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5th June 2024

EHMA 2024 - Bucharest

The socioeconomic impact of in-silico models for implantable medical devices: a conceptual framework

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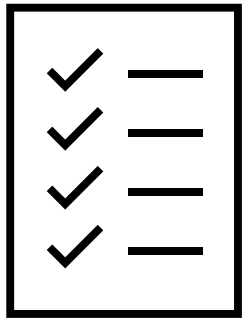
Outline

- Introduction
- What are in-silico models?
- Methodological approach
- Preliminary results
- Conclusion



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 101017578

Outline

SIMCor – In-Silico testing and validation of Cardiovascular Implantable devices

- funded by the **European Union's H2020 research and innovation program** (grant agreement No 101017578)
- consists of 10 work packages and 12 consortium partners from 8 European countries

Fig. 1: Pulmonary artery pressure sensor (PAPS)

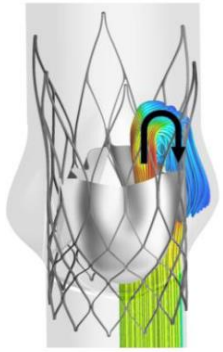


Fig. 2: Transcatheter aortic valve replacement (TAVI)

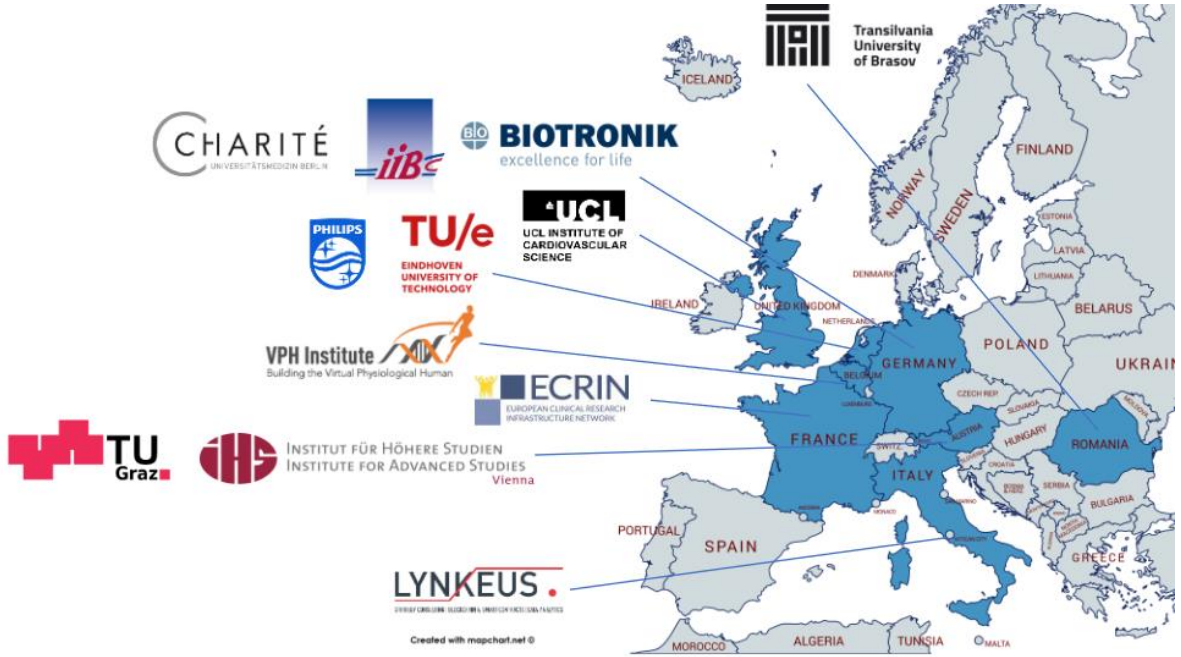


Fig. 3: Consortium partners SIMCor

What are in-silico models?

