7th Concertation and Consultation Workshop on Micro-Nano-Bioconvergence Systems MNBS 2013,

"Innovation and Technology Implementation for European Competitiveness and Better Citizen's Life"

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Tyndall National Institute, Cork, Ireland

Report

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1. Executive Summary

The objectve of this workshop, the 7th in a series of conferences on the development of Micro-Nano-Bio Systems, MNBS, is to share the progress in the field, as well as the opportunities and challenges ahead. Over the years the focus of workshop has shifted from a technology development orientation to a business development one. This year the focus was on the distance to market, the how of translating technology success into business success, and the changes that the Horizon 2020 program will bring in the EU's framework program. To stress the importance of the potential synergies with other smart systems the 2-day workshop was organized in collaboration with EPoSS annual general assembly. The involvement of representatives of key disciplines on the market side such as purchasing and venture capital was sought to give new inputs to the MNBS community. As usual, this workshop offers a podium to enable community building and networking, the sharing of progress in both technology and application development, and the identification of common issues. The program is listed in Annex I.
All in all, the workshop attracted over 184 participants from across Europe, who represented many running FP7 projects a few finished FP6 projects, EPoSS workgroup members and other stakeholders from industry and the public sector. For a summary overview of participants see Annex II.

The workshop was organized around oral and poster sessions, an open demonstrators' facility and plenary/thematic discussions. Oral sessions included keynote presentations, MNBS projects' innovation & technology aspects, industrial issues and issues of joint interest with relevant EPoSS working groups. During the presentations a variety of topics was presented. The keynote part featured the host of the meeting, the Tyndall Institute, as well as the Horizon 2020 program and a successful medical device SME. Two series of presentations mapped the progress in 20 projects with the emphasis on innovation process including prototype validation and distance to market. In the follow-up panel discussion the learning points from the presentations were brought up and plenary discussed.
The industry session handled by COWIN team and involving FoodMicroSystems project highlighted the many aspects of building a lasting business with new technology and new-to-the-world products. Innovation stakeholders especially SMEs, industrials, procurers and investors shared their point of view with the audience in covering diagnostic, life science and agrofood applications. New instruments designed for H2020 as the SME instrument and the PCP have been also highlighted to foster opportunity for new collaborations with a market pull approach. In the plenary discussion that followed the participants were stimulated to share their questions and observations. In preparation of the event, an introduction webinar has been organized by COWIN to encourage participation from the industry in presenting expected output of the event. This webinar was also dedicated to encourage participants to focus on innovation and not technological aspect of their projects. Guidance for presentation prepared by EC projects officers in collaboration with COWIN has been presented. Access to this webinar is available on the following link http://www.cowin4u.eu/public/cowin-tutorial/optimize-your-participation-to-mnbs-2013-eposs-annual-forum-get-ready-to-deliver-your-key-message.

The EPoSS working groups on applied MNBS and on Key Enabling Technologies organized 2 sessions. The talks on applied MNBS dealt with a methodology to develop new MNBS systems, and a first version of a high level roadmap to align the EPoSS and MNBS development. The freshly issued white paper of the ETP Nanomedicine was presented, which advocates a joint effort between the ETP and the Commission towards innovation. Also for Bioelectronics a white paper was introduced that analysed Europe's position in various markets as input to a SWOT analysis and a set of recommendations. The workshop finished with the plenary Consultation session on future challenges and innovation issues.

Progress

Many projects are entering a critical phase, where the technologies need to be brought together and integrated into a prototype, or the initial tests of the prototype are being performed. Others elaborate user requirements or look for exploitation and business opportunities. The projects presented were FP7 running projects, well advanced or recently started. For the majority, planning for the next phase of prototype validation, product design, supply chain, user targeting, clinical validation and commercial roll-out are now taking center stage. With the current emphasis on new economic activities and job creation other competences need to be acquired, with which many consortia have limited experience. And when no commercial partners are part of the consortium, new commercial partners need to be found or the establishment of a new company is required.

As this is new ground for many of the consortia, estimating the time and effort that it takes to achieve all of this is a real challenge. The projected "distance-to-market" values are therefore often, optimistic underestimates. In discussions ideas were discussed on how the thinking about innovation phase could be improved, which has led to recommendations that are included in the report.

During the industry session the innovation part of value chain was discussed in more detail from a no. of different angles, and valuable advice was given on how to increase the chance of commercial success.

In the program that was organized by the EPoSS workgroups a no. of overlapping areas were highlighted where MNBS, EPoSS , the ETP Nanomedicine and Biophotonics could benefit from aligned actions. A common roadmap would accelerate the time-to-market of new products as well as improve their quality and costs. The plans of the ETP Nanomedicine for innovation and the analysis of the MNBS- field can help accelerate the learning curve from new products.

Consultation

The new initiatives that the Horizon2020 framework brings were well received. A revision of the proposals' structure & content and assessment process is clearly needed as the new requirements ask for new competences that must be independently assessed. By considering the funding of projects beyond the proof-of-principle phase to the innovation phase, the new European Framework Programme (H2020) brings considerable contribution to major European policies whether they relate to industry, society or knowledge. This new area is a very competitive world in which highly successful companies operate, and the best-in-class processes on how to be successful are broadly understood. The role of the Commission is catalytic, i.e. to facilitate the interaction between technology developers, SMEs, public organisations, consolidated industry & capital providers and support pre-competitive research and innovation.

New application areas for MNBS were proposed such as integrated diagnosis and therapy, or "Theranostics", a concept that is showing early successes and needs new technology to develop further. Also, personalized medicine, which has been hyped in the media and could take shape in many forms, needs the type of technology that is developed in MNBS projects.
The critical question of how Point-of-Care devices can carve out their own space in a world dominated by central labs for *in vitro* diagnosis was brought up. Finally, market opportunities related to research applications for MNBS should not be underestimated as it can also be an entry point for reaching a larger market. The report indicates some areas in which these devices offer significant promise.

2. Workshop Objectives

This 7th workshop on the development of Micro-Nano-Bio Convergence Systems, MNBS, is building on the progress of many projects and the previous workshops. While in the 6-th MNBS workshop the nascent and complex supply chain with strong interdependencies took central place, this year's emphasis is on innovation and technology implementation for improving European competitiveness and citizen's life. The workshop was therefore organized in cooperation with the Smart Systems community as represented by EPoSS to benefit from synergies such as:

- Community building, networking and brokerage
- Opinion building and consolidation of a joint strategy towards Horizon 2020
- Diffusing and exchanging of information on research & development results and innovative solutions from EC-funded projects and other initiatives in Europe
- Identifying synergies and possible collaborations to tackle critical issues that cover the full value chain from R&D to exploitation
- Taking an active role in defining research priorities and roadmaps for future research and in the forthcoming EU programme for research and innovation, Horizon 2020

The EPoSS Annual Forum with its industrial and applications driven character and its high percentage of delegates from industry was co-located with the MNBS community that features many representatives from research organizations. The goal is to have a perfect match of participants, covering the full value chain from education, through basic research, to successful product launch. This was further supported by the opportunity to exhibit, present and discuss posters and demonstrators. Fittingly, this year's motto for EPoSS Annual Forum was "Gearing up for Horizon 2020: Smart Systems Satisfying Societal Needs, Meeting Market Requirements & Exploiting Cross-Cutting Technologies".

This joint event welcomed also a COWIN Marketplace dedicated to facilitate interaction and one o one meetings between participants. More than 60 meetings took place with technology holders and potential users.

3. Introduction to Micro-Nano-Bio Systems, MNBS

Worldwide, scientific and technological research to develop, manufacture and sell systems that employ nano- and micro-structures is at the forefront of economic competition. The class of devices that combine biological functionality with the ubiquitously sharing of information through networks receives particular attention. A wave of new materials, processes and technologies is being researched that enable highly integrated, miniaturized and compact systems to be assembled. The fruits of these efforts can be used in many areas, such as biomedicine, transport, telecommunications, the food chain, safety, the environment, smart textile & wearable electronics and others.

These fast technology developments are also at the heart of the explosive growth in Life Sciences, which is leading to an ever increasing understanding of life at the sub-cellular and molecular level. By bringing these parallel developments to healthcare, ultrafast and sensitive

systems can be developed to diagnose diseases with high accuracy and speed, and to support and improve body functions or to replace lost functionality. Such systems will help to diagnose and treat the world's major and orphan diseases with better outcomes and at lower costs than previously deemed possible. It could make a substantial contribution to bring healthcare expenditures under control and increase its productivity. At 10% of the world's GDP and continuously surpassing GDP growth, governments around the world are struggling to provide high quality healthcare at affordable costs to their citizens[1,2].

For example, in diagnostics highly integrated, compact devices are developed, so-called point-of-care products or PoCs that incorporate lab-on-a-chip ("LoC") technologies, to achieve integration of the hitherto separate processes of sample preparation, separation, amplification and analysis. New therapeutic devices are envisioned that are implanted to support body functions or organs that are weakened by disease or lost through amputation, or allow high precise surgical interventions to minimize damage to surrounding tissue. Such new products could reduce the severity and mortality of the world's most severe diseases such as heart attacks and failure, stroke, cancer, neurodegenerative and infectious disease.

Tropical diseases such as Malaria kill over 700,000 people yearly in Africa alone. Field diagnosis will enable the right treatment early. (*DiscoGnosis* project).

Time critical diagnostics information can be obtained more rapidly at the point-of-care or point-of-diagnosis, and treatment monitoring with immediate feedback becomes more feasible, e.g. for bacterial or viral infections. Also, more personalized treatment becomes possible by measuring the patient's genetic predisposition to side effects and response. With the quickly diminishing cost of sequencing a complete human genome, new monitoring devices will promote and improve patient follow up, thus addressing the limited caregiver resources, the growth in chronic diseases driven by aging and lifestyle, and healthcare's budget constraints. Such less intrusive, miniaturized and hassle free devices with enhanced patient acceptability will reduce the risk of social exclusion and improve patient support at home.

