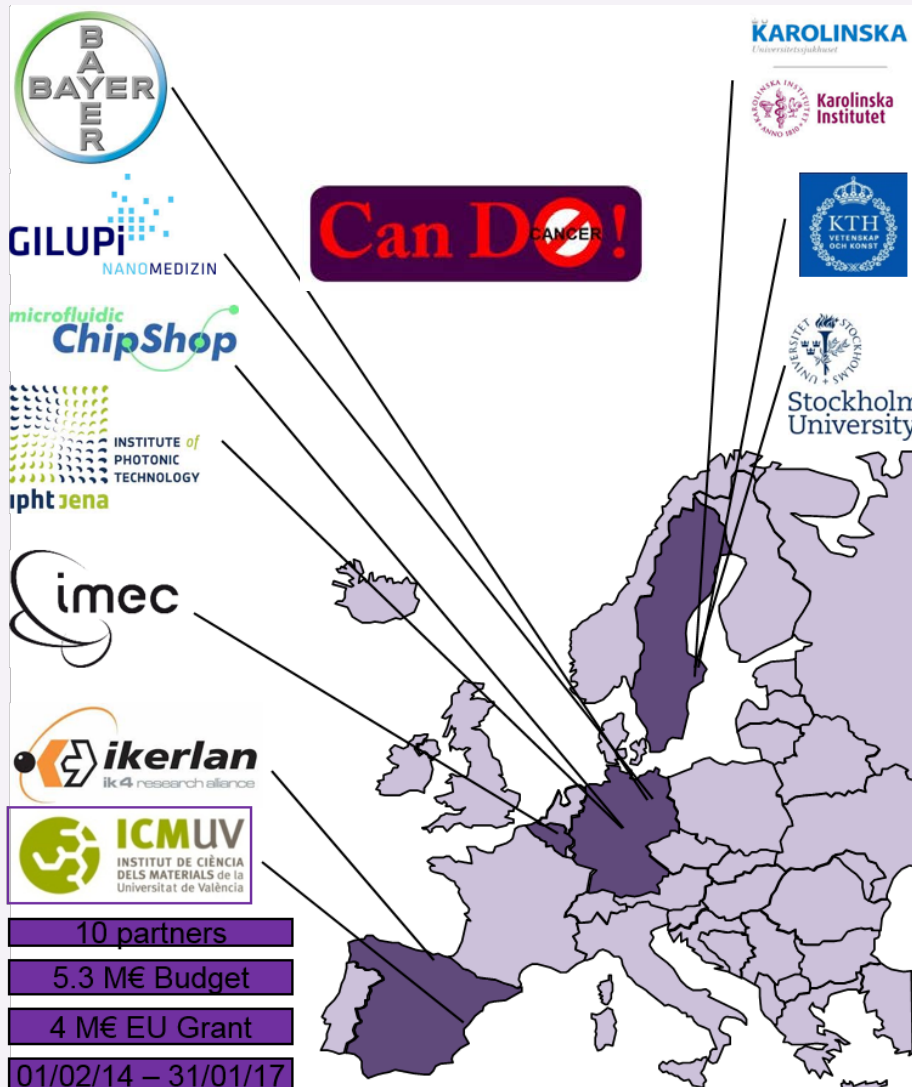


Project Goal and Consortium

Goal and consortium



Prof. Lennart Eriksson (Karolinska)



Pancreas cancer and circulating cancer cells (CTC)

