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Report on the 10th Concertation & Consultation Workshop on Micro-Nano-Bio- Systems-MNBS 2016

Translating Technologies into Competitive, Validated & Manufacturable Products to Impact Quality of Life

Reporter:
Huw Edwards, Oxford, UK

Contact:
Nikolaos Kattavenos, EC, Nikolaos.Kattavenos@ec.europa.eu
Andreas Lymberis, EC, andreas.lymberis@ec.europa.eu

MNBS website: http://www.mnbs.eu

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I. Executive Summary

This report covers the MNBS Workshop held in Otranto, Italy, from 27th to 28th June 2016 within "ISOCS-MiNaB-ICT-MNBS" *Joint Event on* **Sensing for Smart " Anything Everywhere: Materials, Technologies, Applications" (http://www.minabict.eu/)**. A brief review gives a snapshot of the current state of MNBS technology and the market for its products. The objectives for the workshop, as in past few years, was to focus on where MNBS can help resolve society's big problems and to help steer the developing sector by addressing improved translation of research into products, enhancing the connection to the global market and improving collaboration across the sector and between stake holders.

The main subject areas of the workshop, MNBS applications in healthcare, agriculture, food and the environment and European programmes & initiatives supporting MNBS, are presented with a brief update, to give highlights and messages emerging in each of these sectors relevant to the future.

An important concentration of the workshop was, on defining objectively (or quantifying), the progress made by MNBS projects over the last year, particularly in light of the recommendations of the 2015 workshop in Leuven (Belgium). As a driver for progress the workshop focused strongly on the advances made in commercialization of projects and drew on the lessons learnt from late stage or completed projects. The role of validation was strongly reinforced and a clear piece of best practice: ensure validation at the earliest possible stage, emerged. Many projects demonstrated the importance of the development of the commercial team in effective exploitation.

The integration of components remains the principal driver for growth in the MNBS sector, but the importance of the development of new sensor technologies was demonstrated to play a significant role. New sensor technologies and new modalities expand the capabilities of systems, which can become smaller, cheaper, collect more data and be less invasive through adopting new tools. In particular, advances in photonics and chemical sensor tools were presented.

The integration of MNBS into communities to deliver broader societal benefit was discussed, particularly in respect to a number of projects from Italy supporting wellness and social engagement by the elderly. There was a powerful demonstration that MNBS that could be part of more extensive social networks and support in delivering effective management of elderly populations.

The communication functions of the European Commission remains the glue that facilitates coordination & collaboration as well as supports the MNBS community to achieve its objectives in terms of R&D and innovation. Through a number of presentations the changing role of the Commission in this multidisciplinary sector was explained. While it is clear that the funding model and regime is likely to change, the critical role of the Commission remains one of signposting to funds and supporting communication to and between the MNBS community's actors.

A key question raised in Otranto was; "where does MNBS go now?", or at least what do the projects and professionals do going forward? A decade ago an agenda was set for biomedical devices which should be "molecularized, miniaturized, computerized & communicating", in which regard the delivery has been impressive. However challenges remain; global competition, the rapid increase in internet capability, the massive improvements in handheld device technology and bio-genetic technology. Important for the future is the development of the market as well as the technology. Further technological excellence does not guarantee commercial success. The challenges of converting successful lab technology and prototypes to commercial products were raised several times. The low uptake is partly due to the often adopted business model of high volume and low cost (e.g. in PoC diagnostics) and the absence of complete ecosystem. The European Commission has set out a range of activities, ESTHER (Industry driven initiative on Emerging Strategic Technologies for Healthcare), European Technology Platforms-ETPs (e.g EPoSS, Nanomedicine), Public Private Partnerships-PPPs (e.g. Photonics21, IMI, Robotics..) and networking with relevant sectors' associations and groups like

MedTech Europe[1], COCIR[2] etc. to support innovation and take-up of the base MNBS has created forward in specific contexts, such as medical devices or in collaboration with related fields e.g. the Internet of Things.

Recommendations are presented to support the further development of MNBS technologies. The development of the market is critical to the application of MNBS technologies and important suggestions for market development are forwarded. The importance of the commercialization for MNBS was also highlighted and ideas given as to how this can be encouraged. Finally, the role of the Commission in this sector is addressed with indications of how it can best support MNBS in the future.

Under the **Technology** agenda the drive to produce modular technology needs to continue and expand as this feeds the hopper of "open innovation"; the underlying innovation and commercialization model to which the most successful high technology businesses try to work. Within the framework of MNBS there is an end user-need and commercial imperative to incorporate and integrate more technology types into MNBS solutions; a clear example from several presentations is the integration of photonics technology.

The further development of the MNBS **Market** is increasingly based on clear understanding of the end-user benefits of complex integrated technology. The key to market engagement with MNBS therefore is based on clear communications about solutions and effective promotion of the end user benefits. Communications need to address complex physics, mathematical algorithms and biochemical interactions at micro and nano scale in ways that engage the lay audience and convince them of the utility, safety and reliability of new products and solutions. While the integrated technology may be complex, the user interfaces must be simple and intuitive to support market growth. A key to accessing large markets is that the vast majority can use the solutions with ease and that these can be easily integrated into existing frameworks (platforms).

Taking MNBS solutions to **Commercialization** needs to be based on rigorous planning and fit for purpose partnership. To some extent this point is true of any technology introduction, however as the solutions are the product of integrating technologies and components needing market validation, both individually and jointly, the demands of planning are multiplied. Planning complexity needs to be matched with a thorough approach and robust systems at each step towards the market. Throughout the MNBS'16 workshop the importance of validation cases in effective commercialization was stressed. To support the most successful commercialization projects need to plan validation steps, ensure that validation is undertaken as a norm to drive commercialization.

The discussion of the **European Commission's role** in MNBS, is set against the complex and cross cutting nature of all the activities in this field. Individual solutions and specific technology integrations are in a weak position to address large audiences. Logically, the Commission sits at the heart of a multitude of projects providing solutions to a wide range of users. The European Commission can support and drive the sector in the future by acting as policy maker, linking the regional, national and European interest activities and raising awareness of the impact of integrating new technologies in micro and nano systems. The EC's communications are the standard bearer for multi-disciplinary working and the benefits to many areas of society inherent in these solutions. Similarly, the Commission remains well placed to act as sector organizer, by running conferences, workshops and other events supporting the exchange of ideas, encouraging the creation of consortia and a coordinated approach to bringing MNBS solutions to the market.

[1] http://www.medtecheurope.org/

[2] http://www.cocir.org/

II. Introduction and workshop objectives

The MNBS activities supported by the European Commission have drawn together a diverse range of technologies to develop miniaturized, intelligent communicating devices for biological applications. The activities have expanded from a medical core to agriculture, food, veterinary medicine and the environment. The process has built technological capability, integration expertise and application experience. The poor market appreciation of the MNBS concept has already been alluded to in this report. There is still a failure to recognize that the technology to diagnose an early stage cancer, for example, may well be identical to the one used to detect food contamination or pollution of drinking water. The processing algorithms may be the same, although the user interface may present the data differently. Communications between a hospital and a device worn by a patient at home will be no different to those of the offices of a water company and a contamination monitoring device at a pumping station. Further components developed for one application can be used equally well in another field.

What is MNBS?

For over a decade funding and intellectual effort has been directed to the development and commercialization of Micro & Nano Bio-Systems, "MNBS". Underlying this effort has been the idea that the great advances in the biosciences at the micro and nano level combined with similar advances in silicon fabrication and specialist materials and IT and communications technology creates a new market for sophisticated bio-systems. Much of the initial thinking was related to the medical application of such technologies, but at an early stage it was clear that the same technologies could equally be applied to agriculture, food and environmental applications.

The MNBS concept sees the technological integration which can be focused on a wide range of applications. Conceptually the market remains more conservative seeing the application of nanotechnology to agriculture or the use of communicating (bio) sensors in food processing, rather than seeing both as "MNBS" applications. This conceptual "blindness" is reflected in the available market research where figures have to be assembled from nano technology in food, healthcare and agriculture separately and perhaps added to IT and communications in the same fields. For the market "MNBS" does not exist.

The important point about the MNBS concept is that it is inclusive, that it encourages integration, has applications in a wide range of markets and avoids intellectual, market and commercial fragmentation. The highly cross-disciplinary nature of MNBS opens a wide range of new possibilities for intellectual advance and competitive commercial development. MNBS is a platform, which has developed strongly in Europe giving a solid basis for European technology to address problems in a whole range of markets globally.

In the future MNBS may not be a common market term, but should be a commercial term and a defined area of activity within Horizon programmes. MNBS may in the future link to other areas, such as key enabling technologies, big data or systems integration, but the core bio/materials/IT applicability in a range of markets should not be lost as it offers Europe the opportunity to compete internationally.

Micro-Nano-Bio Systems (MNBS) is defined for the purpose of the EC cluster of funded projects as an area covering research, development and system integration across technologies like micro-nano electronics, nanotechnology, biotechnology, biomaterials and ICT to achieve innovation in several sectors and applications e.g. health & care, food & agriculture, environment & safety. The MNBS community is multidisciplinary and the corresponding market goes across existing markets in BioMEMs, Smart Systems, Bio-electronics & bio-photonics, Nanomedicine, Medical Devices & in vitro diagnostics, Sensors and Instrumentation for measurements at the point of need, etc.

The MNBS annual workshop is a vehicle for gathering information and consolidating ideas. Further this report takes what was presented in Otranto and shares the outcomes more widely with all stakeholders in the MNBS community. Through coordination and consolidation of an extensive range of presentations and discussions the objective is to give the MNBS community a basis for future development. *A key aim of the workshop was to establish best practice and templates for technology transfer and technology commercialization of MNBS in a range of applications*. **This links and provides input to the MNBS agenda i.e. to show how MNBS can address Big Societal Challenges.**

The audience confirmed there is unmet need for measurement, control and feedback at a site of action in real time, or close to real time for a wide range of applications including:

- **Agriculture**: to determine quality of the soil, pesticide and herbicide load, antibiotic and growth hormone levels.
- **Food processing** activity: to identify & quantify microbes and metabolic toxins; poisonous heavy elements and compounds which need to be minimized or eliminated to avoid the chronic poisoning of food products.
- **Healthcare**: to support the assessment of patient response to drugs, the identification of bacterium/ virus and determination of pathogen load, deliver subject monitoring at the point of care (POC) and provide wider support to public health with accurate, timely data.
- **Environment**: to identify the occurrence of pollutants at source and aid the separation and removal of undesirable materials from our living environment.

MNBS solutions must demonstrate reliability in real life environment and cost effectiveness: it is imperative that new technology, devices and products are affordable, smart & autonomous, small, intuitive to use and connected, delivering for example, fast and low cost diagnosis, detection of hazards & parameters for enhanced food safety and improved process control.

The mission differentiator for MNBS is in bringing a new class of cost effective solutions to real world problems based on radical and creative technology innovation (not just the development of technologies alone).

As the focus of MNBS '16 is "*How to succeed in the transition from lab technology to real-world applications"*, the report naturally puts the emphasis on this aspect. A snapshot of the global state of the area and the European Union's place in that market is presented in the MNBS'15 workshop report[3].

The workshop linked technology to market analysis with a strong recognition that the technology, exciting as it is, can only succeed when there is strong or unmet market need. MNBS offers solutions to problems across markets in food, agriculture, the environment, healthcare and veterinary medicine. Each sector provides drivers for the market, but also long term trends which will have an impact on market growth (see appendix IV).