Therapeutic devices will allow surgical interventions that today are not possible or lead to serious impairment, e.g. in diseases such as prostate cancer or afflictions of the nervous systems. Other devices envisioned are implantable biochips and autonomous on-body biosensors, which allow continuous monitoring of body functions, networked to the outside world through wearable textile. Projects that are supported in the MNBS program develop:

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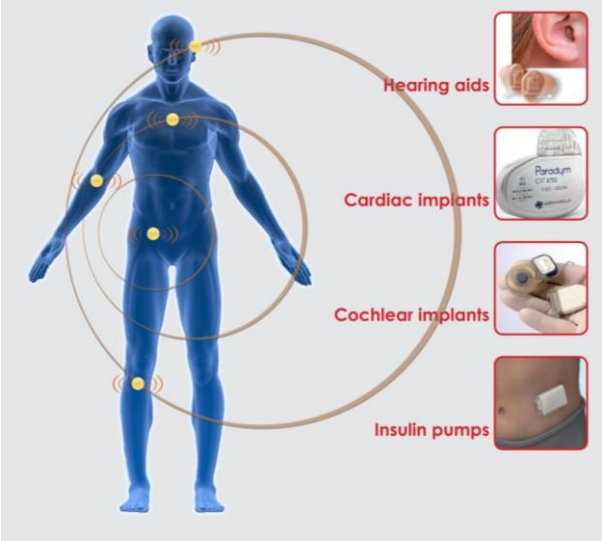
[1] Economist Intelligence Unit, The future of healthcare in Europe The future of healthcare in Europe, 2011

[2] Price Waterhouse Coopers, HealthCast , 2010

- Neuro-interfacing implantable devices that treat phantom limb pain, restore motor functions or intervene in the cardiovascular system
- Minimal invasive devices that can diagnose and intervene at the same time
- Lab-on-a-chip systems employing a variety of technologies for sample handling, separation and identification for both body fluids and food
- Detection and identification of circulating cancer cells
- Improved diagnostic transducers and transponders
- Devices for a new imaging principle
- New sensors, body area networks and biomedical informatics
- Robotic systems for highly precise surgery



Body Areas Networks that are ultra-tiny and ultra-low energy will reduce the risks of device malfunction and social exclusion for the many impaired and disabled people who carry implants or wear medical devices. (*WiserBAN* project).

The technology developed in the MNBS program is also applicable to other areas where it can bring significant impact, such as the food chain and environmental analysis. Assuring safe and high quality food requires protection against bioterrorist attacks and contamination by biological agents such as bacteria and parasites, as well as toxins and chemicals. The current analytical tools to perform the required analysis are either not portable or too complex for field use (HPLC, LC and GC), lack sensitivity (ELISA) or are too time consuming (molecular and microbiological tests). The need for smart, rapid-testing and compact platforms such as developed in the MNBS program is thus clearly established[3]. To generate breakthroughs and commercial success, better coordinated and higher investment is necessary from the public domain but also through public-private partnerships. Well known market success stories like tuberculosis test and robotic surgery required hundreds of millions of euros to develop the basic technology and provide the clinical evidence

Cluster's recent achievements and current status

The cluster's aim is to build a sustainable ecosystem and impact EU policies e.g. industrial, active and healthy aging, food safety, environmental control and quality of life by delivering innovative solutions to meet user needs in broad range of applications. With about 25 MNBS

[3] L.M.L.Nollet, F. Toldra, Advances in Food Diagnostics, Blackwell Publishing, 2007

running projects in September 2013, it significantly contributes to create a critical mass of resources & activities to support the translation of research results into innovative solutions. In 2013 the projects delivered excellent R&D results and contributed to the strategy for EU industrial competitiveness with the collaboration of the European Technology Platforms (ETPs) EPoSS, Nanomedicine, Photonics21. In addition to the large number of ISI publications, dissemination in international conferences and other mass media, the group trained hundreds of graduated and PhD students, produced high value patents and capitalised on growing SMEs and spin-offs with new products and services, e.g.:
-**POC microsolutions SL**, spin-off of Ikerlan created with the technology of OptoLabcard (FP6) and LabonFoil (FP7); http://www.pocmicrosolutions.com/
- ATLAS neuroengineering, spin-off of IMEC and IMTEK, using technology developed in Neuroprobes: http://www.atlasneuro.com/ , and also,
- **bi-flow (D), biosensia (UK), biofluidix (D),** and several spin off projects currently under discussion.

It should be noticed that the MNBS cluster represented about 30% of collaborative projects benefiting from COWIN CSA dedicated to encourage the commercial exploitation of FP6 and FP7 research projects results. MNBS represents a strong opportunity to launch young companies addressing new usages, new market opportunities and new business models to generate jobs and growth. 4 young companies exploiting MNBS projects results have been introduced to private investors.

4. MNBS Workshop, Presentations and discussion

The 7th annual Concertation and Consultation workshop on Micro-Nano-Bio Convergence Systems, MNBS, was held in Cork, Ireland, on September 23 and 24, 2013. The event was organized by the European Commission and the Tyndall National Institute, University College Cork. The Tyndall National Institute hosted the meeting and had delegated Dr Eric Moore as chairman. The meeting combined the yearly MNBS conference with EPoSS' annual assembly, and the participants from both communities were offered 3 days, integrated MNBS and EPoSS program and a COWIN Marketplace. The meeting's 187 participants were offered a three-day program with progress presentations on individual projects, invited presentations from external key stakeholders, a consultation discussion and summary, a on-going poster and demonstrator exhibition, as well as sessions organized by COWIN on the commercialization of the scientific and technological research. The EPoSS sessions gave the opportunity to network and prepare for H2020, to consider a common roadmap, to share experience and lessons learned, as well as to discuss how key technologies developed in the EPoSS program could benefit MNBS projects.

The program and the summary list of participants can be found as Annexes I and II.

4.1 Opening of MNBS and Keynote Session

Andreas Lymberis, European Commission, DG Connect, Components Unit, chaired and opened this session. In his introduction he highlighted the progress made in many application areas and projects, and emphasized that new challenges await the MNBS community in

manufacturing, application selectivity and regulations. Failing in these or other areas such as specificity and sensitivity means failing in innovation. The focus therefore needs to shift to the innovation chain. This was one reason why the MNBS meeting was organized in collaboration with EPoSS, which represents many of Europe's leading companies in the area of smart, integrated systems. Further support for the innovation chain will be provided by the EU's Horizon 2020 program, in which pilot projects for new products and services can be funded. Key to market success is the coverage of the full value chain and early involvement of users, in order to develop ideal solutions and achieve early acceptance of commercial products and services. As a consequence, the processes for the assessment and selection of new projects need to be changed to achieve the migration from good to great!

Kieran Drain, CEO of the Tyndall National Institute, introduced the institute and gave an overview of its development over the last 30 years. The institute was set up to do scientific research in support of the Irish industry and to develop new products and business opportunities. With a focus on smart, integrated systems its research programs cover the whole range from atoms to integrated systems, with a large photonics activity. The staff of 460 researchers and engineers, and 134 students draws upon 38 nationalities. On the basis of a € 200 mln capital investment and 200 partnerships an annual income of €30 mln is generated, 85% of which comes from contracts with customers. The main applications areas are energy, medical technology and agriculture. Ireland is Europe's second largest exporter of medical technology, second only to Germany, with a market volume of €8 bln. Among the Institutes activity areas are atomistic modelling, implantable radiation detectors, swallowable capsules for Crohn's disease and microneedles. It has become Ireland's photonic integration centre for medical applications, and hosts the Irish industry-led Nanotechnology Centre with 15 participating companies. The EU's FP programs have been very supportive as the institute participated in some 80 projects.

Liam Brown, Enterprise Ireland, introduced this Government Agency, a public authority, and its mission to develop export business for Ireland. The country's participation in FP7 [2007-2013] has led €600 mln of investment, and based on this success the ambition for Horizon 2020 is € 1 bln. A focus for Horizon 2020 [2013-2020] will be NMP, Photonics and Biotech, given Ireland's successful position in this area. The agency will focus on enhancing the competitiveness of its industry by supporting a whole range of activities around innovation and the great societal challenges. The EU's Key Enabling Technologies, KETs, play an important role in the selection of projects. The agency actively promotes the involvement of industry and venture capital providers. It was remarked, that many industry leaders already are located in Ireland, attracted by the quality of its English-speaking workforce and low corporate taxrate. The challenge is now to have SMEs grow into large, Ireland-based companies.

Sean McCarthy, Hyperion ltd, Ireland, shared with the audience his experience on how to win with research proposals as the EU moves to the Horizon 2020 framework. Based on his extensive experience with FP programs he presented the process in clear concepts and provided many advices. While the FP7 program has a silo structure, Horizon 2020 is built around programs to address the main challenges to our society e.g. energy, raw materials and the aging population. Other differences with FP7 are public funding up to Technology Readiness Level (TRL) 7, and public procurement acting as source of funding through early adoption programs. It also offers support for risk capital providers and banks. The Horizon

2020 programs pose new challenges to the assessment and selection process, requiring experts to be educated on impact assessment, and processes that lead to successful industrialization and product adoption.

Willy van Puymbroek, European Commission, Head of Unit Components, DG Connect, shared with the audience the development of Europe's strength in Micro- & Nano systems. Over the next 10 years the industry will invest € 100 bln. In support, a Joint Technology Initiative will be established that aims to build new systems from the atomic level up. This JTI is to be funded through a € 5 bln investment for the period from 2014 to 2020. The first calls for 2014 are now under discussion. It will provide funding up to TRLs 7 and 8, and include preproduction.
MNBS is a broad field covering atoms up to systems. Over the period 2007 to 2013 some € 200 mln has been invested by the EU, and another 70% hereof by other funding. DG CNET will manage the KETs Micro-Nano electronics and Photonics. The first call under the Horizon 2020 program is planned on smart system integration for December 10, 2013. Innovation actions and stimulation of access to technologies will be included in the call. In the second call generic micro and nano technologies will be addressed, with coordination and support actions included.