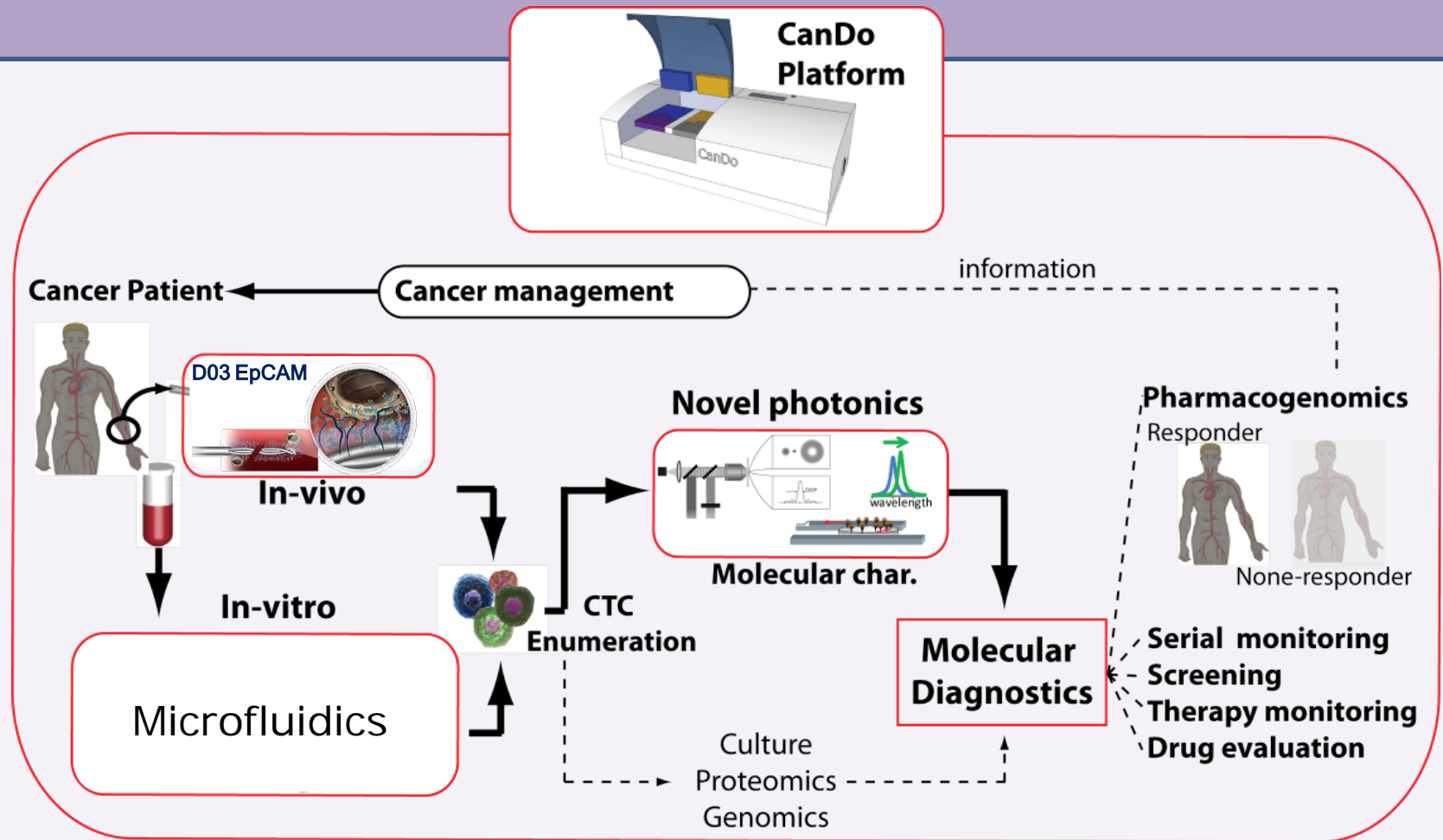
- **Pancreatic cancer** – late diagnosis so 96% chance of death for 68k EC and 45k USA citizens pa.
- *Most relevant biomarkers, CTCs ($< 10^{-9}$ cells) require more reliable and sensitive cell sorting technology.*
- In CanDo we aim to integrate **established technologies** to a diagnostic platform for isolation and characterization of CTC
- **A significant advance in early stage cancer diagnostics and monitoring** for use in *cancer management and drug development.*

A CANcer Development mONitor

FP7-610472-CanDo 4M€, 2014-2017

Project Goal and Consortium

Platform structure



Maximum information from cells can be extracted through a combination of

- **advanced cell enrichment technology**
- with an **integrated detection** method

Project Goal and Consortium

Technologies used to target end user's needs

Cartridge 1: Whole cells

CTC identification and quantification

Methods established in diagnostics

- Immunocytochemistry
- FISH (Chromosomal analysis)