An overview of the MNBS projects, supported by the EC, DG CONNECT under "Electronic components & Systems" area, under FP7 and currently ongoing H2020 research and innovation programme, is provided in the following picture. It represents a total of 39 projects (30 in FP7 and 9 in H2020, selected from 2014 to 2016 calls for proposals) with EC funding of about 145 M€ (108 M€ in FP7 and 37 M€ in H2020 up to 2016)

[3] https://ec.europa.eu/digital-single-market/en/news/report-9th-concertation-and-consultation-workshop-micro-nano-bio-convergence-systems-mnbs-2015

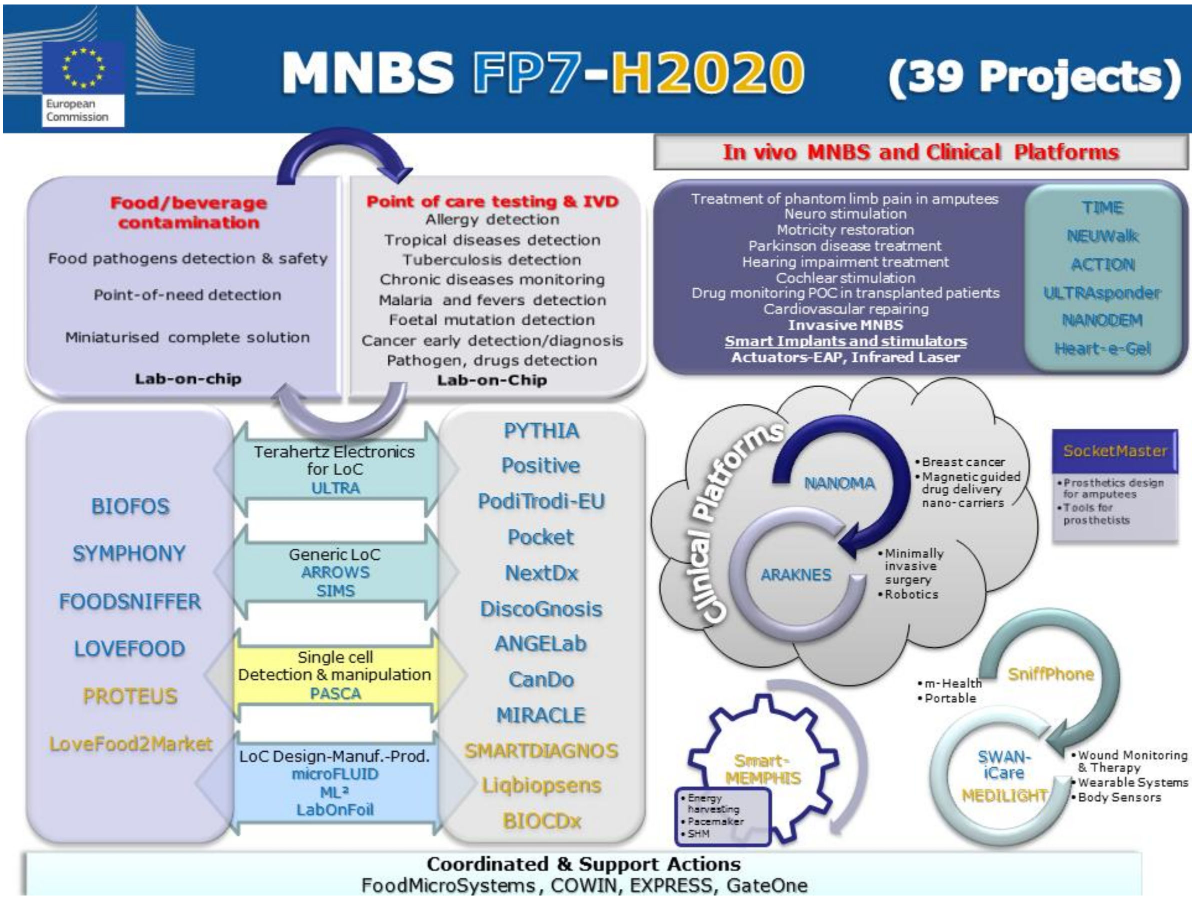


Figure 1 Overview of EC funded projects in MNBS, FP7 and H2020 (up to 2016)

III. MNBS 2016: a snapshot

The most significant "sector of MNBS" regularly reported by Market Research companies is bioMEMS. BioMEMS applications stretch from healthcare and diagnosis to food production and environment management. Bio-Photonics also plays an important role in MNBS in cell and tissue analysis and a range of non-medical applications, but is widely applied in other sectors too. Relevant components within Bio-Photonics market research give an indicator of that part of MNBS technology, including the use of fluorescent markers and a variety of light guide technologies. MNBS is an important part of the healthcare integration and connectivity market, although this market goes far beyond the remit of MNBS. Many MNBS technologies are medical devices or incorporated into medical devices and thus make up a part of the Medical Device market. Here we review market analysis across these areas to draw together the market implications for MNBS.

Drivers and limits for growth in MNBS sectors

The key drivers of the BioMEMS market are:

- Increased use of mobile healthcare devices.
- Creation of patient monitoring systems equipment linking device innovations
- Partnering between pharmaceutical and engineering companies
- Demand for high performance, low cost measurements for an ageing population
- Advent of personalized medicine and companion diagnostics, as an important part of patient care

However, limits on the growth of BioMEMS are identified:

- Poor uptake, because of high R&D cost and long product development times

- Tough regulatory environment
- Lack of standards and data security
- Increased user safety and security concerns around care in the community

The key drivers of bio-photonics market are:

- The non-medical end-use sector
- Environmental monitoring & food analysis
- Early diagnosis, without compromising cellular integrity during investigation
- Lifestyle changes and the growing elderly population

The limits to Bio-Photonics market growth are:

- Low acceptance by end-users
- High cost of the imaging system and price sensitivity
- Concerns about quality and reliability of the product

The drivers of integration and connectivity markets are:

- Rising healthcare costs
- Strong government support and initiatives
- Growing need to improve healthcare by integrating systems
- Efforts to maximize the return on investment.
- Adoption of electronic health records and healthcare information exchange systems
- Rising demand for healthcare in the community

The constraints on these markets are:

- The lack of standard interfaces and interoperability issues
- End-user market s are fragmented
- High cost of implementation for IT integration solutions
- Reluctance of professionals to adopt advanced healthcare IT

Looking more broadly at healthcare markets many of the drivers seen for individual technology areas; bioMEMS and BioPhotonics, recur for the umbrella market. PwC's annual *Top Health Issues* report gives insights into the top 10 issues expected to impact the healthcare industry in 2016 and the following six particularly relevant to MNBS:

- Care in the palm of your hand
- Cybersecurity becomes a medical device industry issue
- Behavioral health rises in prominence
- Care moves to the community
- New databases improve patient care and consumer health
- Healthcare providers are turning to the medical devices to improve efficiency & outcomes and reduce cost & risk

<u>Market Data for MNBS sectors</u>

- BioMEMS

Estimates of the annual market for BioMEMS vary, but growth from USD 2.5 - 2.7 billion last year to USD 7.6 - 8 billion by 2021/3 is suggested in several market research reports, representing a compound annual growth rate (CAGR) of between 19 - 25 percent. The largest sector in which BioMEMS were applied in 2016 was In Vitro Diagnostics with an estimated USD 1.7 billion market. Home Care Devices are predicted to have a CAGR of 37.4% from 2016 to 2022 reaching about USD 1 billion by 2022. Pharmaceutical & Biological Research applications of BioMEMS will reach USD 1.3 billion in 2022. From the technology perspective micro-fluidic devices constitute 86 percent of the BioMEMS market with a 19.2 percent CAGR over the 2015 to 2021 period. Silicon microphones (particularly in hearing aids) and flow meters will support CAGRs of 23.3 and 18.3 percent respectively, 2015 to 2021 (source: Yole Development)

- BioPhotonics

In 2015 the global bio-photonics market was valued at USD 34.29 billion, growing to USD 91.31 billion by 2024, (Grand View Research, Inc. May 2016). EPIC (European Photonics Industry Consortium) registers a similar estimate at USD 37 billion (but 20 percent of this is chemistry). The number of bio-photonic components used in instruments for biology and medicine is expected to increase as much as 15 to 20 percent over a decade, e.g. phase, polarization, and super-resolution techniques. The next 10 years is expected to deliver photonics technology capable of true label-free analysis. There will be a significant migration from chemistry to software (informatics and new measurement algorithms), allowing new market players to emerge. The inherent benefits of bio-photonics are sensitivity, accuracy, non-invasiveness, and real-time output, all of which supports new market development. Agriculture and food testing are likely to be impacted by in-line optical monitoring and handheld micro-fluidics devices, potentially as part of a smart phone based app.

- Integration & Connectivity

The integration and connectivity markets are important for critical functions of MNBS. Both markets are large, overlap with each other and of course overlap with MNBS. The details of size and growth of these markets are drawn from recent reports. The global healthcare integration market is currently projected to reach USD 3.73 Billion by 2021, growing at a CAGR of 10.2 percent between 2016 and 2021. The medical device connectivity market globally will reach USD 1.3 Billion by 2021 from the current USD 413.7 Million in 2016, a CAGR of around 26 percent. (Source: marketsandmarkets.com October 2016 Report: HIT 4666).

- Medical Devices

MNBS is part of the global medical device industry valued at USD 315 Billion in 2016, recording growth of around 6 percent this year. The USA remains the largest producer and consumer of medical devices, with 26 percent of the world market. MNBS is part of the medical device market, but also offers solutions to some of the major problems in the sector e.g. the demand for home care & monitoring. MNBS technologies are demonstrating significantly higher growth rates that the sector overall, a potential indication that MNBS is increasing its share in this large and crucial market.

Medical Devices Market: Forecast for Growth, in USD Billions Region

	2016	2017	2018	2019	2020
Americas	166.6	176.5	187.3	197.9	208.6
Asia/Pacific	68.7	72.6	77.6	82.9	88.6
Central/Eastern	14.6	15.7	17	18.1	19.1
Middle East/Africa	10	10.8	11.5	12.5	13.2
Western Europe	79.5	85.1	92.6	101.4	106.2
Total	339.5	360.8	386.1	412.8	435.8

Source: Worldwide Medical Devices Forecast to 2020 BMI Research London

- Nanotechnology

Market research reports emphasize the enormous growth potential for nanotechnology and often incorporate important aspects of MNBS under this category. The global nanotechnology market growth anticipated is predicted to be 17.5% (CAGR) in the years 2016-2022 (Business Wire, Dublin, 24 March 2016). The current estimate of market value is that “the global nanotechnology industry will grow to reach US$ 75.8 billion by 2020”.

A review of USPTO patent applications for 2015 -2016 reveals that around 20 percent of nanotechnology patents fall in areas linked to the MNBS sector, suggesting a USD 15 billion market with a 17.5% growth rate over the next 5-6 years.

Reviewing the component technologies of MNBS and observing the larger markets in which MNBS is often considered the market will grow at a CAGR of 10-25 percent over the coming 7-8 years; in money terms this means somewhere in the region of USD 15-25 billion, with a significant part of this growth being generated by MNBS replacing older technology and approaches.[4]

IV. Report on presentations and discussions

IV.a: Overview

The workshop reported on MNBS projects funded by the European Union in healthcare, agriculture, food and the environment. The Commission presented the current range of research and innovation programme H2020 and mechanisms available to support MNBS related activities. Presentations also included contributions from wider stakeholder groups, such as large industry (e.g. Roche and Siemens) and Government (e.g. DIMDI and the Dutch National Reference Lab.) to frame the environment in which the sector is developing and to highlight further collaborative opportunities for MNBS, biotech and medtech.

During the workshop there were over 50 presentations, across the sectors addressed by MNBS: food, agriculture, healthcare, veterinary medicine and environment, were given. Reiterating the historical pattern, the biggest area remains health & care. However, the wider application of MNBS in agriculture, food and environment is developing strongly and was well represented. The development of core technology components, which in principle could be applied in several sectors, appeared strongly in Otranto with a significant number of developing MNBS technologies being presented. A substantial number of presentations and keynote talks were directed to the issue of innovation and commercialization. As MNBS has matured, lessons have been learnt and the stakeholders working on research and innovation have a growing experience base in commercialization (exploitation) approaches that could lead to successful products.

[4] BioMEMS market size, industry analysis report, regional outlook, application development, price trend, competitive market share & forecast, 2016 – 2023. GMI344, Dublin, 26th July 2016 Globe Newswire Research and Markets report.
BioMEMS market evolution from 2015 to 2021. Source: Yole Developpement. www.yole.fr

Biophotonics market size to reach $91.31 Billion by 2024 May 2016 Grand View Research, Inc.

http://www.grandviewresearch.com/industry-analysis/biophotonics-market
World biophotonics market - opportunities and forecast, 2014-2022. October 2016 Allied Market Research: MRS – 71744
Biophotonics/market analysis: The four segments of biophotonics market growth. Cochard, Roussel, & Lee. European Photonics Industry Consortium (EPIC) www.epic-assoc.com
Global BioMEMS and microsystem market in healthcare 2015-2019, 9th September 2015, SKU: IRTNTR6896
Worldwide Medical Devices Forecast to 2020, BMI London
PwC Health Research Institute annual top health issues medical device market in 2016
Challenges in the traditional markets and new opportunities in Asia Pacific. Giedre Liorancaite. 28th January 2016. Euromonitor International
Medical Devices. The top 5 trends for med tech in 2016. Stacy Lawrence . 24 December 2015
Medical device connectivity market by product - forecast to 2021: marketsandmarkets.com October 2016 Report Code: HIT 4666

