The Danish Biomarker Network

Kim Holmstrøm, PhD
R&D Manager, Bioneer
Chairman, The Danish Biomarker Network

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Agenda

• Biomarkers in brief
  • What and why?
  • The Biomarker innovation gap

• The Danish Biomarker Network
  • People and organisations behind
  • Purpose of the network
  • Members
  • Activities

• Join us
What are Biomarkers?

“A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention.”

Proposed at the US National Institutes of Health workshop in 1998
What are Biomarkers - examples?

- Tumour antigens
- Cell surface receptors
- Endothelial cells
- Progenitor cells
- Carbohydrate determinants
- Transcripts
- RNA-based markers
- Biomedical imaging
- DNA-based markers
- Regulatory RNAs
- SNPs
- Microsatellite instability
- Chromosomal aberrations
Why do we need Biomarkers?

- The attrition rate during drug development is >80%
  - Block-buster era terminated
  - Heterogeneous patient population
  - “One size does not fit all”
  - Precision Medicine needed

- Medical expenses in the public health care is escalating
  - New innovative targeted but very expensive therapies are offered
  - An increase in the ageing population with increased need for medical care
  - Define the right patients for the right treatment at the right time
Why do we need Biomarkers?

In the clinic to improve

- Diagnosis
- Prognosis
- Prediction of successful treatment – patient stratification
- Response monitoring
- Reduction of side effects

...for the ultimate implementation of personalized medicine

In drug development to determine

- Mechanism of action
- Exposure
- Efficacy
- Safety issues

...more cost effectively to produce safer drugs in greater numbers for more rapid approval
The promise of Biomarkers

Biomarkers represent a key strategy for innovative clinical trials (e.g. patient stratification) that will facilitate cost-effective and speedy assessment of new drugs for efficacy and marketing approval.

.....however!
The Biomarker innovation gaps

- **Gap 1**: Strong focus on discovery, limited on clinical validation and development of prototype biomarker tests
- **Gap 2**: Insufficient translation to robust diagnostic test

Source: Prof. Alain van Gool, Biomarker Development Center (NL)
Some numbers

Eg Biomarkers in time: Prostate cancer
May 2011: \( n=2,231 \) biomarkers
Nov 2012: \( n=6,562 \) biomarkers
Oct 2013: \( n=8,358 \) biomarkers
Nov 2014: \( n=10,350 \) biomarkers
(5 new biomarkers/day)

Source: Prof. Alain van Gool, Biomarker Development Center (NL)
How can we efficiently exploit the potential of biomarkers both in the clinic and the pharmaceutical industry?

- Biomarker development and validation requires:
  - Multidisciplinary effort
    - MD’s, Pharmacologists, Molecular biologists, Biostaticians, Involvement of patients, etc.
  - The use of different technology platforms
    - ELISA, IHC, FISH, NGS, Bioimaging (MR, CT), MS, qPCR ….
  - Access to clinical samples
    - Biobanks, patient records/disease history
    - Retrospective and prospective trials
  - Data management, integration, validation
    - Big Data
    - De-central patient monitoring
  - Regulatory requirements
How shall we prioritize new biomarker developments?

- Indications with lack of precise diagnostics
  - Improvement in patient stratification
- Elucidation of pathophysiology of disease
  - Improvement in drug development success
- Increasing treatment efficiency
  - Lowering treatment costs
  - Early detection

Need for a Biomarker Development Infrastructure to allow the discussion of these questions, making priorities and facilitate and enable development of biomarkers to reach approval
Biomarker Network Initiation

1st Danish Symposium on Biomarkers and the Implementation of Personalized Medicine to the Clinic

Hosted by the Danish Society of Molecular Medicine, Biopeople and Bioneer

January 13, 2015, Hannover Auditorium, Panum Institute, Copenhagen

BIOMARKERS AND TAILOR MADE MEDICINE IS THE FUTURE

150 people attended the First Danish Biomarkers Symposium
The recently held First Symposium on Biomarkers and the Implementation of Personalized Medicine to the Clinic at the University of Copenhagen is a successful example of a fruitful collaboration between Biopeople, Bioneer [an Advanced Technology Group] and the Danish Society of Molecular Medicine. Their joint forces brought people together across scientific as well as public-private boundaries. Approximately 150 people attended the symposium, which was also the kick-off event to establish a Danish Biomarkers Network. The network will provide an open web forum for cross-disciplinary discussions, networking and knowledge sharing in the field of Biomarkers. In addition to the web forum, the network plans an annual biomarkers symposium as well as workshops based on interest and ideas from the audience.
People and organisations behind

