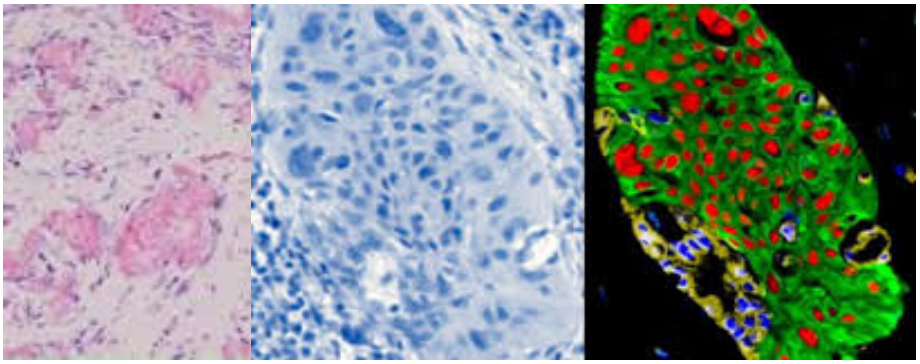
BIOPEOPLE
Denmark's Life Science Cluster

Biopeople Information



2017 – A YEAR FOR BIOMARKERS

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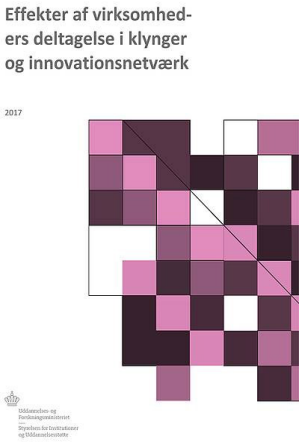

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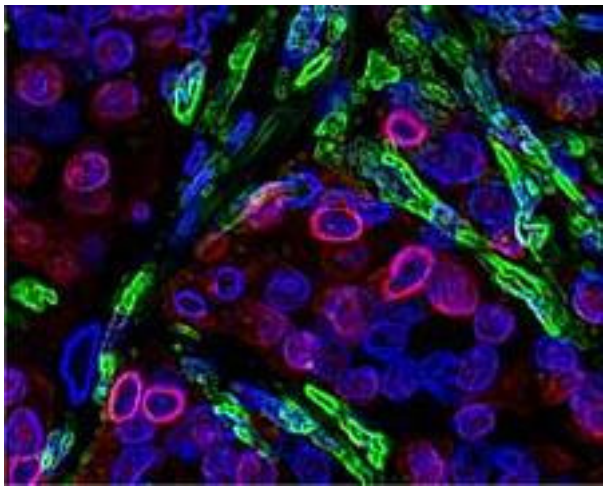

PHOTO: BIONEER

Per Spindler
Director

This spring we witness an increasing interest in biomarkers and Personalised Medicine (alias Precision Medicine) at all levels. The National Strategy for Personalised medicine, which talks about better ways to diagnose diseases, has obviously put a strengthened focus at the increasing role of biobanks and biomarkers in the research settings, as a mandatory ingredient in the development of better medicines that are more effective and future health care systems

There are several activities on both an international and a national level, and they reflect challenges, needs for a structured approach, validation and knowledge sharing on both discovery, research and commercialization levels.

We are deeply involved in dealing with issues around biomarkers – and we support and co-host events where Precision Medicine and biomarkers are on the agenda. We additionally focus on the user-centric aspects of biomarkers including e.g. ethics, user behavior and preferences, information technology and anthropology.

On 25 April 2017, we are co-organisers with the UK Science and Innovation Network, the Department for International Trade and Medicon Valley Alliance of a seminar and a networking event for scientists in academia and industry. The aim of this event is to highlight aspects of Precision Medicine and to provide insight into the opportunities for collaboration between organisations and stakeholders in Denmark and the UK working with biomarkers, companion diagnostics, and cell- and gene therapy in Personalised Medicine.

On 26 April 2017, we help the organizing committee of the first Nordic Precision Medicine Forum in Copenhagen. This forum will bring together biologists, physicians and technology developers to data scientists, patient groups, governments and more. The forum will cover a whole plethora of topics uncovering what the most pressing issues are. Hear about the Governments vision for healthcare in the coming years, and the latest technologies and how they are enabling a sea change in the way we treat patients and disease, and the critical role of biomarkers and the latest diagnostics thinking.

Read more

CONT.

Furthermore, 22 May 2017, Biopeople, in collaboration with Danish and Israeli partners, hosts a symposium on "The Future of Oncology Biomarkers" in Tel Aviv, where Danish companies and researchers will join a Danish delegation to the seminar and conjuring International MIXii-Biomed 2017 Conference. The seminar includes presentations by leading experts on biobanks and pathways from screening biomarkers to diagnostic products, and in-depth roundtable discussions focusing on the latest developments within analytical validation of assay platforms, detection of resistance to treatments, surrogate endpoints and other related issues. The aim of the seminar and related activities is to facilitate in-depth discussions with a view to share knowledge and explore collaboration opportunities. The seminar is part of a high level delegation from 21-25 May 2017 including tailor-made matchmaking, visits to Israeli research centres and official dinners.