Marc O. Schurr, Ovesco Endoscopy, explained how Ovesco as a SME built a position in over 60 countries, with 3000 hospitals as customers. Ovesco developed a patient-friendly wound clipping system for endoscopic investigations based on U shape memory alloys. In his talk Dr. Schurr emphasized the importance of understanding an unmet need as well as the payment system. A new and innovative product that the company has been working on is a steerable robotic system for intestinal intervention. The application under testing is tumour removal followed by wound closure under magnetic control. The system allows for full resection of a 3 cm adenoma, and the product saves the surgeon and hospital time and money, while at the same time helping the patient to a much quicker recovery. A next step is immersive endoscopy for internal surgery. The need for such systems is rising as the prevalence of colorectal cancer is increasing while systematic prevention is under-developed.

4.2 MNBS Projects - Innovation Session Part 1

Eric Moore, Tyndall National Institute, University College Cork, chaired and opened this session. The progress of a variety of analytical and diagnostic projects is reported, which cover a range of application areas in healthcare. As cancer is becoming the leading cause of death in the world, better and earlier diagnostic tools are needed to allow early, life- saving intervention, at the stage that a tumour is still encapsulated and before invasion in the surrounding tissue has occurred. Early detection of circulating cancer cells could direct such a timely intervention. This is quite challenging, however, as the sensitivity and specificity of a diagnostic device for circulating cancer cells needs to be very high. Furthermore, such devices could play an important role in the choice of therapy as such circulating cells would reveal the genetic make-up of the tumour, which can be very specific to the individual and the organ affected. In addition such tools will support the research and development of more effective medicines and of organ regeneration. Identification of the genetic make-up is also very important to identify pathogens in a range of infectious diseases, especially in tropical areas. Another area where DNA analysis in blood samples will make a difference is the diagnosis of

serious genetic deficiencies in the unborn child as early as possible. As the average childbearing age is increasing, the risk of miscarriage, birth complications and poor health expectancy of the progeny grows. The projects *MIRACLE*, *PASCA*, *ProdiTrodi*, *DiscoGnosis* and *ANGELAB* deal with breakthrough inventions in these areas.
Accurate, fast and frequent or timely diagnosis of a large variety of molecules small and large is needed for a wide range of acute and chronic afflictions. Also here Point-of-Care (PoC) devices are the big promise. It is crucial for their success that sample taking and handling, as well as result reporting is easy, intuitive and robust against human errors. NextDx and *NANODEM* aim to develop such PoC platforms for biomarkers that allow prevention, diagnosis and monitoring of cardiovascular disease, psychiatry, pulmonary disease, critical care medicine and transplantation surgery.
As the shortage of available organs for transplantation is likely to persist, helping patients with organ deficiencies to live at home rather than in a hospital is beneficial to patients and the cost of healthcare alike. *d-LIVER* aims to deliver such a system for patients with serious liver conditions.

Road to exploitation and distance to market

- For **Miracle** (Magnetic Isolation and Molecular Analysis of Single Circulating and Disseminated Tumour Cells on Chip), which is now in its third year, the IP position is such that both licensing and direct exploitation are open to further exploitation. Commercialization of some of the key technologies is estimated to be only 1 year out, whereas the integrated module will take 3 years. One reason for this short timeframe is that industry standards and compatibility with mass production technology has been part of the design. This will allow low manufacturing costs as well. Marketing of the project has started through conferences and business exhibitions, and communications with potential partners or customers.
- **PASCA (**Platform for Advanced Single Cell Manipulation and Analysis), which has secured grants for further development, favours direct exploitation through the industrial partners in the project. Improvements in a no. of areas are required, i.e. more robust technology, improved sensitivity, more integration in the analytical environment. Also, proof of concept must be provided. Seven prototypes have been delivered to partners, and the concept is now being marketed at exhibitions.
- **SIMS** (Smart Integrated Miniaturised Sensor System) combines organic and printing technology on a single substrate to design a Point-of-Care device. It has been successfully demonstrated at international exhibitions and conferences in the US, Europe and Asia and was awarded the prize for best publicly funded demonstrator at LOPEC 2013. A preliminary commercialization study identified a new venture as the best option. Several diagnostics companies have shown interest in the technology, and the lead institution, UWE, is funding a more detailed market introduction study. The IP portfolio is being defined.
- **ProdiTrodi** (Technology Platform for Point-of-Care Diagnostics for Tropical Diseases) is aiming very high as the goal is to simultaneously analyze proteins and DNA -strains in complex technology to diagnose tropical diseases. The technology itself will take 3 – 5 years to completion and proof of concept. It will likely take another 3-5 years to get the approval for the first clinical application. Early cooperation with the Brazilian national reference laboratory with competence in the chosen application will help to shorten the

time to market. Discussions on IP and exploitation have started, as have discussions with the ministry of Health in Brazil.

- **DiscoGnosis** (Disc-shaped point-of-care platform for infectious disease diagnosis) is also targeting the diagnosis of multiple panel of tropical diseases and uses a disc-shaped centrifugal platform to achieve this. The platform's modula strategy and sample-to-answer analysis are two strong innovative aspects of the project. Suppliers for the key modules have been identified, and the commercial project partners will take the commercialization responsibility. The responsibility for system integration in volume production is open. The time-to-market is estimated to be 6 - 8 years, assuming that the technology and integration projects are finished as planned. Total costs to reach the market are likely to be a factor of 5 to 10 higher than the current rough estimate of € 1 -2 mln.
- **Angelab** 's (A New GEnetic LABortatory for non-invasive prenatal diagnosis) objective is to replace the current invasive test for potential embryonic genetic deficiencies in the mother's womb by a much more extensive and less costly, non-invasive one. The intention is to broaden the genetic test to up to 50 genetic mutations, in a system with could perform multisample analysis. The knowhow acquired during earlier FP projects will be helping this complex project to reach this goal. This too is a project with a high technology risk. Obviously serious ethical questions will have to be answered as well, since the diagnosis of a disease for which no treatment exists is not easily accepted in many countries.
- **NextDx**'s (Next-generation integrated MNBS-platform for instant diagnostics with single-molecule resolution) objective is to develop integrated technology for on-the-spot-decisions, in which the same analytical quality is provided as in the central lab, but on a timescale of minutes, during the doctor- or nurse- patient interaction. The test should reach the same sensitivity as the lab, be very easy to use and deliver results at a low price. It should be as simple as glucose testing. The technology achieves single molecule resolution to get the statistics right. Highly qualified project partners with longstanding experience decrease the technology and commercialization risks.
- **Nanodem (**NANOphotonic DEvice for Multiple therapeutic drug monitoring) aims to provide a platform to monitor the metabolization of drugs with a narrow therapeutic window on a continuous, in-line application. The individual modules of the envisioned end-products will be marketed by project partners, while commercialization events for the complete product are planned in 3 to 4 years.

4.3 MNBS Projects - Innovation Session Part 2

Javier Bonal, European Commission, DG Connect, Components Unit, chaired the second innovation session. Here the development of a variety of different technologies is reported for applications in food, health and wellness, environmental monitoring and smart textile. Many projects aim to provide analytical and diagnostic information, while others provide therapeutic solutions for a range of afflictions. In food, especially fresh food, the risk of a contamination by pathogens is always present. Also, due to the currently used agricultural processes unwanted substances such as pesticides and allergens are often introduced in too high concentrations, and fungal metabolites can be present. There is therefore an urgent need to detect the occurrence and quantity of such analytes along the supply chain on site for quick interventions and corrective actions. It also fits well with the rising interest of the population in healthy food. The projects *LOVE-FOOD* and Foodsniffer are set up for these areas.

The detection and analysis in the environment of a wide range of compounds is an important tool for the monitoring of industrial processes, earth, water and air quality around the world, and increasingly so since high-population-density sites in the world will increase as cities grow to house 50% of mankind by 2050. The *ARROWS* project aims to provide a solution here.
Overcoming the suffering of paralysis due to spinal-cord damage is a longstanding goal in medicine, the resolution of which may be in sight. Electric stimulation can enable the restoration of motor function for people with severe spinal cord injury. Electric stimulation can also assist to reduce the loss of body control in progressed Parkinson disease, and further improvements here appear possible. This is the application area of *NEUWalk*.
In the cardiovascular system, chronic dilation of arteries over time can cause ruptures. If such an aneurysm develops in the brain, a stroke may be the result, and in the lower part of the aorta, a rupture of the vessel's wall will lead to massive haemorrhage and death. Preventive treatment against such an event involves the placement of an endovascular graft, and is done increasingly minimally invasive under image guidance. If this graft or stent does not fit well enough, leakage around the graft can occur. *Heart-a-Gel* is developing electro-active polymer hydrogels that can close, fill or seal blood vessels and undesired vessel connections.
Diabetic patients often suffer from chronic wounds, the result of obstruction of the blood vessels that serve the afflicated area. By applying so called smart negative pressure wound therapy, the project *Swan-iCare* aims to provide a solution that can promote the healing process.
Increasingly, electronic devices are used in and on the body to support or intervene with body functions. Examples are pacemakers, implantable cardioverter defibrillators, hearing aids, insular pumps, and cochlear implants. The *WiserBan* project's goal is to develop a wireless body network that will monitor such devices and seamless enable communication with and intervention by the medical specialist.
Textiles can be made smart by integrating electronics with the fibers. Such smart textiles could be used to detect fluids in bedlinen for long term care homes or hospitals, to detect stress in leg prostheses or lighten up clothing in case of temperature change or sensing other body variables. Taken up the challenge to apply smart textile technology to bedcare and bodycare is what the **PASTA** project is all about. Applying thin optoelectronics systems to achieve on-body health and wellness systems is the goal of **PLACE-it.**
LOVE-FOOD (Love wave fully integrated Lab-on-Chip platform for food pathogen detection) aims to detect pathogenes in food through label-free analysis with acoustic waves. The goal is to beat the tabletop gold standard. Since it is early in the process, the decision on the type of exploitation will be made after the proof-of-principle has been established and after consultation with industrial partners and potential end-users."

Estimated distance to market is 3 years to finish the project and 3-5 years after project end. The project success also depends on the sensitivity and specificity of the acoustic wave technology, which is believed to be superior to existing ones.

The detection of harmful susbstances in fresh food products through sprectroscopy is the goal of **Foofsniffer** (Safety at the point-of-Need via monolithic spectroscopic chip identiFying harmFul substances in frEsh pRoduce). Aimed at profesional users such as farmers, the food processing industry, public authorities, analytical laboratories and retailers, the project's intention is to detect pesticides, mycotoxins and allergens. It is based on proven detection technology -Mach-Zhender interferometry- that allows label-free identification of small molecules. Technology transfer is planned to the industrial partners, who will also arrange for

the manufacturing. Time to market is estimated to be 3-4 years to come to a prototype for the to-be-selected market segment, one year for industrialization, followed by market launch period.

