Biomediq A/S in collaboration with UCPH

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Mission of Biomediq

To research, develop, validate, and employ quantitative imaging biomarkers based on standard imaging protocols for use in clinical trials and patient diagnosis, prognosis, and monitoring.

We turn images into evidence

Computer-automated quantification of
• Breast cancer risk from screening mammography
• Alzheimer’s from brain MRI
• Osteoarthritis from knee MRI
• Rheumatoid arthritis from hand MRI
• Cardiovascular risk from lumbar x-ray
• Osteoporosis from spine x-ray
History

2001 – 2006 University/company research collaboration
Collaboration between the Image Group and CCBR/Nordic Bioscience in imaging biomarkers for slowly progressing diseases such as arthritis, osteoporosis, atherosclerosis, breast cancer.

2007 – 2008 Subsidiary of Nordic Bioscience
Setting up a daughter company to mature technologies for clinical trials

2008 – 2011 Subsidiary of Synarc Inc.
Applying technologies in collaboration with Synarc in clinical trials

2011 - Independent company
Developing products also outside the clinical trial market

Collaboration with UCPH
• 6 Industrial or co-funded PhD Students
• 2 Industrial or co-funded Post Docs
• DNATF project
Biomarkers

A characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

NIH working group 1998

- Molecular (serum, plasma, urine, CSF), genetic, imaging
- Diagnostic (D), prognostic (P), efficacy (E)
- Clinical use (D, P, monitor treatment response)
- Use in drug discovery and clinical trials (D, P, E)
Imaging Biomarkers

Any measure derived from an image – typically a medical scan such as x-ray, CT, MRI, ultrasound, PET/SPECT etc.

They can be qualitative, semi-quantitative, or quantitative.

They are “derived” manually, semi-automatically, or automatically.

Examples

Tumor size, cartilage volume, BMD, vertebral fx, trabecular structure (texture), density, brain atrophy, ...

Biomediq
The (Imaging) Biomarker “lifecycle”

• Discover biomarker (data, insight, research)

• Demonstrate relationship to disease and/or treatment effect (data, publications, accuracy, precision)

• Peer acceptance (data, publications, validation, collaborations, KOLs)

• Develop “medical device” (QA, ISO 14971, ISO 13485, ISO 62304)

• FDA approval and adaptation (publications, peer acceptance, time, application)

• Market (CROs, pharma, clinical practice, scanner companies)
Development model

**Basic Research**
Theoretical concepts and computational backbone with UCPH

**Contract Research**
Clinical development and first validation

**Analysis as a Service**
Prospective validation in trials

**Software Licensing**
Scalable sales
Breast Cancer

More than 10% of all women get BC. Screening is used for early diagnosis and is differentiated based on age for nearly all women. Breast density estimated from screening mammograms may differentiate risk.

Biomediq has patented technology for texture scoring of screening mammograms adding to risk segregation. Results are published with key opinion leaders from Mayo Clinic and UCSF. Potential is to lower screening frequency for reduced risk women and to refer to more informative imaging for increased risk women.

In US more than 40 mio screening mammograms are acquired yearly at a cost of app. 6 billion USD. Potential savings are 1 billion USD.

Collaboration with UCPH:

- Project from DNATF in collaboration with DIKU, the Capital Region Screening Program, and Department of Public Health, UCPH. Funding is 1/6 UCPH, 2/6 Biomediq, 3/6 DNATF. Project includes research, technological development, business development.

- EU: Collaboration with universities and companies from EU. EU supports 75% (for SMEs) of direct costs plus 60% overhead.
Osteoarthritis

Everybody get OA if they live sufficiently long. Biomediq has a number of patented markers in knee MRI of cartilage and bone.

The core technology is fully automated segmentation owned by Biomediq. It has been prospectively validated in two trials of 500 persons each at three visits on efficacy of Oral Salmon Calcitonin sponsored by Novartis and Nordic Bioscience.

Collaboration with UCPH:
- Industrial PhD: Salary from Biomediq, support from Danish Agency for Science Technology, and Innovation for salary, travel, supervision
- The Danish Council for Strategic Research: Research project funded by UCPH 10%, Biomediq 30%, DCSR 60%
- EU: Collaboration with universities and companies from EU. EU supports 75% (for SMEs) of direct costs plus 60% overhead.
Alzheimer’s Disease

AD is a neuro-degenerative disease where it is believed that amyloid plaques trigger neuronal death. 0.4% (27 million) are affected worldwide. In US 19% of the aged 75-84 and 42% of the population older than 84 years are affected.

As a cause of neuronal death, the cognitive capabilities decrease and the brain structures shrink.

AD is irreversible and cannot be cured. Some symptoms can be relieved.

Biomediq researches the measurement of brain atrophy (shrinkage) and especially the shrinkage of the hippocampus and enlargement of ventricles.

Collaboration with UCPH:
• Co-funded PhD students: Biomediq/UCPH
• Industrial Post Doc: UCPH 1/6, Biomediq 2/6, DNATF 3/6
Early MRI diagnosis / prognosis of Alzheimer’s Disease

Alzheimer's disease (AD) leads to nerve cell death and tissue loss throughout the brain. Over time, the brain shrinks dramatically.

Cell death and tissue loss due to “microscopic” changes in the tissue (prime suspects neurofibrillary (tau) tangles and amyloid plaques).

Research a marker with potential for earlier diagnosis/prognosis compared to the more traditional approaches measuring atrophy. Look at tissue change rather than structural changes. Earlier “treatment” and better stratification for clinical drug trials.

Cannot directly see such changes at the current image resolution. However, they may add up and be visible as textural patterns prior to tissue loss.
Summary

- A small company in research intense
  - continued product development
  - market penetration
- Fruitful collaborations with UCPH for
  - basic research
  - research collaborations
  - PhDs / Post Docs
- Strong partnership with UCPH for
  - national grant applications
  - international networking and grant applications