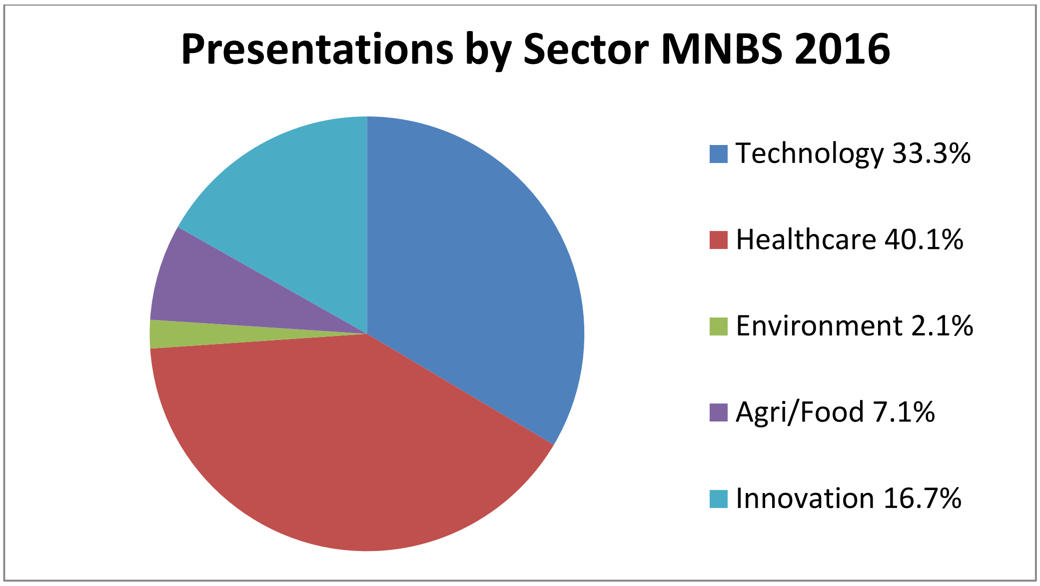


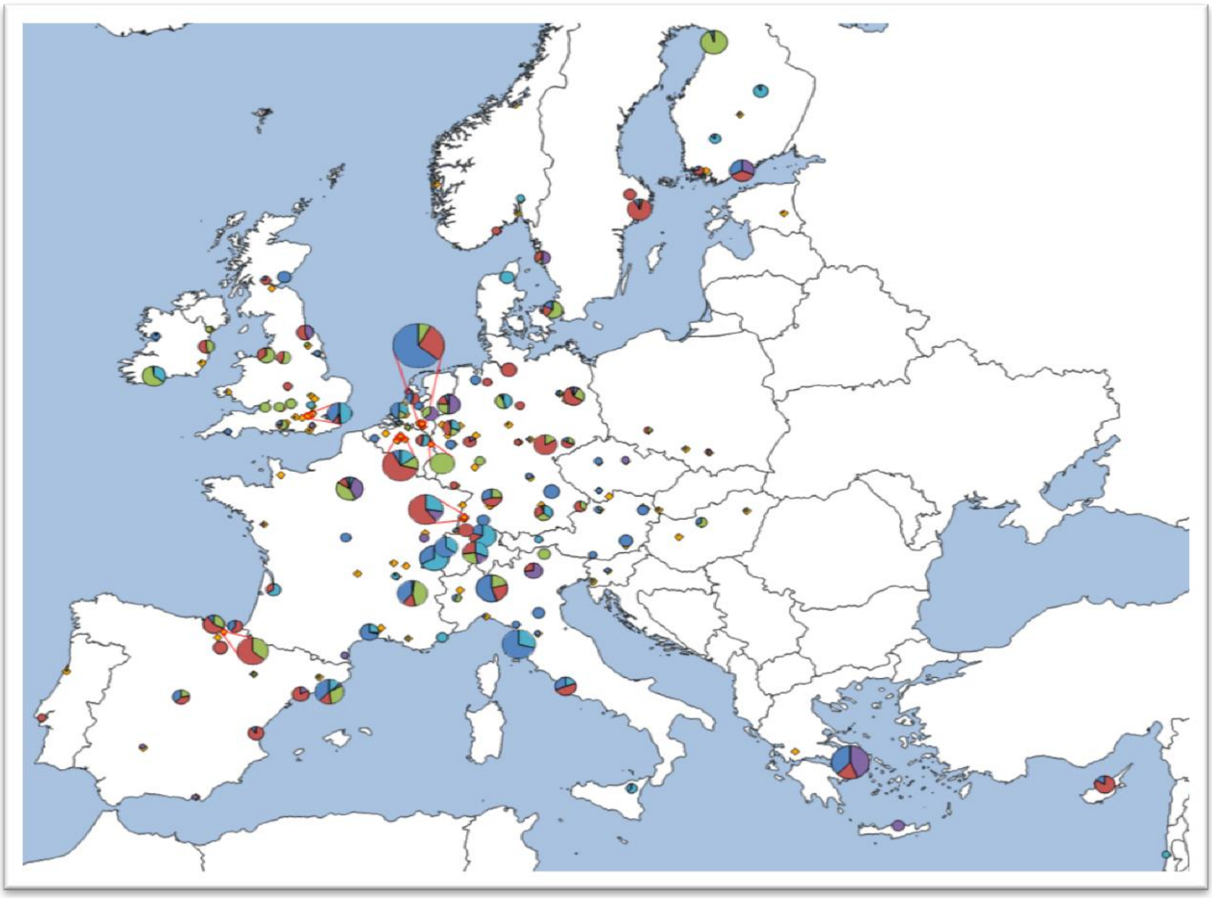
Figure 2: Presentations by MNBS sector, excluding introductory talks and posters

In the 2015 MNBS report the progress of projects supported by the European Union was assessed by the application of TRL criterion. Have projects advanced their TRL over time, has that progress taken place at an "acceptable" rate as was the progress in TRL "good" when bench marked internationally? With the shift of attention to the later stages of commercialization the introduction of Manufacturing Readiness Levels (MRL) enters consideration.

The creation of spin offs is a widely used international measure to quantify the return on public investment in research. As a recognized benchmark it has some utility. The measure recognizes that science or technology has left academe and has created commercial jobs and commercial revenue. However, technology also moves from academia to industry as licenses, which also create jobs and revenue, so measures to capture this should also be applied. To support further economic analysis it will be important to know whether the spin-outs created are EU based or in other jurisdictions and similar information would be necessary for licensees.

Projects may not start with background IP, but the expectation is that IPR will emerge and be protected. A baseline can be set at the submission of proposals and subsequent IPR protection can then be measured against this. Core patents may be augmented by additional related patents and process patents. Patent licensing, either to a commercial user or to other fields should be considered as commercialization. Other forms of IP, such as industrial designs, should also be included, to give a picture of the value created.

To address the issues raised and for consistency with the 2015 MNBS report we have replicated the projects table with appropriate updates (see below in the Progress section).



Clinical & healthcare platforms
Generic MNBS technologies
Health
MNBS in vivo
Food & environment

Figure 3. Geographical distribution and focus of MNBS funded activities

The map is instructive in highlighting a broad band of MNBS activity geographically, from the British Isles down through the Netherlands, Belgium, Eastern France and Germany to the north of Italy; with one significant outlier in the north of Spain and South of Greece. The heart of the sector is clearly the broad zone from the Benelux countries to Northern Italy, while large areas of the Union show very limited activity. This raises the urgent need for a European strategy to link National and regional competence centers and create innovation hubs and sustainable ecosystems for production and commercial roll out of advanced MNBS.

IV.b Sector presentations summary

Agriculture & Food

European agriculture faces a range of major challenges from climate change, new pests and diseases to output quality, harmful residues and pollution management. In an industry where profit margins are very small and technical investment low the demand for sophisticated monitoring at little or no additional cost to the end product poses particular challenges, but specifically demands low cost solutions.

A session at the workshop was devoted to agriculture and food, with the *Love-Food*[5] project taking a lead on simplifying technology of Lab-on-Chip and reducing cost to ensure commercialization and market uptake. Lionix presented the case for effective commercialization of lab-on-chip technologies, focusing on medical applications, although most of the lessons would apply equally to the agri-food sector. The *Biofos*[6] project, which includes Lionix as a partner, addressed lab-on-chip and photonics technology integrated to measure; copper and phosmet in olive oil, Aflatoxin B and ochratoxin A in nuts and Aflatoxin M1, penicillin and lactose in milk. *Biofos* quote: "take lessons from optical communications and invest on hybrid photonic integration for: ultra-compact, ultra-low cost photonic chips". The *Biofos* presentation was strongly focused in three areas; meeting user needs, significant cost reduction in performing important food quality analyses and a detailed plan for commercialization mobilizing skilled partners and stakeholders.

There has been growing consumer demand for the quality, safety and specific detail of inputs to be monitored and reported from "farm to fork". MNBS technologies have been developed to address this challenge. However, the food processing market is highly cost conscious and solutions need not only to be technically viable, but very low cost if they are to be adopted into the food production industry. *Symphony*[7], the milk testing project, has made the low cost per test a key plank of its product development. From technology point of view Symphony uses "Photonics, biochemistry and microfluidics, integrated in a miniaturized smart system that will perform **low cost** label free detection of contaminants in milk". The project has made clear and well structured plans for commercialization and has established associated key performance indicators (KPIs) for "technical performance, added value for users and value communicated to end user"

Environment

Applications of MNBS in the environment sector were covered both in the context of agriculture (pollution) and climate change impacts. Specific presentations focused on the use of MNBS in air pollution and the water sector. The particular challenge for many environmental applications is remote monitoring. The *Proteus*[8] water monitoring system in now close to market, c. 1 year, and is to undergo test application in Paris taking into account security, an important issue for remotely monitored systems.

Healthcare

The healthcare presentations highlighted the wide range of applications of MNBS in medicine and the opportunity to advance the e-health agenda, supporting "wellness", addressing long standing medical issues, moving towards point of care diagnostics and personalized medicine, delivering home care versus hospital care and community level medicine based on aggregate data. Applications were demonstrated in point of care diagnostics, health and disease monitoring, therapy and rehabilitation. As expected there was a strong focus of diagnostics and biomarkers, but new opportunities based on photonics, gas sensing and mechanical detection explored the widening range of applications possible for MNBS in healthcare. There was a strong focus on the commercialization agenda and for the more established projects a discussion and sharing of best practice in technology transfer and commercialization. Professor Cobelli presented the fascinating development of the Dexacom G4 "artificial pancreas" and the incorporation of the University of Padova's predictive algorithms into this commercial device. *SniffPhone* combines breath sensors with a mobile phone to detect volatile biomarkers for gastric cancer. The exploitation plans for this device are thoroughly mapped and include clear use of component manufacturers and then the commercial capabilities of Siemens for

[5] http://love-food-project.eu/doku.php
[6] http://www.ict-biofos.eu/
[7] http://www.symphony-project.eu/
[8] http://www.proteus-sensor.eu/

large scale entry to the end user market. Wound healing represents an area which for a long period has needed innovation to address outstanding problems. *Medilight* presented a creative light based solution which both reduced infection and encourages healing. During the presentation the main partner showed the manufacturing facility that has already been constructed even as the product is in development, clearly demonstrating a commitment to commercialization of the research outcomes.

V Report on MNBS Progress (2015-2016)

Based on the MNBS' 2015 recommendations, the current workshop recorded significant progress, which it is useful to link to the goals set at the end of the 2015 MNBS event in Leuven.

Technology recommendations 2015

- *Healthcare applications of MNBS should remain a major focus for the sector, e.g. PoC diagnostics, personalized medicine and health monitoring.*
- *Expand the applications of MNBS in agriculture, food and environment markets, with a strong focus on low cost systems.*
- *A strong push to modularization is recommended (Lego brick model).*
- *Encourage the links between MNBS and other technology areas.*

V.1 Technology

- Healthcare applications remain the major focus of the sector as evidenced by the significant number of healthcare presentations given (22 out of 54). The application of MNBS spans the improved long term management of chronic diseases, such as Diabetes and to support systems for the elderly, perhaps best demonstrated by "Smart Puglia", but also technologies to address hearing loss, and enabling technologies such as: microgels, novel sensors and the *Discognosis*[9] test platform for malaria.

Healthcare projects continue to support key European healthcare agendas with respect to chronic disease, support for the elderly and ageing well. Innovation continues to be introduced with new technologies, systems (e.g. through enhanced sensing and actuation capabilities) and advanced platforms like organ-on-chip. System integration and greater use of communication technology continues to enhance high quality service delivery (e.g. projects under *INNOVAAL public-private partnership on Active and Assisted Living*).

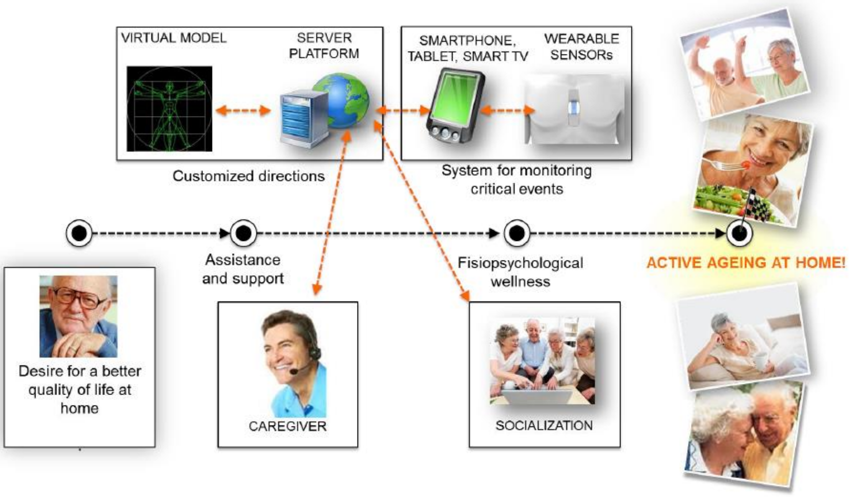


Figure 4. ***INNOVAAL project schematic for Active Ageing @ Home***

[9] http://www.discognosis.eu/

➢ The engagement with sectors beyond healthcare such as food quality, food processing and environmental management, which are dependent on precisely the same technical capacities as healthcare, of sensors, materials, data collection, storage, processing and communication continues to grow. Projects in food safety, agriculture and environmental sectors presented at previous MNBS events have progressed in technical sophistication, demonstration and commercialization. New projects indicate the interest generated by the technology and the increasing market demand for MNBS solutions, e.g. project *Symphony* mentioned above.