The **ARROWS (**Advanced interfaced microsystems Research for analysis of Real-wOrld clinical, food, environmental and Waste Samples) project aims to develop a very compact tandem Liquid Chromatography/Mass spectrometer for the analysis of a broad range of samples and compounds. The market insight is that there is a need for field-based technologies for a broad range of food and environmental applications. The process to come to the choice for the initial application and product specification has been started. No blocking IP has been found, the SME in the consortium could arrange for the manufacturing. The BRIC (Newly advanced economic development countries, Brazil, Russia, India and China) economies are seen as major opportunities. Time-to-market is an estimated 7 to 9 years out.

The objective of the **ML2 (**Design platform for economic production of multilayer Micro-Nano Bio Systems) project is to provide a design and production platform for the low-cost production of smart, multifunctional 3D-components by layered devices. Employing multilayer film technology and using standard functional elements to define a device could substantially reduce the design and manufacturing throughput time. Four modules have been defined that could be exploited commercially, and one partner has finalised a market entry strategy. At the end of the second year a demonstrator will be available. At the end of the project, in 3 years, fully functionality demonstrators should be achieved. Project partners are to take up the commercialization, which gives around 4 years to come to market.

The objective of the **Neuwalk** (novel neuro-prosthetic systems to restore the motor functions of individuals suffering from severe spinal cord injury (SCI) and alleviate the associated symptoms. with Parkinson's disease) project is to develop a demonstrator system for clinical validation on rats, non-human primates and humans suffering from paraplegia and Parkinson's disease. Now 3 years in the project, a demonstrator system for rats with paraplegia has been developed for testing and validation, and has delivered the first, promising results. The system design and development, clinical plan and market analysis has been performed, and the basis for exploitation has been established. Partners outside of the consortium are needed for the technological implementation. The resulting distance to market has not yet been specified, but could well be 5 - 8 years.

In **Heart-e-Gel (**Microsystem integration based on electroactive polymer gels for cardiovascular applications) the aim is to develop a new Electric Active Hydrogel (EAH) device. The chosen gel has several advantages over existing products as well as some disadvantages, and therefore requires good positioning. Part of the time to market is to overcome a no. of technology challenges, such as biocompatibility, performance in blood and infection risk. Since the projected product would be an implantable device, it will need to meet specific manufacturing requirements and pass preclinical and clinical trials. Manufacturing partners have been identified, as have distribution partners. Altogether time to market is likely to be 6-9 years.

In **Swan-iCare** (Smart Wearable and Autonomous Negative Pressure Device for Wound Monitoring and Therapy) "negative-pressure" is used as a therapeutic technique that employs a vacuum dressing to promote healing in acute or chronic wounds. Parameters such as pH, infections markers and known bacteria can be measured and communicated between the wound system and a clinical support environment for intermittent or continuous monitoring.

The project goal is to provide a prototype that will be validated by two medical partners at the end of project time in three years. The functionality of the wound system makes it a Class III or high-risk product in the regulatory system, requiring the associated clinical validation. Time to market therefore is likely to be 6-8 years.

The **WiserBan (**Smart miniature low-power wireless microsystem for Body Area) project employs heterogeneous components, the manufacturing of which is maturing. Redesign and optimization will be needed for other components and manufacturing candidates are available. The industrial partners in the project will define the exploitation roadmap and be responsible for marketing and sales. Now in the third year, another 2 years are required to finish the project, and two to three years later the key modules wil be available for integration into the system. No extensive clinical validation is foreseen.

PASTA's (Platform for advanced textile applications) goal is to build an integrated platform for smart textile applications, such as fluid sensing of bedlinen in hospitals, elderly care centers and homes. This would allow a new form of monitoring while increasing patient comfort. Manufacturing and product marketing will be taken up by a consortium partner. Time to market is estimated as 2-3 years after the project's end, so 3-4 years from now The advantages of smart textile for leg prostheses is the built-in stress sensing, which would allow for better prosthesis fit, leading to more comfort, less injuries and lower costs per patient. Here close cooperation with a prosthesis company needs to be set up. Time to market is estimated as 4-5 years after project end, or 7 – 8 years from now.

PLACE-it (Platform for Large Area Conformable Electronics by InTegration) is set up to develop a platform for large area, comfortable electronics system for on-body health and wellness, by using thin, lightweight and freeform optoelectronics technology. The technology is currently being tested in the market. The project has delivered demonstrators and formulated design rules for the industry. A supply chain for the platform that will alow a range of products to be designed will need to be set up. The targeted applications are in phototherapy, automotive industry, architecture and fashion. An industrial partner in the consortium will bring the ensuing products to market. Time to market of the first platform products is estimated as 9 - 18 months after project end.

4.4 Panel Discussion: "From R&D to Innovation in MNBS"

During this session a no. of observations on the presentations were discussed, feedback was given and suggestions were made in the MNBS community on the innovation process and the common challenges to come to lasting innovation and new economic activities.

a) Highlights

- **Customer insight**. Many projects start with good understanding of the technology development and the associated challenges, but a relatively vague concept of the product, its users and the usage. Experience tells us that the most successful innovative projects do it the other way around. Based on a validated customer insight it is explicitly formulated what the future product will do, how it will be superior and by which type of user it will be used for what. This knowledge increases the chance of success significantly. *Obtaining such a customer insight is a study in itself*.
- **Product uniqueness.** A new-to-the-world product cannot have all the whistles and bells that existing products have expanded into overtime. *Aiming for a unique benefit in the first*

implementation is crucial for market success.

- **Product complexity.** There is natural temptation to develop a product architecture that can easily be expanded into a broadening set of applications. Such a architecture typically takes longer and is more expensive than a simpler, dedicated one. Therefore a careful trade-off is necessary at the beginning of the project. *It is easier to expand the architecture of a successful product than to simplify that of an unsuccessful one*. It is also key to focus on the core function and specification creating differentiation on the market.
- **Business development** is a process in it, and immature in many projects. Understandably, in the research community this discipline is not at the forefront of people's mind. However, to increase the chance of business success dramatically it is an absolute must that users' needs are well understood at the beginning of the project, and the business planning process runs ahead of the technology development. When business development is concerned, expression of interest in a technology is not enough. Real commitment to acquire the technology or to invest in it is necessary. It requires to structure the relevant industrial and value chain for technology adoption.
- **Start-up companies** consume much more resources, people and money than in many project presentations is assumed. The cost to come to a proof-of-principle prototype is often far minor than the cost to provide regulatory, clinical and economic benefit.
  With a relevant analysis of the value chain and how the innovation will impact it, it is possible to consider the start-up exploitation business model while defining the R&I project. Exploitation plan should be defined accordingly.
- **Stopping projects**. Some projects will not reach proof-of-principle by the end of the funding period, and others may not be viable at all. New funding decisions should be based on good-practice criteria and structured reviews; continue to fund unsuccessful projects is not only wasting money but also, even more importantly, draining resources and talented people from more promising projects.
- **Distance-to-market** can be understood as the timespan needed to the point that customers can place orders. For many of the projects in this report reimbursement will need to be established as well. While there will always be customers who buy any new product, reimbursement is most often needed to achieve volume.
- **Exit options** presented include licensing, uptake by commercial partners and new company establishment. The experience of one presenter indicated that licensing is not very attractive, because it is passive and lacks control by the IP-owner, and often the license-taker will not throw their lifeblood at it. On the other hand, there are examples in the electronics industry where licensing schemes have been hugely successful for new product categories in established markets.
- **The project assessment** process needs updating, as it was observed that experts generally downgraded proposals with too specific product goals as being not new enough.

b) Recommendations for improving the development process of new businesses:

- Project proposals should include a clear description on how a validated customer insight will be achieved.
- Project proposals should provide details on how the product uniqueness will be established.
- Project proposals should specify the process to come to the right trade-offs.

- The business development process should be explicitly described.
- Proposals that come as the follow-up to earlier projects should be critically reviewed on past performance against plan, as well as the chance of success of the new proposal.
- The profile of experts as well as the assessment process need to be reformed to include more business expertise to judge proposals against the state-of-the-art. The processes that Venture Capital companies employ provide a good model. One of the key characteristics is a review of the team behind the project.
- Expertise on how to seed and catalyze successful new business development is not evenly distributed across Europe; an exchange of experts across the continent, both of seasoned and new talent could help to accelerate success.

4.5 Industry Session

This session was set up to organize a discussion between invited panellists and the audience to define the most attractive MNBS topics to focus on in Horizon 2020, in order to turn smart system solutions into new products and services with the support of the European Commission. This session has been organized by COWIN and Food Microsystems team and chaired by Geraldine Andrieux-Gustin, Yole.
The programming of this interactive session included five introductions on a variety of topics, and opened with the presentation of the results of FoodMicroSystems project's roadmapping and lessons learnt by the COWIN action (dedicated to the support of the commercial exploitation of the results of EU projects). Also presented by the European Commission were the so-called PCP (Public Pre-Commercial Procurement) and SME instruments to facilitate the entry of participants in Horizon 2020.
This session has been designed to be very interactive. Before the start, a questionnaire has been distributed to audience to get their point of view on the topics to focus on in Horizon 2020. The same questions were asked to the panellists and their feedback was compared with the one of the audience. This approach enabled facilitating the interaction in highlighting the main points of agreement and disagreement between the panellists active on the market, procurement and investment and the technology holders.

After presentation of the panelists and before the interactive session and to facilitate the debate, 2 presentations of ongoing CSA (coordinated & support action) Food Microsystems and COWIN have been done to share key information and best practices with the participants.

