



Bringing Health Innovation to the Next Level

Health Innovation Netherlands (HI-NL)
Lessons Learned

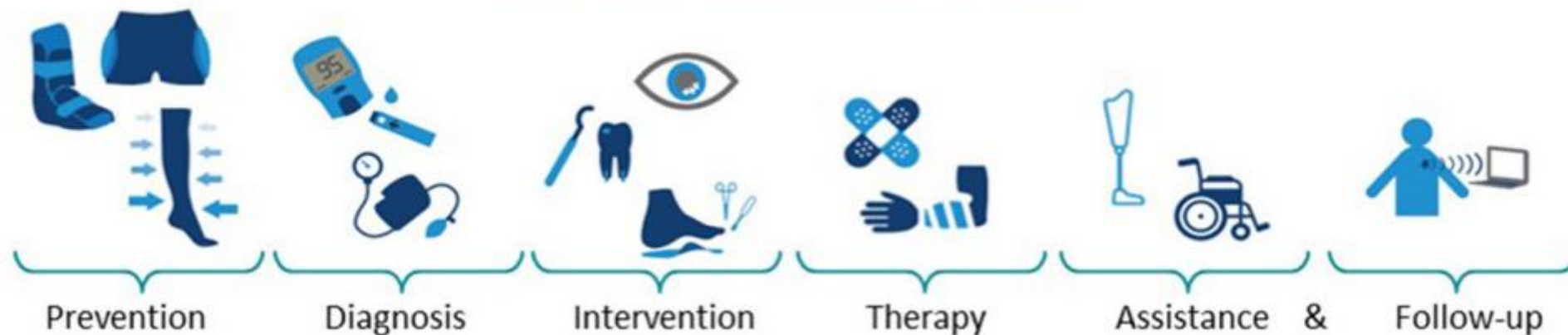
Focus on MedTech

Products, services or solutions used to save and improve people's lives.” (MedTech Europe)

- *Medical devices*
- *In Vitro Diagnostics (IVDs)*
- *Digital Health Solutions*



EXAMPLES OF MEDICAL TECHNOLOGIES



The MedTech explosion



>500k devices
>400k health apps

1900

2021

Context of this workshop

FDA: ~22,000 premarket submissions are made per year

< 7-9% of these products reach the market (can take up to 17 years)

Warty, et al. (2021). Barriers to the Diffusion of Medical Technologies Within Healthcare: A Systematic Review. IEEE Access. PP. 1-1. 10.1109/ACCESS.2021.3118554.



Context of this workshop

A wide range of factors may support or hinder implementation

- Frameworks available

The barriers and facilitators of radical innovation implementation in secondary healthcare: a systematic review.

Thijssen, S.V., et al. (2021)

Journal of Health Organization and Management.
Ahead-of-print.

<https://doi.org/10.1108/JHOM-12-2020-0493>

Consolidated Framework for Implementation Research (CFIR, Damschroder, 2009)

- 5 major domains consisting of 37 subcategories

Authors		Cramer <i>et al.</i> (2014)	Dugstad <i>et al.</i> (2020)	Dugstad <i>et al.</i> (2019)	Coccia (2014)	Mikhailova (2018)	Söderholm <i>et al.</i> (2010)	Tanniru <i>et al.</i> (2018)	Van Bockhaven <i>et al.</i> (2017)	Melkas <i>et al.</i> (2020)
Type of innovation		Organizational	Organizational	Technological	Treatment	Technological	Technological	Technological	Technological	Technological
Study design		Longitudinal	Cross-sectional	Observational	Longitudinal	Single case	Single case	Single case	Multiple case	Observational
Level of evidence		4	3	4	4	4	4	4	3	4
Main categories CFIR	Sub-categories CFIR									
I. Intervention characteristics	A. Intervention source									
	B. Evidence strength									
	C. Relative advantage									
	D. Adaptability									
	E. Trialability									
	F. Complexity									
	G. Design quality									
	H. Cost									
II. Outer setting	A. Patient needs and resources									
	B. Cosmopolitanism									
	C. Peer pressure									
	D. External policy and incentives									
III. Inner setting	A. Structural characteristics									
	B. Network and communications									
	C. Culture									
	D. Implementation climate									
	1. Tension for change									
	2. Compatibility									
	3. Relative priority									
	4. Organizational incentives and rewards									
	5. Goals and feedback									
	6. Learning climate									
	E. Readiness for implementation									
	1. Leadership engagement									
	2. Available resources									
	3. Access to knowledge and information									
IV. Individuals involved	A. Knowledge and beliefs about intervention									
	B. Self-efficacy									
	C. Individual state of change									
	D. Individual identification with organization									
	E. Other personal attributes									
V. Implementation process	A. Planning									
	B. Engaging									
	1. Opinion leaders									
	2. Formally appointed internal implementation leader									
	3. Champions									
	4. External change agents									
	C. Executing									
	D. Reflecting and evaluating									

