ESI Funds for health

Building knowledge & capacities

Workshop Report

‘Research and Innovation in health’
20-21 June 2018
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Introduction

The fourth event from the series of six workshops organised within the 'ESI Funds for Health' project took place on 20-21 June 2018 in Breda, the Netherlands and covered the topic of 'Research and Innovation in health and the life sciences' (i.e. thematic block 4 of the project). It was organised in cooperation with the partners of the i-4-1-health project funded by the Regional Cooperation (Interreg) program of Flanders-the Netherlands, which served as the 'host' project for the event. Four members from the 'ESI Funds for Health' project attended the event (Matthew Jones, Agnieszka Markowska and Rosa Castro from Milieu and Joanna Lane from the partner Health ClusterNet) together with two representatives of DG SANTE (Katarzyna Kielar-Kowalczyk and Louikianos Gatsoulis), one representative of DG RESEARCH and one representative of the Joint Research Centre (Nida Kamil Ozbolat). Professor Jan Kluytmans and Ina Willemsen (Amphia Hospital) also participated and spoke on behalf of the i-4-1-health consortium and presented the project to the audience.

The event spanned over two days and included a smaller peer review around the host project (Day 1) and a larger thematic workshop (Day 2). The peer review took place on the premises of the Amphia Hospital and had 14 core participants from seven Member States (not including the European Commission, Milieu and partners). The core participants included three main contact points and coordinators of the host project (Interreg BE-NL) and representatives of five other Member States (Belgium, Czech Republic, Denmark, Italy, Romania) coming academia and research institutions, healthcare institutions, a regional managing authority and a Ministry of Health. Most participants are implementing ESI funded projects with a health-related R&I goal.

The thematic workshop took place at a different, larger venue and had 38 participants (not including 3 participants from the European Commission, 3 participants from Milieu and 1 participants from the partner Health Cluster Net. The participants at the thematic workshop had different backgrounds and varying experience with the ESIF and came from fifteen different Member States. There were participants who attended the peer review and also other representatives of academic institutions, professional associations, Managing Authorities, the health industry and NGOs. A full list of participants who attended the events is contained in Annex 3.

Key messages from the event

Based on the presentations and discussions, the following are the key messages stemming from the two-day event:

- Research and Innovation in the health area is usually a complex and long endeavour. This is also due to heavier legal, ethical and regulatory requirements than any other innovation area and has an important impact in the way funding should be planned and accessed. As a consequence, the sustainability of projects poses critical questions for this thematic block.
- Hence, it is important that research projects understand the available funding sources and how ESIF can produce better results when combined with other funding sources. The need to enhance and facilitate synergies between ESIF and other research funds has been thoroughly examined in several documents and guidelines (e.g. in the document "Enabling synergies between European Structural and Investment Funds, Horizon 2020 and other research, innovation and competitiveness-related Union programs, Guidance for policy-makers and implementing bodies", 2014).
- Under this theme, ESIF can support R&I projects related to health in different phases of the R&I process. Many projects in this theme focused on developing new products or processes in the

health sector. For these types of projects, the long and costly development timeframe poses a particular challenge.

- The question of which phases in the R&D timeline are ESIF supporting and which phases they should support was discussed. The possibilities are various, and this remains an open question for debate.

Lessons for future events/projects

This was the fourth of the six events, so sufficient experience had been learned previous to this workshop. However, due to the topic of this workshop, there were some specific lessons that could be useful for other events, especially the e-health workshop planned to take place on September in Budapest. Useful lessons to consider in the next workshops include:

- Consider the audience of each event. For this workshop, most project beneficiaries were research institutes, healthcare organisations and private companies. This posed problems with attracting a larger number of representatives from Ministries of Health in different Member States, but it also created opportunities for fostering dialogue between public authorities, research organisations and private companies.
- Allow more time for discussions in smaller groups. The feedback received from many participants is that they particularly enjoyed the breakout sessions and the opportunity to interact with other peers and with other people having a different perspective on the topic. Breakout sessions where all participants are divided into smaller groups of 10-15 are a good way to discuss the key questions and ensure all participants share their views but according to the feedback received, it would be important to consider that for future events, these sessions could either be longer, or more than one breakout session could be organised during the day.