Figure 5. A demonstration of engaging with key relevant stakeholders to support commercialization (Symphony)

➢ In 2015 there was discussion of developing MNBS as a "component industry", something akin to the chip or microprocessor approach with technology developers, transfer of the technology to ever more complex chips and the integration of the components into more complex and powerful systems. The workshop in Otranto saw several presentations where this principle is not only established, but is under development. The modularization approach has taken root and was apparent in the presentations of MiNAB-ICT, Sensor ab, Discognosis and "nanogels for fibre optic nanoprobes", where the discreet component for many applications ethos was apparent. The development of components to address problems faced by broad sections of the MNBS community is advancing and being promoted. The new building blocks support the development of new system features and the creation of new integrated products. A growing toolbox is emerging including MOX sensors, WO_3 based sensors, e-Nose technology (see picture 6) and confocal 3D imaging. The new modules are not quite "plug & play" as yet, but the capability of MNBS to provide solutions to a wide range of healthcare, food and environment issues is growing steadily with these compatible technologies.

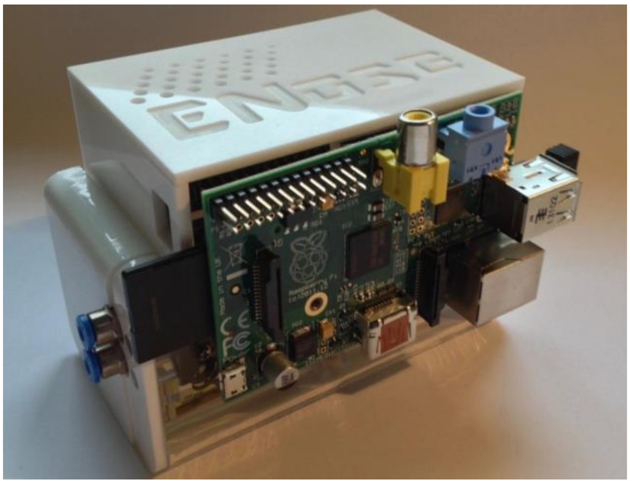


Figure 6. ENose, electronic volatile molecule sensor system. A component for integration into commercial systems

- Links to other technology areas

The enhancement of sensing capability with communications ability, was an important theme in Leuven and emerged strongly again in the 2016 workshop. The artificial pancreas presented by Prof. Cobelli reinforced links to algorithm development, communications technology and component technologies from outside the consortium necessary to offer an integrated platform. Furthermore, Organ-on-Chip platform will offer unique opportunities for the development of new in vitro disease models through duplication of key function of living organs. OoC take advantages of the toolbox and components developed in LoC area and brings together biotech, medtech and life scientists around solutions developed and tested in the lab.

The case for autonomous systems made in MNBS'2015 was enhanced and reinforced by developments presented in Otranto. Dynamic management of water sensors within a water quality system as presented by Symphony now need to integrate with established water management systems as they move into the commercial sphere. *SniffPhone*[10] links volatile gas markers for gastric cancer to a mobile phone which can connect to powerful computational capability and report to doctors. The doctor can then use the mobile link to manage the patient in the case of a positive result. The system supports both the individual and population level analysis. The *SniffPhone* product by virtue of its connectivity operates as an autonomous medical monitoring and feedback device.

The importance of photonics to the future of MNBS was once again reinforced by the widespread use of this field by the MNBS community. Two important papers demonstrated the use of photonics in imaging, firstly with new technology in confocal 3D imaging and secondly, with microgels, as material with tuneable photonic responsivity, in label free fibreoptic nanoprobes. New and exciting, sensing, monitoring and management capabilities are offered by collaboration with the photonics sector.

One of the promising MNBS area for new discoveries and applications is Organ-on-Chip (OoC), a powerful technology for creating novel human organ and disease models. It can combine robust establishment of induced pluripotent stem cells (iPSC) in life science research and the ability to derive adult stem cells from several organs that can form ‘organoids’ in culture, as well as several rapid technological advances in microfluidics, microelectronics and microfabrication. Rapidly developing 3D bioprinting technology will be a valuable tool to establish the desired precise organization of the multiple cell structures on chip devices (see HOPE flagship). The application spectrum of organ-on-chip technology is very broad, ranging from drug and disease target identification and regenerative medicine to the testing of non-medical compounds, such as food additives, environmental

[10] http://www.sniffphone.eu/

contaminants or cosmetics. Organ-on-chips are expected to ultimately have a significant impact on the healthcare of millions of patients by providing personalized medicine, fewer treatment failures, more effective precision drugs with fewer side effects (www.hdmt.technology).

Market action recommendations 2015

- *Provide strong support to industrial development and optimise the routes to commercialization.*
- *Systems carry out sophisticated functions, users require simple comprehensible output.*
- *Credible demonstrations, in a wide range of activities to engage users and the public.*
- *Demonstrate cost effectiveness.*

V.2 Market

- In the last year many projects in the MNBS field have advanced their commercial position and have been able to reflect on the experience. This has also allowed for the sharing of best practice with the wider MNBS community.

AngeLab[11] presented an excellent case study which not only addressed technology and market, but demonstrated clearly the case for cost effectiveness, the establishment of demand, the validation necessary to make a commercial case and an understanding of product manufacturing as opposed to lab demonstration.

In similar vein, *LiqBiopSens*[12] has developed a thorough understanding of its user needs. The basic technology then addresses a whole series of unmet needs with early, accurate diagnosis of colorectal cancer at lower cost. Clear road mapping of the technical and commercial development is in place. To follow the demonstration phase the team have considered validation, manufacturing and distribution, thus adding important dimensions to the meaning of technology readiness.

CanDo[13] shared the commercial development of their technology, highlighting the road mapping approach as a tool for addressing risk.

The *POCKET*[14] project starts from establishing user need and a unique position for the technology. The steps of clinical validation, IP management and partnering support the development and its commercialization. Underlying the successful commercialization approach is the creation of a supporting ecosystem in which the product can thrive.

Symphony, in the food testing sphere, gives both detailed insight into technical advances and develops a very thorough commercialization case. The project presents a sophisticated user engagement model drawing input from, partners, stakeholders, the scientific community and users. The translational roadmap has been developed by the consortium alongside defining the roles of partners in delivery clearly. The Symphony EC project hopes to deliver an endpoint at TRL 5, however well budgeted and sensibly timed plans are in place to take the technology to commercialization. It is notable that parallel component technologies will be incorporated, each with its own timed and costed development path, as the product advances towards commercial application.

The Horizon 2020 *Medilight*[15] project will take this innovative wound healing technology to TRL 6, over its three year life. However the consortium has already made clear plans for; IP, manufacturing and market introduction with specific partners tasked with delivery in the latter two cases. Component

[11] http://angelab-systems.eu/
[12] http://liqbiopsens.com/en/#.WCnsif6QJD9
[13] http://www.fp7cando.eu/
[14] http://www.pocket-proj.eu/
[15] http://www.medilight-project.eu/

technologies for microelectronics, light source technology and a new green light source are allocated to specific partners.

- One recommendation from 2015 which was not strongly represented in the 2016 presentations was the need for simple output. Many projects are dealing with complex data, often relying on multiple sensor technologies. With many data streams and sophisticated data integration it is important that the output is comprehensible to end users. In some cases the users will be highly qualified scientists or doctors with time to unravel the intricacies of the data. More often, however, the users will be very busy, under time pressure or may just have basic qualifications.

The design of interfaces is vital to the successful uptake of MNBS technologies in healthcare, food production and environmental management. That said some projects, such as the WIISEL insole presented good examples of very clear and easy to understand interfaces. Projects need further encouragement to realize and emphasize the importance of the user interface in supporting effective commercialization.

- ✓ Credible demonstrations

In plotting the route to commercialization, presentation after presentation stressed the need for credible demonstrations. Project demonstrations come in the lab, in real situations or in some medical applications proxy demonstrations and then commercially or in the clinic, as the project Discognosis performed at the Institute Pasteur in Dakar, Senegal. Laboratory and prototype demonstrations need scientific validity and peer review and thus should be backed by high quality academic publications. For medical applications, demonstration in clinical situations requires compliance with regulations for test design, operation and data analysis. Market demonstrations, of food and water testing solutions require customer engagement for credibility. In commercialization terms the above evidence is “de rigeur”, but needs to be accompanied by evidence that IP has been secured and protected within this process.

- ✓ Cost Effectiveness

Cost effectiveness remains a significant driver behind the introduction of new technology. While in all fields; medicine, agriculture and environment, more monitoring and feedback is demanded, there is also a demand for minimal or reduced cost. The demand to contain healthcare costs demands that MNBS solutions either cost less than current approaches or address outstanding problems at reasonable cost. In agriculture and environment the demand is for very low cost systems that do not add significantly to consumer bills. While the focus of the meeting was the route to commercialization there was no greater emphasis on cost effectiveness than at previous MNBS workshops, perhaps because most of the systems are still some years from deployment and the true marketed costs remain unclear. Broadly, the smart economy is a cost effective economy and MNBS will need to do more to present a strong case for cost effectiveness in face of competition from existing solutions.

Commercialisation recommendations 2015

- Operate to and deliver data that fits international standards
- Encourage the development of supply chains.
- Establish MNBS as safe and environmentally friendly.
- Develop information resources supporting the commercial evaluation of the market.

V.3. Commercialisation

- New technology can deliver new data; however, in most cases MNBS is collecting the same data using new approaches. Several presentations in the workshop benchmarked data collection against existing technology, to show performance equivalent to, or better than the "gold standard". Much regulation in agriculture and food, in the environment sector and in medicine relates to standards and in some cases even as to how data points are to be measured. MNBS solutions need to be cognizant of the data standards with which they must comply in developing products of real commercial potential. Alternatively, there needs to be strong evidence of engagement with standards and regulators in the establishment of new benchmarks based on MNBS technology to prepare the route to commercial development.

- The development of supply chains is strongly evidenced in MNBS projects in general, but some were rather more specific in their presentations about the actors engaged, the technology and services to be supplied by partners, sub-contractors and third parties. For example *Discognosis* included in the consortium all partners proving the entire value chain of components, as well as the SME Mast Group Ltd for direct commercialization". The *Angelab* project brings together a whole supply chain of partners to address a range of problems from basic bioscience to manufacturing and market entry. A similar picture is presented by the *CANDO* project.

The *Pocket* story goes further not only showing the supply chain for commercialization but indicating two component developments that will be commercialized in their own right by MTW and ChipShop. Action is explicit about the complex of technologies that need to be brought together from a range of suppliers to deliver an integrated high performance micro device to address hearing loss. The hDMT presentation on a human organ disease model on a chip presented a clear graphic breaking out the product and project components and then indicating, in a colour coded table, the members of the supply chain.

So, overall the projects have a clear view of their supply chains both internally and externally. Projects are often specific about parts of the supply chain that are currently unfulfilled, such as manufacturing or distribution contractors, however this is partly because projects at the lower TRLs have yet to encounter these issues. However, as indicated many projects already include a full supply chain appropriate to a marketed product. The advantages of this approach are that component and service suppliers are involved at the earliest stages in product specification and as the products emerge manufacturing and distribution can be planned in close concertation with technical team.

- Many MNBS projects address safety and the creation of an environment supportive of human activity. This is particularly true of the MNBS projects supporting wellness and active ambient living amongst the elderly. The "Active Ageing at Home" project demonstrates the use of sensors and a range of communicating devices to support the elderly in being active and engaged in society by encouraging exercise, supporting social engagement and involving participants in intellectual activity. The approach is holistic showing that by deploying devices and systems in a comprehensive manner can deliver great benefits to society.

  A variety of testing, management and monitoring projects, in the MNBS fold, address the quality and safety of key foods and resources. The accurate, timely and point of use detection of pathogens, spoilage and contamination ensures that all citizens live in a safe and protective environment. Projects such as Symphony testing milk and Proteus managing water quality will ensure a safe and friendly environment once deployed. Both projects report progress with their plans since their inception last year.

- In discussing commercialization most MNBS projects were keen to address information resources for commercial evaluation. Projects focused on validation at the demonstration phase, in particular by the market and regulatory bodies. The *Discognosis* project, on the detection of fever related infectious diseases, reported significant product validation work in Africa and component compliance with international standards. They strongly recommended that projects address validation at an early stage.

The WIISEL smart insole technology for assisting the elderly reported product testing against an established gold standard and extensive validation work, with plans in place to extend the validation to new international markets. Projects such as, *Medilight*, which are at an earlier stage identify in their development roadmaps a plan for dealing with the medical regulatory authorities.

Overall within the healthcare projects CE marking and meeting the requirements of regulatory bodies is planned and budgeted going forward. A strong message articulated throughout the product sessions and very specifically in some cases was; "begin validation and regulatory compliance as soon as possible" to support and maximize the chances of successful commercialization.

EC role as suggested in 2015

- *To continue promoting MNBS through all the channels that reach technologists and industrialists*
- *To sign-post applicants to the most appropriate EC programmes.*
- *To support community organisation*

V.4 EC action

The European Commission supports the MNBS sector with funding, networking, events, communications and actions contributing to EU policy priorities like DSM (Digital Single Market) and DEI (Digitising European Industry). From the discussion sessions in Otranto it is clear that active links are in place with related activities such as ICT, photonics, Nanomedicine and materials and there is engagement across programmes (e.g. ICT, NMBP), initiatives and stakeholders' groups (MedTech Europe, ESTHER, Photonics 21 WG3, etc). To emphasize this and engage the MNBS community several presentations were given in Otranto by Commission staff to highlight the opportunities and activities in place.