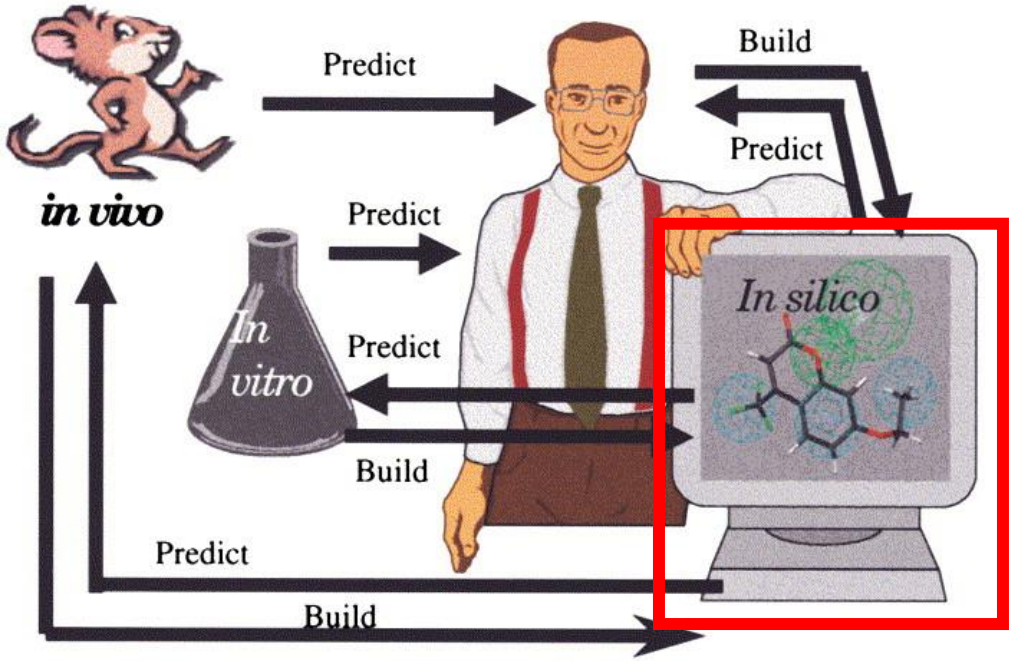


Fig. 4: Source: Ekins, S., & Wrighton, S. A. (2001). Application of in silico approaches to predicting drug–drug interactions. *Journal of pharmacological and toxicological methods*, *45*(1), 65-69

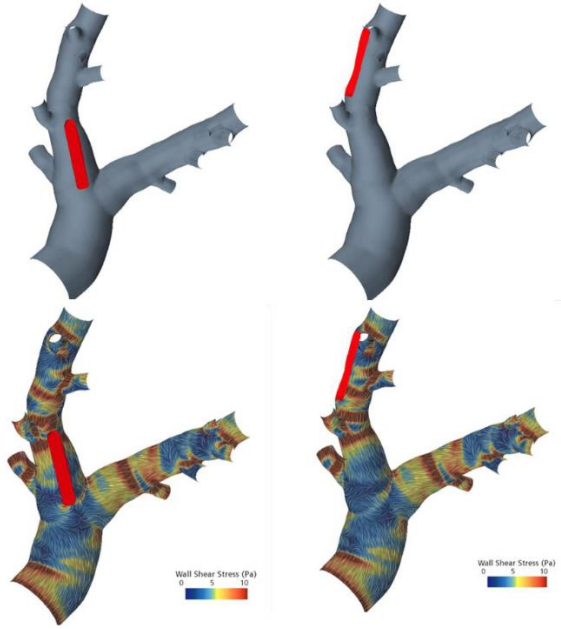


Fig. 5: Source: SIMCor Deliverable 7.5 – Uncertainty quantification and re-definition of input space