Patrick Salomon, introduced the FoodMicroSystems Roadmap, which aims to identify the key opportunities of smart systems technologies in food applications. A report describing the potential of the MNBS research and 5 detailed reports on different topics, i.e. needs and constraints for implementation, MST in meat, dairy, beer & wine, fruits & vegetables and the packaging sector have been issued. Three technology roadmaps were provided. The study found that safety, quality, sustainability, and tracking & tracing stood out as overriding needs of consumers and public authorities. For analytical results the immediacy came out as a key requirement. MNBS systems will have to produce results of comparable sensitivity as

laboratory equipment, and will co-exist with these systems. New solutions are clearly needed, as the interests of consumers do not align with those of the food industry and food outlets. This is especially important since there appears to be a low level of trust among consumers, and the consumer *a priori* perception was found to be negative. Key in the follow-up actions will be the active participation of the food industry.

Régis Hamelin, COWIN, gave highlights of the COWIN support action. COWIN's main objective is to support the commercial exploitation of EU research projects results. One of the focus was to help the launch and growth of companies in the smart systems sector by activities such as first strategic customer acquisition, business plan development, partner and OEM search and identification, supply chain development and Venture Capital (VC) provision. Some 130 projects have found their way to COWIN, and about 20 VCs are in the network. Central in COWIN's thinking is the business case approach. A number of illustrations were given, such as helping a laser manufacturer find a MEMS foundry by reusing a semiconductor project's result; finding a distribution partner for the Atlas project; bringing 2 potential customers to the Excelera project; helping the lab-on-foil project to find a potential customer and investor, and many others.

Javier Bonal, European Commission, gave details on the funding instruments for Horizon 2020. Goal of the new instruments is to help companies survive the valley of death. These instruments will support commercialization efforts, facilitate and support network building, offer debt financing and connection to PCP. The latter is intended to steer development towards specific public sector needs (demand driven innovation), where more R&D is required to de-risk technology and the competiveness of the developed solution is to be established before committing to large scale deployment. Public procurement/demand driven innovation can open markets for industry/researchers and thus *create economic growth and jobs in Europe.* Another innovation instrument is PPI, Public Procurement of Innovative Solutions, where public solutions are close to the market and would be provided if clear requirements and sufficient market demand are established. PPI does not require any R&D activity, and is intended to develop commercial supply relationships, in which the public sector acts as a facilitator that establishes a *buyers group* with the critical mass to trigger the industry to scale up its production chain to bring products on the market with the desired quality / price ratio within a specific time. Other innovative instruments will be fast track innovation, inducement pricing, Commercial Supply Agreements, CSAs (Coordination and Support actions), for market uptake and support for European Platform agendas.

Alexandra Donny, HAPPI, spoke on how public procurement of innovation projects could help to bring solutions for the Healthy Aging arena. The HAPPI project is a web-based platform where public authorities and companies can share their solutions as suppliers or procurers. It is intended for young products, which are not widely known. It is tied into the PPI initiative, and tenders for new products that will be launched in 2014.

Manus Rogan, Fountain Healthcare Partners, spoke about his experience with 3 FP7 projects which created start-ups and very good products which are now close to market success and an exit through the Merger & Acquisition process, i.e. are acquired by other companies. His experience was that European professors can well become scientific officers of companies and compete in this respect with their colleagues from Harvard.

Panel Discussion. The panellists Shane Moynihan (Biosensia), Iñaki Gutiérez-Ibarluzea (OSTEBA), Fredirico Morais (FIAB) and Guillaume Lhermte (Primadiag) joined the speakers for this part. Several points were made during the discussion:

- Hospital procurers look for solutions that not only offer quality care, but especially lower the overall cost. They focus on the needs of nurses and the technical staff, as here their influence on the choice of supplier is large. Doctors in general chose supplier and product themselves. Procurers ask for early involvement by suppliers. VCs do the same, the judgement whether a new product takes cost out of the care process is the all-important criterion for investment decisions.
- Other important questions for new products concern safety, the effectiveness – does it work? -, comparison with other products, contribution to quality improvement. Cultural differences may show up in differences in the relative importance of these criteria.
- For food, one of the requirements is for more intelligence in the analytical devices and lower cost for the traceability packaging.
- The results of a questioner amongst the MNBS community were discussed, from which a clear preference for more food safety applications emanated, and a more equal distribution between medical and research applications. In the discussion it was stated, that food safety does not drive new applications, but reuses equipment developed for the medical and research fields. It was not clear why food scored so high. Although it may be that food safety may increase the need for better equipment, a solid business case is needed before investing. It was also ventured that markets outside Europe could be interested in equipment to meet EU standards.
- In the panel it was observed, that in the VC community Point-of-Care, PoC, is seen as one of the most promising areas. Nevertheless, many start-ups are active in the PoC area, but most fail as a good investment proposition. The central lab model works very well and is cost effective. Some tests, e.g. sexually transmitted diseases, could benefit from immediacy as many patients do not return for the test result. Throughput time requirements can be a critical parameter in the diagnosis. For example, for acute diseases, e.g. sepsis, a short throughput time can mean the difference between life and death, and therefore drive the demand for PoC. When catching an infection or flu, only if it is bacterial will an antibiotic makes sense; a PoC test in the doctor’s office would be a great help in prescribing the right medicine and reducing the ever rising number of multi-resistant bacteria.
- Another issue for reflexion on the reason of low-commercial success of Lab-on-Chip for PoC applications, despite the intensive funding and research & development activities in the field, is related to the fact that most of the developments are aiming for disposable, low cost and therefore low functionality chips. The disposable model approach doesn't necessarily fit all LoC applications, and especially the lower volume, niche oriented commercialization routes. These societally and economically interesting niches are specifically suited for exploitation by high-tech SMEs, who are also the current driving force of innovation in the LoC sector. What is necessary for this model to work is higher acceptable costs per chip. This can be reached by using a reusable model with more functionality on the chip. Such a chip would exploit the real strength of micro/nano technology, namely function integration, whereas past and present Lab-on-a-Chip commercialization attempts have only strived for low cost, which is only valid for mass volumes and low functionality chips is being strived after. The reusable model will open up many opportunities in commercially feasible and less investments requiring applications in niche-markets, such as in food safety & quality and environmental analysis.
- Change in the behaviour of doctors could also contribute in making PoC devices more competitive.

- Also the home market was brought up, especially in connection with patients who suffer from a chronic disease and need home and drug compliance monitoring.
- Since the problems with breast implants in Europe happened, the regulatory environment has become much tougher. Now it is easier to obtain approval in the USA.

5. Session organized by the EPoSS Working Group on Applied MNBS

The objective of this session was to provide an opportunity for the EPoSS and MNBS communities to network and discuss how future calls in HORIZON 2020 can be met.

- **Renzo Dal Molin**, SORIN, and **Jesús Ruano**, IK4-IKERLAN introduced the session and discussed the EPoSS AMNBS workgroup's Status Report and Internal Matters.
- **Andreas Lymberis**, European Commission, explained how over the past years the thinking on Europe's competitiveness and innovation has further evolved. This new thinking has been incorporated in the Workprogramme 2014-2015 on LEIT (Leadership in Enabling and Industrial Technologies) ICT Challenges involving MNBS- Biophotonics and cross-KETs (Key Enabling Technologies). Over the past 15 years Research & Development has been at the heart of the FPs, and the hard question to answer has been on the output and impact of these programs. Now the clear goal is to improve the economies of the EU member states and create new jobs as the EU slowly moves out of the debt crisis. For our community the question to focus on is how we can make MNBS a European success story. MNBS is about converging technologies applied to help meet the grand societal and industrial challenges. Biophotonics can also be seen as part of MNBS as there are many overlapping applications. In Horizon 2020 Research & Innovation (R&I) will be funded, including significant innovation actions, supply chain development and first market actions. There are many tools in H2020 to help achieve this. Participants were invited to talk to the Commission on these tools as they are not obvious at first sight.
- **Jesús Ruano** talked about a methodology to develop micro-nano-bio systems, and how at Ikerlan a structured approach was developed. In MNBS the same modules can often be used for different application areas, such as medical, food and the environment. Whatever you do, you need a project plan and a product architecture that is scalable, modular and can evolve with time. It helps to make scenarios on product usage, and visualize these with cartoons. There are many advantages to a structured approach with a well-defined architecture and interfaces. Could the community agree on a developing methodology or an interface standards? This would clearly save time and money. Despite fluidics isn't the same as electronics, the market, in the near future, might take some initiatives which can be the seed of a future standard.
- **Renzo Dal Molin** introduced a high level roadmap with the objective to align the EPoSS and MNBS developments, and sought real time feedback from the participants. Detailed comments were given on the identification of applications, time periods of the map, ownership of data as well as privacy arrangements. A proper structuring of the many topics along levels of aggregation would be valuable. Some participants felt that cost and value across purposes and benefits would need a place in the roadmap. External events such as major epidemics and bio-attacks could also be considered as input to the roadmap. Opportunities to define standards could be integrated in the map. Both the opportunities from a technology as well as from applications perspective should be

considered. An updated version of the roadmap would be delivered in the first quarter of 2014.

- **Patrick Boisseau**, CEA-Leti, now elected chairman, gave an update on the ETP Nanomedicine. The area of *in vitro* diagnostics is common with MNBS. Recently some large deals have been struck in the US nanomedicine area, and the question was raised why this did not happen in Europe. One likely reason is the lack of successful translation of European research results into business success. Currently there are 85 projects in the EU, which represent a funding of over € 400 mln. In response to these developments, the ETP has launched a white paper to advocate a joint effort between the ETP and the Commission to dramatically improve the business record. Discussions on the implementation of the translation hub (including pre-clinical and early clinical development) have started.
- **Dominque Delmas**, Futurs Health Products**,** spoke about the white paper on MNBS-Bioelectronics and the many applications that are known for these fields. The paper analyses the position of Europe in the various markets, and performs a SWOT analysis. This has resulted in a set of recommendations for multiple areas, among which standardization and regulatory affairs.

