

Editorial

Domenico Alexakis



The NTN Swiss Biotech™ takes flight and contributes to the innovation spirit in Biotechnology and Life Sciences in general. Switzerland is rated as top innovative country

again and repeatedly. This is satisfactory but resting means losing ground. Therefore it is of utmost importance to bring together competencies which will deliver good output that can be transformed into Innovation. After all, only ideas that make it to the market eventually can be labelled as true innovation.

Switzerland – Guest Country at BIOTECHNICA 2013, 8 – 10 October

Europe's No.1 Event for Biotechnology, Life Sciences and Lab Technology

Featuring new topics and innovative market-places, BIOTECHNICA 2013 will again serve as the central hub for Europe's biotech sector. For the twentieth time BIOTECHNICA will bring exhibitors and trade visitors together to do business. One of the keynotes of this year's trade fair will be bio-economics. Switzerland - the first Partner Country to be honored at BIOTECHNICA - will also be a focus of attention.

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Green light for Campus Biotech!

The former Serono headquarters in Geneva is now the Campus Biotech

The sale of the former Merck Serono site, located in the centre of Geneva, Switzerland, has been finalized. The buyer is the consortium behind the Campus Biotech initiative: the Ecole Polytechnique Fédérale de Lausanne (EPFL), the University of Geneva, Hansjörg Wyss, the Wyss Foundation and the Bertarelli family.

Campus Biotech reached a major milestone. The sale of the former Merck Serono site, located in the centre of Geneva, Switzerland, to the Consortium behind the Campus Biotech initiative has been finalized. The Ecole Polytechnique Fédérale de Lausanne, the University of Geneva, Hansjörg Wyss, the Wyss Foundation and the Bertarelli family will now move forward together to implement the vision behind Campus Biotech, bringing new life and fresh investment to the biotechnology sector in the Lake Geneva region and so generate a vast range of opportunities for both scientists and entrepreneurs.

The EPFL will receive a donation of CHF 100 Millions from the Wyss Foundation to create with UNIGE a Wyss Institute in Geneva along the same principles as those of the Wyss Institute for Biologically Inspired Engineering at Harvard in Boston.

In addition, the Bertarelli Foundation will contribute its existing EPFL chairs and increase its donation by 2 additional chairs to the Wyss Institute.

The Wyss Foundation and the Bertarelli family have financed Campus Biotech for the acquisition of the Sécheron site to allow the creation of a shared Biotech campus.

The EPFL and UNIGE will occupy 15000 m² of the Sécheron site. Half of this surface will be occupied by the Wyss Institute for Bio- and Neuro- Engineering, the other half by research groups from EPFL and UNIGE.

For the remaining available spaces, Campus Biotech will seek to attract start-ups, industry and other businesses, which would benefit from this unique scientific and entrepreneurial environment.

The Campus Biotech Consortium would like to thank both, "Le Conseil d'Etat Genevois" and the Swiss Confederation for its support.

Speaking on behalf of the EPFL, its President Patrick Aebischer said: "This project constitutes a unique opportunity to increase research and development in the Biotechnology Sector of the Lake Geneva region and its related job creation."

Speaking on behalf of UNIGE, its Chancellor Jean-Dominique Vassalli said: "This project creates a fantastic opportunity of a close collaboration between EPFL and UNIGE in the area of applied biomedical research."

Speaking on behalf of the Wyss Foundation, Hansjörg Wyss said: "The Wyss Institute shall be a multidisciplinary Institute whose mission will be to develop biologically inspired solutions that will solve critical medical problems and to translate these transformative technologies into products that have an impact on society and the world."

Speaking on behalf of Campus Biotech Sàrl, the entity formed by the Wyss Foundation and the Bertarelli family to buy the site, Ernesto Bertarelli said: "We are absolutely delighted to be moving forward with Campus Biotech. A central element of our plan is the creation of a Wyss Institute focusing on Bio- and Neuro-Engineering. We have been much encouraged by the wide support for our project which we believe will bring immense value to the Geneva Lake region and Switzerland as a whole." - Campus Biotech press release - Source: Mediacom

NTN Partners:



Biotechnet Platform Biosynthesis

Linda Thöny-Meyer



Economic biosynthesis of biomolecules and polymers involves a broad palette of biotechnological competences, ranging from protein engineering and strain construction, metabolic engineering, fermentation/cell cultivation and downstream processing to polymer- and bioanalytics. However, general and straight forward strategies to best produce specific biomolecules.

The biotechnet platform Biosynthesis with its members from the different academic institutions provides the necessary know how to solve specific biosynthetic problems together with industry.