In H2020 Work Programme 2016 – 2017 several calls for proposals linking to MNBS have been implemented. This includes, for example:

- Cross-KET (Key Enabling Technologies) for Diagnostics at the point of care (joint call between DG CONNECT-ICT and RTD-Nanotechnologies, Advanced Materials, Advanced Manufacturing and Processing, and Biotechnology (NMBP), closing in January 19, 2017
- Societal challenge 1 (Health, demographic change and wellbeing) calls, covering in 2016-17 activities from research to market. Strong emphass is put to establish links with activities of European Innovation Partnerships and bring together resources and knowledge across different fields, technologies and disciplines
- Biophotonics call (2016)
- Smart Anything Everywhere Initiative, call 2016 focusing on Network of competence centres

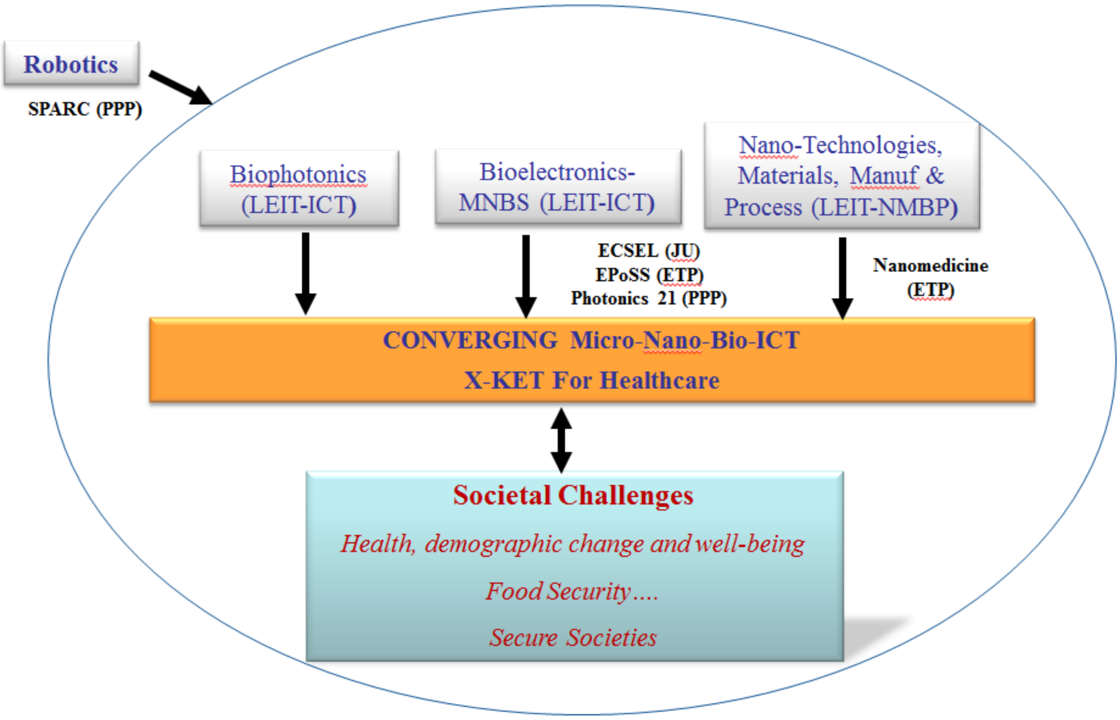


Figure 7. Main EC topics contributing to MNBS within H2020

Community organisation recommended 2015

- Action to promote MNBS, as it lacks adequate profile and a strong voice.

V.5. *MNBS Community*

The EC and cluster members participated, organized and promoted MNBS through key interdisciplinary events, e.g.
- Organisation of Workshop on 'Cross-cutting Key Enabling Technologies for Health', 13-14 Sep 2016, including Call Information and Networking as well as Stakeholders' consultation on cross-KETs for Health: EU current position and future.[16]
- Participation in relevant working groups meetings e.g. within European Technology Platforms and Private Public Partnerships (Photonics 21, Robotics-SPARC, ECSEL)
- Contribution in the discussions and preparation of ESTHER position paper.
- Preparation of MNBS portfolio Analysis, encompassing projects funded from several thematic areas in FP7 and H2020. The study will be released in December 2016.
- Participation in conferences promoting innovation (e.g. Innovation Days in Life sciences, medtech and Biotech, Paris 3-4 Oct 2016).
- Progress of the MNBS website (www.mnbs.eu) with improvement of the design and completion of all projects data and reports until October 2016
- Preparation of the WP 2018-20. Discussions started in 2017 and will be concluded in 2017.

- Participation in a consultation meeting organized by DG Agri on "Digitization of Agri-Food sector", Sept 2016[17]

The critical meeting on Cross-KET for Healthcare, organised in Brussels in September 2016, addressed the barriers to transferring cross-KET and system solutions to real application in healthcare, setting

[16] https://ec.europa.eu/digital-single-market/en/news/workshop-cross-cutting-key-enabling-technologies-health
[17] https://ec.europa.eu/programmes/horizon2020/en/news/digitising-agri-food-sector-workshop

the research agenda strategy for 2018-2020. It included discussion of: the European Technology Platform in Nanomedicine, Photonics21, the European Platform on Smart Systems Integration (EpoSS), EUMATand ESB (Biomaterials), COCIR. In addition the status of the task force on 'Emerging and Strategic Technologies for Healthcare' ('ESTHER') was presented.

The need for connected healthcare via eHealth, mHealh and integrated care and coordination with European initiatives and Health policies e.g. "European Innovation Partnership on Active and Healthy Ageing" and the "Blueprint of digital transformation in health and care" was explained. Policies were presented on Innovation Hubs for Health, Smart Connected Devices and Digitizing Smart Health and Care.

From the workshop several key questions are in the spotlight e.g. What is being done in Europe today to accelerate the development and the use of these advanced technologies, enabling new solutions for healthcare, agrifood, environment, security? What role can Horizon 2020 play in supporting innovation hubs and translate technology solutions from the lab to the real life applications? What are the opportunities for researchers and other actors in the field? How the group can contribute building a critical mass of EU actors forming an innovation and sustainable ecosystem along the value chain ?

The MNBS group should reflect and take a position on these important questions.

V6. Projects

MNBS projects' progress is depicted in the following table*.*

Project	Field	Current TRL	Euro M to TRL9	Years to TRL9	IPR Protected	Components "Lego bricks"	1 Mkt Need %	2 Prototype	3 Validated	4 Spin - offs	5 Response time emergency	6 Peer review publications	7 Connected	8 Tech convergence	9 Autonomous	10 MRL	Commercialisation approach	Partners
ANGELAB	M	5	1.5	2	Y	Y	X	Y	P	N	X	N	N	Y	N	7	Partners,3rd parties	15
Discognosis	M	5	5	5	Y	Y	X	Y	P	N	Y	Y	N	Y	N	3	Partner	7
NANODEM	M	3/4	8-10	5-6	FTO	Y	60	Y	N	N	Y	Y	N	Y	N	5/6	3Commercial partners	9
SYMPHONY	F	3	6	5	TBC	Y	X	Y	P	N	X	Y	N	Y	N	3-4	3 Commercial partners	7
CanDo	M	2	5	5	FTO	Y	X	X	P	N	X	N	X	X	X	TBC	Partners	10
NextDx	M	3	20 est.	5-7	TBC	Y	X	N	P	N	Y	Y	Y	Y	Y	3	3 Commercial Partners	6
Pocket	M	3	5	5+	Y	Y	X	X	P	N	X	N	N	Y	N	3-4	Partners	6
ACTION	M	5	X	5 to 8	Y, FTO	Y	X	X	P	N	X	Y	Y	Y	Y	3-4[18]	1 partner	7
SMARTDIAGNOS	M	3-4	2-3 est.	5-6	TBC	Y	X	N	N	N	X	N	N	N	Y	2-3	4 Commercial Partners	10
SWAN-iCARE	M	6 est	X	1.5 to 3	Y	N	X	N	P	N	X	N	Y	Y	Y	TBC	1 Partner	11
MEDILIGHT	M	5	2	6	Y	Y	X	P	N	N	X	Y	Y	Y	N	4	1 partner	7
Socket Master	M	3	7	6	Y	N	X	Y	P	N	N	N	N	N	N	3	JV	8
LOVE FOOD	F	4	6	6	Y	Y	X	Y	N	Y	N	Y	N	Y	Y	TBC	Manufacturing Partners	6

[18] The ACTION project has several components, which are at a different MRLs ranging from 2 to 9.

SNIFFPHONE	M	3	6	3	Y	Y	X	N	P	N	X	N	Y	Y	Y	4	Major commercial partner	9
LOVEFOOD2MARKET	F	4	3	3	Y	Y	X	Y	N	Y	N	Y	N	Y	Y	TBC	Manufacturing Partners	6
FOODSNIFFER	F	5	6	4	Y	Y	60	Y	P	N	Y	Y	Y	Y	Y	3-4	Manufacturing Partners	10
BIOFOS	F	2	8	5	Y	Y	70	Y	P	N	N	Y	Y	Y	N	3	4 Manufacturing Partners	10
ML2	M /E	6	2	3	Y, FTO	Y	50	N	P	N	X	Y	N	Y	N	8	2Commercial Partners	12
PROTEUS	E	6	5	3	Y	Y	X	Y	P	N	X	N	Y	Y	N	TBC	Partners	9
liqbiopsens	M	5	7	5	Y	Y	90	N	N	N	1y	N	N	Y	N	3	JV	6

Table 1. MNBS projects' progress indicators 2016

Table legend:

Project: acronym
Field: Medical [M], Agriculture & Food [F], Vet. Medicine [V], Environment [e] & General [G]
Current TRL (see appendix 3): Overall TRL stated by project or estimated from presentation
M Euro to TRL 9: Cost in millions of Euro, stated by project or estimated from presentation, to reach TRL 9 overall
Years to TRL 9: Time in years, stated by project or estimated from presentation, to reach TRL 9 for product.
IPR: Patents [Y], IPR position to be confirmed [TBC], freedom to operate confirmed [FTO], unclear [?]
Components: Potential or plan to commercialise project device presented; yes [Y] or no [N]
Commercialisation approach: Who will commercialise project output?
Partners: How many partners are involved in the project?

Not reported: X

Measures added since 2015:

How much the solution (or system) developed meets the market needs identified by the project (%) **1**
Working prototype in real setting (Y/N) **2**
Real validation (N = No, P = Prototype, C, n/a) **3**
Created spin-offs (Y/N) **4**
Time to response to emergency demands i.e. time to develop and validate a solution to tackle emergent issues (e.g. contagious virus) **5**
High impact factor publications (Y/N) **6**
Connected world (Y/N) **7**
Technology convergence (Y/N) **8**
Autonomous systems (Y/N) **9**
MRL (Appendix 3), manufacturing readiness level (as raised by the BIOFOS project in Otranto) **10**

It is noted that in general the recorded progress from last year is at best one year closer to TRL 9. In several cases the expected cost of reaching TRL 9 has risen. The partnerships have remained stable, no withdrawals are noted, but neither are there additions. Some projects have refined their intended commercialization plans e.g. Socket-Master have settled on a Joint-Venture at this stage. While most projects have IPR plans few if any of the projects not carrying patents have declared new (initial) patent applications. Most projects are component based offering the possibility of the components being applied in new applications in future projects. Several projects anticipate commercialization being a joint activity between the partners, but with most handing this responsibility to the commercial partners alone. Partnerships vary between 6 and 15 organisations.

MNBS'15 raised a key question “Who is to measure yearly progress in MNBS and how?” In this regard additional points (1 – 10) were added to the progress table, headed in green in the extended reporting table. The additional table entries based on the measures proposed in Leuven 2015, raise the following points:

1; the question appears difficult to answer
5; it is unclear what was intended in 2015 for this measure
6; very few projects report peer reviewed publications in high impact journals BUT this may be a lack of reporting NOT a lack of activity
Columns “Lego” & 4; are indicators of “OPEN INNOVATION”
IP is important in commercialization. Not enough projects are recording IP
7, 8, 9; address integration, smart developments, some projects perform well and overall around 50% of records are +ve

The TRL and years to market are a progress measure. Where this analysis, crude as it may be, reveals interesting results is on those measures related to commercialization, where more work is needed and on integrated smart systems where significant activity is recorded.

VI. MNBS going forward & Recommendations

Introduction

The area should develop along an open innovation model, requiring an integral chain support & financing, covering all steps from research to enabling technology, to application and market development. Figure 8 shows the importance of the different steps along the innovation chain and matching funds in the case of the Netherlands.

In Europe MNBS EC funding has rather focused on R&D with application in mind, for the last 15 years. The sector has worked hard to establish that the fundamental technologies are equally applicable across a range of applications from health and veterinary science to food processing and the environment. MNBS has been sustained on the basis of a range of underlying building blocks with use in a wide range of markets.

It appears that in the future Healthcare use of MNBS will be mainly supported by cross-cutting activities e.g. KETs and ESTHER initiatives, while food and other bio-applications would be enabled by the support of advanced MNBS through smart systems' development. The later funding might be limited (as indicated from within H2020) and the strategy might be to co-operate with health or agrifood programmes on topics of common interest while the components research and development could be supported through KETs and PPPs programmes (e.g. Photonics21, Nanomedicine, ECSEL).

