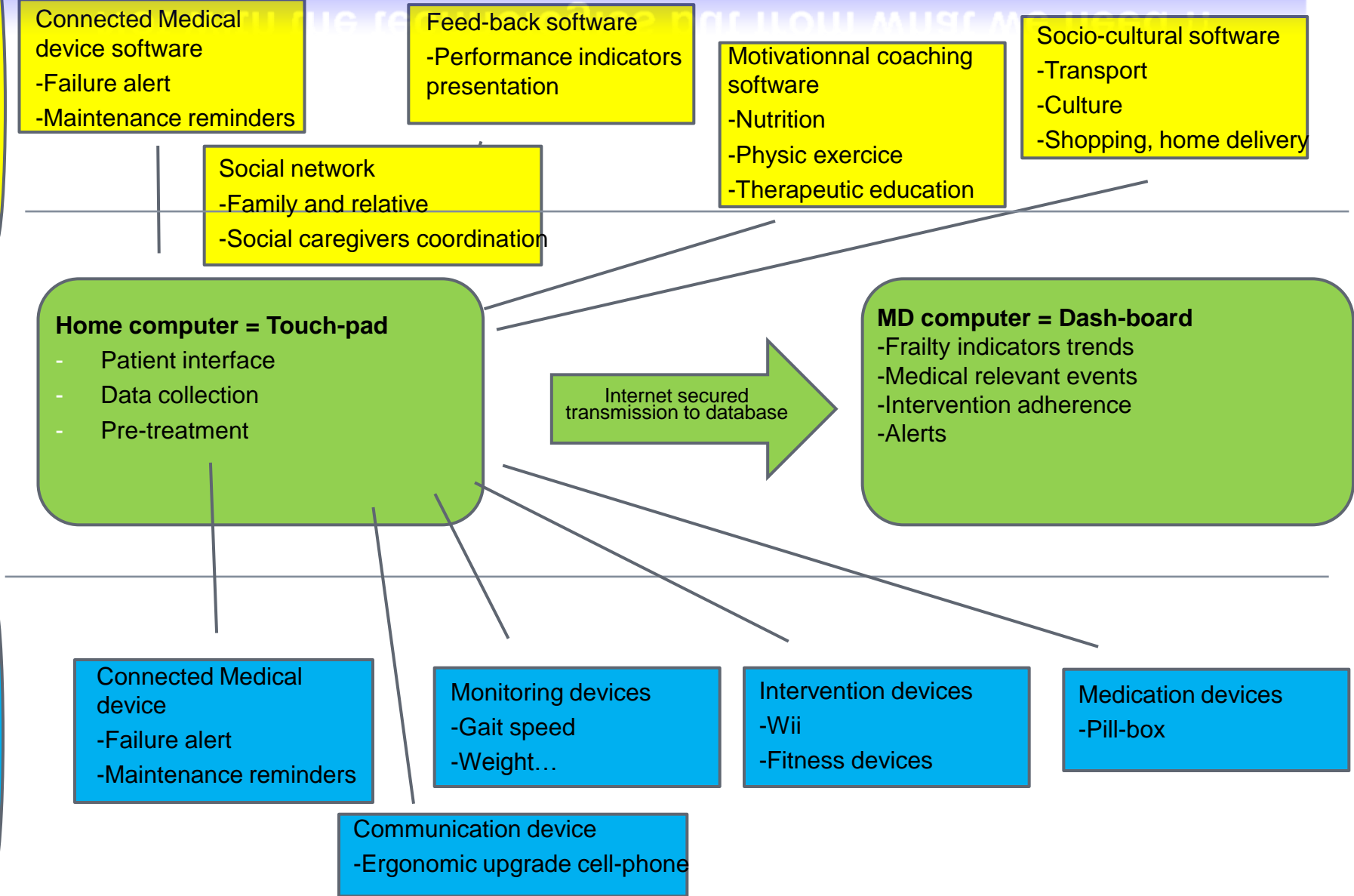
Connected Medical device
 -Failure alert
 -Maintenance reminders

Monitoring devices
 -Gait speed
 -Weight...

Intervention devices
 -Wii
 -Fitness devices

Medication devices
 -Pill-box

Communication device
 -Ergonomic upgrade cell-phone



Method and results

Our goal was to build a **one-page “pocket work plan” for health technology development** for people who want to develop a health device but do not exactly know how to do (e.g. young start-uppers). It could be used by all kind of stakeholder, whatever their culture (technical, human sciences, etc.) and their organization (e.g. academic, SME's).

First we have described the different dimensions of evaluation to identify essential partners to built an efficient consortium

Secondly we have proposed different critical phases for the technological development and evaluation

Then we Have proposed a framework to describe relationships between development phases and evaluation dimensions → **this is the basis of a concrete working plan (e.g. work-packages)**

Results

Characteristics of health technologies as compared with drug development:

- Evaluation of technology is multidimensional and multidisciplinary;
- Results are more dependent on the implementation context of the technology;
- Technology evaluation is non-linear, more iterative (feed feedback loops);
- Quantitative research strategies need to be combined with qualitative strategies;
- Less time is available for technology evaluation because of the quickly changing market, etc.

Results

Evaluation dimensions	Phases of development				
	Specifications	Lab tests	Living-lab	"Real-life" evaluation	Post-marketing studies
Technical	Technical requirements	Risk analysis, technical conformity	Technical feasibility	Technical fiability	"Residual risk" evaluation
		Interoperability			
		Ergonomics, man-machine interface			
Medical	Medical needs	Use case	Clinical feasibility	Global impact on the human subject: medical services rendered	
Human and social science	Acceptability evaluation and iterations			Global impact on the society: social services rendered	
	Processes evaluation				
Economics	Health-economics context	Preliminary economic model	Cost analysis	Overall health-economics impact	
				Business plan	
Legal and ethical	Legal/ethical implications and declarations	Consortium agreement	Ethical consequences in the use of technology		
			Intellectual property		

A basis to: (i) identify the relevant partners for a consortium, (ii) built a first draft of a work plan, (iii) and provide a first idea of each partner tasks.

Results

This multi-phased design, from lab test to field tests, allow to perform iterative modifications of the devices thanks to end user's recommendations.



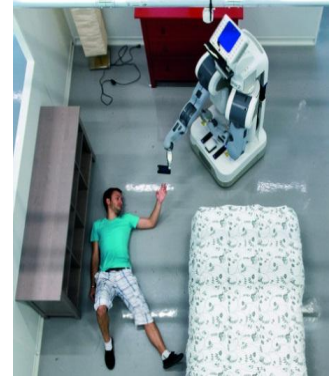
e.g. young volunteers in a lab
(technical performances of the first prototype)



e.g. healthy old people in a living lab
(acceptability of the second prototype)



e.g. frail individuals in a clinical comparative study at home
(acceptability in real-life conditions)



Discussion and conclusion

Our method is successfully tested through several completed or ongoing³ projects that have been funded by health authorities and ratified by clinical research ethical committee.

No matter the type of technology, its development stage, and the clinical application, our method was easily adaptable, flexible and scalable.

Our proposed “pocket tool” is a valuable support, for example during a first meeting with a technical partner (not yet versed in health technology development and assessment), **to evaluate the feasibility of a project** and is also the **basis of a first concrete working plan** (e.g. work-packages).

3.Piau A, Charlon E, Campo E, Vellas B, Nourhashemi F. A Smart Insole to Promote Healthy Aging for Frail Elderly Individuals: Specifications, Design, and Preliminary Results. JMIR Rehabilitation and Assistive Technologies 2015;2(1): e5 p.1; doi:10.2196/rehab.4084