Read more

Our activities broadly reflect the importance of biomarkers, the Biomarker Network, which we chair together with Bioneer, has become a dynamic network of stakeholders all interested in biomarker development, and the 'Biomarkers as an emerging growth area' project is in progress.

We work to start up a new international partners project within the biomarker field together with the North Denmark Region and - the so-called BiC project – Biomarker Commercialization in the Baltic Sea Region. The BiC project will address the challenges for development and market uptake of innovations. A specific challenge is to involve industry (Pharmaceutical and diagnostic enterprises, SMEs, investors) much earlier in the development and commercialization process of biomarkers, while research institutions need guidance to select the most relevant biomarker discoveries and conduct a development plan that meets early requirements from relevant industry partner. The consortium behind BiC will by compiling their knowledge and experience, build a solid network across the Baltic Sea Region (BSR) to share their competences. They intend to create synergies that shift the challenges of commercialization of biomarkers discoveries and assist biomarkers in reaching their full potential.

Finally, we are in the planning process of the 2017 Biomarker Agora, which takes place 1 November 2017 with exhibitions, speeches and networking all around biomarkers. The meeting concept of the Agora is new. It is an agile small and tailor-made meeting format with networking of different stakeholder groups aiming to foster new thinking and collaborations.

DANISH CLUSTERS HELP INDUSTRY GROWTH

Clusters bridge companies and researchers and promote the development of new partnerships and new innovative products and services. A newly published study by the Ministry of Higher Education and Science shows this

The Education and Research Ministry conducted the study in 2016 as an electronic survey among 42 of the most important clusters in Denmark. The questionnaire was sent to more than 3.700 industry participants with 888 answering the questionnaire.

The study shows that companies that are active in clusters get 21-40 % increase in new collaborations - on top of current collaborations. New collaborations include companies, universities, nationally or abroad as are relevant to grow the product and service development of the Danish company.

Mr. Soeren Pind, Minister for Higher Education and Science, who is pleased with the results of the survey, concludes that clusters in Denmark contribute to the industry growth and motivate more companies to become active in the activities of the clusters.

Read the full survey here (Danish)

Read the press release from the ministry here (Danish)

CORS SYMPOSIUM IN COPENHAGEN: A PLATFORM TO DISCUSS INTERNATIONAL DIMENSIONS OF ACADEMIC REGULATORY SCIENCE

The Copenhagen Centre for Regulatory Science and Denmark's Life Science Cluster, Biopeople, organised a symposium on research and education in regulatory science on 27 March 2017. The symposium had the pleasure of hosting a high-level delegation from Fudan University, Shanghai, China

The delegation from Fudan visited SUND for the first time in March as a follow up on the initiation in December 2016 of a collaboration between the Copenhagen Center of Regulatory Science (CORS) and Fudan University in China. Fudan University is in the process of establishing a center inspired by CORS. The two faculties plan to exchange both students and teachers and initially SUND offers to send teachers to Fudan.

Help facilitate capacity building

At the symposium, which took place in the new Maersk Building at the University of Copenhagen, Senior Regulatory Affairs Intelligence Manager from Novo Nordisk A/S, Anette Hjelmsmark, reflected on the drug regulatory reform in China from the industry perspective. In particular, she stressed that collaborative educational activities in regulatory sciences could help facilitating capacity building in Good Clinical Practices and clinical site inspections in China before New Drug Application approvals.

Dr. Abby (Yang) Yu, the Dutch Medicines Evaluation Board, and the Netherlands (Photo: Biopeople)

Experience from Holland

Dr. Abby (Yang) Yu, Clinical pharmacokinetics assessor, shared the experiences of PhD training from the Dutch Medicines Evaluation Board (CBG-MEB) as well as an impressive research programme of MEB, representing approx. 4 % of agency budget in three thematic tracks:

- Drug Development & Innovation
- Regulation & Decision Making
- Consumer Use & Safety.

Dr. Yang also explained how the agency connects to the Academic Network Regulatory Research of the Netherlands.

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Regulatory research and education

Professor and Director Marieke De Bruin of the Copenhagen Centre for Regulatory Science talked about the progress in establishing CORS and highlighted the mission driven approach of the center. The aims of the center being to influence and conduct regulatory research and education in an international perspective. Seen from a research and education perspective, the center shall make a clear mark on regulatory decision-making - to the benefit of stakeholders such as patients, authorities, payers and industry. The science focus on the medicinal product life cycle and science that assists producing evidence, it facilitates tools & standards, and evaluates testing performance and truly reflects the mission of the center. All to advance regulatory decision-making.