Note(s): Red represents a barrier, blue a facilitator, and purple both a barrier and facilitator

Context of this workshop



Health Innovation Netherlands (HI-NL) aims to **stimulate the development and implementation of safe, valuable, affordable, profitable and cost-effective health innovations.**

HI-NL focuses on the evaluation of medical devices and biomarkers (MDR-IVDR).

Introducing the workshop speakers



Prof. Erik Koffijberg
University of Twente
Discussion leader



Dr. Naomi van der Linden
University of Twente
Discussant
“The Approach”



Dr. Kevin Jenniskens
Utrecht University
Discussant
“The Learnings”



Prof. Manuela Joore
Maastricht University
Discussant
“The Future”

All speakers are independent external experts contributing to facilitating the HI-NL process.

In addition to personal insights from the discussants, the workshop includes input from:

Prof. Maroeska Rovers (Health Innovation Netherlands; TechMed Centre, University of Twente; MITec, RadboudUMC); Paul de Vries (Lygature); Mark Pieters (Lygature);

Prof. Erik Buskens (UMC Groningen); Dr. Thea van Asselt (UMC Groningen); Prof. Carl Moons (UMC Utrecht); Dr. Tim Govers (Radboud UMC); Arjan van Manen (Skyline DX).



The Approach

Naomi van der Linden

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Monday, 7 November 2022 | 13:30-14:30

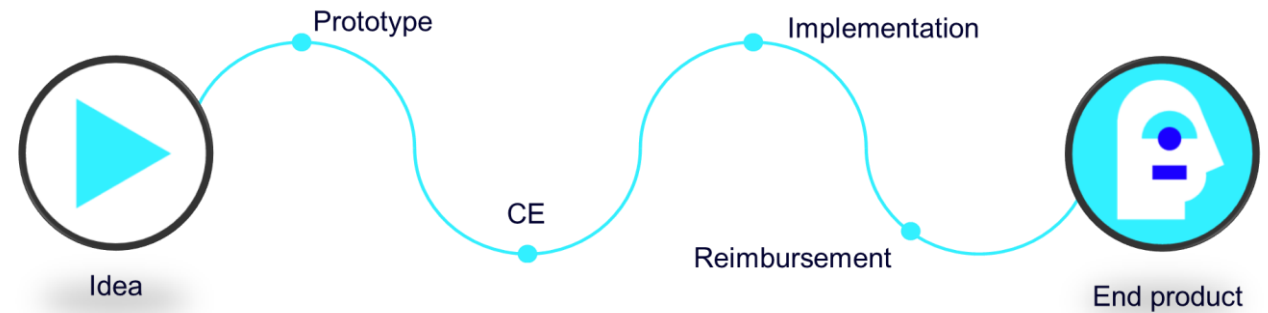
HI-NL approach

A video on the HI-NL approach can be accessed through:

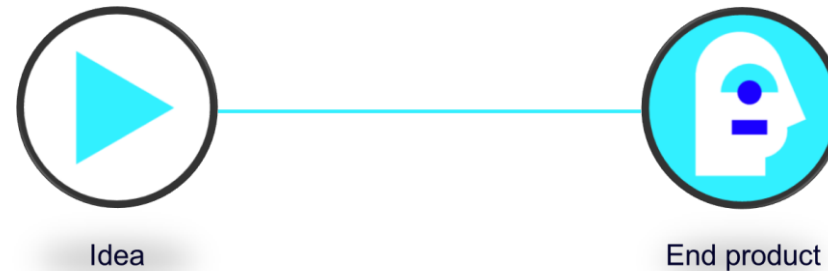
<https://www.healthinnovation.nl/>

Providing a clear path for innovations

The way to market is a bumpy ride – with many stakeholders involved sequentially.