H2020 is now focusing on research and innovation to support policy priorities e.g. Digital Single Market and DEI-Digitizing European Industry where driving technologies are Big Data, Internet of Things, Robotics and Artificial Intelligence etc. This may leave little funding for a strategic support to smart system integration and MNBS. The change demands a review of opportunities, structure and sectors for application to find funding support in the future. Discussions with DG AGRI were reported as underway about joint collaboration in the area of ICT for farming and agriculture.

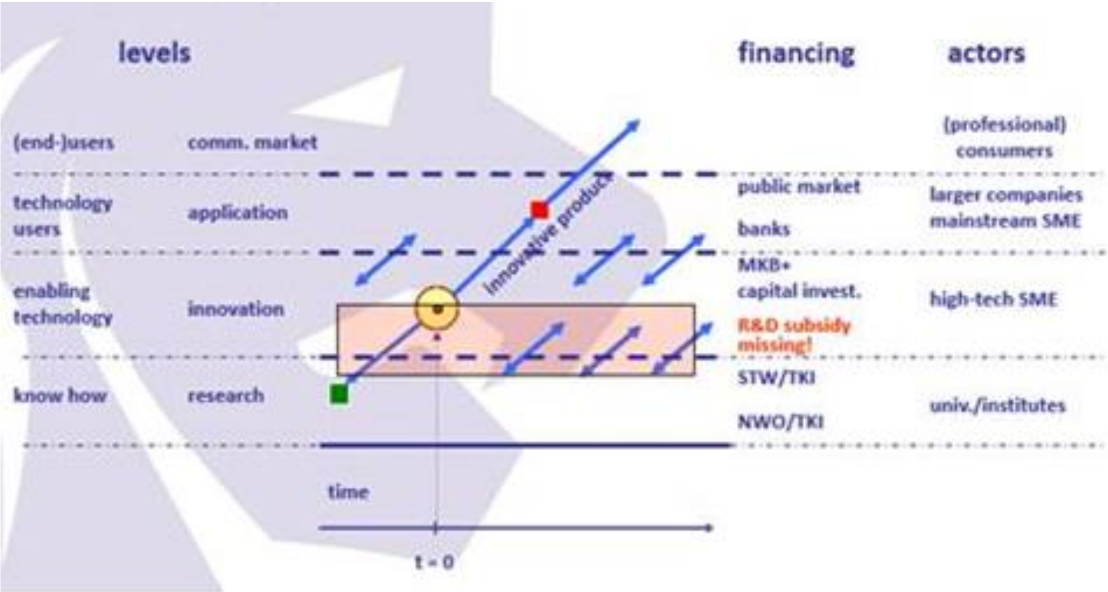


Figure 8: Open Innovation Model & schematic presentation of R&I funding in the Netherlands; Henk Leeuwis, 2016.

Technology

The development of technology has continued with increasing evidence that some groups and businesses recognize the relevance and importance of the sub-component approach discussed in 2015 at Leuven. Good examples of this commercial approach were presented by *Discognosis* where new diagnostic channels and capabilities can be plugged into the device as component units. Lionix technology demonstrated similar flexibility in being able to “componentize” food analysis testing. Optimization of components allows developers to focus on performance while commercially more routes to the market are offered by this approach. A market in component technologies supports open innovation. Expanding the number of technologies that can be integrated into devices creates systems with wider potential applications and thereby greater market potential. Facility to acquire and integrate components also drives open innovation, creating a component marketplace.

Concerns were raised during the session that the developments above ran the danger of abandoning science focused on concrete applications. It was recognized that Technology Platforms, manufacturing, PPPs and biotechnology (KET) are all undertaking excellent science in the fields covered by MNBS, however globally we have reached a stage where technologies have to be deployed and digitised. It was also noted that PPPs and JUs were instruments with a specific purpose and with a limited lifetime, thus more emphasis should be placed on KETs within H2020. Europe is unlikely to become a world leader in MNBS applications following the above approach, but rather a supplier of some component technology. ***The integration activity embedded within MNBS provides the international competitive edge and the opportunity to lead industry in a wide range of important application areas globally.***

The current discussions between industrial technologies and societal challenges (e.g. Health, Food safety, etc) in H2020, and the socio-economic reality remind us how important is to reach all communities and bridge the gaps. It is indeed an important target to achieve innovation acceleration through different instruments, meetings, industry driven initiatives (like ESTHER) and through next WP 2018-20.

Recommendations:

Modularize (e.g. create standard components and interfaces) what does it mean?
Integrate more technology types

- **The push to create platforms where material, IT, communications and particularly analysis "cartridges" are interchangeable is encouraged.**
- **Technology needs to be drawn from a wide base, often from outside the core sensor technology sphere e.g. photonics, algorithm development and communications.**

Markets

MNBS position in H2020 WP 2018-20: Funding Opportunities and Risks

There are a wide range of funding possibilities in the Digitising European Industry, Key Emerging Technologies, Artificial Intelligence Big Data and Robotics agendas, where the establishment of pilots and the creation of competence centres could play a significant role in supporting the MNBS field. The trend to move the centre of gravity from ICT to BIO may benefit MNBS in the long run. ***The key risk associated with the changes foreseen and the opportunities arising from them is that knowledge, expertise and experience in product integration will become fragmented and thus difficult to focus in competitive international markets.***

Recommendations:

Adopt measures to support cohesive technology and industry sector development, see modularization recommendations above and communication recommendations below.

Commercial Landscape

Creating a Component Marketplace

The market still does not recognize MNBS; agriculture is understood, as is IT and medical devices, whereas a platform that crosses IT, communications, life sciences and nanotechnology is not grasped. Intellectually, technically and scientifically a micro or nano-scale cartridge containing biochemical components, processing IT and communications capability could monitor contamination in a food factory, or a diabetic at home or identify contamination in a water system. Consumers and critically industrial markets will engage with cheaper, faster, more accurate, more reliable solutions, but will see them from their own perspective; customer communication must engage via traditional market sectors and educate users about the new market (MNBS). Technological sophistication to deliver end user benefit may be the driver for the technologists and the developers, but end users in the internet era face a cascade of data, devices and delivery interfaces. The user interfaces for MNBS solutions need to be simple and rapidly absorbed, to encourage uptake, use, safety and user evangelism. Apple have survived the onslaught of Microsoft through superior interface design.

Recommendations:
Improve communication with all end user groups
Use or Integrate Simple user interfaces

- **Make the market far more aware of MNBS.**
- **Utility is important and device and system interfaces need to be simple and easy to understand for consumers.**

Incubation

Not all consortia contain the expertise to achieve full market access. ***Early stage and spin-out companies would benefit from specific funds to address the route to significant international markets.*** Technology platforms and CSAs could be the vehicle to support the later stages of the innovation process taking successful products to global markets. The current position is that project exploitation and business cases are not usually business plans and these have to be developed and delivered by teams with limited experience in this activity. There is a great danger that projects will produce viable products, but then stumble when trying to access larger markets. The need for feedback after the completion of projects was stressed, to achieve the continuity and support necessary to enter major markets successfully.

Commercialization needs an economic case, a quality case, supported with an appropriate commercial team (which may mean new partners), with access to and an ability to communicate with key stakeholders. The presentations in Otranto which focused on the lesson for commercialization, such as Lionix, demonstrated the importance of detailed planning from the first experiment to product sales and from scientific publications to patents and commercial agreements. Technology and regulatory approvals need to be backed up with detailed consideration of the route to the market and comprehensive plans for manufacturing, distribution, storage and long term quality management. Key steps in commercialization rely on validation.

A strong message emerged on the need to very high quality validation, that validation should be achieved as early as possible and should be appropriately recorded and communicated. Validation is frequently a driver for funding and always for regulators and market introduction.

Recommendations:
Projects to make more rigorous commercialization planning
Project requirement to: Define and build Validation cases

- **There needs to be a robust commercial plan which is delivered by the commercial team.**
- **Plans need to be supported by good validation, appropriate demonstration.**

Market Development

Significant changes are in train within H2020 with new agendas and new tools emerging over the last year. The MNBS community needs to be flexible in its responses to these changes and creative in its view of itself. However, whatever flexibility and gymnastics is found by the MNBS community should be matched with Commission flexibility in finding the parts of its schemes and programmes that would benefit from the MNBS approach and capability built up over more than a decade. Further active communication by the Commission with the MNBS research and development base is likely to pay dividends. MNBS is a bank of intellectual property in which considerable investment has been made, over the next decade it will be possible to draw down against this account if the technologists, the SMEs and the researchers involved are informed of active areas in which they can engage. Any analysis of the global markets indicates the ferocious competitive activity in this field. Europe's research groups, academic or commercial are highly capable and are keen to address this market. The Commission remains the guardian of the MNBS "brand" and plays a key role in communicating the story of cross sector integration to deliver new products, new devices and new technologies with advanced functions and communication that are in some senses sector neutral. The Commission manages a significant number of projects in this field and is in the best position to communicate the stories emerging from these projects in a coherent manner. Indeed they can draw out the cross-cutting application of bioMEMS, bioPhotonics, integration on a chip and communicating devices with advanced processing algorithms. The main actors in the sector are often focused on technology development, the Tyndall Institute mammary probe, or addressing specific markets, as Symphony in the dairy market. The Commission is in a unique position to appreciate the wider picture and act as organizer of the players.

Recommendations:

European Commission role
Maintain the leadership of Sector communicator
Strengthen the Sector organizer role

- **Further active communication by the Commission with the MNBS research and development base is likely to pay dividends.**
- **The Commission should actively pursue and support Community organization with MNBS stakeholders**

Appendix 1 - Programme

Overview of the ISOCS-MiNaB-ICT-MNBS 2016

MNBS'16 Workshop Programme

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MONDAY, JUNE 27TH

08.15 Registration

08.45 – 09.00 Opening Session

09.00 – 09.30 Plenary Session

A. Lymberis, EC, DG CONNECT - Setting the scene of MNBS

09.30 – 10.50 Session 1 - Devices and Technologies for Smart Living (Chair: L. Lorenzelli)

9.30-9.50

Keynote

K. Mitsakakis, "Disc-shaped point-of-care platform for infectious disease diagnosis (discogonsis), a success story with lessons to be learned"

9.50-10.05 E. Campo, D. Brulin, Y. Charlon, A. Piau, "A smart sensing device for monitoring the frail people at home"

10.05-10.20 F. Adrover, J. Mitrovics, S. Udina, "Using smartphones for disease prevention and diagnosis"

10.20-10.35 A. Kita, P. Lorenzi, G. Romano, R. Rao, A. Suppa, L. Della Torre, M. Pessione, A. Berardelli,F. Irre, "Smart sensing system for the detection of gait disorders"

10.35-10.50 M. Di Rosa, V. Stara, L. Rossi, "Sensing insoles for independent and safe elderly living: the case study of wiisel"

10.50 – 11.15 Coffee break

11.15 – 13.05 Session 2 - Projects innovation session: MNBS enabling bio-medicine & health (Chair: N. Kattavenos)

11.15-11.30 D. Manessis, "Medilight- Miniaturized smart system for light stimulation and monitoring of wound healing"

11.30-11.45 J. M. Ruano, "Angelab- A New Genetic LABoratory for non-invasive prenatal diagnosis"

11.45-12.00 A. Cantarero, "CanDo- A CANcer Development mOnitor"

12.00-12.15 P. Bienstman, "Pocket - Development of a low-cost point-of-care test for Tuberculosis detection"

12.15-12.30 M. Romanelli, "UNIPI, Swan-icare- Smart Wearable and Autonomous Negative Pressure Device for Wound Monitoring and Therapy"

12.30-12.45 M. Fretz, "ACTION- Implant for Optoacoustic Natural sound enhancement"

12.45-12.55 A. Arnau Vives/R. Fernandez, "LiqBiosens- Reliable Novel Liquid Biopsy technology for early detection of colorectal cancer"

12.55-13.05 A. Wolff, "Smartdiagnos- Next generation sepsis diagnosis"

13.05 – 14.00 Lunch

2 ISOCS-MiNaB-ICT-MNBS (Otranto, 25-29 June 2016)

14.00 – 15.00 Session 3 - Poster session (5 minutes pitch) and exhibition (Moderator: L. Francioso)

Authors Poster title

P1 A. Leone, G. Rescio, P. Siciliano A low power and open platform for healthcare applications through nfc technology

P2 A. Zacheo, A. Quarta, F. Limana, M. De Luca,C. Bucci, G. Gigli, Lipid-based vesicles for biomolecules delivery

P3 A. Zizzari, M. Bianco, L. Laureana del Mercato, M. Carraro, M. Cesaria, R. Rella, M. Bonchio, R. Rinaldi, I. Viola, V. Arima, Microfluidics and self-propelling catalytic systems

P4 M. Bianco, V. Arima Quartz crystal microbalance: label-free and real-time monitoring for biosensing

applications
P5 A. Gaiardo, P. Bellutti, M. Crivellari, V. Guidi On the optimization of mems device for chemoresistive gas sensors
P6 S. De Vito, E. Esposito, M. Salvato Comparing machine learning architectures for mobile air quality multisensory devices calibration
P7 L. Velardi, A. Valentini, G. Cicala, Effect of rich-diamond and rich-graphite nanodiamond layers on the efficiency of photocathodes
P8 G. V. Bianco, M. M. Giangregorio, M. Losurdo, P. Capezzuto, G. Bruno
Graphene with engineered properties for vapor sensing
P9 F. Rossia, F. Micheletti, R. Pini, R. Piazza, V. Ferrari, S. Condino
In-situ laser fenestration of endovascular stent-graft in abdonimal aortic aneurism repair (EVAR)
P10 S. Rizzato, E. Primiceri, M. S. Chiriacò, Anna G. Monteduro, V. Tasco, A. Passaseo, A. Colombelli, M. G. Manera, R. Rella, G. Maruccio Advancing lab-on-chip performance by innovative sensing strategies
P11 D. Sancarlo , A. Matera , G. D'Onofrio , A. M. Mariani , D. Ladisa , E. Annese , F. Giuliani , F. Ricciardi , A. Greco
Remote monitoring of subjects affected by metabolic diseases: the metabolink project.
P12 D. Sofia, A. Giuliano, D. Barletta, M. Poletto High resolution monitoring of dusts emission near power plants