In presenting a very carefully chosen title "Factors ensuring effective Direct to Healthcare Professional Communication of Risk Minimization Initiatives", PhD-candidate Mathias Møllebæk of the Copenhagen Centre for Regulatory Science, explained how modern rhetoric may and will advance risk communication for human medicines.

Bridging Europe and China

Director of Biopeople, Per Spindler, summarized the presentations. In reflecting of issues bridging Denmark/Europe and China, researchers in regulatory sciences need to build insights into the national / regional regulatory systems, and their differences. Furthermore, the educational initiatives that will support advancements in the regulatory systems need considerations of transparency and neutrality. This to be considered in view of the multi-stakeholder approaches, for instance patients and industry, often encountered in regulatory research and educational activities.

Please find link to presentations

About Regulatory Science
Regulatory science is the science of developing and validating new standards and tools to evaluate and assess the benefit/risk of medicinal products, facilitating sound and transparent regulatory decision making''Through analysis of regulatory frameworks itself and their effectiveness, however, regulatory science can also advance knowledge of these systems in general.

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BIOMARKER COMMERCIALIZATION IN THE BALTIC SEA REGION

Biopeople and Ideklinikken in Aalborg are two of nine partners in the Baltic Sea Region with a common interest in the commercialization of biomarkers. The nine partners have formed a consortium called BIC, which stands for biomarker commercialization. They want to contribute with knowledge and experience across the Baltic Sea Region to create synergies that assist biomarkers in reaching their full commercialization potential. In January 2017, the partners applied for Interreg funding of the biomarker commercialization project (BiC) and now wait for the repl

The background for forming BIC is the expectations that the global biomarkers market expects to reach a market share of $45.55 billion by 2020 of which healthcare and R&D expenditure are the key growth drivers ("Biomarkers Market - Global Forecast to 2020").

Significant challenges

These expectations are interesting considering the perspectives of Biomarkers' discovery, which along with the growing need for developing medicines that are more precise is an area that becomes increasingly important in research and industry. It gives rise to new areas of diagnostics and treatment and could form the foundation for new innovative drivers for both researchers, enterprises and SMEs. The challenges, however, for market uptake of these innovations are significant, as the development and commercialization of biomarkers is time consuming, difficult and expensive.

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Research institutions need guidance to select the most relevant biomarker discoveries and conduct a development plan that meets early requirements from relevant industry partners, and it is also considered a challenge to involve industry (Pharmaceutical and diagnostic enterprises, SMEs, investors) much earlier in the development and commercialization process of biomarkers.

Solid network in the Baltic Region

The consortium behind BiC will compile their knowledge and experience, and build a solid network across the Baltic Sea Region (BSR) to share competences. The main object of BiC is to develop a platform that provides tools to support the different phases of a new commercialization process, including the assessment of the maturity level of the biomarker project and clarify the expectations from the industry.

Through the platform and the tools, the consortium will define the downstream pathway from research, validation, development to the market, co-created with industry. The project will provide the industry with an incentive for engaging in biomarkers at a much earlier phase or pave the way for successful spinouts. The consortium will test, validate and adjust the commercialization tools developed in at least nine pilot projects based on biomarker projects.

The BiC tools will include:

- a Biomarker Development Tool
- a Screening and Selection Guide
- a Framework for Technology Translation into clinical setting
- Business Model Templates
- BSR Biomarker Platform, Technology presentation and match making tools

The overall output of BiC will contribute to improving commercialization and competitiveness of biomarker discoveries within the Baltic Sea region and the long-term benefits will be better medicines and treatments. The BiC platform and the tools will be transnationally available via Scanbalt Business Club beyond the project period.

About Biomarkers

Biomarkers consist of cellular, biochemical or molecular changes measured in tissues, cells or fluids such as blood, brain cerebrospinal fluid, muscles, nerve, urine or skin. With the help of relevant tools or technologies, biomarkers can predict, diagnose and provide information on individual's health, thus contributing to the development of personalized medicine.

BiC Consortium partners

Ideklinikken at Aalborg University Hospital, the University of Turku, Finland, The University of Vilnius, Lithuania, and the 6 innovation clusters Biopeople (Denmark), Bio-Con Valley (Germany), Turku Science Park (Finland), Tartu Botechnology Park (Estonia), WroclawTechnology Park (Poland) and ScanBalt covering the Baltic Sea Region.

EUROPEAN HEALTH CATAPULT

CALL:
2017 EUROPEAN HEALTH CATAPULT CONTEST - DEADLINE 30 APRIL 2017

EIT Health together with Health Axis Europe (HAE) is now seeking applications from suitable companies and individuals for its 2017 European Health Catapult Contest.