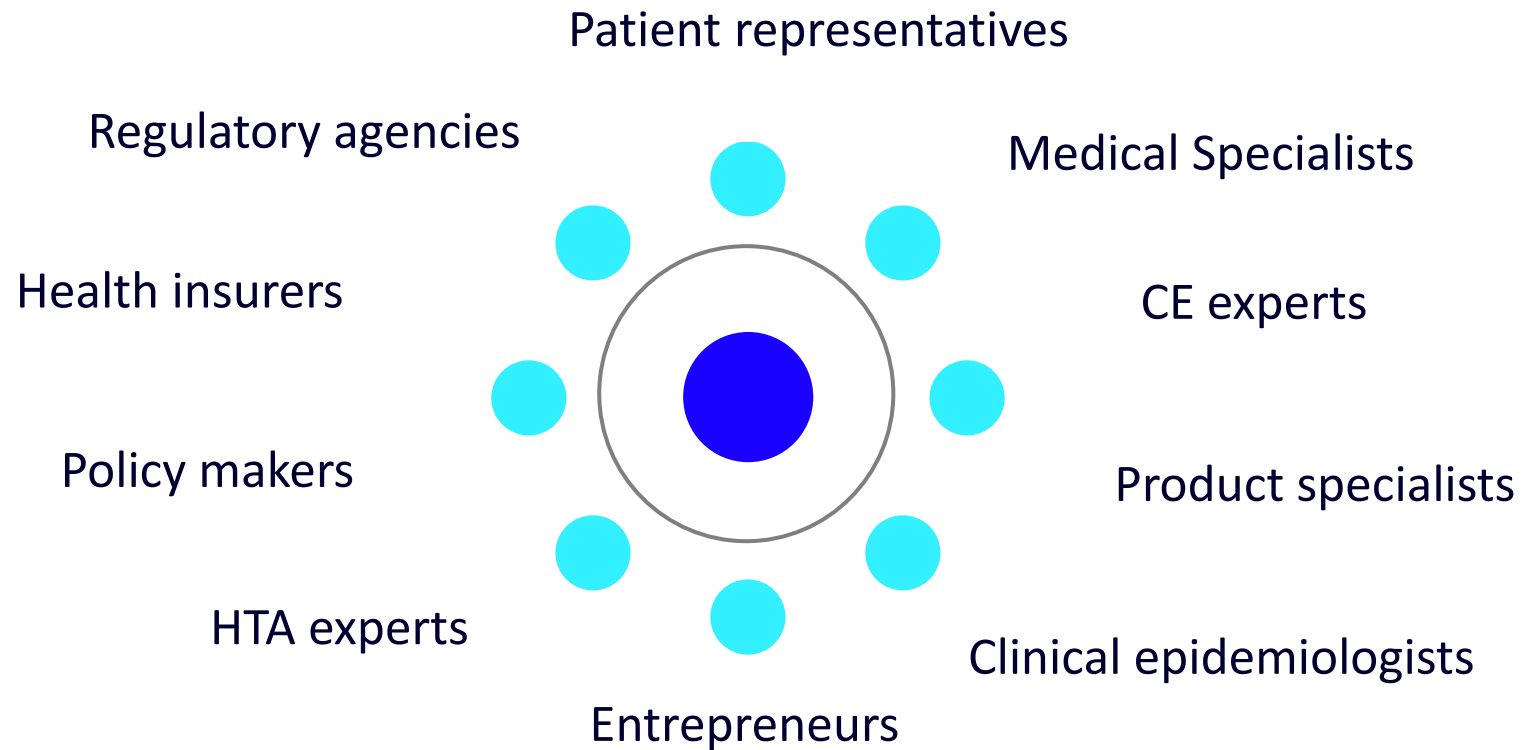


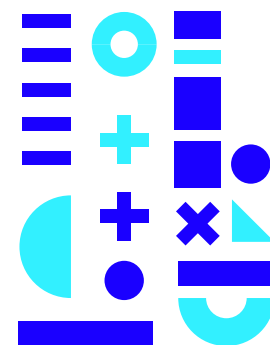
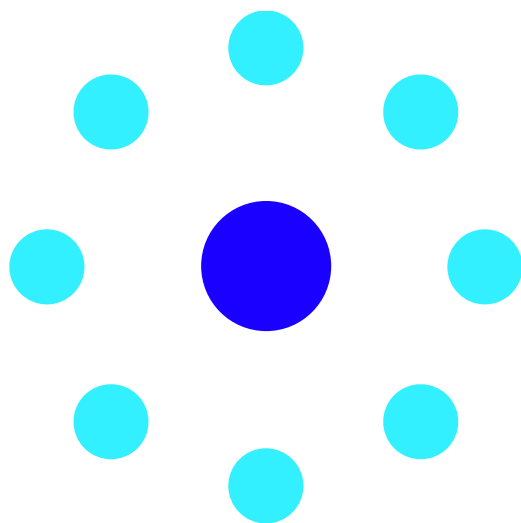
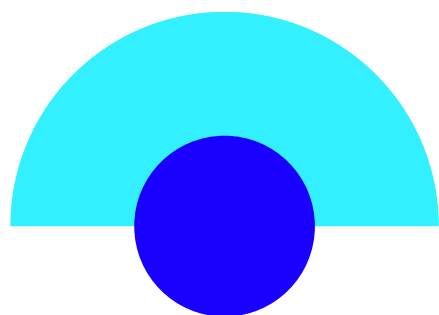
HI-NL brings stakeholders together early on, providing a **clear path** and **tailored guidance endorsed by all stakeholders**.



HI-NL approach

Early dialogue with all stakeholders



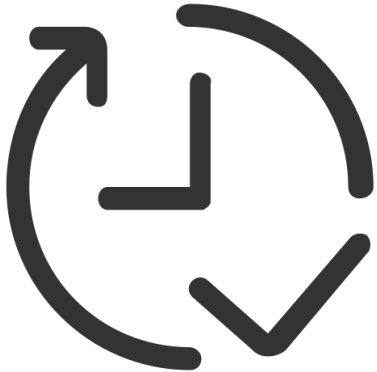


Topics of discussion in the Round Table

- Problem
- Population(s)
- Positioning
- Value proposition
- Stakeholders
- CE marking
- Evidence
- Implementation
- Other

When, how and for whom?

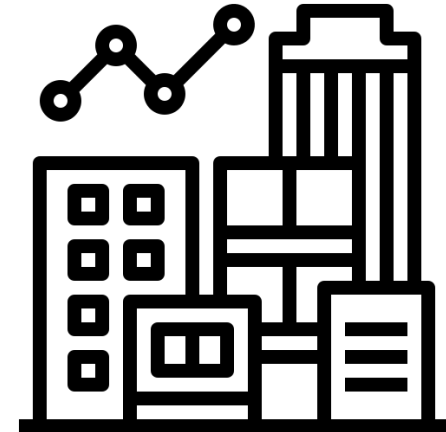
Early



Not-for
profit



Small and large
enterprises





The Learnings

Kevin Jenniskens

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Monday, 7 November 2022 | 13:30-14:30

Case study: SkylineDx – SKY92

- Newly diagnosed multiple myeloma (NDMM)
- Guidelines: management options, but no specific guidance
- SKY92: genetic prognostic risk profile for NDMM
- Goals
 - Accurate prognosis
 - Improve patient satisfaction & physician confidence on treatment choice
 - Impact on clinical outcomes (escalate or de-escalate treatment)
- Evidence available (at start HI-NL round table service)
 - Prediction model validation studies
 - Single study on physician confidence on treatment choice
 - No evidence on impact

Case study: SkylineDx – SKY92



What do other innovators say?



HI-NL provides access to all important stakeholders for my innovation

HI-NL saved us a lot of time - probably years

The fact that the advice is independent and a consensus is highly valuable

Without HI-NL we would never have such good insight into the innovation journey ahead of us

Access to this level of expertise in such structured way and short timeframe is impossible to get anywhere else

Answers to all our questions in one report

The preparation and collaboration with the case team is of high quality

The advice in the Innovation Guide has positively redirected our innovation strategy

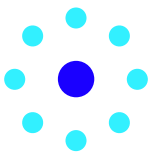
Answers to questions we did not even know we would have

