Endodrill® Model X - a new endoscopic biopsy instrument taking multiple cancer samples of varying depth in one single session

Reporting

Project Information

Biopsy X
Grant agreement ID: 816708

Closed project

Funded under
H2020-EU.2.3.
H2020-EU.3.
H2020-EU.2.1.

Overall budget
€ 71 429

EU contribution
€ 50 000

Coordinated by
BIBBINSTRUMENTS AB
Sweden

Periodic Reporting for period 1 - Biopsy X (Endodrill® Model X - a new endoscopic biopsy instrument taking multiple cancer samples of varying depth in one single session)

Reporting period: 2018-03-01 to 2018-08-31

Summary of the context and overall objectives of the project
With more than 3.7 million new cases and 1.9 million deaths each year, cancer represents the second most important cause of death and morbidity in Europe. Early and accurate diagnosis is a major societal challenge. Endoscopy with biopsy sampling are gold standard for diagnosis of some of the most common cancers. However, none of market available solutions has reached the required performance enabling substantial decrease in examination time and increased sampling accuracy. This unmet clinical need is a business opportunity that BiBBInstruments AB has identified and thus developed EndoDrill® Model X, a new innovative single-use medical instrument, enabling taking multiple samples in one session, without removing the instrument between every biopsy. Additionally, EndoDrill® Model X offers the possibility to sample both superficial and deeply situated biopsies, a unique feature in itself. BiBB’s innovation is beneficial for several reasons as it: saves healthcare resources (time and money), significantly reduces patient’s discomfort during the examination and saves patients’ lives by offering earliest possible cancer diagnosis.

The overall objectives of Phase 1 project were to evolve EndoDrill® Model X and transform the initial business plan into a robust strategy for international commercialization.

**Work performed from the beginning of the project to the end of the period covered by the report and main results achieved so far**

The work performed (covered by the report) included performing technical, operational, organizational, market, commercial and financial feasibility, resulting in a business plan development and formulation.

Key milestones achieved: (1) Sampling principle has been validated in a pre-clinical setting; (2) User needs have been established trough structured interviews; (3) Freeze of design specifications; (4) Manufacturability for volume production has been validated; (5) Partners identified and contacted (6) Project plan developed; (7) Business plan created and validated.

**Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the project so far)**

The EndoDrill® Model X is a completely new and unique concept, featuring multiple biopsy sampling as well as sampling of both superficial and deep tumor tissue. Our strategic objective is to deliver a global solution that will become a gold standard biopsy sampling instrument. The SME Instrument funding will be used to boost the development, including clinical trials and preparation for global commercialisation, for rapid international expansion. The outcome of the project will be a market and investment ready product, with clinical safety and efficacy data required for a global market entry. Our project will have a tremendous effect on cutting down healthcare costs, saving lives and will help EU-countries to meet the challenge of quick and reliable diagnosis of cancer.