Finding new avenues for breast cancer detection

Oncobiome

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What does the purple ribbon stand for?

Successful treatment of breast cancer relies on early diagnosis, cancer should be detected and excised before spreading.

The 5-year survival for localized breast cancer cases[1]:
- 95-99%: stage 0 (in situ) - II
- 86%: stage III cases (spread to multiple lymph nodes)
- 28%: stage IV cases (metastases formed)

New breast cancer cases (estimates for 2021)
US 281 000 incident cases → 40 000+ deaths[2]
EU 355 000 incident cases → 85 000+ deaths[3]

[1]American Cancer Society https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html
[2]https://www.breastcancer.org/symptoms/understand_bc/statistics
[3]https://ec.europa.eu/jrc/en/news/2020-cancer-incidence-and-mortality-eu-27-countries

Why are cancers missed or left to grow?

There are challenges in breast cancer screening that prevent early detection.

- **Patient adherence**: low participation rate at screening (~10-90+% of the target population in the EU had 1 screening in lifetime) – fear of pain, fear of radiation, scheduling issues or accessibility (e.g. disability or remoteness).[1]

- **Technology issues**: problems with sensitivity (chance for not diagnosing a case) in difficult radiological environment (e.g. dense breast – 40-50% of all cases)[2,] upon low radiological signs of the tumor (e.g. lobular breast cancer – 10-15% of all cases[3], or small and non-calcifying tumors).

These problems affect patients, the participating medical staff and the insurance providers.

[1]https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Archive:Breast_cancer_screening_statistics
[2] Ho et al. Dense breasts: a review of reporting legislation and available supplemental screening options. AJR Am J Roentgenol. 203(2):449-56, 2014.
[2]Sprague et al. Prevalence of mammographically dense breasts in the United States. J Natl Cancer Inst. 106(10), 2014.
[3]Li et al. Trends in Incidence Rates of Invasive Lobular and Ductal Breast Carcinoma. JAMA. 2003;289(11):1421-1424.

Oncobiome Approach

- The microbiome is the bacterial ecosystem of the human body and responds to changes in health, as breast cancer.

- We propose stool microbiome-based breast cancer screening technology.

- Bacteria in the colon are sampled non-invasively from stool, at-home, and are sensitive to breast cancer tumors[1].
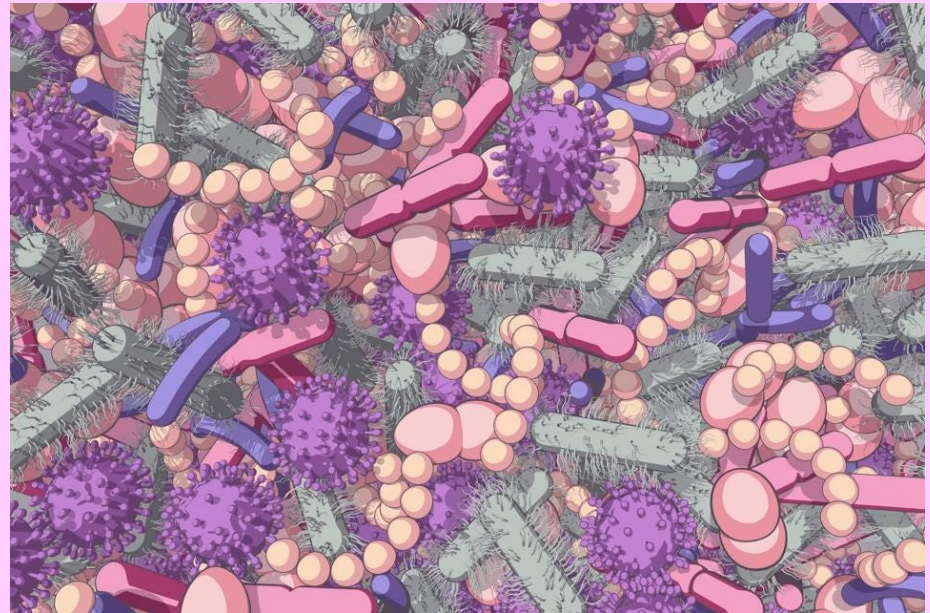
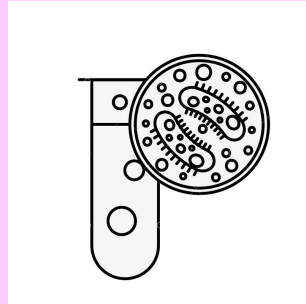[1]Goedert *et al.* (2015). J Natl Cancer Inst *107*, djv147
[1]Kovacs *et al.* (2019). Sci Rep *9*, 1300.
[1]Miko *et al.* (2018). Biochim Biophys Acta Bioenerg *1859*, 958-974.
[1]Sári *et al.* (2020). Physiology International, DOI: 10.1556/2060.2020.00016.
[1]Sári et al. (2020). Cancers (Basel) *12*, 2915.