Main findings and conclusions

Overview of findings from the desk research and expectations for the event

R&I in health and the life sciences counts for a large number of the projects mapped during the 2017 research on ESIF projects across the EU-28 (1435 projects out of a total of 6414 projects representing approximately 22% of all projects. The total budget of all R&I projects is nearly EUR 1.2 billion, around 20% of the all health-relevant projects so far; and the average project budget is very high (around EUR 2.5 million compared to the average project size of around EUR 1.1 million). The Interreg programmes have the largest spending on this theme, followed by Hungary, Poland, the UK, Portugal and Belgium.

Most projects are supporting the development of innovative products and processes, while projects supporting research infrastructure, changing care models and clinic-industry collaboration were less numerous.

Projects in this theme were funded in 19 Member States. While over half of these projects (57%) are from Italy, most Italian projects had incomplete information and a rather small budget. After Italy, the countries with the largest number of projects are Portugal, the three Interreg cooperation programs and Poland. No projects supporting this theme were found in Austria, Cyprus, Croatia, Ireland, Luxembourg, Slovenia and Slovakia. Figure 1 below presents the total allocation for this theme per country.

The workshop therefore sought to understand better how key projects supporting research and innovation in health were planned and conceived, namely:

- Which thematic objectives, investment priorities and strategic objectives from the relevant Operational Programmes are addressed through research and innovation projects reviewed at the workshop? What is the rationale behind this? Are there other ways in which these kinds of projects could be designed and supported within the ESIF planning and spending mechanism?
- Which institutions are involved in identifying and developing research and innovation projects?
- How are the projects reflecting national and regional-level strategic approaches to addressing health challenges? What is the role of regional smart specialisation strategies with regard to R&I priorities and opportunities?
- For large projects in various phases of research and development, how are these projects designed? What are the key challenges and success factors?
- Are there other important factors that have not yet been picked up by the ESI funds for health project that should be included in the final report on the R&I theme?
- What can be done in the current and upcoming MFF to ensure key R&I in health priorities are supported by the ESI funds?

The answers to these questions, as well as other key issues that emerged during the discussion are considered critical for the project final report, which aims to draw conclusions about the extent to which current ESIF spending in the area of health supports strategic policy goals, as well as learn lessons about how projects are designed and implemented and draw conclusions and recommendations for how spending can be improved in the area of health.

Key conclusions from the peer review/Day 1

- ESI funds have been instrumental in allowing R&I projects to take place and have enabled cross-border cooperation that would not have happened otherwise.
- The intersection between research and business is sometimes problematic. Private companies are concerned about: (1) intellectual property rights to the outcome of research after the project in order to commercialise it; (2) investing with the risk of no return on their investment; and (3) often focus on a short-term exit strategy rather than long-term progression of an idea. Large research projects with diverse partners participating, each one having different incentives, mindsets and regulations to comply with, are often difficult to be launched and implemented.
- SMEs often have low incentives to participate in these research and innovation projects or it can be difficult to bring them to a project due to regulatory hurdles regarding access to public funding.
- Most of the project leaders have a research background, and some participants feel that the administrative burden is too heavy for them to spend enough time advancing with their project. However, the extent of administrative burden can vary significantly depending on the managing authority.
- Information about other projects doing similar things is desirable but not necessarily easy to access. Participants proposed that the European Commission could create or help create an easily accessible database of projects funded by ESI.
- There is uncertainty about how to combine ESIF funds with H2020 funds. H2020 funds seem out of reach for some participants.

Representatives of projects funded in (countries and Interreg) presented their R&I projects:

- Some of the projects presented are addressing and developing innovative solutions to tackle different health-related challenges (e.g. antimicrobial resistance, early diagnosis of breast cancer, osteoporosis and bone-fractures, rehabilitation of elderly population or patients that have suffered a stroke).
- Other projects presented innovative ways of pulling together financial and human resources to enhance R&I activities related to health in a broader way. For instance, some projects consisted in platforms to allow drug discovery, a network for biomedical research and a research centre specializing in toxic effects of pollutants for human health.