6. MNBS Cluster Project Elevator Pitch session & Poster Exhibition

The objective was to complement the innovation projects' session by gathering projects' current status and future plans in terms of technologies and enabling applications. Eric Moore, Tyndall National Institute, University College Cork, chaired this session. The projects had the opportunity to present in 3 minutes the essence of the project's poster. Projects from other funded programs were also given the possibility to present their technology e.g:
- ALIVE: An Interdisciplinary research platform for coupling engineering sciences and life sciences (http://www.laas.fr, cvieu@laas.fr).
- Smartphone-based low cost calorimetric readers and in vitro diagnostic technologies for point of care applications (Sandeep.kumar.vashist@hsg-imit.de)
- Mobile diagnostics in mHealth by use of smart systems (http://www.fruct.org/)
- Microneedles: A breakthrough Technology for Transdermal Delivery, Sensing and Diagnostics (conor.omahony@tyndall.ie)

The session gave the opportunity all participants to have an overview of the great technological advances made by the European teams and to "measure" the significant prototyping, validation and manufacturing challenges ahead. This was the first time in the MNBS workshop that participants had the opportunity to present posters and to give an elevator pitch on their technology offering. A broad range of technology solutions arising from different projects were presented. This session was very successful in enabling participants to focus on the key innovative aspects of their poster and deliver to the workshop delegates in a structured and intense setting.

There were 55 posters on display during the joint event and over 20 elevator pitches were presented. Delegates were able to view the posters during the associated coffee and lunch breaks. This brought an additional scientific aspect to the workshop and proved to be an excellent platform for delegates to discuss potential collaboration during the breaks. The best

three posters were selected by an independent judging panel, consisting of industry and stakeholders.

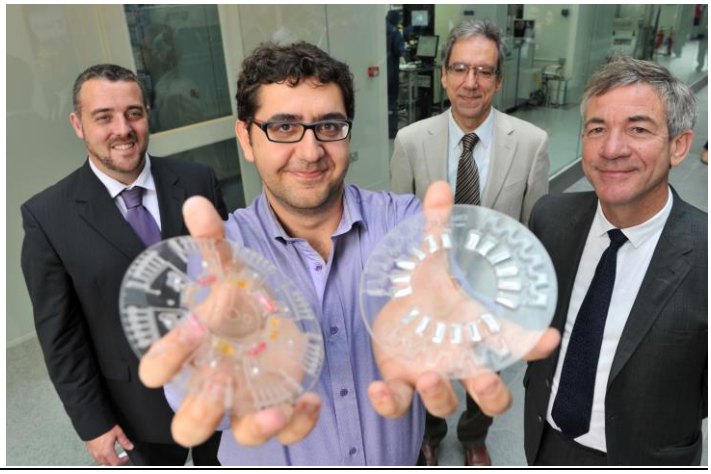
The overall winner of the innovation award was the project, DiscoGnosis, which is focused on the development of a Disc-shaped Point-of-Care Platform for Infectious Disease Diagnosis and was represented by the project's coordinator Konstantinos Mitsakakis, IMTEK, DE.

The poster awards went to the following three posters;

Micro-structured Impedance Electrodes for the Detection of Breast Cancer and Ductal Carcinoma in situ. Niall T.P. Savage[1], Brian D. O'Donnell[2], Martin J. O'Sullivan[2] and Eric J. Moore[1], [1]Sensing and Separation Group, Department of Chemistry and Life Science Interface Group, Tyndall National Institute, University College Cork, Ireland. [2]BreastCheck and Cork Univ. Hospital, Cork, IR.

Key micro/nano technologies for advanced molecular to organ biomonitoring. R. Villa, G. Gabriel, A. Guimera, E. Prats, X.Illa, A. Moya and J. Yeste. Centro Nacional de Microelectronica, Campus UAB. 08193 Bellaterra, ES.

Novel Smart Sensor Glove for Arthtitis Rehabiliation. B. O'Flynn, J. Torres Sanchez, P. Angrove, J. Connolly, J. Condell, K. Curran & P. Gardiner, Tyndall National Institute, Univ. College Cork, IR.



DiscoGnosis Coordinator Konstantinos Mitsakakis, IMTEK, DE (award of the best innovation presentation) showing the LabDisk prototype with event co-organisers (from left to right) from Tyndall (Eric Moore, left) and the EC (Andreas Lymberis, Willy Van Puymbroeck).

7. Session organised by the EPoSS Working Group on Key Enabling Technologies

The objective of this session was to present the key technologies that the Smart System community had defined within the MNBS sector and to discuss opportunities in Horizon 2020.

The session was chaired by **Michael Scholles,** Fraunhofer IPMS, chairman of the EPoSS Key Technologies Working Group. He discussed technologies for Smart Systems and their possible applications. A SWOT analysis has been made, and the required investments to develop the technologies further have been estimated. His presentation was based on the respective chapter of the newly published Strategic Research Agenda of EPoSS.
Patrick Salomon, enablingMNT GmbH, talked about food processing and its relevance as an application area for Smart Systems Integration with Micro System Technologies. As described before, a roadmap has been developed and identified a no. of opportunities. The question that offers itself now and was posed to the audience is on how to move forward.

In the plenary discussion that followed a number of remarks were brought forward:
- the Food industry is interested in more and and more frequent in-line testing to monitor process control. Could the same chip be reused, or would one-off chips be required to accomplish this?
- Extreme cost reduction in the whole process is desirable, as consumers have a low tolerance for price increases
- Is sampling of dairy products sufficient, or is control of the complete batch required?
- In the roadmapping exercise only a few people from the food-processing industry participated, and they had instructions to be tight-lipped. One point they could make was that the manufacturing cost of food must be low.

8. Wrap-up and Consultation

Chaired by **Andreas Lymberis**, the goal was to summarize the major findings from the previous sessions and brainstorm on furure challenges and innovation issues, with as background the innovative instruments to be implemented in Horizon 2020 and the indicative list of questions prepared by the EC and sent to the participants beforehand. The main points that were made are summarized below:

- Integrated Diagnosis and Therapy, often referred to as "Dx&Tx" versus the currently separated processes in time and place, was predicted to become a booming business, for which names such as "Theranostics" and "Immersive Medicine" have been coined. An example is the area of digestive tumours. There is a real and large medical need, and some companies are investing large amounts of money here. This area is therefore expected to create new jobs.
- A new, emerging area within the MNBS scope could be the "organ-on-a-chip". Here cell cultures are created, mimicking a 3-dimensional organ in mini-format in a microfluidic chip, to be used as organ or disease models.
- The Commission's initiatives to support Public Pre-Commercial Procurement and Public Procurement of Innovation activities were well received and applauded. The participants were asked to identify candidates and networking for possible relevant PCP (2014-15) and PPI (2016-17). However, as this is completely new subject the audience will need time to prepare and to kick-start this initiative. It was remarked that the 2 initiatives needed prioritization, while they also should be kept together and not separated out.
- By the Commission it was stated, that the proposals in response to the coming calls needed to be in line with the H2020 requirements.
- Another new requirement to a proposal is the obligation to be explicit about who will benefit

from the project and when. This is an essential part of a business case. If a new company needs to be launched to make the business fly, this will have to be prepared during the project. It was remarked that in order to attract third party or venture capital in the startup, it is customary that the management team invest its own money as well.

- There is also the promise of "personalized" medicine"; a concept where a patient gets a treatment that takes the individual's specific proteome and genome into account. This is expected to take place for home as well as hospital-based medicine. The obvious first applications are in the identification of a person's specific gene mutations that are known to give side effects for specific medications. This should be possible with MNBS-based diagnostic devices, and lead to products called diagnostic companions, which work in tandem with specific drugs.
- Critical questions to answer are: the central lab is very efficient, and generally has a low cost per diagnosis or food analysis. How can MNBS compete with this model? Which specialty will be the first customer and why?
- In reaction, it was observed that the central labs cannot provide fast feedback, or give answers to questions such a whether the fish is fresh. As for market uptake, low- and middle-income countries could be amongst the early adopters, as here central labs and the transport infrastructure are less well developed.
- Another question was whether there is a need to invest more in Research or in Innovation for food applications. In response, it was felt that in order to identify the possible application pull, we need to better understand who wants what.
- Architecture and standardization was again brought up as an area that could contribute to lower costs and faster time to market. Making an inventory of all technologies and associated interfaces used in the past and current projects could be a start in order to establish how standards for interfacing could make sense. This would probably hold across application areas, e.g. medical and food, even though the device form factors and applications would be different.
- The question was raised, whether a horizontal call would make sense to identify the most likely type of physician and specialty to help the community focus their product development.
- Some felt that the general practitioner and prevention should be the prime area of focus.
- The Commission was asked to help the community to become successful in innovation by supporting clinical studies and developing a view on security, bio and chemical attacks. In response other support programs by the Commission for SMEs were brought forward, which include support for clinical trials in the 2016-2017 timeframe.
- A request was made for more meetings to discuss roadmaps and associated common interest subjects, and to mix "bloodgroups". For some areas Commission members act as coordinators, e.g. Heiko Frima for Nanotherapeutics (DG research).
- Next year's Workshop , MNBS'14 will be organised in Toulouse, France, by LAAS-CNRS, Micro-nano-biotechnologies (http://www.laas.fr/index.php).

9. Recommendations.

➢ **Proposal development and evaluation process.** The Horizon2020 requirements for proposals are heavily emphasising the innovation and business case aspects, broadening the expertise needed in the MNBS community as well as in the Commission. An important condition for success is the early understanding of the application problem to be solved, and the key characteristics of the solution that the proposal intends to develop. Many important

decisions consequently need to be made early, such as the application, the key user, the new product or system characteristics including price and its uniqueness, and the process improvement for the user that the product is aiming for. Thus, the availability of serious field research leading to a realistic, validated customer insight that yields a significant market opportunity is a basic requirement. Another requirement is a viable go-to market strategy, and in the case of a start-up, the understanding what it takes to launch a new company. While the latter need not necessarily be detailed in the proposal, the process to achieve this should.
These new competences need to be developed in the community, and also in the proposal review process. This will have consequences for the selection of experts, who will need to be familiar with the business characteristics beyond the technology. This should not be taken lightly, as the Venture Capital industry has learned, and which is the basis for successful venturing. In fact, if the proposal asks for EU funding for Innovation, the review process should be split in two parts, an initial review at the project proposal time, and a business review by the time prototype results are available and clinical trials are needed. For the latter review, the systematics can be learned from the VC industry.

