# Micro-tumor Guided Cancer Therapy Selection MicroCaT

## Rendicontazione

Informazioni relative al progetto

**MicroCaT**

ID dell'accordo di sovvenzione: 777718

Sito web del progetto

**DOI**
10.3030/777718

Progetto chiuso

**Data della firma CE**
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**Data di avvio**
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**Data di completamento**
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**Finanziato da**
SOCIETAL CHALLENGES - Health, demographic change and well-being

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**Contributo UE**
€ 2 986 699,25

**Coordinato da**
2CUREX A/S
Denmark

# Periodic Reporting for period 3 - MicroCaT (Micro-tumor Guided Cancer Therapy Selection MicroCaT)

**Periodo di rendicontazione:** 2020-02-01 al 2021-03-31

## Sintesi del contesto e degli obiettivi generali del progetto

Colorectal cancer (CRC) is the second biggest cancer killer in Europe. Once diagnosed with CRC, many patients receive chemotherapy that is based on standard protocols comprising combinations of several drugs. The effectiveness of each of these drugs has been established in clinical trials which

have determined an average effect on a group of patients. However, just like every human is unique, so is each cancer patient's tumor. A tumor's sensitivity or resistance to therapy differs from one person to the next. This explains why many patients fail to show significant improvement in response to an initially chosen chemotherapy protocol. At the same time these patients suffer from unwanted side effects and after two months are switched to another drug regime – giving rise to additional drug and hospital costs.
The overall objective of the MicroCaT project is the clinical validation and commercialization of IndiTreat®, an ex-vivo chemosensitivity test developed by 2cureX A/S, a Danish SME. IndiTreat® is a functional precision medicine test using live 3D microtumors prepared directly from a patient's tumor. These microtumors are exposed to a variety of different drugs, drug combinations and targeted therapies and – put simply – IndiTreat® measures in real time which treatment causes the microtumors to die. It such allows the selection of the most effective and least toxic drug regimen for each individual patient prior to initiating treatment. For the oncologists and patients this greatly improves the probability of selecting an effective drug treatment.
In the field of cancer biology, it is now well established that cancer cells interact directly with their micro-environment. Within a tumor, cancer cells "talk" to each other and to all the surrounding cells that all participate and contribute to the cancer process. The 3D microtumors used in IndiTreat® best reflect the situation of a patient's tumor environment which is essential to accurately predict the clinical response of the individual patient. Together with the Lillebaelt Hospital Vejle (LHV) Denmark, 2cureX conducted an interventional study with metastatic colorectal cancer patients and established both clinical evidence and utility of IndiTreat®. Communication and dissemination of MicroCaT project activities are under way to bring this breakthrough innovation to the attention of clinicians, patients and health assessment authorities. Commercializing IndiTreat® will enable 2cureX to significantly grow and expand its business.

## Lavoro eseguito dall'inizio del progetto fino alla fine del periodo coperto dalla relazione e principali risultati finora ottenuti

The work performed during the MicroCaT project centred around five main activities: First, to provide the basis for expanding the IndiTreat offering to Germany and the UK, 2cureX has established an operational 2CX Branch (100 % subsidiary of 2cureX A/S) in Hamburg, Germany. In parallel we have enabled a 2curex partner, the QEHB in the UK to perform IndiTreat® measurements.
Second, 2cureX has established a Quality Management System (QMS) and performed and documented all experiments necessary for the CE-marking of IndiTreat®. 2cureX filed a Declaration of Conformity with the Danish Medicines in October 2018. It enables 2cureX to market IndiTreat® as a CE-IVD product under the Directive 98/79/EC for in vitro diagnostic medical devices. A major investment in the third year was to get the ISO 13485 compliant QMS audited and to future-proof IndiTreat® such that it will also conform with the IVD-Regulation that all CE-IVD products need to comply with by May 2022.
Third, the clinical validation of IndiTreat® has been carried out together with the Lillebaelt Hospital Vejle (LHV) Denmark. This interventional trial is aimed at demonstrating the ability to generate tumoroids from needle biopsies of the patient's liver metastasis and to perform IndiTreat® measurements guiding drug therapy in patients suffering from metastatic colorectal cancer. The first

patient was registered in the study in October 2017, and in December 2020, the last patient received IndiTreat-guided treatment. It now has been shown that 50 percent of the patients receiving IndiTreat® guided therapy did not experience any growth (progression-free survival or Progression-Free-Survival, PFS) of their liver metastases after eight weeks of treatment. The standard of care (SOC) for these difficult-to-treat patients gives a PFS value of 20 percent. On Mai 19th, 2021 ASCO published the outcome of the clinical trial in the ASCO meeting library (https://meetinglibrary.asco.org/record/198560/abstract). It demonstrates that the primary endpoint of the trial was met.