Key conclusions from the thematic workshop/Day 2

The thematic workshop had two main parts:

1. Navigating access to EU funding for research and innovation in health: The first part of the workshop featured presentations from representatives of the European Commission's Joint Research Centre, DG RTD and DG SANTE. The presentations discussed how synergies between ESIF and H2020 could be used strategically, and ways that the private sector could be involved with projects.
2. Experience working with ESIF-funded projects – this second part gave participants opportunity to exchange experiences, share good practice and common challenges. It featured a presentation from the Contractors about their work on ESIF health projects, short presentations by the projects that participated in the peer review, and a break out session where all participants were encouraged to share and discuss their experience.

With its wider audience compared to the peer review, the workshop took a broader approach to the use of ESIF funds in R&I projects, looking at strategic opportunities for using the funds and for accessing the Horizon 2020 research funds. The key discussion points during the workshop can be divided into two main thematic categories:

- Strategic use of funds
  - Synergies between ESIF and H2020 funding;
  - Bidding strategies for H2020 funding;
  - Smart specialisation at regional and national level – challenges and opportunities.
- Management of ESIF-funded R&I projects
  - Process from concept to research to commercialisation
  - Involvement of private investment in ESIF-funded research health projects
  - Balancing administrative responsibilities and research efficiency

Key conclusions

- Enabling synergies between ESIF and other funds for R&I, especially H2020 is a key question for this theme, but one that remains open in practice. Within this question, the problem of how to succeed in competitive H2020 calls was thoroughly discussed and participants agreed that there are obstacles impeding the full realisation of synergies between ESIF and H2020 but also successful initiatives such as the Stairway to Excellence programme presented by a representative of the JRC. Participants were interested in knowing more about related funding opportunities and take advantage of synergies in the use of different EU, national and regional funding.
- The role of smart specialisation strategies was discussed, and several participants shared their experiences. In general, participants felt that smart specialisation strategies had a limited role in helping steer or plan investments in R&I in several regions/countries. This was the case when the strategies were limited to mention all or most sectors, without developing a strategy or emphasis in particular areas.
- Many project beneficiaries shared their experiences and challenges in managing projects in terms of human resources, administrative burdens, etc, and how these challenges impact their research activities.
- The issue of dealing with the lengthy and costly process to bring innovations to the market was also discussed. One of the main obstacles for projects was the difficulty of collaborating with SMEs and business given the different incentives that different parties in a consortium usually have. For instance, issues related to access to the results of research and intellectual property rights for different stakeholders and partners in ESI funded projects seems to be an important issue for many projects.

The spending trends identified during the desk research and the peer review indicate that at the moment the ESIF are primarily used to fund R&I projects focusing on developing innovative products and processes at different phases of research and development (and with different technology readiness levels (TRLs) as mentioned by several participants.

Nonetheless, and as shown by the projects presented during the workshop, there is also an important number of projects, with larger budges overall, which focus on supporting research infrastructure, changing care models and clinic-industry.

Discussions during the workshop served to corroborate the importance of ensuring the sustainability of long and costly R&I projects and for this purpose, the possibility of enabling synergies with other EU (e.g. H2020 and others), national and regional funding was also identified as a recurrent concern for project beneficiaries and authorities.
As one of the challenges that ESI Funds seeks to address is to bridge the gaps between regions lagging behind in terms of R&I capabilities, enabling synergies between ESI Funds and H2020, including by using ESI Funds to allow projects to reach the maturity needed to apply for H2020 was highlighted as a priority.

While the development of a Research and Innovation Strategy for Smart Specialisation (RIS3) is a prerequisite to access ESI Funds, discussions during the workshop evidenced that the potential of RIS3 to foster their competitive strength, and to enable them to contribute to main societal challenges still needs to be further developed.

Last but not least the programming of ESIF and the design of concrete projects that will be funded should be inclusive and involved relevant stakeholders. Particularly important to consult and involve are SMEs and patients that might collaborate in projects, including those that need the participation of patients in trials. Several administrative challenges also seemed to be obstacles to more collaborative projects with the participation of SMEs.

Annex 1: Peer review presentation and discussion summaries (Day 1)

The peer review was built around presentations by representatives from ESI-funded projects from different Member States. Participants introduced the objectives and structure of their projects as well as the challenges that they faced. The discussion allowed participants to talk further about their experiences, shared difficulties and ideas for best practice. The day was divided into two by a tour of the innovations implemented by the host project 'i-4-1-health' in Amphia Hospital.

