Institution: University of Glasgow (UofG)		
Unit of Assessment: UoA12 Engineering		
Title of case study: Diagnostic research develops the first digital home-based bowel cancer screening test		
Period when the underpinning research was undertaken: 2000−2010		
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:**
Prof Jonathan Cooper	Lecturer	1991–1996
	Senior Lecturer	1996–1998
	Professor	1998–present
Prof David Cumming	Professor	1999–present
Period when the claimed impact occurred: August 2013–present		
Is this case study continued from a case study submitted in 2014? Yes		

1. Summary of the impact

Bowel cancer has become the third most prevalent cancer in China, with >375,000 new cancers/year and ~190,000 deaths/year. Barriers to early detection include the lack of accurate and sensitive screening tests. To overcome this, UofG research developed the first, digital home-based bowel screening test, produced by UofG spin-out company, ModeDx. Oxford MEStar acquired ModeDx (2016) and developed the test for Chinese markets, led by UofG's Prof Cooper, as Advisory Board Chair. Having passed clinical trials, gained CE marking and Chinese National Medical Products Administration approval, the device is being mass-produced as a digital health screening product to address the rising challenge of recent growth in bowel cancer prevalence, attributed to China's aging population and a more westernised lifestyle with increased dietary fat, obesity and physical inactivity.

2. Underpinning research

The Advanced Medical Diagnostics Group in the School of Engineering has developed new biosensors technologies, based upon electrochemical systems. Led by Prof. Jon Cooper, this research started in 1999, supported by a GBP3.2 million DTI-EPSRC Foresight LINK "Lab on a Chip" programme. The project was coordinated by Dr Derek Craston (now The UK's Government Chemist) and was carried out in collaboration with GlaxoSmithKline (GSK), Unilever and Kodak together with a group of small and medium-sized enterprises, including Epigem.

During this period, Cooper's research enabled the development of new, advanced microfabrication techniques for microfluidic on-chip sensing and interconnect technologies for microfludics. Subsequently working with Prof Cumming's research group, Cooper integrated the biosensing technologies into analytical microfluidic devices, with low-power complementary metal-oxide-semiconductor (CMOS) application-specific integrated circuits (ASICs) for both veterinary and medical diagnostic as well as cell-based assays [3.1].

Following this research, Profs Cooper and Cumming investigated the use of sensors and optimised packaging in a fully functional, ingestible prototype pill-like diagnostic device. This work and the earlier DTI-EPSRC research, was instrumental in producing a pill-based sensor device [3.2-3.4], composed of two sensors that measured pH and temperature, reflecting the physiological environment in the gastrointestinal tract (as indicators for disease) [3.2]. Each sensor was controlled by an ASIC, that incorporated a power saving serial bitstream data compression algorithm that was found to extend the lifetime of the pill by 70%. An integrated radio transmitter was used to send the signal to a local receiver, prior to acquisition on a computer. A permanent magnet was also incorporated in the device to enable non-visual tracking of the system within the gastrointestinal tract.

The pill-based sensor presented challenges when ingested, but the underpinning circuit research [3.1-3.4] and radiotelemetry sensor design [3.2, 3.3] were applicable to the development of sensors that could be incorporated into devices to detect blood in stool (an indicator of bowel

cancer). Adaptation of the existing pill-based sensor for use in a bowel cancer screening device was inspired by a GBP1,390,000 'Integrated Diagnostics for Environmental and Analytical Systems' grant awarded by the Scottish Funding Council (2000).

This led Prof Cooper to develop intellectual property and design and develop the first digital home-based bowel screening test, using the blood's peroxidase activity. In short, haemoglobin, present in blood catalysed redox electrochemical reactions that could be detected at the biosensor using the miniaturised ASIC previously developed. As a result, UofG spin-out company, ModeDx, was launched in 2008 to commercialise the diagnostic product ***me***asure® BOWEL HEALTH which became available for sale across the UK (with the devices eventually being marketed and sold on the high street through Boots, and on-line through Amazon).

3. References to the research

3.1. Igata, E., Arundell, M, Morgan, H, and Cooper, J.M. (2002). Interconnected Reversible Lab-on-a-Chip Technology. *Lab on a Chip*, 2, pp. 65-69. ISSN 1473-0197 (doi: 10.1039/b200928p) * [Available on request from HEI]

3.2. Johannessen, E.A., Wang, L., Reid, S.W.J., Cumming, D.R.S., and Cooper, J.M. (2006). Implementation of Radiotelemetry in a Lab-in-a-Pill Format, *Lab on a Chip*, 6, pp. 39-45. ISSN 1473-0197 (doi: 10.1039/b507312j) * [Available on request from HEI]

3.3. Johannessen, E.A., Wang, L., Wyse, C., Cumming, D.R.S. and Cooper, J.M., (2006). Biocompatibility of a lab-on-a-pill sensor in artificial gastrointestinal environments. *IEEE Transactions on Biomedical Engineering*, *53*(11), pp.2333-2340. (doi: 10.1109/TBME.2006.883698) (eprints id: http://eprints.gla.ac.uk/3881/)

3.4. Cumming, D.R.S., Hammond, P.A, and Wang, L. (2010) Wireless endoscopy: technology and design. *Microengineering in Biotechnology*. pp. 221−246. (doi: 10.1007/978-1-60327-106-6_10) [Available on request from HEI]

*=best indicators of quality

4. Details of the impact

UofG spin-out company, ModeDx, was launched in 2008 to commercialise ***me***asure® BOWEL HEALTH. Despite the product showing potential and achieving sales online and in the high street, investors recommended adapting it for use in the rapidly emerging healthcare market in China. In 2016, ModeDx and the IP/technology underpinning the ***me***asure® BOWEL HEALTH device were acquired by Oxford MEStar (a company that enables the translation of products and services from the UK to China). Acknowledging Cooper's expertise and the technology he developed at UofG, Oxford MEStar invited Cooper to take the role of Chair of the Advisory Board, where he plays a key leadership role in the continuing development of ***me***asure® [5.1 page 3]. The impact arising from Cooper's research at UofG is primarily commercial – a successful spin-out company was created, which following its acquisition, has contributed to innovation in China through the design of new products to address barriers to bowel cancer screening.