Medical development cycle of medical devices

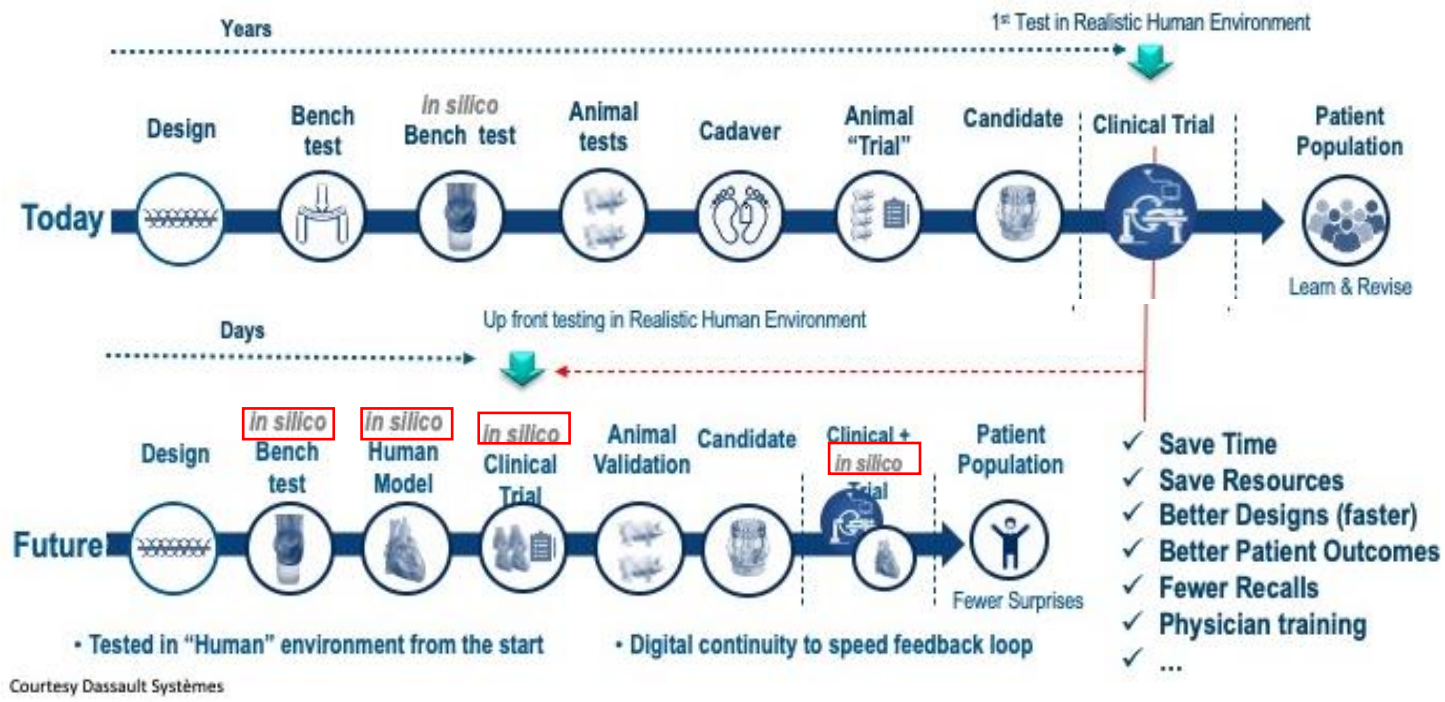
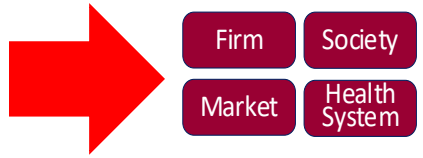


Fig. 6: Potential effect of in-silico models on medical development cycle of medical devices

Research Question
What are the potential impacts of in-silico technologies on firms, markets, health systems and society?