- **Handheld Point of Need systems and the central lab.** There are many opportunities available for such devices as these offer possibilities that the central lab cannot. For example,

- In acute situations fast diagnosis is often required, e.g. a patient with a suspected heart infarction in an ambulance. A blood-based diagnosis made in the ambulance can be wirelessly transmitted and the hospital prepared before the patient arrives, and thus be life-saving.
- In most chronic disease the monitoring of one or more biomarkers is needed to prevent a relapse to the acute condition and increase the patient's compliance. A periodic, immediate feedback from a handheld, patient-friendly PoC device to patient and monitoring personnel is required. The coming availability of micro needles that allow painless taking of minute samples, fit for MNBS devices, will accelerate the acceptance. Of such devices.
- A bacterial infection in the Intensive Care Unit needs to be treated immediately and cannot wait the 3 days, that a central lab needs for bacterium identification, in order to choose the right antibiotic. For traffic and violence accidents such a device would be valuable as well.
- A handheld device would also tell the office-based, general practitioner whether an antibiotic is required, and help choose the right one for infectious disease at hand.
- During tumour resection surgery, the measurement to determine whether all tumour tissue has been removed while the patient is still "open" would reduce the chance of recurrence significantly.
- Strong interest was put on food application where one of the requirements is for more intelligence in the analytical devices and lower cost for the traceability packaging. Food safety does not drive new applications, but reuses equipment developed for the medical and research fields. Although it may be that food safety may increase the need for better equipment, a solid business case is needed before investing. It was also ventured that markets outside Europe could be interested in equipment to meet EU standards.

ANNEX I Announcement and Program

MNBS 2013

"Innovation and Technology Implementation for European Competitiveness and Better Citizen's Life"

Aula Maxima at University College Cork, venue for the EPoSS Gala dinner event on Wednesday 25th September

The 7th Annual Concertation and Consultation Workshop on **Micro-Nano-Bio Convergence Systems**, **MNBS** 2013, will take place from 24th-25th September 2013, in **Cork**, Ireland.

This year's event will be hosted and co-organised by **Tyndall National Institute** on behalf of the **European Commission** and is an excellent opportunity to

• diffuse and exchange information on research & development results and innovative solutions from EC-funded projects and other initiatives in Europe. • identify synergies and possible collaborations to tackle critical issues covering the full value chain from R&D to exploitation. • meet with key representatives from industry, research, users and the European Commission, • take on an active role in defining research priorities and roadmaps for future research and in the forthcoming EC programme for research and innovation, Horizon 2020.

MNBS 2013 will emphasise on innovation and technology implementation for improving European competitiveness and citizen's life. The programme includes oral and poster presentations from running and finished R&D projects, coordinated and support actions presentations and invited sessions, bringing technologies and solutions providers closer to business and to end-users, technology roadmaps and ideas to build the innovation supply chain.

This year's annual Consultation and Concertation Workshop on Micro-Nano-Bio Convergence Systems will for the first time be held in conjunction with the **EPoSS General Assembly & Annual Forum 2013**.

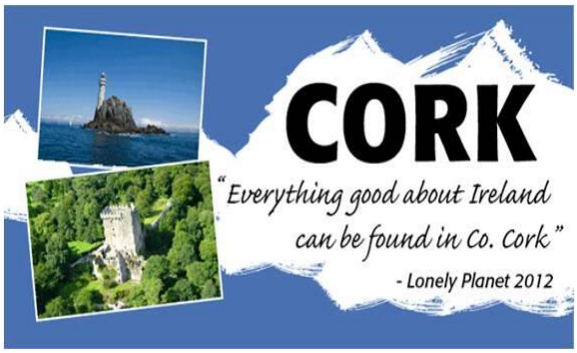
The joint 3-day event will be held **24th - 26th September 2013**, with

MNBS 2013 on 24th - 25th September 2013, and

EPoSS General Assembly & Annual Forum 2013 on 25th -26th September 2013.

Poster & Demonstrator Exhibition

Participants are invited to exhibit and present posters and demonstrators on Smart Systems research, products and technologies. Since the space for posters and demonstrators is limited, the organisers will follow a first come, first serve policy. Posters should be in A0 portrait format and need to be printed and brought to the venue.



This year the organisers explicitly invite the Smart Systems community to bring demonstrators, and particularly encourage "live" demonstrations in the exhibition room.

COWIN Marketplace

Parallel to MNBS 2013 and the EPoSS Annual Forum 2013, COWIN organizes a COWIN Marketplace and COWIN Tutorials with selection of topics leading to success for innovative projects.

Dedicated to encourage the commercial exploitation of Smart Systems technologies developed in the course of FP6 and FP7 research projects, COWIN Marketplace is an excellent opportunity for you to benefit from synergies in terms of:

- Networking with technology brokerage, potential partners and customers through one o one meetings pre-qualified for you;
- Setting-up new collaboration for innovation projects through the new instruments the EC is developing in Horizon 2020

With COWIN Marketplace, you optimize your time schedule while multiplying contacts with relevant partners or potential customers in your fields of interest. COWIN also facilitates your access to funding opportunities to accelerate your development and strengthen your leadership. In parallel of the Marketplace, COWIN is organizing training sessions to give you key information on best practice in setting up successful collaborations and exploitation of innovative research results.

Programme

Throughout the 3-day event, there will be a poster and demonstrator exhibition that will illustrate Smart Systems projects, and showcase innovative products and technologies. A **COWIN Marketplace** will be organised on all three days, and attendees will have the opportunity of guided **site visits** of the facilities at Tyndall National Institute. Please follow this **link** to the EPoSS full programme.

1st Day – Tuesday, 24th September 2013: MNBS 2013

09:00	**Registration & Welcome Coffee**
09:30	**Opening and Keynote Session** **Chair:** **Andreas Lymberis**, European Commission, BELGIUM • **Andreas Lymberis, MNBS Coordinator, European Commission, BELGIUM** • ***Welcome Address for MNBS Workshop*** • **Kieran Drain** • **Liam Brown** • **Seán McCarthy, Hyperion Ltd, IRELAND** ***Getting ready for Horizon 2020*** • **Willy Van Puymbroeck, European Commission, BELGIUM** ***Smart Systems*** • ***& Nanoelectronics (including ECSEL), H2020 Industrial competitiveness-LEIT*** • **Marc O. Schurr, Ovesco Endoscopy AG, GERMANY** ***Innovation Delivered:*** • ***From Identifying Unmet Market Needs, Over European RTD Projects*** • ***to Commercialization*** • **Tyndall National Insitute, IRELAND** • ***Opening Keynote*, Enterprise Ireland (EI), IRELAND** • ***Keynote*, Tyndall National Insitute, IRELAND**
11:30	**Coffee Break** **& Opportunity to Visit the Poster & Demonstrator Exhibition**
12:00 - 16:10	**MNBS Projects-Innovation Sessions** The objective of the sessions is to identify and share best practices on the innovation process. How to Identify and address the key issues (e.g. stakeholders requirements and supply chain, key competitive value, manufacturing and industrialisation, regulation and standardisation) for making an MNBS project an innovation success story is the challenge of the cluster, even more now that we enter in a new era of "integrated" research & innovation towards Horizon 2020, the new 7 years Framework Program. A panel discussion will allow the exchange of ideas among the audience, summarise the contributions and draw conclusions.
12:00	**MNBS Projects-Innovation Sessions Part 1** **Chair:** Eric Moore, Tyndall National Institute, University College Cork, IRELAND 9 x 8 minute MNBS project presentations focusing on the innovation process in R&D • **MIRACLE**- Magnetic Isolation and moleculaR Analysis of single CircuLating and disseminated tumour cElls on chip. • **PASCA**- Platform for Advanced Single Cell Manipulation and Analysis. • **SIMS-** Development of a Smart Integrated Miniaturised Sensor System for analytical challenges in diagnostics, industry and the environment**.** • **POSITIVE-** A highly integrated and sensitive PORous SIlicon based lab on a chip for multiple quantitaTIVE monitoring of Food allergies at point of care. • **PodiTrodi-** Technology Platform for Point-of-Care Diagnostics for Tropical Diseases. • **ANGELAB-** A New GEnetic LABortatory for non-invasive prenatal diagnosis**.** • **Discognosis-** Disc-shaped point-of-care platform for infectious disease diagnosis. • **NextDx-** Next-generation integrated MNBS-platform for instant diagnostics with single-molecule resolution. • **d-LIVER-** Developing an “ICT-enabled, cellular artificial liver system incorporating • personalized patient management and support”
13:30	**Lunch**

	& Opportunity to Visit the Poster & Demonstrator Exhibition
14:30	**MNBS Projects-Innovation Session Part 2** **Chair:** **Javier Bonal**, European Commission, BELGIUM 10 x 8 minute MNBS project presentations focusing on the innovation process in R&D • **NANODEM-** NANOphotonic DEvice for Multiple therapeutic drug monitoring • **LOVE FOOD-** Love wave fully integrated Lab-on-Chip platform for food pathogen detection**.** • **FOODSNIFFER-** Safety at the point-of-Need via monolithic spectroscopic chip identiFying harmFul substances in frEsh pRoduce. • **ARROWS-** Advanced interfaced microsystems Research for analysis of Real-wOrld clinical, food, environmental and Waste Samples. • **ML2-** Design platform for economic production of multilayer Micro-Nano Bio • Systems. • **NewWalk-** novel neuroprosthetic systems to restore the motor functions of individuals suffering from severe spinal cord injury (SCI) and alleviate the associated symptoms. with Parkinson's disease (PD). • **Heart-e-Gel-** Microsystem integration based on electroactive polymer gels for cardiovascular applications. • **SWAN-iCARE-** Smart Wearable and Autonomous Negative Pressure Device for • Wound Monitoring and Therapy**.** • **WiserBAN-** Smart miniature low-power wireless microsystem for Body Area • **PASTA-** Platform for advanced textile applications
16:10	**Coffee Break** **& Opportunity to Visit the Poster & Demonstrator Exhibition**
16:20	**Panel Discussion Focusing on the Topic "From R&D to Innovation in MNBS"** The objective of this session is to summarise the previous innovation sessions and to provide feedback and suggestions to the MNBS community on the innovation process and the common challenges that have been identified by the existing projects in the MNBS cluster**.**
17:00	**Industry Session** **Chairs:** **Géraldine Andrieux-Gustin,** Yole Développement, FRANCE **Christophe Cotillon,** ACTIA, FRANCE This session will be an interactive discussion between key panelists and the audience to define key attractive MNBS topics to focus on in H2020 to turn smart systems solutions into new products and services with the support of the European Commission. This interactive session will include a presentation of Foodmicrosystems roadmap and lessons learnt by COWIN action dedicated to support the commercial exploitation of EU projects results. The European Commission will also introduce the PCP (Pre-Commercial-Procurement) and SME instruments to facilitate the entry of participants into H2020. This session will include the following presentations: • **Patric Salomon,** enablingMNT GmbH Presentation of FoodMicroSystems Roadmap, the key opportunities in food applications for MNBS • **Régis Hamelin,** EURIPIDES Bridging the gap from technologies to market, COWIN activites, results and best practices identified