15.00 – 16.40 Session 4 - Enabling health and AAL applications (Chair: R. Guenzler)
15.00-15.20
Keynote 1
J. van den Eijnden-van Raaij (hDMT), "Organ on chip"
15.20-15.40
Keynote 2
F. Cavallo, "Service robotics design for assisted living applications in the robotics innovation facility (RIF)"
15.40-15.55 F. Rossi, G. Magni, R. Pini, L. Menabuoni, F. Leoni, B. Magnani, "Laser assisted robotic surgery in cornea transplantation"
15.55-16.10 A. Leone, L. Francioso, A. Caroppo, G. Rescio, C. De Pascali, G. Diraco, "Integrated sensors platform for critical events detection of elderly people"
16.10-16.25 M. Cavone, M. Di Ciano , G. Grasso, D. Morgese, "Between prometheus and hermes: designing the next medicine in Apulia region"
16.25-16.40 D. Sancarlo, G. D'Onofrio, F. Ricciardi, F. Giuliani, A. Greco, "Managing active and healthy aging with use of caring service robots (MARIO)"
16.40 – 17.00 Coffee break

17.00 – 18.30 Session 5 – Technology transfer & end-user issues (Chairs: A. Lymberis, P. Siciliano)
Speakers to address key horizontal MNBS issues e.g. users' needs, technology assessment, standards, interoperability, manufacturing, costs, market and real life implementation.
17.00-17.30
Hans Peter Dauben, DAHTA - German Agency for Health Technology Assessment, Lifecycle and appropriate use of medical technologies
17.30-17.45
Antonio Arnau Vives, AWSensors, Technology Transfer: experiences and lessons learned
17.45-18.00
Henk Leeuwis, Lionix BV, How to facilitate the commercialisation of LoC?
18.00-18.15
Milena Sinigaglia, DAREPuglia District, Agri-farming end-users needs
18.15-18.30 Discussion

TUESDAY JUNE 28TH
9.00 – 9.30 Plenary Session
C. Cobelli, University of Padova – Artificial Pancreas: Models, Signals, Control and Clinical Results
09.30 – 11.20 Session 6 - Smart Sensors I (Chair: J. Gardner)
9.30-9.50
Keynote
C. Cane , S. Vallejos, E. Figueras, I. Gràcia, "Direct integration of gas sensitive nanostructures into microdevices using aerosol assisted chemical vapor deposition: processing and gas sensing performance"
09.50-10.05 L. Cavanini, L. Ciabattoni, F. Ferracuti, A. Freddi, S. Longhi, A. Monteriù, M. Prist, L. Trollini, "A co-simulation module for cyber-physical automation system"
10.05-10.20 B. Andò, S. Baglio, V. Marletta, "A inertial microsensors based wearable solution for the assessment of postural instability"
10.20-10.35 T. Chalyan, L. Pasquardini, F. H. Falke, E. Schreuder, C. Pederzolli, R. G. Heideman, L. Pavesi, "Aflatoxin m1 sensors based on asymmetric mach-zehnder interferometers"
10.35-10.50 V. Donzella, G. Dhadyalla, P. Jennings, "High sensitivity integrated optical sensors to reduce automotive greenhouse emission"
4 10.50-11.05 M. F. Santangelo, E. L. Sciuto, S. A. Lombardo, A. C. Busacca, S. Petralia, S. Conoci, S. Libertino, "Bioluminescence detection system based on silicon photomultiplier"
11.05-11.20 W. Messina, N. T. P. Savage, M. Fitzgeralda, L. O'Regan, S. Carey, C. Kennedy, M. W. Bennett, B. D. O'Donnell, M. J. O'Sullivan, E. J. Moore, "Gold impedance microelectrodes fabrication on a silicon probe for breast cancer detection"
11.20 – 11.40 Coffee break
11.40 – 13.25 Session 7 - Project innovation session: MNBS enabling smart agriculture, food, environnement & PoC (Chair: A. Lymberis)
11.40-11.55 H. Leeuwis, I. Zergioti, "BIOFOS- Micro-Ring Resonator-Based Biophotonic System For Food Analysis"
11.55-12.10 L. Lorenzelli, "SYMPHONY- integrated system based on photonic microresonators and microfluidic components for rapid detection of toxins in milk and dairy products"
12.10-12.25 N. Giunta, "PROTEUS- adaptive microfluidic- and nano-enabled smart systems for water quality sensing"
12.25-12.40 E. Gizeli, "LOVEFOOD2MARKET- a portable micronanobiosystem and instrument for ultra-fast analysis of pathogens in food: innovation from love-food lab prototype to a pre-commercial instrument"
12.40-12.55 T. Bastuck,"ML2- scaling the complexity of technological platforms for a fast route to exploitation"
12.55-13.10 L. Lorenzelli, "SOCKETMASTER- development of a master socket for optimized design of prosthetic socket for lower limb amputees"
13.10-13.25 F. Adrover, "SNIFFPHONE- smart phone for disease detection from exhaled breath"
13.25 – 14.20 Lunch
14.20 – 15.00 Session 8 - Poster session (5 minutes pitch) and exhibition
(Moderator: L. Francioso)
Authors Poster title
P13 V. Varlamava, G. De Amicis, A. Del Monte, R. Rao, F. Palma Developments of the pinned photodiode terahertz rectifier
P14 S. Velappa Jayaraman, G. Magna, A. Mencattini, M. Luce, A. Cricenti, E. Martinelli, C. Di Natale Classification of afm images by means of an unsupervised feature extraction and immune network model
P15 J. Díaz, E. Gizeli, L. Francis, R. Miñambres,
M.J. Serrano, R. Fernández and A. Arnau Vives.
Liqbiopsens- reliable novel liquid biopsy technology for early detection and monitoring

of colorectal cancer
P16 P. Casacci, M. Pistoia Remote circadian rhythm monitoring in
alzheimer-affected people: a telehealth experience
5 P17 S. Capone, M. Tufariello, A. Forleo, F. Casino, P. Siciliano
Analyzing exhaled breath by a modified gc
with dual detectors [ms+sensors]
P18 L. Lorenzelli, A. Adami SYMPHONY project: microfluidics and
photonic sensors for milk analysis
P19 A. Caroppo, A. Leone, P. Siciliano ICT platform for cognitive stimulation in
Alzheimer's disease patients
P20 M. A. Signore, A. Taurino, C. De Pascali, I.
Farella, F. Quaranta, L. Francioso, A. Campa,
M. Masieri, M. C. Martucci, P. Siciliano
Sputtering deposition and characterization of
AlN thin films for piezoelectric devices
15.00 – 16.00 Session 9 - Projects innovation session: smart living technologies (Chair: C. Cané)
15.00-15.15 P. Siciliano, "The Cluster on Smart Living Technologies"
15.15-15.30 F. Piazza, "SHELL - Shared interoperable Home Ecosystems for a green,
comfortabLe and safe Living"
15.30-15.45 G. Borrelli, "Active Ageing @ Home"
15.45-16.00 M. Sacco, "Design for All - SW Interoperability and advance Human Machine
Interfaces in design for Ambient Assisted Living"
16.00 – 16.15 Coffee break
16.15 – 18.00 Session 10 - Panel discussion: future challenges and opportunities of MNBS and
smart world Items to be discussed
EC initiatives, Open calls related to MNBS and Smart World, National and Regional
initiatives, etc.
Moderator: P. Siciliano
Panel
Speakers
A. Lymberis, EU Commission N. Kattavenos, EU Commission
EC funding opportunities and Future Directions in H2020
R. Guenzler, Hahn-Schickard, Germany
"EPoSS activities in MNBS" & "The SmartAnythingEveryhere initiative"
A. Agrimi, Director of Research & Innovation Service at Puglia Region "Smart Puglia 2020" Francesca
Rossi, "The Photonics Public Private Partnership & Photonics21 Work Group
3 Life Sciences & Health"
Discussants A. Lionetto, ST Microelectronics M. Conti, Director of ICT Department CNR
S. Longhi, Rector of Polytechnic University of Marche
J. Gardner, ISOCS
F. Rossi, IFAC CNR C. Cané, CNM-CSIC
20.00 – Social Dinner

WEDNESDAY JUNE 29TH
9.00 – 9.30 Plenary Session (Chair: TBA)
A. Lionetto, ST Microelectronics - 2020 Vision leading technological innovation
09.30 – 10.50 Session 11 - Smart Sensors II (Chair: L. Francioso)
09.30-09.50
Keynote
J. Gardner, University of Warwick, "Low cost CMOS thermopile for gesture
detection"
09.50-10.05 A. Aliberti, A. Ricciardi, M. Giaquinto, A. Micco, M. Ruvo, A. Cutolo, A. Cusano,

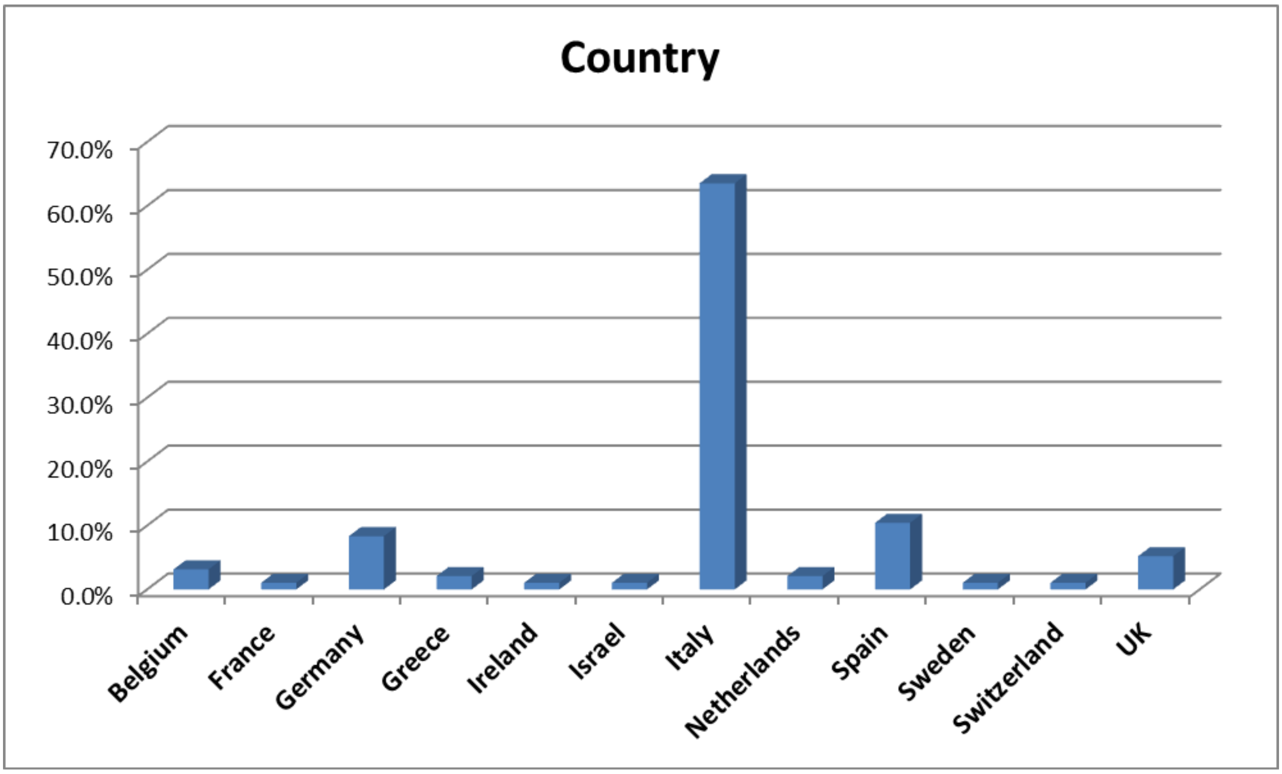
“Microgels as functional material for advanced label free fiber optic nanoprobes”
10.05-10.20 J. Burgues, J.M. Jiménez-Soto, S. Marco, “Estimation of the limit of detection in temperature modulated mox sensors”
10.20-10.35 A. Staerz, M. Epifani, N. Barsan, U. Weimar, P. Siciliano, “Surface reactions effect on selectivity of wo3 based sensors”
10.35-10.50 L. De Stefano, J. Politi, M. Terracciano, A. Di Matteo, I. Rea, P. Dardano, “Hybrid microneedle arrays for biosensing and drug delivery”
10.50 – 11.05 Coffee break
11.05 – 12.25 Session 12 - Materials and technologies (Chair: S. Iannotta)
11.05-11.25
Keynote
S. Iannotta, “Bioelectronics based on organic electrochemical sensing and memrisistive devices: a promising novel perspective for neuromorphic and biocompatible systems”
11.25-11.40 L. Francioso, C. De Pascali, A. Grazioli, V. Sglavo, S. D’Amico, M. Pasca, C. Veri, P. Siciliano, “Heatsink-free wearable thermoelectric generator with a fully electrical high efficiency DC-DC converter”
11.40-11.55 P. Vazquez, A. Sheehy, L. Smith, Eric Moore, “Carbonanotube modification of microreference electrode for improved stability of potential”
11.55-12.10 P. A. Benedetti, “The video-confocal method in 3d optical nanoscopy”
12.10-12.25 R. Capuano, A. C. Domakoski, E. Martinelli, A. Bergamini, R. Paolesse, C. Di Natale, “Diagnosis of arthritic diseases by electronic nose analysis of synovial fluid”
12.25 – 13.00 Conclusions
13.00 – 14.00 Lunch