The product - What do we offer?

The patient samples stool at home.

There are already services using home-collected stool
↓
Reduced adoption risk with regard to patients!

Fresh stool is fixed and shipped.

Samples are assayed in a central lab.

Regionally compliant program to share the report with patients and clinicans (EMR).

The kit can be distributed by the medical staff, can be available off-the-shelf or can be distributed in partnership with companies with similar activities (e.g. Cologuard).

The results are actionable and can drive clinical decisions.

Technology

- We identified a proprietary marker set with 92% sensitivity and 74% specificity.

- Markers are in different phases of patenting.

- The markers are 100% sensitive to hard-to-detect lobular cases.

- The markers can identify early-stage cases the best.
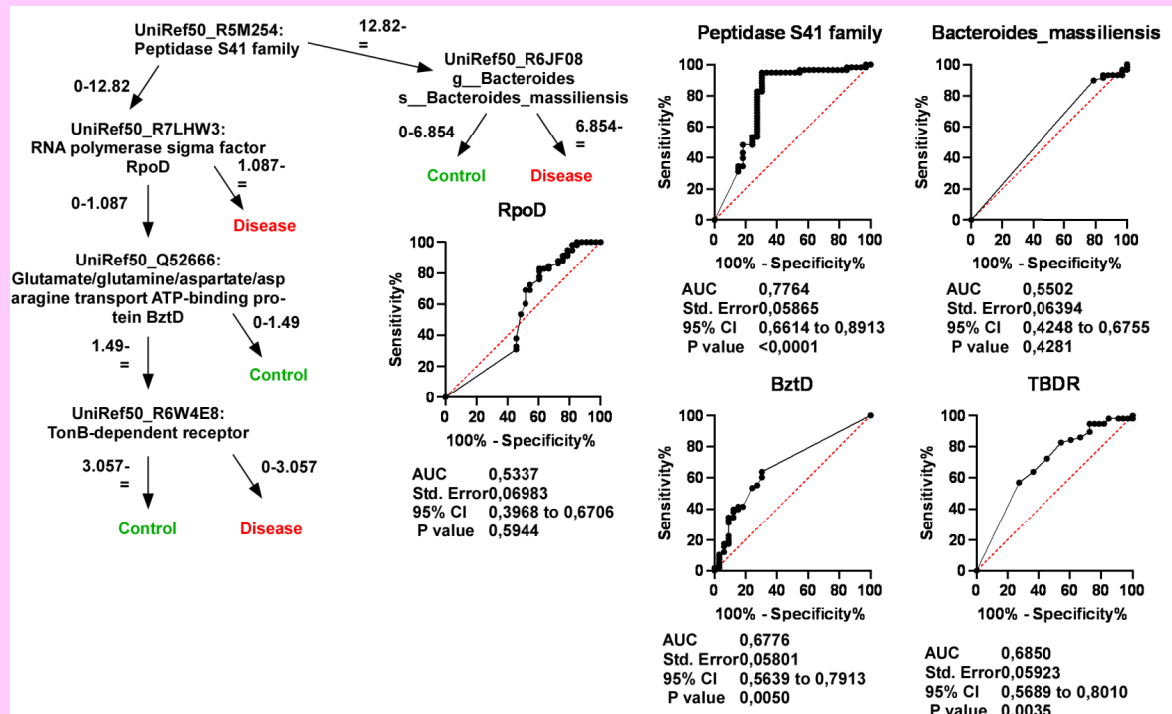
Competing approaches

|	Patient adherence				Technical issues		
	Pain, radiation discomfort	**Medical staff needed**	**Accessibility**	**Scheduling**	**Sensitivity Specificity**	**Costs**	**Labor intensiveness for the medical staff**
Mammography + manual examination	✔	✔		Needed	Sens. 77-91% Spec. >95% (lobular 57-81%)	Low	Low/medium labor intensive
Ultrasonography		✔		Needed	Sens. 82-85% Spec. 80.1%-85% (lobular 57-79%)	Low	Labor intensive
MRI	✔	✔		Needed	Sens. 75,2-100% Spec. ~70% (lobular 93%)	High	Labor intensive
Oncobiome assay			✔	Done at home	Sens. 92% Spec. 74% (lobular 100%, cave, low case numbers)	Medium	No direct labor for the medical staff

No personal contact - COVID

Traction

- Concept developed and research began in 2014.

