Zilico - Non Invasive Cancer Diagnostic

What is the innovation?

Zedscan is an objective device that can differentiate between normal, pre-cancerous and cancerous cells. The device can be used for patients who have been referred to the colposcopy clinic because of a positive cervical smear result. It uses electrical impedance spectroscopy (EIS) that provides a real-time diagnosis, removing subjectivity and potentially avoids the need for a biopsy. Once Zedscan becomes established it will significantly reduce the need for an independent biopsy. The technology will more than pay for itself through reduced histopathology and lab costs.

What problem does it solve?

Cervical cancer diagnosis is a multi-step process. The first stage is a smear test which involves taking a sample of cells from the cervix. These are sent to a cytology laboratory for examination by a skilled histo-pathologist. Patients demonstrating a positive smear are then referred to a clinic for a magnified visual examination of the cervix by a colposcopist who seeks to discriminate between normal, pre-cancerous, and cancerous cells. This is highly subjective and the only way to positively confirm diagnosis is by a biopsy. Ethical and economic issues mean that it is not practical for every woman to have a diagnostic biopsy as a routine screen. The current multi-stage diagnostic method has many shortcomings including:

- Poor performance (false results), resulting in missed positives in smears and leading to over-treatment in colposcopy,
- A time delay in getting results to patients,
- Significant costs in running the screening programmes.

What was the inspiration for the idea?

The idea for a new detection device originated from research by Professor Brian Brown, Head of Medical Physics at the University of Sheffield, and John Tidy, a Gynaecological Oncologist at Hallamshire Hospital (Sheffield Teaching Hospitals NHS Foundation Trust). They found that EIS can differentiate between the electrical resistivity of normal, precancerous and cancerous cells. By comparing actual readings against a data bank of well characterised tissues it is possible to indicate the likelihood of cancerous legions being present with a high degree of accuracy and reproducibility. Their work led to the development of a unique diagnostic device able to reliably detect pre-cancerous cells in the cervix.

Was there any IP, how was it protected, were there any complications?

Yes to all three! The University of Sheffield held the original patent on the application of EIS technology to the detection of cancerous tissues. Having failed to find a commercial partner, the University let the patent lapse in 2004. Medipex got involved and quickly identified the commercial opportunity, identified a partner and funding and managed to secure patents on some improvements rather than the original technology. The company also trademarked the names (Zilico and Zedscan), domain names and amassed a significant amount of knowhow (trade secrets) around specific technical aspects of the design and the characterisation of tissue using EIS technology.

What happened next?

Following a successful clinical study, Medipex were asked to assess the opportunity and, if appropriate put in place a commercialisation plan in 2005 as they had the most relevant expertise in the medical technology arena. Medipex put in place an interim management team, developed the business plan, secured initial investment in 2006 and established a new company, Zilico Ltd, to exploit the opportunity. Another successful funding round saw a full time CEO and Technical Director recruited to take over the day to day running of the business. Medipex continued to support the business initially as a founder investor on the board of Zilico. Medipex continue to support Zilico through its wider stakeholder engagement with the investment and clinical community.
Zilico obtained CE mark regulatory approval during 2014 and successfully launched the product on the market. Sheffield Teaching Hospital became its first major NHS customer. NICE published a Medtech Innovation Briefing in Feb 2015 that favourably reviewed ZedScan. The purpose of these Briefings is to encourage rapid uptake of promising new innovations.

Where is the innovation now?

Zedscan is now on the market, in the UK it is being sold via a specialist distributor. It still requires significant inventor support as a key opinion leader in cervical cancer supported by peer reviewed paper. Through wide scale evaluations the NHS it is slowly starting to make use of Zedscan. Overseas sales in Europe are also starting to grow as the CE certification means it has basic market authorisation across EU.

Future plans for the innovation?

A second application of the technology will be targeted at the very large cervical screening market (e.g. Smear test). Additional clinical applications are being investigated including oral and oesophageal cancer, anal cancer as well as an application to diagnose pre-term birth in babies.
Disruption to the clinical pathway by the introduction of vaccines has resulted in other products being developed. The recently introduced HPV molecular test will be the likely choice of front-line screening in the developed world as the test is very sensitive though the bio-marker is not very specific. A recent update from The U.S. Preventive Services Task Force (USPSTF) suggest that in the USA they require further evidence before HPV tests will be used as a primary screen. However, the test will require a triage (a test to identify those HPV-positive women most likely to require referral) because it only confirms the presence of HPV rather than detecting actual disease and most HPV infections are self-resolving, and therefore a test that would confirm disease state, like ZedScan, would have significant utility.

Patient and Clinical benefits of ZedScan:

- Reduces the number of diagnostic biopsies by an estimated 30-50% and reduces the related morbidity (through a reduction in subjectivity of the colposcopy examination)
- Provides diagnosis in real time – earlier detection
- Performance is better - better predictive outcome when compared to current technique
- Reduces anxiety in patients (instantaneous results)
- Reduces co-morbidity due to avoiding unnecessary biopsies
- Ascertain exact location of lesion
- Although the technology was developed for the cervical cancer application, the underlying principle of using EIS to examine tissue structure will be applicable to other cancers e.g. oral (research underway), anal, vulval and vaginal cancers.

Any lessons learned?

The time it takes to take a working prototype and launch a medical device is significant and is often 7-10 years before it is likely to start generating any commercial return. The costs of underwriting this type of medium term development are also significant and this is against a backdrop of increasing safety regulations, changes in clinical practise, tightening of healthcare budgets and the possibility of disruptive technologies, e.g. HPV tests. It is therefore essential to have a very clear view of the challenges before deciding on embarking on this type of development and to ensure you have the correct partners who can help to de-risk and manage the project.