Institution: University of Northampton		
Unit of Assessment: 32: Art and Design: History, Practice and Theory		
Title of case study: Embedding user-centred design into the development of innovative medical devices		
Period when the underpinning research was undertaken: 2008 - 2019		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
1. Dr Friedemann Schaber	1. Senior Lecturer	1. 2005 - present
2. Vicki Thomas	2. Senior Lecturer	2. 2005 - present
3. Steve McGonigal	3. Senior Lecturer	3. 2015 – September 2018
Period when the claimed impact occurred: 2018 - 2020		
Is this case study continued from a case study submitted in 2014? No		

1. Summary of the impact

The University of Northampton's (UoN) recent Knowledge Transfer Partnership (KTP) with Lightpoint Medical, graded 'outstanding' by the funding body, Innovate UK, resulted in the innovation of the company's design process for their medical devices. Researchers from the Art and Design department worked with Lightpoint medical to embed new operating procedures into their company, focussed on user centred design, and to navigate the complex regulatory environment governing the manufacturing and distribution of these products. This resulted in improved product design and the development of **SENSEI**, a new device for radio-guided laparoscopic surgery in cancer patient's treatment.

2. Underpinning research

Art and Design has a long history of research into user centred design through KTPs. This research has provided new inclusive, iterative and objective driven design methods, with a focus on the role of design as a project management tool **[3.1, 3.2, 3.3]**.

Their recent work has focused on the cross-disciplinary benefits of KTPs with the medical industry, through which they have targeted medical innovations and the development of medical devices **[3.4]**. In 2019, **Dr Friedemann Schaber** and **Steve McGonigal** began a research partnership with Lightpoint Medical, a medical device company dedicated to improving health outcomes for cancer patients through precision guided surgery. Lightpoint Medical develops surgical imaging technology to scan for cancerous tumours, and instruments to detect cancerous tissue within the body to more accurately direct surgeons during surgery. **Schaber** and **McGonigal** worked with the company to develop a product prototype to create new surgical advances in laparoscopic surgery, embed user-centred design within the company's product development process, and update their existing products **[3.4]**.

The research led to a proof of principle concept for **SENSEI**®. The researchers defined the requirements for the product through observing and documenting user simulations, prototype testing, pre-clinical and clinical trials both in the UK and within Europe. They developed an in-depth knowledge of stakeholder requirements and subsequent user needs. The resulting product design prioritised optimising spatial detection and probe sensitivity, intuitive physical manipulation, clearly visible and audible notifications, and easy to interpret outputs, while also strictly adhering to international standards for regulatory safety requirements **[3.4]**.

In addition to their research on individual product design, the researchers translated their knowledge into a new product development process to define and refine products. Overall, their research has identified new opportunities for networked partnerships between medical device manufacturers, technology developers, healthcare practitioners – especially clinicians and nuclear medicine staff – and academic researchers.

3. References to the research

[3.1] Thomas, V., & **Schaber, F.** (2008). Knowledge transfer: industry, academia, and the global gift market. *Design Management Journal*, *4*(1). https://doi.org/10.1111/j.1948-7177.2008.tb00015.x

[3.2] Schaber, F. and Turner, R. (2010). "Design and Local Development, Case Studies from the UK" paper presented at the 1st International Congress on Design and Innovation of Catalonia, Sabadell Barcelona.

[3.3] Schaber, F., Thomas, V. and Turner, R. (2011). "Designing Toys, Gifts and Games: Learning through Knowledge Transfer Partnerships" in *Handbook of Research on Trends in Product Design and Development*. (eds.) Silva, A. and Simoes, R., Hershey, Pennsylvania: IGI Global, p. 482-498.

[3.4] Oldfield, F., Denman A.R., Patrick, C., **Schaber, F.,** Forbes, S., **McGonigal, S.** (2019). *From Physicist's workbench to clinical device: how a Knowledge Transfer Partnership can develop new clinical equipment*. Abstract and Paper presented at Institute of Physics and Engineering in Medicine (IPEM) Annual Medical Physics and Engineering Conference (MPEC), 28 August 2019, Bristol, United Kingdom.