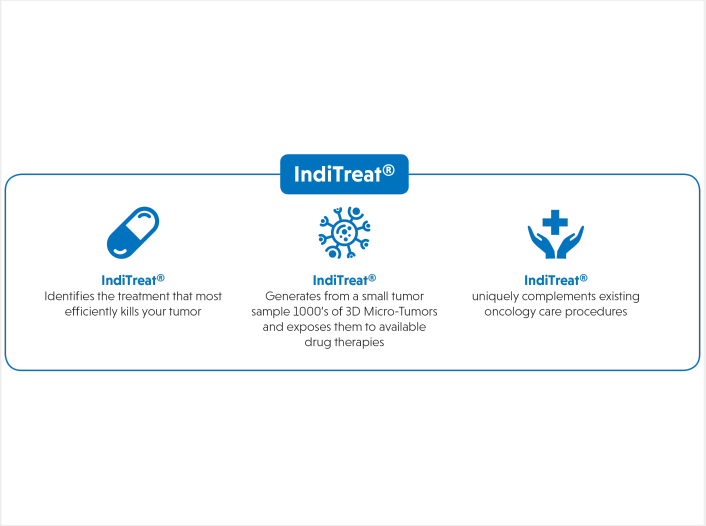
Fourth, after the IPO at the Nasdaq First North in November 2017, 2cureX has executed a very comprehensive dissemination and communication program comprising > 50 Press Releases, 40 non-scientific and non-peer reviewed publications, 15 Investor Presentations. 2cureX actively participated in 10 conferences. This has been flanked by social media activities on Twitter and LinkedIn. Finally, to prepare for market replication we have met and conducted interviews with target customers and added their input into a revised business plan. IndiTreat® was officially launched at the virtual ESMO (European Society of Medical Oncology) conference in September 2020. We have completed all pre-commercialisation activities and are now offering IndiTreat® testing in several regions throughout Europe.

Fifth, together with a consulting company specializing in market access we have reviewed the launch readiness of IndiTreat® and closed gaps. We have conducted multiple pre-commercialisation activities to establish logistics e.g. transportation of fresh tissue, defined treatment regimens, and reporting requirements for different European regions. Together with an external partner we developed a health economic model that will be used in in preparing the HTA dossiers for GE, UK and other European markets. The material is also helpful for negotiating contracts with IndiTreat® customer hospitals and local distribution partners. Finally, we have started to adapt and optimize IndiTreat® so that it is compatible with 3D microtumors derived from pancreas cancer patients.

## Progressi oltre lo stato dell'arte e potenziale impatto previsto (incluso l'impatto socioeconomico e le implicazioni sociali più ampie del progetto fino ad ora)

The valuable insights gained from IndiTreat® testing can be used i) during primary treatment to choose between multiple equivalent treatment options, ii) if the patient is not responding to a chosen treatment or iii) if the cancer recurs. The IndiTreat® variant for colorectal cancer now has a European CE-IVD approval. In addition to the clinical validation study performed within the MicroCaT project, 2cureX has started additional clinical studies with leading cancer hospitals in ovarian and pancreatic cancer. 2cureX successfully operates a 2CX branch in Hamburg. With the CE-IVD marking of IndiTreat®, 2cureX made a very important step to market and develop IndiTreat® further in Europe. With strong clinical data, good dialogue with customers and patients, 2cureX has launched IndiTreat® in the fall of 2020. During the next couple of years 2cureX expects to become a key player in the area of functional precision medicine of several cancer entities in key European markets. To support this expansion, the company will grow both with regard to staff and business units. Most

importantly, IndiTreat® will contribute to reducing cost and lost time associated with ineffective therapies and improve the quality of life of numerous European cancer patients.




IndiTreat(R) Features

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**Permalink:** https://cordis.europa.eu/project/id/777718/reporting/it