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

T. Czyponka, S. Eisenberg, M. Reiss, M. Kraus and D. Rösler
Outline

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


Fig. 5: Source: SIMCor Deliverable 7.5 – Uncertainty quantification and re-definition of input space
Medical development cycle of medical devices

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

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

Preliminary conceptual framework 3/4
Preliminary conceptual framework 4/4
Preliminary results: Expert interviews

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
Preliminary 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

- **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

03.07.2024  David Rösler - Institute for Advanced Studies
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
Suggestions for further interview partners?

Notified Bodies or Purchasers from Hospitals?

David Rösler
Institute for Advanced Studies, Austria
Josefstädter Straße 39, 1080 Vienna
Tel: +43 1 59991 273
david.roesler@ihs.ac.at
5th June 2024

David Rösler

Thank you for the attention!

David Rösler
Institute for Advanced Studies, Austria
Josefstädter Straße 39, 1080 Vienna
Tel: +43 1 59991 273
david.roesler@ihs.ac.at