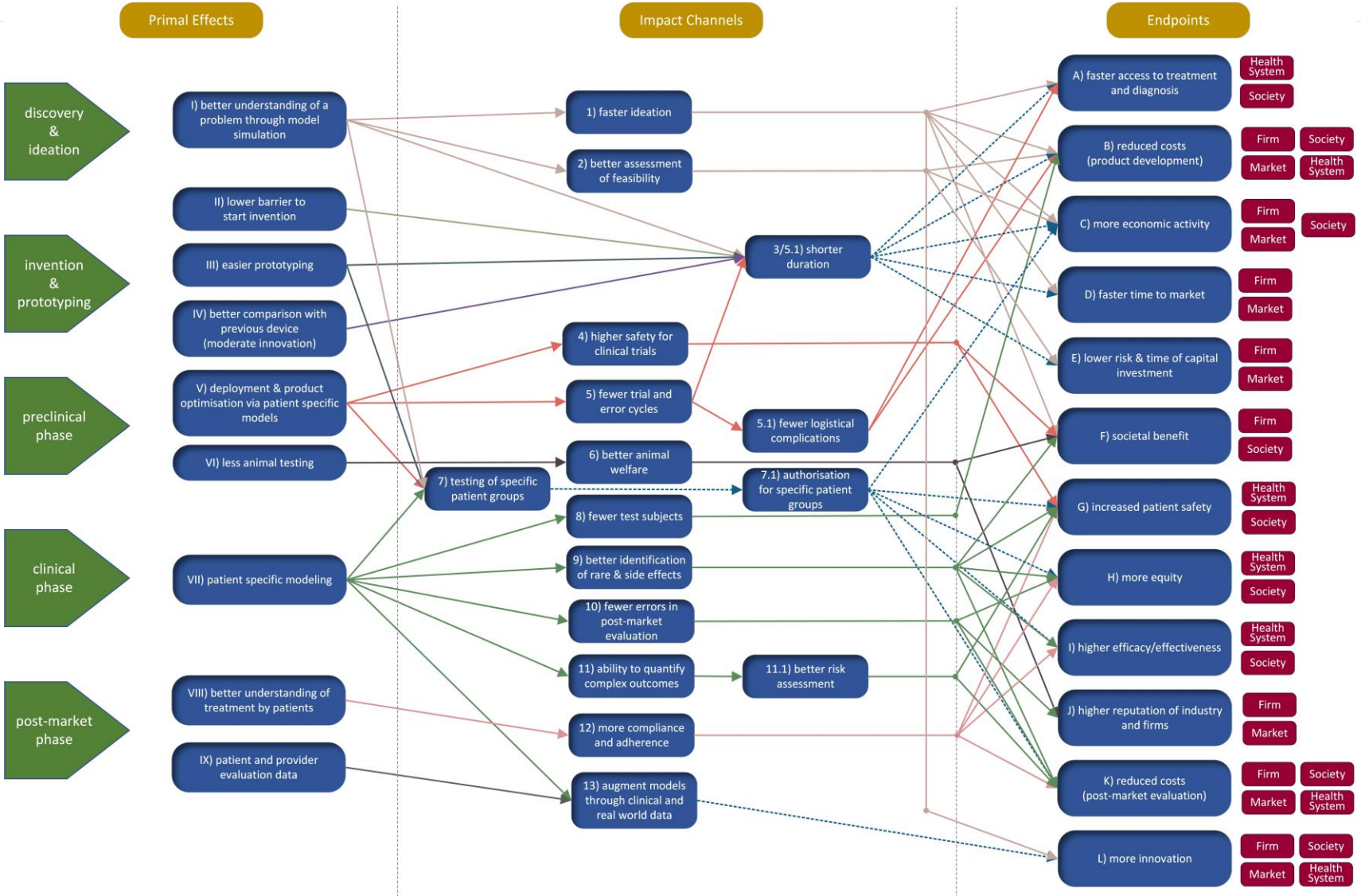


Methodological approach

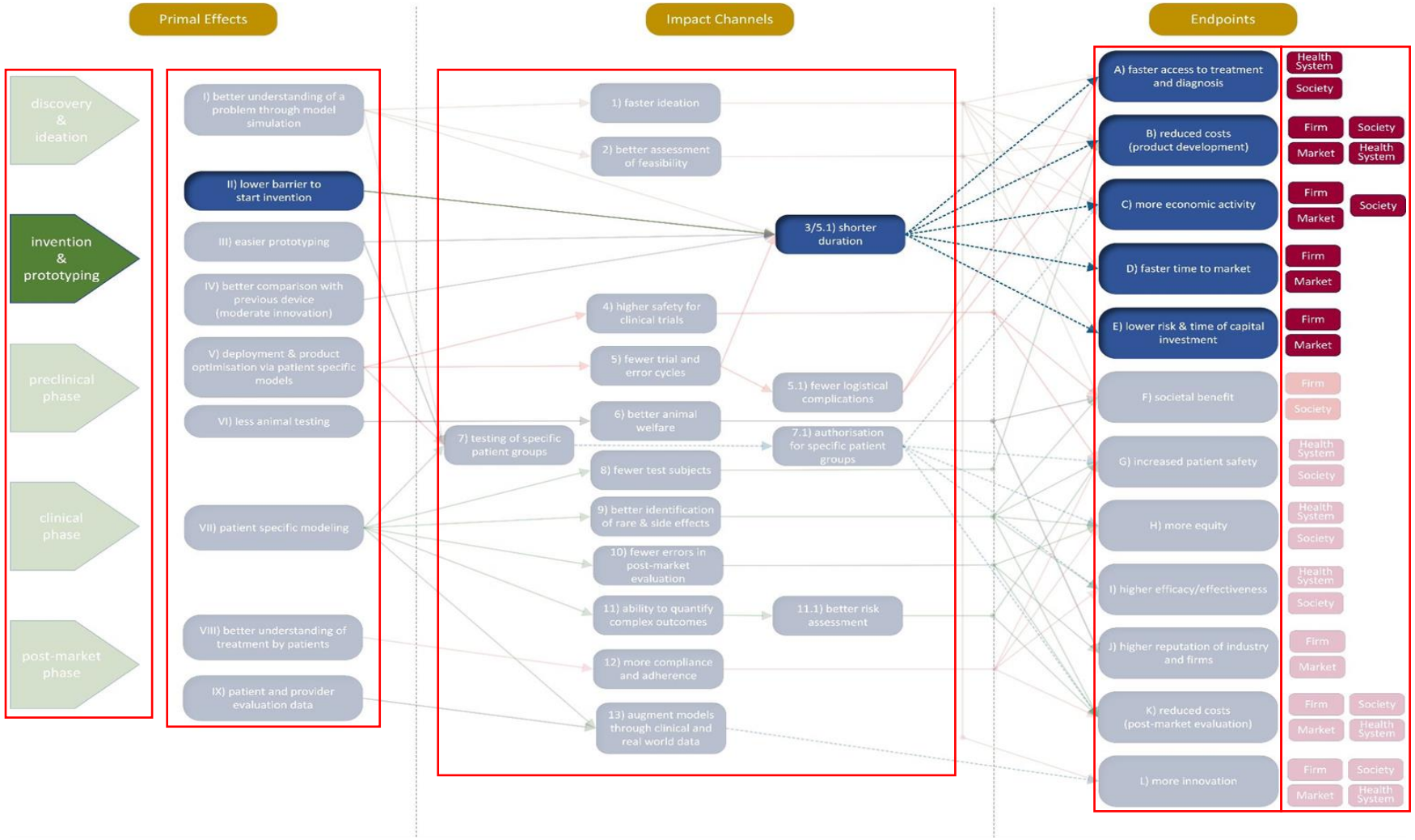
- Iterative framework development (Jabareen, 2009)
  - Scoping review (Von Elm, 2019)
  - Expert interviews
    - First: Explorative
    - Second: Different stakeholders
      - Academia, Industry, Regulators, Health Care Professionals
    - Qualitative content analysis (Mayring, 2015)
  - Focus groups with patients (Kitzinger, 1995)
  - Derivations from (health) economic theory

Elm, E. et al. (2019). Methodische Anleitung für Scoping Reviews. In: Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 143.
Jabareen, Y. (2009). Building a conceptual framework: philosophy, definitions, and procedure. International journal of qualitative methods, 8(4), 49-62
Mayring, P. (2015). Qualitative Inhaltsanalyse: Grundlagen und Techniken. Beltz Pädagogik
Kitzinger, J. (1995). Qualitative Research: Introducing focus groups. BMJ 311:299