Presentations

Presentation: 'Presentation of the project 'i-4-1 health' by Professor Jan Kluytmans, Amphia Hospital, Breda

- Prof Kluytmans started his presentation by describing the problem of antibiotic resistance. He explained how this emerging problem must be addressed with a one-health approach, meaning that solutions must consider how the problem is present within healthcare, community care (e.g. nursing homes) and animal farms.
- Prof Kluytmans also explained how the problem of antibiotic resistance is featuring at a very high level within global (e.g. UN and WHO), European and national policy. Antibiotic resistance has received increased attention at all these levels, and some countries are particularly affected by this (e.g. African and Asian countries and Italy and Greece within the EU).
- When introducing the i-4-1 health project, Prof Kluytmans explained that this cross-border cooperation funded by the Interreg Flanders-Netherlands programme is approaching the problem of antibiotic resistance through a one-health approach. The name of the project stems from 4 "i"s: innovation, integration, intelligence and "iris" (which is the measurement process developed by the project. This large cooperation using a one-health approach was possible due to the involvement of human healthcare and animal healthcare institutions, universities, high schools and some companies in both sides of the BE-NL border.
- The project aims at measuring the problem of antibiotic resistance in Belgium and the Netherlands, also taking into account that resistance is more spread in Belgium than in the Netherlands and that antibiotics are more frequently used in Belgium due to a number of factors.
- Prof Kluytmans explained that while the problem of antibiotic resistance is usually more evident at the level of healthcare, given that patients can be more easily diagnosed and resistant bacteria more easily identified, this is only the tip of the iceberg; antibiotic resistance is present at higher levels in the general population, including in homecare and nursing homes and within livestock activities.
- The i-4-1 project developed a system called "iris" (Infection Risk Scan), which along with a whole genome sequence to track the spread of resistant bacteria, allows to measure the phenomenon of antibiotic resistance by using uniform, objective and relevant measures. The next step in the project is the development of an app to facilitate measurements by the relevant iris experts and to send data about those measurements.
- When talking about the experience in implementing the project, Prof Kluytmans mentioned that inter-sectoral collaboration is very fruitful but also very complicated to navigate. Involving different stakeholders in the project has been key to its success but it has also been a difficult part of the work. Other important hurdles experienced during the project related to regulatory requirements needed to undertake health studies (e.g. approval by Institutional Review Boards for ethical and privacy concerns). While clinical practices would not require approval by an IRB, research studies need this approval to be able to publish their results and this further complicates

these types of projects. As a consequence, clinical trials tend to be organised almost exclusively by pharmaceutical companies -given the hurdles that other actors would have to overcome.

Presentation: Health-i-care (Interreg, DE, NL) by Dr Corinna Glasner, Health-i-care

- Dr Glasner began her presentation by describing the aim of the Interreg programme to be a source of cross-border integration and balanced development, and by touching on the differences and similarities between Dutch and German health systems and the challenges and opportunities that this could bring.
- Introducing the Health-i-care project, she said that anti-microbial resistance was rising in her region and that it was necessary to act now. The project aims to strengthen innovation in the border region between the Netherlands and Germany in order to encourage the development of technologies that can protect the population from anti-microbial resistance. It acts through education, screening and surveillance, competence-building and research and innovation.
- The Health-i-care project is based on a three-point system of science, health and business. This combines the strengths of these different sectors to ensure that there is a market for the research that is being done. It is essentially a consortium led by business but with science and health partners.
- Taking a concrete example of an innovative use of technology, Dr Glasner described a project to increase awareness of bacteria among children through developing soap dispensers for schools that are appealing and educational, and which can measure the frequency that they are used.
- Regarding the functioning of the project, Dr Glasner said that at times the difference in mind-set between research and business could be a challenge, and that the ideal situation was when SMEs involved in the project had a scientist in the department, because this helped to improve understanding.
- Asked by another participant why businesses were willing to spend time on this, Dr Glasner said that the project offered businesses access to a network of science and health partners that they needed to create products and make money.