Submission deadline: 30 April 2017 (noon, CET)

Application form here:

https://eithealth.wufoo.com/forms/european-health-catapult-2017

EIT Health together with Health Axis Europe (HAE) is now seeking applications from suitable companies and individuals for its 2017 European Health Catapult Contest.

Who can participate?

European micro and small enterprises (< 50 employees), spin-offs and start-ups that are

- Active in the fields of Medtech, Biotech and Digital Health
- Already incorporated and operating in an EU Country
- Have innovative business concepts
- Are looking for seed or series A funding

Teams wishing to participate in the European Health Catapult will be evaluated based on the quality of their executive summary, the quality of the technology, the consistency and quality of the team.

All information submitted will be treated in confidence

Fields marked * are mandatory

You may contact the following program organisers for questions:

APPLICATIONS FOR Scandinavian COUNTRIES

Palle Hoy Jacobsen (pallehoy.jakobsen(at)eithealth.eu)

Lykke Margot Ricard (lykke.margot(at)sund.ku.dk)

Or visit http://www.europeanhealth-catapult.eu/

Please refer to the program description in the 2017 Accelerator Program Call Document found here.

SEMINAR ON PATIENT INVOLVEMENT IN MEDICAL RESEARCH

'Biomarkers as an emerging growth area' is a project with partners representing ICT, Pharma and users. The project held a conference on 2. March 2017 on patient involvement in medical research

At the seminar the overall subject was how to involve patients in medicines development: what are the benefits and what are the drawbacks - how may the pressent approach be approved?

The seminar for the first time brought together public partners, patient organisations and the medical industry to discuss this issue, which is increasingly on the agenda at a European and a national level.

Central questions as the below came up during the day and initiated fruitful discussions among the audience and the presenters.

How are patients involved in medical research and development in Denmark.
How is this involvement regulated and prioritized. What kind of experience do we have?
What are the roles of patients involved
Potential and drawbacks for patients, researchers, policy developers, authosities, pharmaceutical companies etc.
BRANDBASE, Biopeople and InfinIT are partners in the project which is funded by the Research and Innovation agency.

KORA, the Danish Institute for Local and Regional Government Research hosted the seminar.

Please see presentations and videos from the seminar here.

Please see the program here.

Please see presenter biographies here.

A BRIDGE TO BIOMARKERS RESEARCH ICT CLINICAL USERS

MVA UPDATE: STRONG SUPPORT TO COPENHAGENS EMA CANDIDACY

The Swedish-Danish board of Directors of Medicon Valley Alliance strongly supports Copenhagen´s EMA-candidacy and the efforts being made to by special envoy, former Novo CEO, Lars Rebien Sørensen, to promote Copenhagen and the Medicon Valley region, which is objectively the strongest Nordic candidate.

Medicon Valley Alliances Swedish and Danish board members have agreed to support Copenhagen as EMA candidate, but from a regional perspective. "Copenhagen is quite simply the strongest and most realistic Medicon Valley based candidate" Petter Hartman, CEO Medicon Valley Alliance, states.

Medicon Valley Alliance will among other things work to ensure that the documentation supporting the local candidacy is made available to relevant decisionsmakers. As such the "State of Medicon Valley 2016- analysis" published in November last year can serve as a welcoming pool of knowledge and help to emphasize how Copenhagen is actually not just a Danish candidate, but a truly Nordic one.

Among the members of the board are among others chairman, CVP, Søren Bregenholt, from Novo Nordisk A/S, Dean of the Faculty of Medicine, Gunilla-Westergren-Thorsson, from Lund University, Director Development, Mikael Stamming from Region Skåne, Director Director, Growth & Innovation, Tue David Bak, Region Zealand and Simon Feldbæk, LEO Pharma .

Calendar

26 April 2017	Nordic Precision Medicine Forum
7 May 2017	10th Global Conference for Clinical Nanomedicine and Targeted Medicine, Basel
9 May, 2017	Danish IP Fair 2017, Copenhagen
18 May 2017	Knowledge for Growth 2017
21 May 2017	The Future of Oncology Biomarkers Round Trip and Conference, Tel Aviv
21 May 2017	Future Medicines For One World Conference: drug discovery, development and clinical usage, Stockholm
22 May 2017	Seminar on Oncology Biomarkers, Tel Aviv
29 May 2017	MVA Oncology Network's 3rd Meeting, Copenhagen
12 September 2017	Nordic Life Science Days 2017, Malmö
10 October 2017	BIOTECH Cluster SME Mission & BioJapan, Japan (EU Delegation)
1 November 2017	2017 AGORA
22 January 2018	Training Course in Safety Sciences - Regulatory Requirements and Guidelines (IMI SafeSciMET), Lisbon