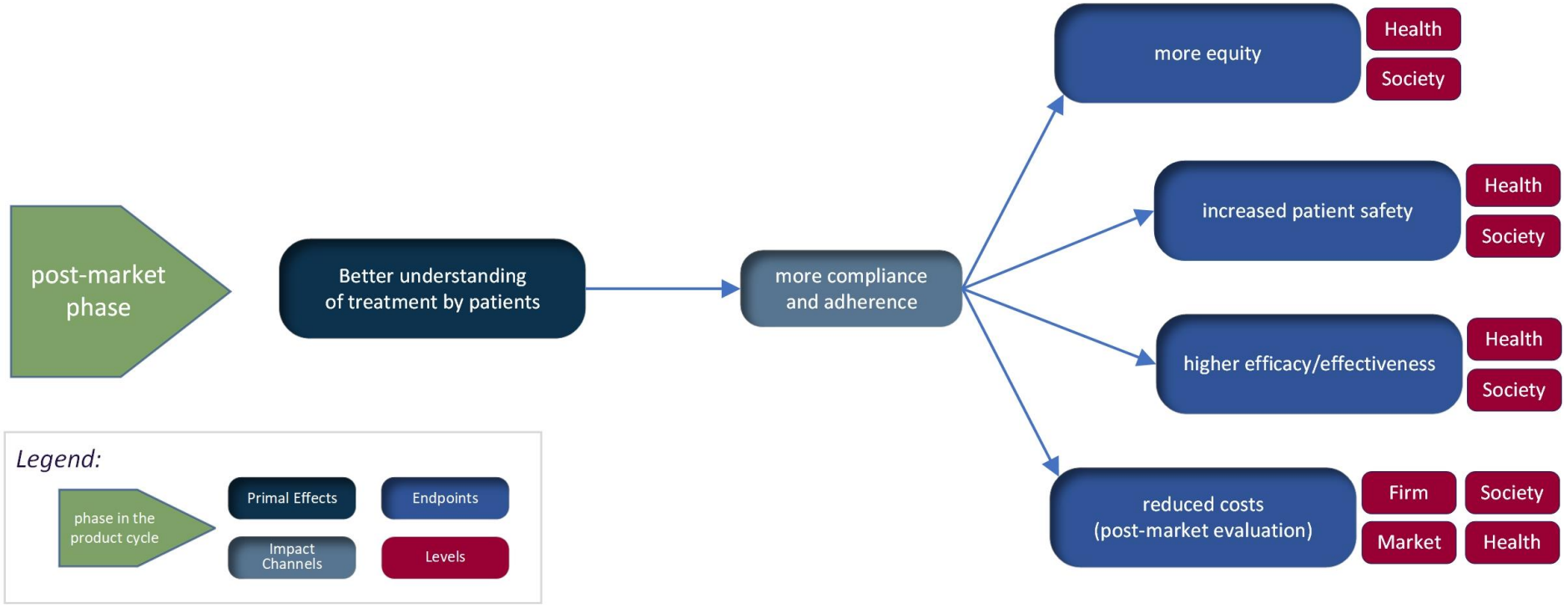
Preliminary conceptual framework 1/4



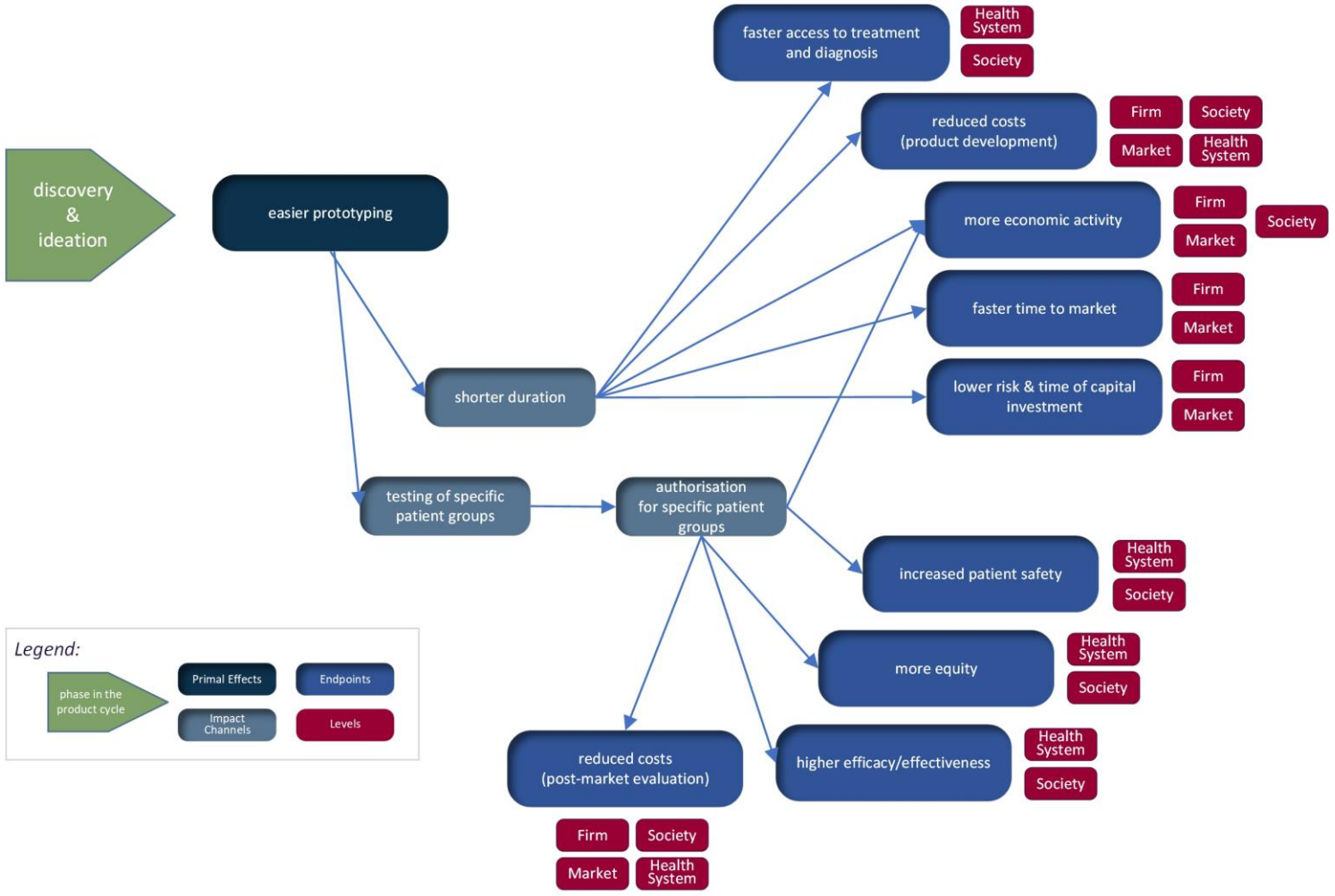
Preliminary conceptual framework 2/4



Preliminary conceptual framework 3/4



Preliminary conceptual framework 4/4



Preliminiary results: Expert interviews

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Progress with interviews

- 33 interviews conducted (+7 pending)
- international perspectives with experts from various fields around the globe

