Publishable Summary

Summary
Cancer is the second largest cause of death and morbidity in Europe, with over 3 million new cases being diagnosed each year and can affect anyone – the young and old, the rich and poor, men, women and children. The most effective treatment method for most forms of cancer is early detection followed by surgery. The problem with surgery is that even after the cancerous tissue has been removed, cancers frequently recur. This is a result of incomplete excision of the original cancerous tissue or inadequate clearance of surgical margins. Tumors fail to be completely excised because the surgeon only has the visual appearance of the tumour and palpation to differentiate malignant from benign tissue. Consequently, there is an urgent clinical and market need for improved tools to detect cancerous tissue during surgery.

The Cerenkov Luminescence Imaging (CLI) Project aims at developing two real-time imaging devices during surgery and will enable surgeons to more accurately resect tumors and thereby reduce the likelihood of post-surgical recurrence. However, all efforts to develop an intra-operative imaging modality capable of accurately detecting cancer during surgery have so far been unsuccessful.

The project entitled CLI will evaluate the imaging technology in patients undergoing surgery for gastric cancer and brings together a wealth of knowledge and experience of partners from Hungary (Cromed Research, Semmelweis Egyetem and OSSKI), Germany (ABX-CRO) and the United Kingdom (LightPoint Medical and Sagentia).

Ian Quirk, Director of Clinical and Regulatory Affairs at Lightpoint Medical commented “At Lightpoint we’re excited to be a part of a collaboration involving such high calibre collaborators in this Framework Program 7 project, kindly funded by the European Commission. Significantly improving outcomes in cancer surgery at the core of everything Lightpoint strives to achieve and this project offer the opportunity to apply that ethos to gastric cancer.”

Description of work performed
The CLI Project had its 1st Consortium Meeting in February 2014, which helped to establish good communication and collaboration between the partners. Since then, the Consortium have built on its strong foundations and achieved positive results within a short space of time.

Lightpoint has worked in cohort with Sagentia to develop, optimise and produce the CLI specimen analyser and the BetaScope for use in the study. The documentation on the design and regulatory issues not only of the devices themselves, but also activities associated with the submission of dossiers for such regulated devices to be approved for clinical use in studies.

Training was provided on the Specimen Analyser to the pre-clinical team in Budapest on 30th May 2014 and for the BetaScope on 9th Sep 2014, which provided an overview of the operating software and user interface, examples of images acquired, practical information and review of instructions for use.

The Hungarian authorities approved the ethical approval for the use of the devices in the preclinical trials and in September 2014 the first preclinical trials begin at the Frédéric Joliot-Curie National Research Institute for Radiobiology and Radiation Health (OSSKI), along with the first calculations for the dosimetry (ABX-CRO).
Expected Final Results
The state-of-the-art for intraoperative cancer detection is visual and tactile assessment, are in limited cases, pathology. However, visual and tactile assessments have very low sensitivity, specificity, and objectivity. Further, tactile assessment cannot be performed for endoscopic procedures. Pathology requires upwards of thirty minutes, which lengthens the duration of the surgical procedure, and requires invasive tissue sampling.

Emerging technologies that could compete with CLI either have low diagnostic performance of require costly and lengthy development of novel imaging agents. CLI offers a unique opportunity due to its high diagnostic performance and its compatibility with approved diagnostic agents. The specific advances that this project will bring include:

- Improved sensitivity and specificity for intraoperative cancer detection
- Prototype for manufacturing scale-up, and clinical trials
- Preclinical and clinical validation
- Known radiation dosimetry
- Improved usability and performance based on surgeon-user feedback

It’s anticipated that this project will yield substantial new intellectual property, know-how, and business services.

For more information on the CLI project, please visit our website or contact us directly.
Website: http://www.clioproject.eu/
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