

PRE-CLINICAL STAGE TO DEVELOP A MULTIMODAL HIGHLY-SENSITIVE PHOTONICS ENDOSCOPE FOR IMPROVED IN-VIVO COLON CANCER DIAGNOSIS AND CLINICAL DECISION SUPPORT

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INTRODUCTION

The PICCOLO project proposes a new compact, hybrid and multimodal photonics endoscope based on Optical Coherence Tomography (OCT) and Multi-Photon Tomography (MPT) combined with novel red-flag fluorescence technology for in vivo diagnosis and clinical decision support. Using both it will be provided high-resolution structural and functional imaging, giving details of the changes occurring at the cellular level comparable to those obtained using traditional histological techniques and major benefits over traditional colonoscopy. Gastroenterologists will get immediate and detailed in situ identification of colorectal neoplastic lesions and facilitate accurate and reliable in vivo diagnostics, with additional grading capabilities for colon cancer. as well as in situ lesion infiltration and margin assessment.

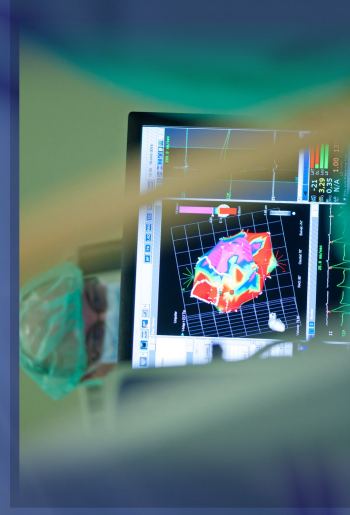
OBJECTIVES

The current project aims to establish and show the different phases of the preclinical trials to be held during the development of this device under GLP conditions.

METHODS

The preclinical stage of the study will be divided in three phases involving technicians, gastroenterologists and pathologists:

- 1. LABORATORY TRIALS.** Ex-vivo samples from organic tissues will be used to perform a functional testing of the system in lab settings allowing, test the laser safety, imaging and adjust the parameters acquisitions before to generate the database.
- 2. ANIMAL TRIALS.** The aim to generate a well annotated database for training, testing and validate the system, with clinical, imaging white-light, OCT, MPT and Histology information, used to train, test and validate the algorithm of the CAD system. These trials will be divided into two sub-phases: (1) Safety trials (an adaptation of ISO 10993) in two different stages with New Zealand Rabbits and Large White Pigs; (2) Validation of lesion recognition, in which we will use the species Pirc F344 / NTac-Apcam^{1,3,7} of a CRC Rattus norvegicus model in groups at different ages (2, 4 and 8 months of age), and a model of hyperplasia developed in its wildtype.
- 3. VALIDATION OF USE.** Large White Pigs will be used to ensure that the device conforms to defined user needs and intended uses, under actual or simulated use conditions.



RESULT DISCUSSION

The proposed preclinical methodology will allow to validate the imaging biomarkers and CAD software of this new multi-photonic endoscope for lesion diagnosis in a pre-clinical stage under GLP conditions using in vivo tissue analysis, quantify the ability of the new endoscope to assess lesion infiltration and assure the safety of the new device on animal model.

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