Presentation: BONE: Bio-Fabrication of Orthopedics in a New Era (Interreg FR-CH) by Lorenzo Moroni, Maastricht University

- Mr Moroni began by introducing the BONE project. Backed the Institute for technology-inspired regenerative medicine (Merlin), the project aims to accelerate the use of electrospinning technology to create 3D smart implants. The project receives € 2.7 million of its € 3.4 million budget through Interreg funding (60%)
- The ultimate objective of the project is to be able to demonstrate implants and validate them in preclinical studies, finally moving the project from TLR6 to TRL8, with the system completed and qualified through test and demonstration.
- In terms of the structure of the project, Mr Moroni explained that there were three parts to the consortium: technology development, preclinical assessment at universities and industrial translation.
- Whereas other participants mentioned that the connections between business and science sometimes produced challenges, Mr Moroni said that this had not been an issue with the BONE project, perhaps because the consortium was smaller.
- Asked whether it was rather optimistic to say that the project could reach TRL8, Mr Moroni said whilst this would not happen for the device itself, it would be possible for the technology.

Presentation: Fast Breast Check (Milan, IT) by Cinzia Mambretti, Fondazione Politecnico di Milano

- Ms Mambretti introduced the "Fast Breast Check" project as giving a new opportunity for breast cancer detection, particularly targeting young women, and women with small or dense breasts.

The project partners are 2 SMEs: Novaura as the main contractor and Veespo, and the Fondazione Politecnico di Milano. Operational stakeholders include the European institute of Oncology; S. Raffaele Hospital, Europa Donna, Rosa per la Vita, Uni Milan department of Mathematics. The project is funded by ERDF.

- She explained that the project was the continuation of previous projects, starting with a conception period between 2012 and 2015 which included theoretical development, definition of a new biomarker and patenting, and then another project which further developed the concept between 2015 and 2017. The current project began in 2017 and runs until 2019. As well as validation trials with more than 300 examinations, it involves awareness raising among young women.
- Current challenges for involve getting clinical validation ready and involving women in the project. This can be done through social media and testimonials, and the project will also use an app that will obtain data that can be aggregated and analysed. Another hurdle refers to the Health Technology Assessment and obtaining the approval for reimbursement within the healthcare system.
- The project has already applied for the Horizon 2020 instrument funding SMEs for the development of the project – it has received the seal of excellence but no funding.
- Asked whether the test would be expensive, Ms Mambretti replied that it would not necessarily be expensive, and that part of the assessment process was to determine whether hospitals will get the test reimbursed from the state, which would mean that it would be free for women. She said that it was expected to cost around 100 EUR for women in Italy. Surveys amongst women have already been conducted with this information and there is a good level of interest. The technology will be commercialised within the private healthcare system.

Presentation: COILED (NL) Jac Wijkmans

- Mr Wijkmans began the presentation by introducing the background to the COILED project. The project is a public-private drug discovery platform, 45% funded by the ERDF. The project started in July 2016, the first hiring was done in February 2017 and the project was fully resourced in September 2017.
- Mr Wijkmans said that many of the partners come from a network of contacts that he built up whilst working for a multinational pharmaceutical company. He explained that building partnerships involving SME's had not been simple. A major question that he was asked was how the SME would be reimbursed for what they bring to the partnership. Many were unwilling to invest because they felt that they would not be not paid anything. It was not possible to find investment from patient organisations because they said that their structure did not fit with financial instruments, so receiving money from them would require using traditional instruments.
- Some of the challenges for the project included organising the consortium, establishing clear rules for access to results and intellectual property to make COILED look good and build a sustainable platform; attracting more funding, through drug discovery and extending therapeutic focus to key areas; accessing very specific specialists.
- Mr Wijkmans said that one of the problems he encountered was getting businesses to leave behind 'exit thinking', where the final financial compensation for leaving the project is the top priority. Rather, to make the project sustainable there needs to be a means of rechannelling the money made back into the fund, not just taking the money and leaving.
- Other hurdles related to the cooperation between different regions within the Netherlands, which was not easy to achieve and cooperation with University Technology Transfer Offices (TTOs).
- Asked to go into this further, Mr Wijkmans said that part of the problem is that people with a business background arrive in the project and make their claim to own a part of the project intellectual property. This can bring a negative energy into the project.