New methods in CanDo

- Raman
- SERS

Cartridge 2: Nucleic acids

CTC molecular analysis

RCA products on beads

Methods used in diagnostics

- FISH (Mutations and Expression)
- PCR + sequencing
- NGS, CGH

New methods in CanDo

- Padlock probes
- Ring resonators

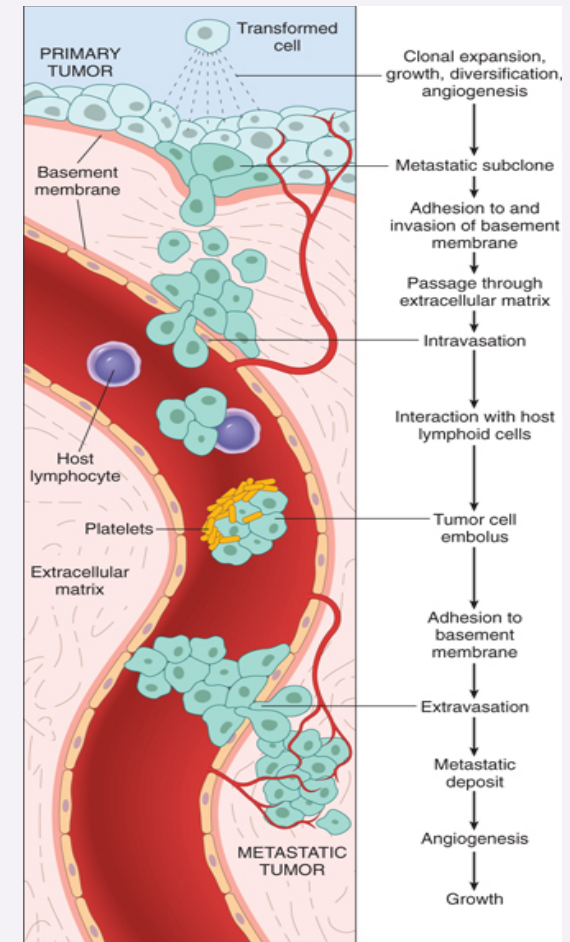
Users' Needs and Unique Value

Introduction to the problem

Pancreatic Duct Adenocarcinoma (PDAC) and Circulating tumor cells (CTC)

- ❑ Cancer is a **dynamic and heterogeneous** disease with progressive genomic and phenotypic changes.
- ❑ Diagnosis is dependent on **morphological and molecular** analysis of the cancer cells
- ❑ Treatment is dependent on **early diagnosis and identification of molecular targets**
- ❑ Today PDAC is **diagnosed late in advanced stages** and has a **bad prognosis**. Treatment is often blind without previous profiling (80%)
- ❑ CTC enables **early diagnosis, profiling, guided treatment and follow up**. In addition CTC make relevant cancer cells available for **research and development of new drugs**