HI-NL literally brings **the whole system in one room** matched to my innovation

Strengths



Desk research



Round table discussion



Advisory report

- Early to late innovation assessment
- Pressure cooker
- All relevant stakeholders are involved
- Innovators linked to our (national) network
- Innovator gains insight on aspects that are not their expertise
- Stakeholders can't point at each other
- Stakeholders can speak their minds (closed doors session)
- Combined detailed advise based on all stakeholders
- Concrete steps forward

Lessons learned

- Innovators don't always know what they want
- During desk research; be the devil's advocate
- Innovators often have more evidence than initially presented



The Future

Manuela Joore / Bram Ramaekers

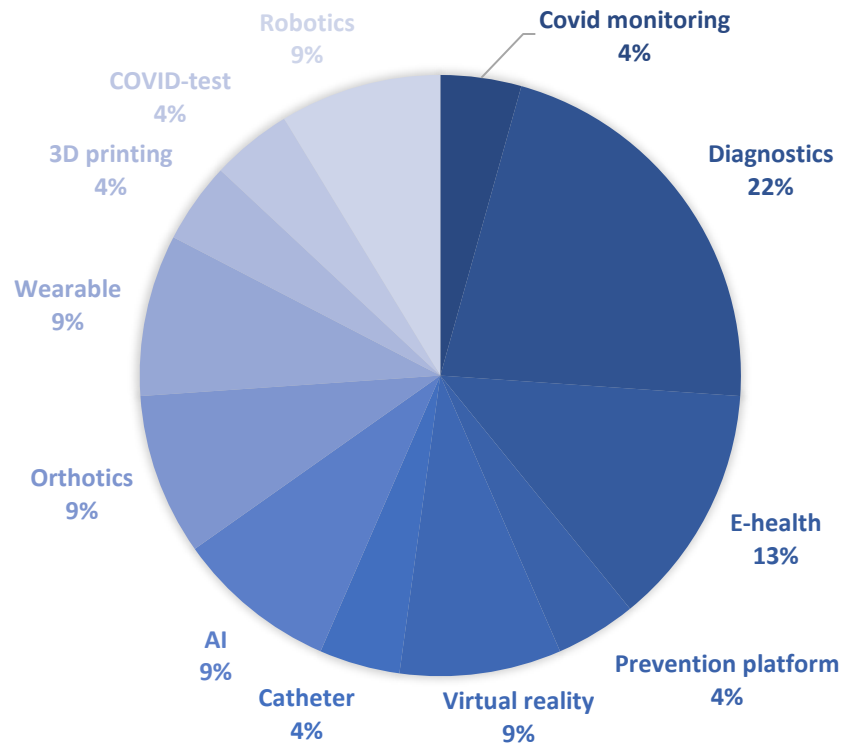
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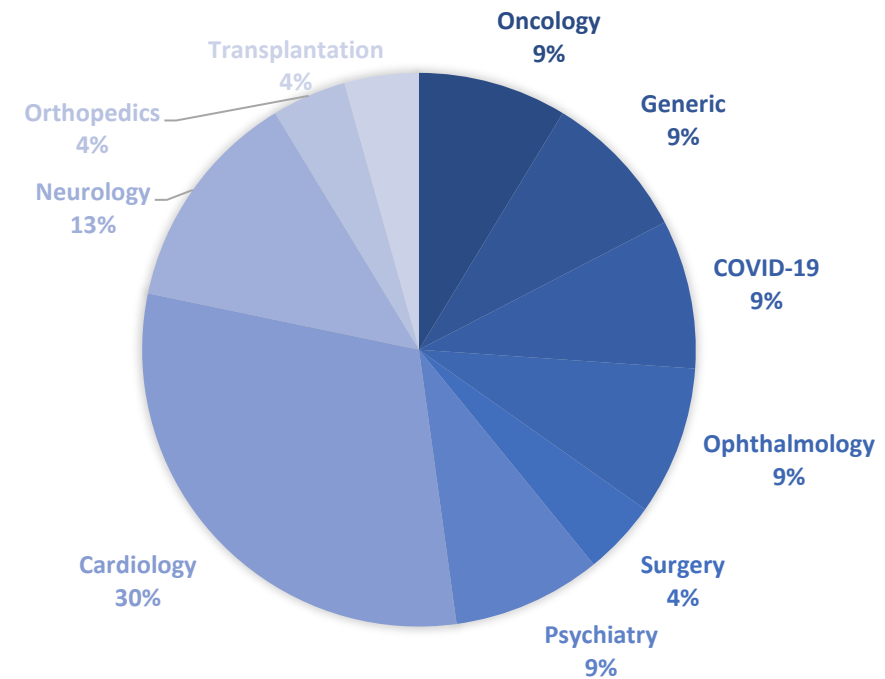
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Where do we go from here?