- Non-dilutive continuous support since 2014, as grants in proof-of-concept or excellence programs.

- We are in constant relationship with clinicians to fine-tune the content of our service.

Team

- Peter Bai, inventor, PhD, scientific leader, involved for 7 years.

- Márton Haraszti and András Bulkai for business development, collaborating for 4 years.

- The members of my laboratory collaborate on wet chemistry.
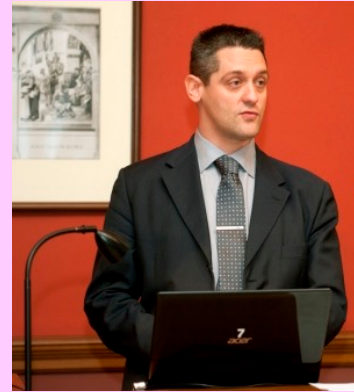
Conclusion

- Late diagnosis of breast cancer leads to preventable mortality and is an unmet medical need.

- Stool microbiome can improve early detection and address early breast cancer detection.

- The Oncobiome assay benefits patients, the medical staff and the insurance providers.
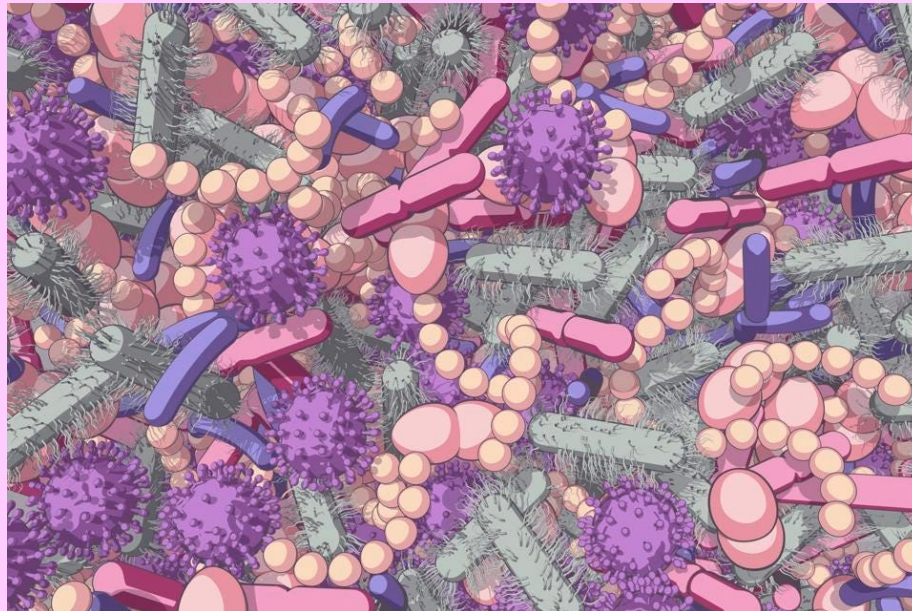
Goal set and progress

The technology is very early stage, therefore, even basic assessments and hypothesis testing was missing. We aimed for de-risking the project and assessing long-term aims.

Science/Hypothesis learnings, Clinical Feedback:
- Identified the reasons for late tumor detection.
- Learned that lobular is a hard-to-detect subtype that in combination with our science findings, we identified a good entry market and a new RnD focus.
- Identified that adoption risk on the side of the costumers is low.
- Our method does not require physical personal contact (COVID19).
- We have set out for marker validation.

Product design learnings:
- Changed our plan for developing upfront a POC device to a central lab approach.

Potential Challenges:
- Potential adoption risk among clinicians.
- Team building.

Potential Partners/Related products:
Identified potential partners (Cologuard).

Certain questions will remain open as it takes more time to answer them than the timeframe of IDEA2 (e.g. question of team).