4. Details of the impact

The research supported Lightpoint Medical's product design process. This occurred through embedding user-centred design in their planning process and increasing 'the breadth of information substantially within the company' **[5.1]**. As a result, Lightpoint Medical has improved their product design, been able to successfully navigate the regulatory environment, and increase the efficiency of their product for treating cancers, with impacts on both doctors and their patients. The success of this partnership was reflected by the funding body, Innovate UK, who graded it as an 'outstanding' knowledge transfer partnership **[5.2]**.

Changing Operating Procedures and Product Design Methods for Lightpoint Medical

Lightpoint Medical formalised the researcher's methodology and guidelines for best practice within the company's product development process, and introduced a new standard operating procedure **[5.3, 5.4]**. This includes 'increased capabilities within user-centred design', with the integration of a high level of user engagement, usability observations and interviews into the product design process; additionally, a user interaction framework has been established to guide the future development of the company's products **[5.1]**. The research also led to the development of an anatomical pelvic phantom to aid current and future development work and reduce the reliance on animal studies though providing a non-patient method for training users. The new protocols and procedures have improved 'efficiency throughout product development and commercialisation' within the company **[5.1]**.

As a result of working in partnership a new position, Creative Product Designer was established (2020) to ensure the new standard operating procedures are implemented in all future product designs. Lightpoint has 'permanently embedded [the post] within the company' to ensure 'that usability remains integral to the company's product development process for future innovations' **[5.4]**. Additionally, the company has increased their investment in research and development,

including the engineering team and the team for clinical project management, resulting in five new staff members **[5.1, p. 10]**.

The partnership also resulted in the establishment of new 'long-term collaborations with leading clinicians' **[5.4]**. This improved the functionality and marketability of products by embedding a 'corporate culture of usability and user-centred design' **[5.4]** into the product development process. Overall, the research created a cultural change within the organisation, ensuring 'that usability and user-centred design is fully valued and implemented' as 'a central component of the company's development' **[5.1]**. This has ensured that the companies technologies are highly responsive to user needs, 'increasing the potential for clinical translation, commercialisation and improving patient outcomes' **[5.1]**.

Creation and Development of New Products

The new design process has resulted in bringing the raw prototype for **SENSEI®** to clinical trials, though the trials have been delayed by the Covid pandemic. **SENSEI®** has been submitted for CE marking, receiving a first official audit, which took place in October 2020 with the report pending. In addition, **SENSEI®** has received US FDA approval for investigative use (see https://senseisurgical.com). The proof of principle research allowed Lightpoint Medical to incorporate usability and user centred design from the very early stages of the development of their laparoscopic imaging device, changing the way the product was manufactured. This resulted in a device that more accurately identifies cancerous tissue, using minimal-access surgery, and minimises the amount of adjacent normal tissue removed, reducing short-term problems, bed-stay, and chances of recurrence. The user-centred development process ensured the product addressed these unmet user needs. As a result of the KTP, Lightpoint have increased investment in clinical trials for **SENSEI®**, as well as for additional research and development of future versions of the technology by GBP1,350,000 **[5.1, p. 10]**.

Existing products, such as Lightpath (Imaging System), are also being re-evaluated through the new design process, to improve user acceptability, and spatial detection and sensitivity, and are also entering new clinical trials to assess improved performance, and potential in new applications.

Helping navigate regulatory policies

The regulatory environment for the development of medical devices changed considerably during the project period, with the transition in the EU to the Medical Device Regulation (EU) 2017/745 (MDR). Under the MDR, the requirements on medical device manufacturers to demonstrate thorough usability engineering for regulatory approval is now much more stringent and onerous. Lightpoint's Chief Operating Officer has testified that the research partnership was 'essential in ensuring that the product fully [met] the needs of robotic cancer surgery' contributing to its 'regulatory approval' **[5.4]**. This has better positioned the company for the market and increased commercialisation of the company's products. The laparoscopic device has received international safety standards approval, and entered an international phase I Clinical Trial in January 2020, though the conclusion of this trial may be delayed by the Covid-19 pandemic.

5. Sources to corroborate the impact

[5.1] Final Report - Lightpoint Medical KTP

[5.2] KTP Outstanding Certificate from UKRI
https://pure.northampton.ac.uk/ws/portalfiles/portal/15843536/KTP010795_200623140240_Grade_Certficate.pdf

[5.3] Lightpoint Medical, Usability Engineering Process: Guidelines and Procedures

[5.4] Lightpoint Medical Chief Operating Officer Testimonial