Type of innovations



Indication / (disease)domain



N = 23

Future Challenges and Opportunities



How

- Go international?
- Single advice or iterative approach?

What

- Add research and educational activities?
- Next to technology also problem as starting point for advice?

How: go international?



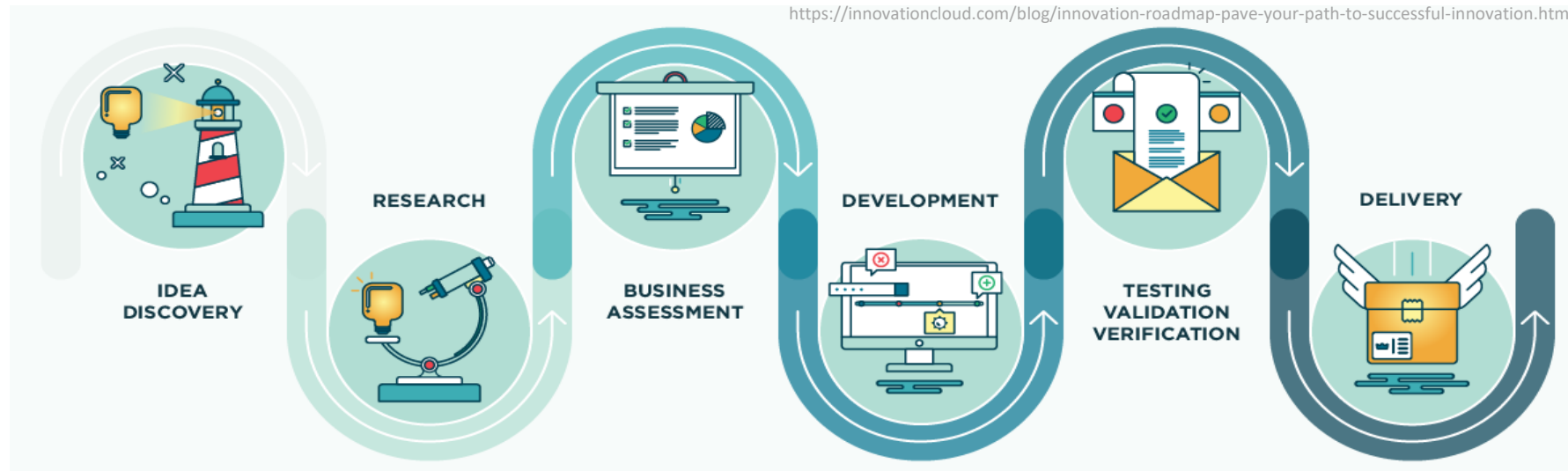
HI-NL

- Linked to Excite International
- Already interest from Europe, US and Asia

To consider:

- Health technology market IS international
- But use and regulations (may) differ between jurisdictions
- How to decide when to 'go abroad'?

How: single advice or iterative approach?



- At the moment, we give a single advice, but:
 - innovation is a process
 - It would be interesting to see the impact of our advice
- To consider:
 - How to organise?

What: add research and educational activities

- Research
 - Evaluate the impact of our approach
 - Evaluate the usefulness of our methods
 - Continuous learning
- Education
 - Disseminate our 'philosophy'
 - Disseminate our methods
- To consider:
 - Funding opportunities
 - Stay practical and service oriented

What: technology or problem as start?

- At the moment a *technology* is the starting point
- We trialed Round Tables around a *problem*
 - To stimulate value driven innovation (instead of technology driven)
 - To stimulate system change
- To consider:
 - Need to agree on the problem
 - Who are stakeholders?
 - Who are problem owners?

Future Challenges and Opportunities



How

- Go international?
- Single advice or iterative approach?

What

- Add research and educational activities?
- Next to technology also problem as starting point for advice?



Discussion

Erik Koffijberg

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