CTC are **selected, spreading** cancer cells

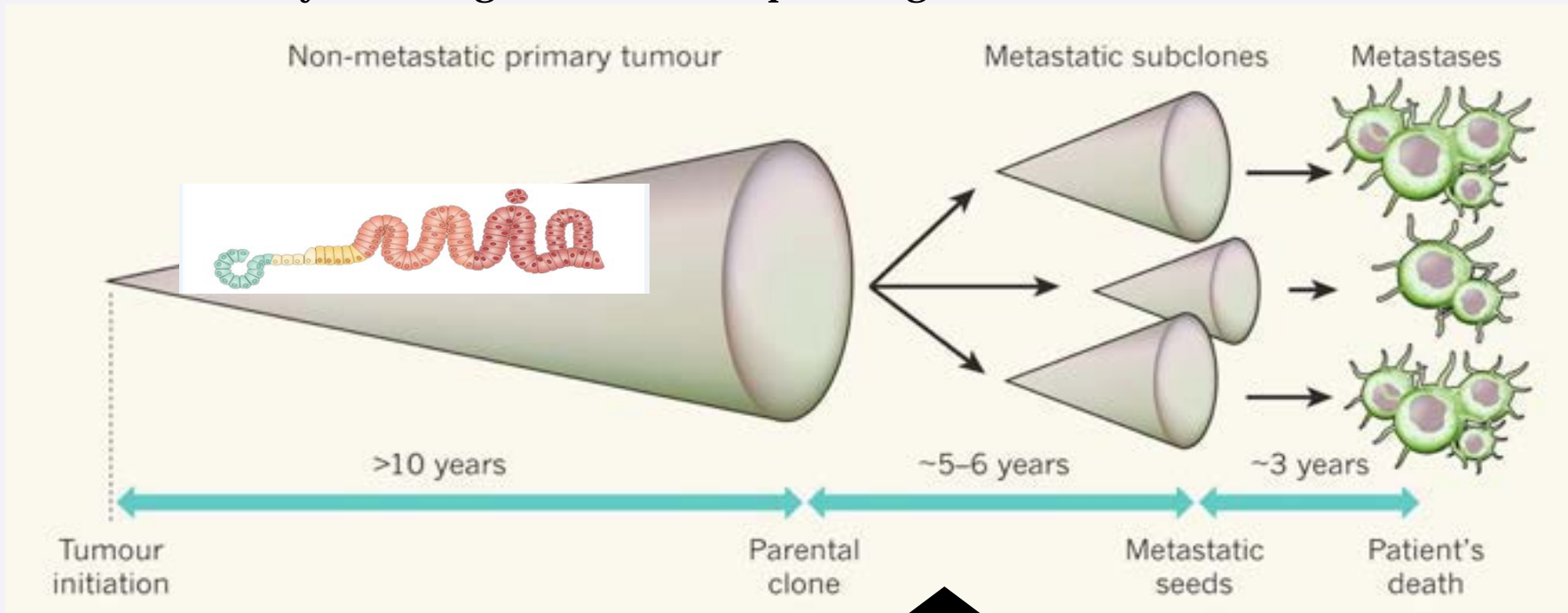


Users' Needs and Unique Value

Introduction to the problem

Morphologic and molecular diagnosis

CTC – for early and longitudinal follow up through the entire clinical course



Standard procedure, 20% respectable

80% no material for molecular profiling

CTC
selected
spreading

↑ ↑
Risk groups

↑
Pre-Op

↑
Post-Op

↑ ↑
Follow up

↑
Relapse
Drug resistance

Users' Needs and Unique Value

Users' needs, how we know and validate them, position in value chain.

Healthcare

- Follow up on risk groups
- Early diagnosis and profiling
- Staging
- Preoperative targeted treatment
- Follow up treatment and relaps
- Continuous profiling of resistant cells

Academia

- Cancer development
- Preneoplastic and preinvasive stages
- Cancer prevention
- Cancer progression and spreading
- Clinical studies
- Validation of new therapies

Pharma comp

- clinical trials
- Predictive biomarkers for personalized medicine
- Pharmacodynamic biomarker for novel therapy
- Research on treatment of resistant cancer cells

Endusers from all categories are active partners in the project.

The endusers needs are defined and validated in CanDo

The partners of CanDo are credible parts of the market



Users' Needs and Unique Value / Innovation process & Road to exploitation

How the user's needs are addressed in the innovation process?

- ❑ **All stakeholders are involved in defining the users specifications** of the platform: Academic, Clinicians, Pharma companies
- ❑ **Stakeholders needs are continually monitored**, any changes are reflected in the end users specifications and therefore technical specifications.

Why technology under development has a unique value for the market users?

- ❑ **The stakeholders requirements define a platform that addresses needs not currently met and therefore has a unique value.**

Road to Exploitation

- ❑ SWOT analysis performed.
- ❑ GILUPI plans to commercialize the CanDo platform, a coherent road to exploitation for the users targeted.
- ❑ Why?:
 - *Valuable contacts to Key Opinion Leaders already established*
 - *Distribution structures and sales channels already established*
 - *Experience in getting regularity approval*
 - *Two products on the market*
 - *Own production facility*



Innovation process and Road to exploitation

With Unique Selling Points (USPs) identified, Freedom To Operate (FTO) is then assured as part of the IPR strategy

Current FTO status:

- Initial patent database searches (GILUPI, imec, UVEC, SU) revealed no relevant IPR conflicts

Future actions:

- Internal: European patent databases will be searched for relevant IP rights continuously throughout the project
- External: Expert attorney FTO review planned

IP:

- No contractual agreement yet in place for exploitation of the IP. Final year.

Manufacturing/Access to market:

- Gilupi can arrange for the manufacturing and has direct access to market.

Distance to Market

How far from the market is the project now and at the end?

3-5 years? 2-3 years?

What it needs to be done after the project is finished to arrive to the market?

Further investment of resources.

How do you identify the non-technical steps needed to go to the market and its influence in the technical development? How do you manage it?

Gilupi (and Bayer) have the commercial know-how.

How much money and time it will be needed. How do you know it?

70M€?

Conclusions

- ❑ CanDo develops a comprehensive point of care cancer diagnostics platform for isolation, quantification and characterization of CTC with minimal operator interaction.
- ❑ The consortium contains end users from all categories as well as companies for design, production and marketing of the platform.
- ❑ No relevant IPR conflicts found so far
- ❑ Consortial agreement on manufacturing and marketing
- ❑ Clinical validation, is key factor of success in this Project (see Poster).