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Materials Science & Technology

Biotech meets Medtech

On September 17 – 19, 2013, the World Medtech Forum Lucerne opens its doors for the second time. Manufacturers, suppliers, research and educational institutes as well as institutional partners in the medical technology industry come together for a fruitful exchange of ideas. The conference combined with a tailor-made trade fair gives opportunities for networking in new and appealing premises in Lucerne and explores, among other topics, the interface between Biotech and Medtech. Renowned scientists and innovative entrepreneurs present latest developments like novel, blood-based biomarkers for the early detection of prostate cancer as well as tissue engineering and advanced cell-based medical therapies. The world of Neurosciences offers sophisticated brain research with emphasis on brain plasticity and regeneration. The challenging story of researchers who replicate a human brain in a mobile device will also be presented during the Forum. For further information see www.medtech-forum.ch

http://medtech-forum.ch/de/medtech_messe/Messe/Center-of-Attention



SwissPedNet: Research collaboration dedicated to children



David Nadal

Medical treatments for sick children are notoriously problem-prone, as both diagnostic methods and drugs used have usually been developed for and tested in adults only. Many reasons impede pediatric drug research compared to research in adult patients: patient numbers are lower, and particular ethical and psychological concerns have to be considered. This all hampers planning and conducting clinical trials in children. SwissPedNet has been founded to counteract this situation.

SwissPedNet aims to support clinical research in pediatrics via a research network of clinical

pediatric hubs within Switzerland. Hence, the task of SwissPedNet is to promote, facilitate, coordinate, and conduct clinical trials and help to develop new technologies devoted to children ranging from newborns to adolescents, in all pediatric disciplines. The ultimate goal is to enhance clinical research in pediatrics both by supporting pediatric clinical scientists to foster their commitment to high-quality clinical research and by encouraging an increased overall acceptance in the community of trials in children.

On a local level, we established Clinical Pediatric Hubs within all eight Class A children's hospitals, they are closely linked to the corresponding Clinical Trial Units (CTU). The Clinical Pediatric Hubs are still lacking appropriate funding. SwissPedNet strives toward an improvement of this situation by establishing proper infrastructure in all Pediatric Hubs in near future in order to proceed with a nationwide clinical pediatric research as highly demanded globally.

On a national level, closely linked to the Swiss Clinical Trial Organisation (SCTO), the national coordinator operates from the SwissPedNet coordination office. Among other duties, the

tasks and aims of the coordination office include facilitating access to investigators and patients in Switzerland, establishing a "one stop shop" for third parties to work with several study sites, and providing common conditions in all Pediatric Hubs.

SwissPedNet is a young initiative of the eight pediatric Class A hospitals of Switzerland. Although we are still in a start-up phase, we are ready for all interesting collaborations and keen to work together with all stakeholders on the medical progress and the improvement of pediatric research in order to implement evidence-based medicine also for our children.

Prof David Nadal, President SwissPedNet

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Promotion supporters:



Swiss Participation in the EU's seventh research framework programme, Interim Report 2007-2012

Swiss researchers compete well for FP7 research funding.

FP7 grant funding secured by Swiss researchers by participant category:

- Over two-thirds of FP7 funding awarded to Swiss researchers was secured by the FIT Domain and cantonal universities.
- Small and medium enterprises 10,9 %
- Non-Profit-Organisations 7,2%,
- Cantons and cities 0,5 %,
- Confederation 1.0%
- FIT domain 40,0 % Universities 28.3 %
- Industry 9,3 %
- Universities of applied sciences 2,8 %

The most heavily funded research themes also generally tend to be those with the highest number of Swiss participations. European Research Council (ERC) grants alone accounted for CHF 436 million or 28% of total research funding paid to Swiss researchers. ICTs came in second (CHF 296 million or 19%) followed by Health (CHF 182 million or 12%).

Switzerland compares favourably with other countries

So far, the average FP7 success rate is about one project proposal out of five (22.3%). Swiss researchers achieved a 25.3% success rate with their project proposals, which is significantly higher than the average success rate. This indicates that Swiss research proposals are generally of higher quality. Switzerland ranks 4th in terms of FP7 success rate compared to associate and member countries, falling behind Belgium, the Netherlands and France. This is an excellent outcome.

If we consider the current 2,678 Swiss participations in FP7 projects (including project coordinations), we find that Swiss researchers account for 3.3% of all participations. This proportion is significantly higher than the proportion that Switzerland achieved under FP6 (2.6%). Switzerland ranks 9th in terms of the number of participations. The proportion of secured FP7 grant funding awarded to Swiss researchers stands at 4.3% (CHF 1.56 billion), which is considerably higher than the 3.1% figure achieved for secured FP6 grant funding. The difference between the proportion of Swiss participations and the proportion of secured funding can be explained by the fact that researchers based in Switzerland are quite successful at obtaining ERC grants.