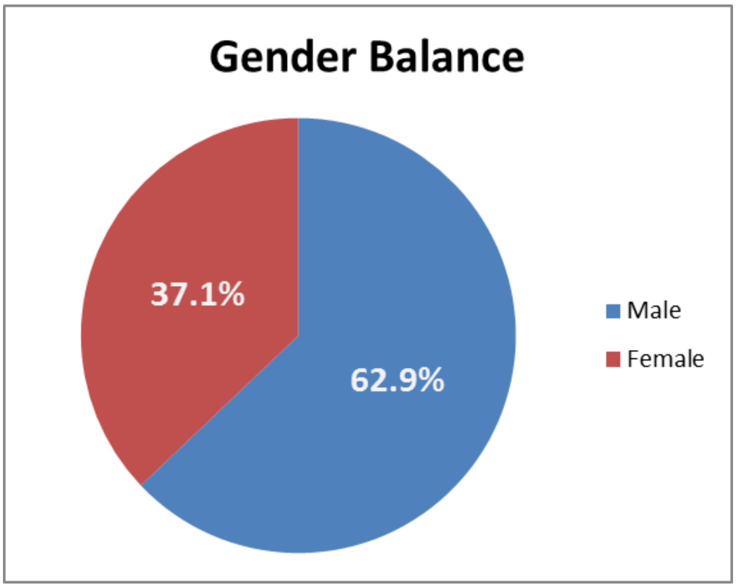
Appendix 2- Summary overview of participants

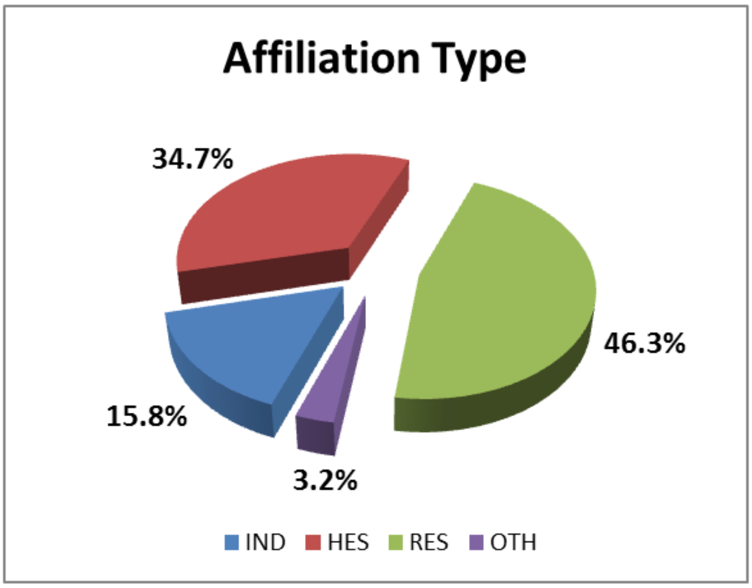
Gender	Total	Percentage
Male	61	62.9%
Female	36	37.1%

Type	Total	Percentage
IND	15	15.8%
HES	33	34.7%
RES	44	46.3%
OTH	3	3.2%

Country	Total	Percentage
Belgium	3	3.1%
France	1	1.0%
Germany	8	8.3%
Greece	2	2.1%
Ireland	1	1.0%
Israel	1	1.0%
Italy	61	63.5%
Netherlands	2	2.1%
Spain	10	10.4%
Sweden	1	1.0%
Switzerland	1	1.0%
UK	5	5.2%




Gender Balance
37.1%
62.9%
Male
Female


Affiliation Type
34.7%
46.3%
15.8%
3.2%
IND
HES
RES
OTH

Appendix 3 - TRL and MRL level description

TRL Description

Level 1 - Basic Research: basic principles are observed and reported
Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include fundamental investigations and paper studies.
Level 2 – Applied Research: technology concept and/or application formulated
Once basic principles are observed, practical applications can be formulated. Examples are limited to analytic studies and experimentation.
Level 3 – Critical function, proof of concept established
Active research and development is initiated. Laboratory studies aim to validate analytical predictions of separate components of the technology. Examples include components that are not yet integrated or representative.
Level 4 – Laboratory testing of prototype component or process
Design, development and lab testing of technological components are performed. Here, basic technological components are integrated to establish that they will work together. This is a relatively "low fidelity" prototype in comparison with the eventual system.
Level 5 – Laboratory testing of integrated system
The basic technological components are integrated together with realistic supporting elements to be tested in a simulated environment. This is a "high fidelity" prototype compared to the eventual system.
Level 6 – Prototype system verified
The prototype, which is well beyond that of level 5, is tested in a relevant environment. The system or process demonstration is carried out in an operational environment.
Level 7 – Integrated pilot system demonstrated
Prototype is near, or at, planned operational system level. The final design is virtually complete. The goal of this stage is to remove engineering and manufacturing risk.
Level 8 – System incorporated in commercial design
Technology has been proven to work in its final form under the expected conditions. In most of the cases, this level represents the end of true system development.
Level 9 – System ready for full scale deployment
Here, the technology in its final form is ready for commercial deployment.
Level beyond 9 - Market introduction
The product, process or service is launched commercially, marketed to and adopted by a group of customers (including public authorities).

MRL Description

MRL 1: Basic Manufacturing Implications Identified
This is the lowest level of manufacturing readiness. The focus is to address manufacturing shortfalls and opportunities needed to achieve program objectives. Basic research (i.e., funded by budget activity) begins in the form of studies.
MRL 2: Manufacturing Concepts Identified
This level is characterized by describing the application of new manufacturing concepts. Applied research translates basic research into solutions for broadly defined military needs. Typically this level of readiness includes identification, paper studies and analysis of material and process approaches. An understanding of manufacturing feasibility and risk is emerging.
MRL 3: Manufacturing Proof of Concept Developed
This level begins the validation of the manufacturing concepts through analytical or laboratory experiments. This level of readiness is typical of technologies in Applied Research and Advanced Development. Materials and/or processes have been characterized for manufacturability and availability but further evaluation and demonstration is required. Experimental hardware models have

been developed in a laboratory environment that may possess limited functionality.

MRL 4: Capability to produce the technology in a laboratory environment

Required investments, such as manufacturing technology development identified. Processes to ensure manufacturability, producibility and quality are in place and are sufficient to produce technology demonstrators. Manufacturing risks identified for prototype build. Manufacturing cost drivers identified. Producibility assessments of design concepts have been completed. Key design performance parameters identified. Special needs identified for tooling, facilities, material handling and skills.

MRL 5: Capability to produce prototype components in a production relevant environment

Manufacturing strategy refined and integrated with Risk Management Plan. Identification of enabling/critical technologies and components is complete. Prototype materials, tooling and test equipment, as well as personnel skills, have been demonstrated on components in a production relevant environment, but many manufacturing processes and procedures are still in development. Manufacturing technology development efforts initiated or ongoing. Producibility assessments of key technologies and components ongoing. Cost model based upon detailed end-to-end value stream map.

MRL 6: Capability to produce a prototype system or subsystem in a production relevant environment

Initial manufacturing approach developed. Majority of manufacturing processes have been defined and characterized, but there are still significant engineering/design changes. Preliminary design of critical components completed. Producibility assessments of key technologies complete. Prototype materials, tooling and test equipment, as well as personnel skills have been demonstrated on subsystems/ systems in a production relevant environment. Detailed cost analysis include design trades. Cost targets allocated. Producibility considerations shape system development plans. Long lead and key supply chain elements identified. Industrial Capabilities Assessment for Milestone B completed.

MRL 7: Capability to produce systems, subsystems, or components in a production representative environment

Detailed design is underway. Material specifications are approved. Materials available to meet planned pilot line build schedule. Manufacturing processes and procedures demonstrated in a production representative environment. Detailed producibility trade studies and risk assessments underway. Cost models updated with detailed designs, rolled up to system level and tracked against targets. Unit cost reduction efforts underway. Supply chain and supplier Quality Assurance assessed. Long lead procurement plans in place. Production tooling and test equipment design and development initiated.

MRL 8: Pilot line capability demonstrated; Ready to begin Low Rate Initial Production

Detailed system design essentially complete and sufficiently stable to enter low rate production. All materials are available to meet planned low rate production schedule. Manufacturing and quality processes and procedures proven in a pilot line environment, under control and ready for low rate production. Known producibility risks pose no significant risk for low rate production. Engineering cost model driven by detailed design and validated. Supply chain established and stable. Industrial Capabilities Assessment for Milestone C completed.

MRL 9: Low rate production demonstrated; Capability in place to begin Full Rate Production

Major system design features are stable and proven in test and evaluation. Materials are available to meet planned rate production schedules. Manufacturing processes and procedures are established and controlled to three-sigma or some other appropriate quality level to meet design key characteristic tolerances in a low rate production environment. Production risk monitoring ongoing. LRIP cost goals met, learning curve validated. Actual cost model developed for Full Rate Production environment, with impact of Continuous improvement.

MRL 10: Full Rate Production demonstrated and lean production practices in place

This is the highest level of production readiness. Engineering/design changes are few and generally limited to quality and cost improvements. System, components or items are in rate production and meet all engineering, performance, quality and reliability requirements. All materials, manufacturing processes and procedures, inspection and test equipment are in production and controlled to six-sigma or some other appropriate quality level. Full Rate Production unit cost meets goal, and funding is sufficient for production at required rates. Lean practices well established and continuous process improvements ongoing.

The long term market trends and unmet needs are:

Agriculture markets

- rapid monitoring of crop status, environmental and soil conditions
- compliance with agricultural regulations with respect to crops and inputs
- support for land management e.g. soil conditions
- storage and barn condition management
- feedback and optimization to reduce production costs
- support for “farm to fork” management of crops

Food Processing Markets

- input monitoring and control
- process management and control
- identification of spoilage and contamination
- quality and storage life monitoring during warehousing
- evidence for consumers of origin, quality and shelf life status
- process optimization, waste reduction and cost effectiveness

Environmental markets

- water catchment management
- drinking and waste water management at reduced cost
- continuous monitoring of water quality
- detection of contamination; microbial and pollutants
- rapid detection of sources of contamination at low cost
- rapid and dynamic air quality measurement

Healthcare markets

- the growing elderly population in Europe
- long term or chronic conditions in the elderly
- monitoring and maintenance in the home is widely seen as desirable
- demand for systems, not just devices and sensors.
- clear case for major cost reduction
- high quality healthcare delivery within strict financial constraints
- solutions that fit seamlessly into daily life and that are unobtrusive

Veterinary market

- combat new threats created by climate change
- rapid identification and monitoring of disease threats
- testing at the farm or animal unit (POC)
- support “farm to fork” management of stock
- support for zoonotic disease control legislation

STAKEHOLDERS

Market development and product commercialization relies on clear identification of and engagement with all relevant stakeholders. By sector these are seen as:

Agriculture

- Farmers
- Framing Co-operatives
- Farm owners
- Farming associations e.g. olive growers
- Government bodies under Ministries of Agriculture (legislators & regulators)
- Product purchasers (processors, wholesalers, supermarkets consumers)
- Farm advisors and other service providers
- Agricultural hauliers

Food

- Food processing companies
- Food wholesalers
- Trade associations in the food sector
- Supermarkets and other retailers
- Government regulators (food standards)
- Transport companies
- Food product support companies (coatings, additives)
- Nutritionists (both production and regulatory sides)

Environment

- Water companies
- Local, regional and national Government bodies
- Service suppliers to the water sector (testing labs)
- Land owners within a catchment
- Water users (industry and the public)

Healthcare

- Doctors and other healthcare professionals
- Patients, broadly defines to include the elderly and "worried well"
- Hospitals, clinics and other service providers
- Government, legislators, regulators at local, regional & national levels
- Insurance companies
- The healthcare industries (devices, diagnostics, pharmaceuticals & medical supplies).
- Ex-clinic support (care homes, specific support services etc.)
- Families and carers

Veterinary medicine

- Vets and other animal health professionals
- Government, legislators, regulators at local, regional & national levels
- Insurance companies
- The veterinary industries (devices, diagnostics, pharmaceuticals & medical supplies)
- Farmers and farming businesses
- Owners of companion animals

Route to market

The route to market requires a credible plan which can address a range of critical issues;

- Credible evidence of quality
- Stake holder engagement
- Commercial support
- Financial resources, or route thereto
- Infrastructure to implement technically
- Infrastructure to market and sell products
- Communications to support marketing activity
- Appropriate staff, networks and contacts
- A compelling cost-benefit case