Kim Holmstrøm, MSc, PhD, R&D Manager
Initiator, co-founder and chairman of The Biomarker Network
10+ years of expertise in Biomarker R&D

Elias Zafirakos, MSc, EBA, LAICS
Co-founder and vice chairman of The Biomarker network
10 years of expertise in cross disciplinary innovation management
Complementary organisational expertise

**Bioneer**

Technology service provider:
- Biomarker discovery
- Biomarker validation
- Molecular histology
  - HTP RNA *in situ* hybridization
  - HTP IHC
- Biomarker assay development
  - Multiplex *in situ* biomarker analysis
  - Companion diagnostics

**Biopeople**

Danish Life Science Cluster
- Networking initiatives to stimulate innovation
- Cluster management
- Matchmaking and knowledge sharing
Purpose of the network

• To link researchers and companies within Biomarker research
• To create a forum for discussing Biomarker topics
• To create a network that spans the different scientific disciplines that relates to Biomarker research and development
• To promote collaboration within Biomarker research and development
• To identify unique Danish strongholds necessary for biomarker development nationally but also in a pan-European context.
• To facilitate the translation of Biomarkers into approved and clinical use
Members of the network

Status: a total of 203 members

120 organisations represented

- 43 companies
- 26 hospital depts.
- 34 university depts.
- 17 other organisations
Examples of Danish companies:
Network activities

• Workshops based on Members interest
• An annual Symposium
• LinkedIn group for members to connect, distribute material etc.
• Website, [www.biomarkers.dk](http://www.biomarkers.dk), where presentations, events and contact information is available
• Newsletters
Areas of interest

Workshop topics and interests

- Preclinical biomarkers
- Biomarkers for inflammation and autoimmunity
- Comp Dx/Multi-marker Comp Dx
- Epigenetic biomarkers
- Disease specific biomarkers
- Allergy and autoimmunity
- Molecular methods for bacterial/viral diagnostics
- Fluorescent peptides
- Liquid biopsies
- Activity probes for proteases
- +25 other topics
Activities

Two workshops are scheduled on:

- Biomarkers in autoimmune diseases – workshop 6/11-2015
- Companion Diagnostics – under planning

2\textsuperscript{nd} Biomarker Symposium

- Spring 2016
Workshop on biomarkers and autoimmune diseases
6 November 2015, 13:00-16:15
University of Copenhagen, Auditorium 3,
Universitetsparken 2, 2100 Copenhagen

Where are we lacking biomarkers to diagnose autoimmune diseases? Are there any common features and complementary knowledge about biomarkers that can be shared and exploited across the different autoimmune disease areas?

Three presentations followed by an interactive workshop session:

- **Biomarkers for monitoring rheumatoid arthritis – at the foot of the mountain** v/Bent W. Deleuran, Professor, Biomedicine Health, Aarhus University
- **Biomarkers used in diagnosis and treatment of chronic inflammatory bowel diseases (IBD)** v/Andreas M. Petersen, Clinical Associate Professor, Hvidovre Hospital, Capital Region of Denmark
- **Multiple sclerosis: biomarkers for diagnosis, prognosis and treatment response** v/Finn T. Sellebjerg, Clinical Professor, University of Copenhagen

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Participation is open for all interested from industry and academia and is free of charge but on-line registration is required at www.biopeople.dk. We especially invite SME’s to participate.
Latest news

Funding of 2.8 mio. DKK (~51.6 mio. JPY) received to support the Development of Biomarkers as a promising new area of growth based on the continuation and support of the Danish Biomarker Network from the Danish Ministry of Higher Education and Science:

- BioPeople – Innovation management
- InfinIT – ICT/Big Data
- BrandBase – Patient response/input, Ethics
- Bioneer – Biomarker R&D
Join us

- The network is open to all interested parties
- It is free of charge
- Currently includes Denmark, Sweden and Germany
- We welcome new members on a global scale

Visit us:

www.biomarkers.dk

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Supported by:

Ministry of Higher Education and Science
THANK YOU FOR YOUR ATTENTION