Positive net financial return

Since it became associated with EU research framework programmes in 2004, Switzerland has derived a positive net financial return from FPs. In other words, the amount of FP project funding secured by Swiss researchers exceeds the financial contribution that the Confederation has paid the EU. While it is not possible to estimate the definitive financial return Swiss researchers have been particularly active in ICTs, health, nanotechnologies and the FP7 "People" programme, which encourages the mobility of researchers. Number of FP7 participations by specific programme and research theme Swiss researchers compare very favourably with their counterparts in other European countries

Secured FP7 grant funding by country Horizon2020 – next-generation FP in preparation

FP7 will come to a close at the end of 2013. The European Commission has presented its proposal for the next-generation FP "Horizon 2020 – Framework Programme for Research and Innovation". This proposal is currently being debated in the European Parliament and the European Council. The decision regarding this programme must be made by the end of 2013 at the very latest in order to ensure entry into effect by 1 January 2014.

Switzerland is working to achieve a smooth transition in its association from FP7 to Horizon 2020. The Federal Council submitted its dispatch on funding of Swiss participation in this new programme generation to the Federal Assembly in February 2013. This dispatch will be examined in the summer session of 2013. Negotiations on Swiss participation in Horizon 2020 are planned for the second half of 2013.

0% 5% 10% 15% 20% 25% Information and Communication Technologies Health –

Source:

SERI News – June/13

link: www.sbfli.admin.ch/pub_frp7



Regulatory Affairs – a key success factor for Life Sciences

regulanet® (supporter of SBA) is a network of regulatory affairs consultancies with members in over 90 countries throughout the world. Founded in 2001 and led by Dr Regenold GmbH, regulanet® offers services to a wide variety of national and international healthcare and pharmaceutical clients.

The network uses state-of-the-art tools to ensure efficient communication and access to information between members and clients. regulanet® provides advice and assistance on national and international projects and marketing authorisation procedures, including the decentralised, mutual recognition and centralised procedures within Europe.

4th Annual Symposium of the Swiss Clinical Trial Organisation

Good Governance in (Clinical) Research with Human Data and Tissue

Thursday, 20 June 2013

Geneva, University Hospitals Geneva

The 4th annual Symposium of the Swiss Clinical Trial Organisation (SCTO) – this year on the subject of «Good Governance in (Clinical) Research with Human Data and Tissue» – was organised in collaboration with the University Hospitals Geneva and the Medical Faculty of the University of Geneva. The event was supported by the Swiss National Science Foundation.

Biobanks, organised collections consisting of biological samples and associated data, have gained great significance for research and personalised medicine. While biobanks are increasingly recognised as a crucial infrastructure for research, the legal and ethical requirements for the procurement, storage and use of human tissue samples are still rather heterogeneous across different countries: a significant variability emerges with regards to privacy and data protection requirements among biobanks, and widely varied practices are observed regarding collection, storage and consent procedures. Furthermore, rapid technological developments and globalisation have brought new challenges for the protection of personal data in general.

The scale of data sharing and collection has increased spectacularly as well. Individuals increasingly make personal information available publicly and globally. Technology has transformed economy, social



swiss
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life and research. Personal data concerning health are a sensitive category of data, and their processing is therefore highly regulated. How to find a balance between adequately protecting the fundamental rights of individuals/patients and at the same time

not blocking (clinical) research – and as a consequence, progress in favour of patients?

Various stakeholders from academia, industry, authorities and patient advocacies gave a comprehensive overview on the latest developments and challenges in this currently extremely dynamic area as well as an outlook to the future. The symposium achieved a high attendance of more than 170 registered participants from Switzerland and abroad. http://www.scto.ch/en/Events/Symposium_2013.html

Rare Diseases / Orphan Medicinal Products

Rare Diseases

Rare diseases are diseases which affect a small number of people compared to the general population and specific issues are raised in relation to their rarity. In Europe, a disease is considered to be rare when it affects 1 person per 2000. A disease can be rare in one region, but common in another. There are also many common diseases whose variants are rare.

There are thousands of rare diseases. To date, six to seven thousand rare diseases have been discovered and new diseases are regularly described in medical literature. The number of rare diseases also depends on the degree of specificity used when classifying the different entities/disorders. Until now, in the field of medicine, a disease is defined as an alteration of the state of health, presenting as a unique pattern of symptoms with a single treatment.

What is an Orphan Drug?

The so-called 'orphan drugs' are intended to treat diseases so rare that sponsors are reluctant to develop them under usual marketing conditions.

The process from the discovery of a new molecule to its marketing is long (10 years in average), expensive (several tens of millions of euros) and very uncertain (among ten molecules tested, only one may have a therapeutic effect). Developing a drug intended to treat a rare disease does not allow the recovery of the capital invested for its research.

Orphan drugs may be defined as: Drugs that are not developed by the pharmaceutical industry for economic reasons but which respond to public health need.

Actually, the indications of a drug may also be considered as 'orphan' since a substance may be used in the treatment of a frequent disease but may not have been developed for another, more rare indication.

More information on community platform of SBA available ([where?](#))



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Published 3 times a year (print or pdf.)

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