- **Francisco Bonal, DG CONNECT,** European Commission
  European Commission policy and tools to support innovation in H2020, SME and PCP instruments highlight
- **Alexandra Donny,** Resah-IDG
  HAPPI, a Public Procurement of Innovations project to bring solutions for Healthy Ageing
- **Manus Rogan,** Fountain Healthcare Partners
  Experience of a private investor sharing the risk to bring early stage technologies into the drug discovery and diagnostic market

The following panelist will participate in the interactive discussion**:**

- **Shane Moynihan,** Biosensia, Head of Engineering
- **Alexandra Donny,** Resah-IDG, Deputy Director
- **Iñaki Gutiérrez-Ibarluzea,** OSTEBA, Knowledge Manager
- **Federico Morais,** FIAB, Manager of Innovation & Technology
- **Remigio Berruto**, FoodforLife European platform
- **Manus Rogan,** Fountain Healthcare Partners
- **Guillaume Lhermite,** Primadiag
- **Francisco Bonal,** DG CONNECT, European Commission

19:00 **End of Day 1**

2nd Day – Wednesday, 25th September 2013: MNBS 2013, EPoSS General Assembly 2013

8:30 **Registration, Welcome Coffee**
& Opportunity to Visit the Poster & Demonstrator Exhibition

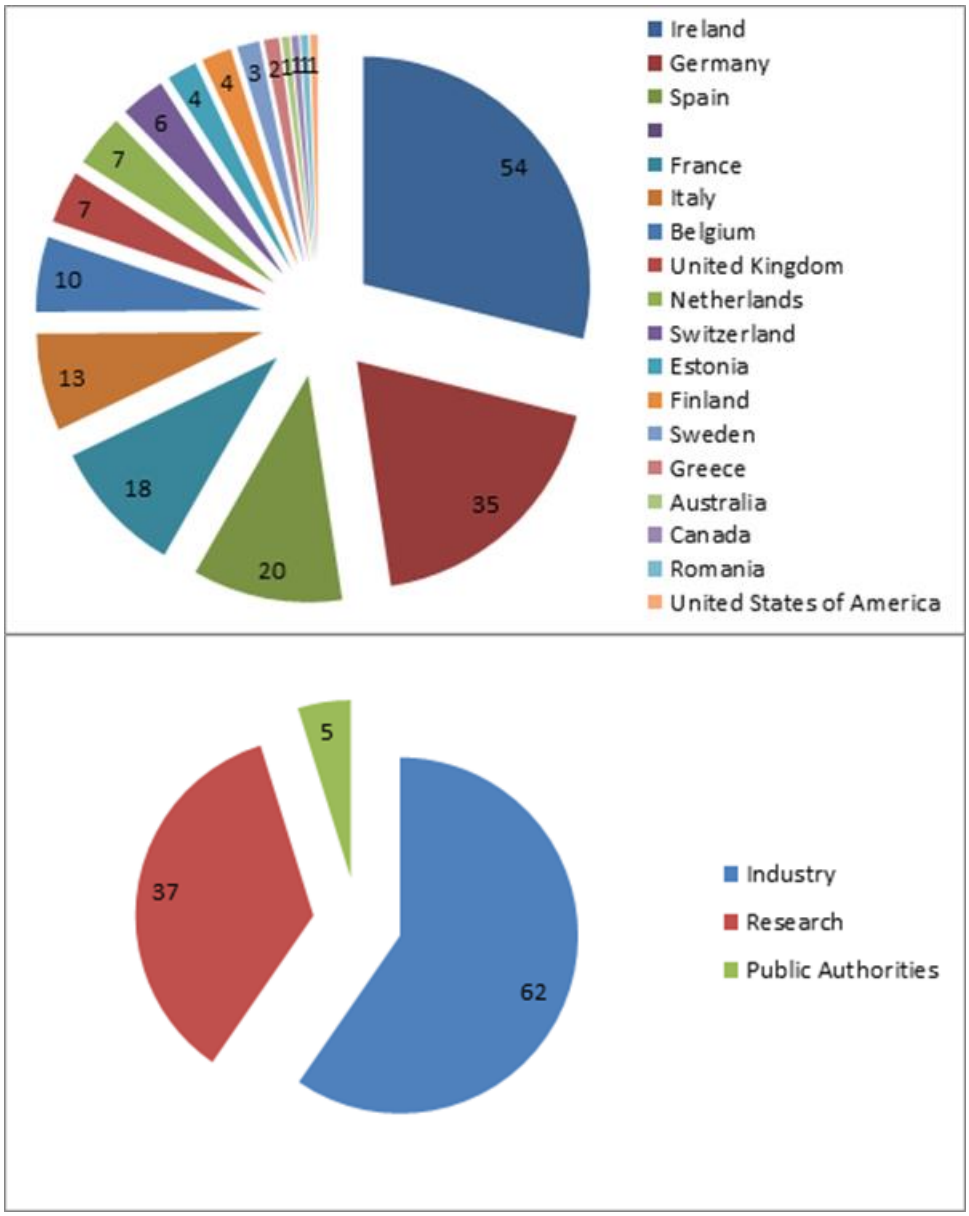
09:00 **Session organised by the EPoSS Working Group Applied MNBS**
(open to all participants)
Chairs:
Renzo Dal Molin, Chairman of the EPoSS Working Group Applied MNBS, SORIN CRM, FRANCE
Jesús Ruano, Chairman of the EPoSS Working Group Applied MNBS, IK4-IKERLAN, SPAIN
The objective of this session is to provide an opportunity for EPoSS and MNBS projects to network and discuss how to influence future calls in H2020.
Renzo Dal Molin, SORIN CRM, FRANCE
Jesús Ruano, IK4-IKERLAN, SPAIN
Welcome & Introduction,
WG Status Report & WG Internal Matters (5 min)
Andreas Lymberis, European Commission, BELGIUM
Setting the Scene: *Horizon 2020 - WP2014-15 ICT Challenges involving MNBS-Bioelectronics-biophotonics and Cross-KETs (10 min)*
Jesús Ruano, IK4-IKERLAN, SPAIN
Presentation & Discussion: *Methodology for the Development of In-vitro Diagnostic Systems (15 min)*
Renzo Dal Molin, SORIN CRM, FRANCE Interactive Road Mapping Exercise: *MNBS / Bioelectronics (30 min)*

	Patrick Boisseau, CEA-Leti, FRANCE Presentation & Discussion: *ETP Nanomedicine White Paper "Contribution of Nanomedicine to Horizon 2020" (10 min)* **Dominique Delmas**, Futurs Health Products, FRANCE Presentation & Discussion: *MNBS / Bioelectronics White Paper (15 min*
10:30	**Coffee Break** **& Opportunity to Visit the Poster & Demonstrator Exhibition**
11:00	**MNBS Cluster Project Elevator Pitch Session** **Chair**: **Eric Moore**, Tyndall National Institute, University College Cork, IRELAND *The objective of the session is to gather projects' information on their current status and future plans with focus on the technological aspects. Running FP7 projects but also interested terminated projects will have the opportunity to present 3 minute short presentations on the project poster.* *There will also be an opportunity for a few other pitches from poster presenters (10 additional pitches from other programmes etc…) over the 1.5 hour session. We can accommodate 26 x 3 minute pitches in 1.5 hours.* **In parallel:** **EPoSS Steering Group Meeting** (for EPoSS Steering Group members only)
12:30	**Lunch** **& Opportunity to Visit the Poster & Demonstrator Exhibition**
13:30	**Session organised by the EPoSS Working Group Key Technologies** (open to all participants) **Chairs**: **Michael Scholles**, Chairman of the EPoSS Working Group Key Technologies, Fraunhofer IPMS, GERMANY **Wolfgang Dettmann**, Infineon Technologies AG, GERMANY *The objective of this session is to present key technologies that the Smart Systems community has identified within MNBS and to discuss opportunities in Horizon 2020.* • **Michael Scholles**, Fraunhofer IPMS, GERMANY *Welcome & Introduction (5 min), WG Status Report & WG Internal Matters (5 min)* • **Michael Scholles**, Fraunhofer IPMS, GERMANY Presentation: *The Role of MNBS and Related Technologies in the Smart Systems SRA (15 min)* • **Patric Salomon**, enablingMNT GmbH, GERMANY Presentation: *Food Processing – a New and Relevant Application Area for Smart Systems Integration!? (15 min)* • **Plenary Discussion** *Smart Systems Technology Strategies Towards Horizon 2020 (20 min)*
14:30	**Wrap-up and Consultation Session** **Chair:** **Andreas Lymberis**, European Commission, BELGIUM *The objective of the session is to summarise the major findings from the previous sessions of the day and brainstorm on future challenges, bringing together technologies, societal challenges and innovation issues, with background the innovation instruments to be implemented in H2020.*
15:30	**End of MNBS 2013**

	& Registration for EPoSS General Assembly 2013 (Coffee and snacks will be served)

Annex II. Summary Overview of participants

Participants by Country	
1) Ireland	54
2) Germany	35
3) Spain	20
4) France	18
5) Italy	13
6) Belgium	10
7) United Kingdom	7
8) Netherlands	7
9) Switzerland	6
10) Estonia	4
11) Finland	4
12) Sweden	3
13) Greece	2
14) Australia	1
15) Canada	1
16) Romania	1
17) United States of America	1
Total	187



Represented Organisations by Organisation Type	
Industry	62
Research	37
Public Authorities	5
Total	104