
Research question

Fundamental research in medicine development is nowadays mainly performed in industry (Hedner & Thornblad, 2014). The costs of R&D for developing a medicine have increased over the years and the chance of failure is high. The high costs are related to these higher drug failing rates and the costs for clinical development increased as well (DiMasi, 2014; Hedner & Thornblad, 2014). Not only are the costs increasing, at the same time industry's investments in fundamental medicine R&D are decreasing, resulting in a situation where the costs increase, but additional investment lacks behind (Hedner & Thornblad, 2014).

High risks, involved in fundamental medicine R&D, force industry to show risk-avoiding behaviour (Bharwani & Mathews, 2012). Some believe that this behaviour can potentially harm fundamental research in medicine development (Helleday, personal communication, December 8, 2014).

Strategies to decrease high risks are open innovation and user engagement. Open Innovation is a paradigm that assumes that firms can, and should, use both external and internal ideas and paths towards the market, as firms look to advance their technology; think for instance of licencing agreements (Chesbrough, 2003). The other strategy is user engagement, engaging the user and society with research; think for instance of patient groups who collect their own data for scientists (Epstein, 2008). Whereas open innovation offers the possibility to decrease risk and costs by sharing amongst each other and enlarge revenue due to the collaboration between firms, user engagement enables investigations into domains considered to be less economically promising by providing funding, primary data and support (Epstein, 2008; Hedner & Thornblad, 2014). Decreasing the risks lead to a decrease in R&D costs as well (DiMasi, 2014). Open innovation and user engagement could thus be considered as promising strategies to tackle the problems fundamental medicine R&D is facing.

Research question:

How can open innovation and user engagement help to tackle the problems fundamental research within medicine development is currently facing?

Sub-questions:

- 1) What benefits and barriers of using open innovation in fundamental medicine R&D can be identified in the literature?
 - 2) What benefits and barriers of using user engagement in fundamental medicine R&D can be identified in the literature?
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- 3) What are possible benefits of open innovation and user engagement in the current practice of fundamental medicine R&D and what holds organisations back to use open innovation and user engagement?
 - 4) What insights and findings about open innovation and user engagement, acquired from literature and in current practice, are relevant when aiming to tackle real life barriers and profit from the benefits in the field of fundamental medicine R&D?
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Scientific and TIW relevance

The thesis will provide insights in the application of open innovation and user engagement in the field of fundamental medicine R&D by drawing upon both theoretical insights as well as empirical findings. The research will investigate the role of society and industry. In its theoretical approach it will thus draw upon two bodies of literature, namely the field of Science and Technology Studies and Business Economics. It is expected that the findings from theoretical and empirical studies will provide fruitful insights, enabling the creation of a framework that aims to be applicable for fundamental research within medicine development.

Method

Qualitative methods are chosen, as they are most suitable to answer the stated 'how' and 'what'-questions investigating the different actors in a real life situation (van Aken et al.,2007; Yin, 2009). Sub-questions 1 and 2 will be answered through an in-depth literature study. Key insights, in the field of open innovation, addressing issues such as coupled process (since both outside-in and inside-out open innovation will be addressed) (Gassmann&Enkel,2004), partnership (Jakobsen et al.,2011) and open source (Allarakhia,2014) will help to address sub-question 1. Within the STS literature on user engagement crowd sourcing (Lessl et al.,2011), crowd funding (Hughes,2012) and patient groups (Epstein,2008) will help to address sub-question 2.

To answer sub-question 3 a case study will be conducted. The study will take place at the Helleday Lab (Karoliska Institutet, Stockholm), where I will stay for 5 months. The Helleday Lab develops a new cancer medicine, which is currently in the stage of fundamental research. The Lab experiments with open innovation and user engagement. A single case study approach is chosen, as the Lab can be seen as a representative for a fundamental research organization in the field of medicine development (Yin,2009). Within the organization multiple subunits will be questioned, like legal, managerial and scientific, relating to what Yin (2009) calls "the single case embedded design". The empirical data will be gathered by conducting semi-structured interviews, desk research and participant observations. Semi-structured interviews (5-10) are chosen as it is assumed that during the interviews broad insights about experiences of actors will be shared that cannot all be predicted in advance (van Aken et al.,2007). The participant observations will be recorded through notes (van Aken et al.,2007).

Sub-question 4 integrates the theoretical and empirical insights of question 1, 2 and 3. The results of the previous questions will be combined in order to create an applicable framework on how to tackle the problems fundamental research within medicine development is currently facing.

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