The commercial value of the technology underpinning the UofG device was highlighted by a successful funding round in 2014 [5.2], which followed GBP600,000 of funding in 2010 [5.3] and GBP1,100,000 in 2012 [5.4]. In February 2014, ModeDx announced that it had received a European CE mark for the ***me***asure® BOWEL HEALTH product, and that it had successfully completed a significant funding round led by new investor, Longwall Venture Partners. Following securing the funding to develop the company, the Head of the Scottish Investment Bank (SIB), commented, "*SIB, through its Scottish Venture Fund, is delighted to further support this ambitious Scottish life sciences company. MODE has shown a commitment to innovation and the development of new products that enhance healthcare provision, and we are pleased to be able to build on previous Scottish Enterprise support from SMART:SCOTLAND to help them accelerate their growth plans*" (2014) [5.2]. The CE Certification was received following review

by an external notified body and enabled MODE to *"sell **me**asure® into the 'over the counter' home healthscreening market"*. The approval followed MODE's earlier achievement of ISO 9001 and ISO 13485 quality management systems [5.2].

At the time of acquisition, Oxford MEStar was quoted in a press release: *"We are excited about the long-term commercial potential of using this technology. We believe the IP developed by Mode, a proprietary electrochemical detection technology, is an important component that we can use to develop handheld test devices manufactured at low cost and in high volumes… We will continue to work in partnership with the University of Glasgow and maintain a corporate presence in Scotland"* [5.5].

A key commercial goal of Oxford MEStar is to bridge the gap between UK biotech companies and Chinese markets. Oxford MEStar reported: *"We believe there is enormous potential in this market for China; the current technology in China is not restrained by a lack of funding, but its lack of advanced technology and resources, which are readily available to Oxford MEStar. We are equipped with the right resources, and an abundance of knowledge and expertise to bring British bio-businesses and technology to the Chinese healthcare market"* [5.6]. By acquiring the technology developed by Cooper and working with the UofG, Oxford MEStar has been able to meet its commercial goal of taking UK biotechnology advances to China [5.6]. Building on this goal, Oxford MEStar have further developed the device, with guidance from Cooper, to make it more suited to Chinese markets [5.1].

In China, the incidence of bowel cancer has risen in recent years [5.1], and while some countries have strong participation in bowel screening programmes, in Asia there is low public awareness and little support by health authorities for bowel screening. Following the acquisition of ModeDx, Oxford MEStar are now mass-producing ***me***asure® in China via Scottech Medical Co. Ltd (Oxford MEStar's sister company), in Tianjin [5.1 page 1]. Building upon the original UofG research, an improved version of the product was developed for launch in China. In order to secure this place in the Chinese medical diagnostics market, Oxford MEStar carried out clinical trials in two hospitals in China [5.1 page 2]. These trials showed that ***me***asure® can detect faecal occult blood, using the existing hospital-based diagnostics as the gold standard/reference [5.1 page 2]. In December 2019, Cooper evaluated the results from these hospital trials, which represented a critical step in the device gaining Chinese Food and Drug Administration/NMPA approval [5.1 page 2]. The success of the ***me***asure® product has directly led to Scottech Medical increasing its staff from 5 to 18 between 2016 and 2020 [5.1 page 1].

Following ***me***asure® being approved in China, Oxford MEStar are further developing the original UofG-based technology to function with Bluetooth, creating new products that are compatible with smartphone and tablet apps [5.1 page 3]. This is an important adaptation made by Scottech Medical, enabling the device to fit with society's changing needs around digital health and to make the device particularly useful in low-resource areas and community health centres [5.1 page 3]. The versatility of the device is enabling adaptations to be made so that products remain at the forefront of technological advances, with Cooper's leadership being crucial to the continued commercial viability of Scottech Medical [5.1 page 3].

5. Sources to corroborate the impact

(PDF uploaded for all the documents listed)

5.1. Letter of support from Deputy General Manager, Scottech Medical
5.2. '*Parkwalk closes Opportunities Fund and syndicate investment into Mode Diagnostics*' – Press release from Parkwalk Advisors. February 2014. https://parkwalkadvisors.com/2014/02/mode-dx-2/

5.3. *'MODE Diagnostics Ltd – Secures £600,000 funding to develop home diagnostic products'*- Press release from IPG Group Plc. September 2010. *https://www.ipgroupplc.com/media/portfolio-news/2010/2010-09-16*

5.4. *'Mode DX ltd - MODE Diagnostics attracts over £1,100,000 funding to develop health & wellness home diagnostic products'* – Press release from IPG Group Plc. July 2012. https://www.ipgroupplc.com/media/portfolio-news/2012/2012-07-02

5.5. '*Oxford MEStar to develop diagnostic products in cancer and infectious diseases using intellectual property acquired from University of Glasgow spin-out, Mode Diagnostics Limited*' – Press release from Oxford MEStar. August 2016. http://www.oxford-mestar.com/oxford-mestar-mode-diagnostics-limited/

5.6. '*Bridge to China - China is becoming the second largest economy in the world; Oxford MEStar is seeking this opportunity, and is in the process of building such technology transfer relationships with Chinese from British bio-businesses'* – from Oxford MEStar website. http://www.oxford-mestar.com/products/bridge-to-china/