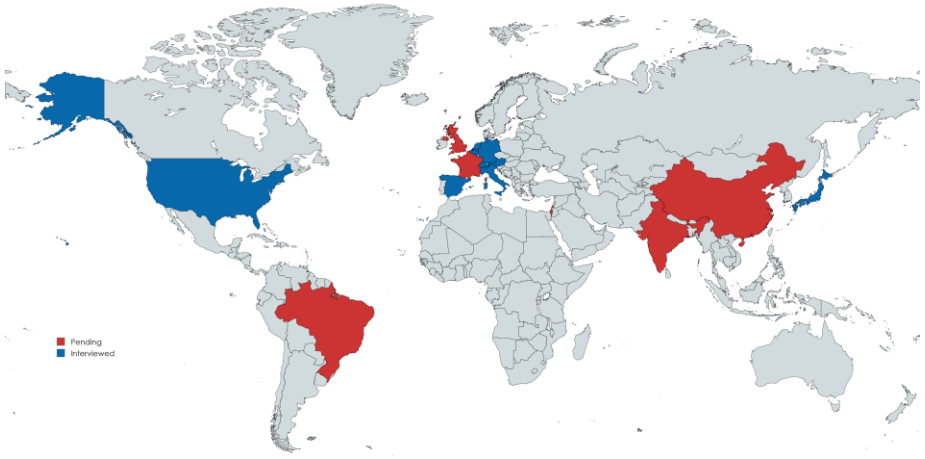


Fig. 7: Geographic representation of interview partners

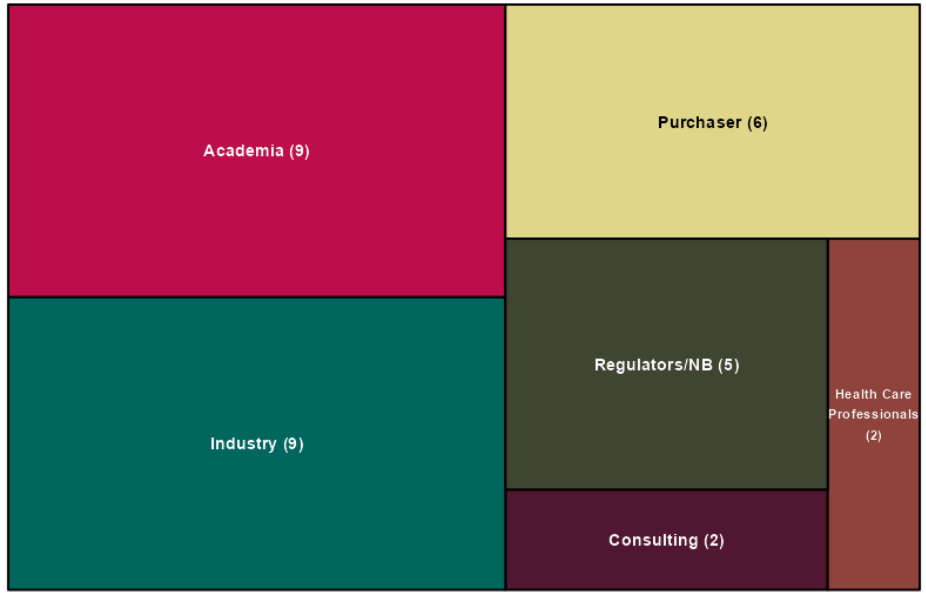


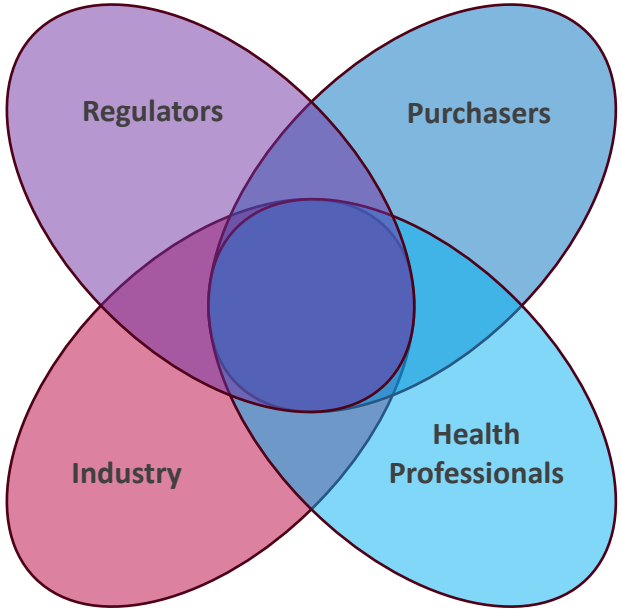
Fig. 8: Expertise area of interview partners

Preliminiary Results: Expert interviews

- Potential to reduce the **use of animals** and **clinical cohorts** is unclear
- More **regulatory guidance** regarding in-silico-VC in US compared to EU

- **Time-to-market** is likely to be shortened
- In-silico is applied to **very specific questions** in development so far

Insights



- **Competition** more relevant than production costs
- Balance between **price and efficacy** of devices depends on hospital operators

- **Training of clinicians** as a limiting factor
- **Increased safety** in clinical trials and post-market

Summary

- Systematically illustrate the potential impact of in-silico methods
- Framework as a guidance for different stakeholders
  - Necessary capital to start product development
    e.g. 10% less
  - The amount of competition on a certain market
    e.g. more firms with a similar product
  - Health care expenditure for a certain disease
    e.g. lower health care expenditure on chronic heart failure
  - Available treatment for specific population groups
    e.g. approval of treatment for children
  - Potential to enhance safety in every step of development cycle

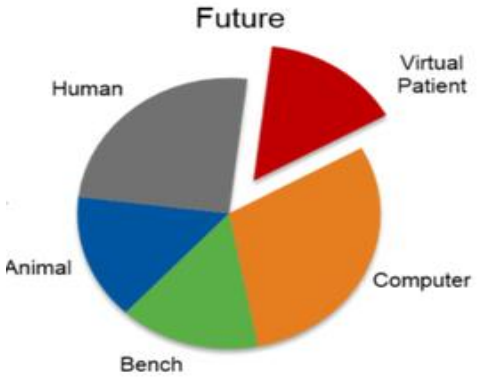


Fig 9: Source: https://mdic.org/program/computational-modeling-and-simulation-cms/ retrieved on 17th October 2023

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Suggestions for further interview partners?

Notified Bodies or Purchasers from Hospitals?

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Thank you for the attention!

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