Presentation: REFBIO (II) (Interreg Spain-France-Andorra) by Marisol Fragoso, Navarrabiomed

- Introducing the background of the project, Ms Fragoso explained that the project is a regional strategy (now a RIS3) designed to coordinate research efforts between neighbouring regions in France and Spain and builds on the work of the first REFBIO project. Within this strategy, health has been identified as one key area for sustainable R&D. Navarrabiomed was created by the government to encourage R&D in the public health sector.
- Coordinated in Navarro, Spain, Ms Fragoso said that the original project aimed at developing cross-border cooperation in the framework of the POCTEFA call in 2007-2013. The project lasted 24 months but did not finish. The project funded collaborative projects and other small projects. The network took over a year to set up – this was partly because of the lack of a shared language, but also legislative differences either side of the border and cultural differences. Following positive responses from researchers, the neighbours decided that they wanted to continue to work together and so a second edition of the project was launched, REFBIO II.
- Ms Fragoso continued that one of the challenges was that it was very difficult to engage with companies. This was because of rules for receiving financing stating that companies must declare any access to funds to prove they are not receiving an advantage -most likely to avoid falling within strict state aid rules.
- Developing material transfer agreements (MTAs) and clear intellectual property rules as well as dealing with regulatory requirements, were also important hurdles within the project.
- In terms of the funding received, 20 projects have been proposed through the project, 13 have been approved with funding of around €240,000. The REFBIO project aims to identify one star idea that will be submitted to apply for Horizon 2020 funding.

Presentation: AgeWell (RO) by Giuseppe Carbone, University of Cassino / Technical University of Cluj-Napoca

- Mr Carbone began by explaining that the main goal of the project was to attract foreign researchers to Romania who can bring expertise, exploring available knowledge in robotics and seeing how much can be transferred into practical application.
- Mr Carbone said that the key to success of the project was knowing each other well – he had known his partners for 20 years. Another key aspect was having a multi-disciplinary team, although there are language barriers that exist between different types of expertise, even if the same language is being spoken. An Important hurdle for the project have been the level of administrative requirements solicited by the authorities
- Looking to the future, Mr Carbone said that this project would not bring designs onto the market – a follow-up project would be needed for this. However, this would be difficult because Horizon 2020 funding is drifting towards being more focused on financing a few big projects rather than many small ones.
- He mentioned that in robotics only around 1% of proposals will get funding, which is problematic given that such a huge amount of effort is required to write a proposal. He called for the EU to give a make the process for accessing funds simpler. In the past there were two rounds, which meant that less time was wasted just to propose an idea.

Presentation: RECETOX by Vojtech Pribyla, Masaryk University

- Dr Pribyla explained the RECETOX project, which relates to a research centre based in Brno. The centre works on the health effects of persistent organic pollutants (POPs), polar organic compounds, toxic metals and their species and natural toxins – cyanotoxins. This work directly contributes to identifying health problems linked to the environment.
- Facilities of the centre have been built with the support of ESIF funds in different programming periods.

- Also, with the help of ESIF, the centre has expanded in terms of research activities and human capacities. Because of its grow, the centre has now received a variety of funds, including through a H2020 project. The centre itself contributes with around 10% own resources, receives another 10% government, and the rest from the EU.
- Going forward, an important challenge for the centre is the end of programming period and how to ensure the sustainability and grow of the centre.

Discussions

Key questions and discussion points:

- A major problem that sparked discussion involving all participants was the administration associated with running projects, with reporting being as frequent as every three months for some of the participants, and each time requiring 200-300 pages. It was pointed out that this was not a requirement of the European Commission and participants based in other Member States confirmed that the frequency and length required for their reporting was considerably less. Frequency varied greatly between participants, from every three months to annually, and it was suggested that it may be helpful for the Commission to set out a template with generalised rules for reporting.
- Managing relations between partners from research and academia and partners from the business world was mentioned by several participants as sometimes being challenging.
- Several participants mentioned that potential business partners were sometimes reluctant to join a project because of worries about being penalised. Others mentioned their own difficulty in working with businesses, both in that they felt that they could not offer a no-risk return on businesses' money, and because they felt that some businesses were too focussed on making a quick return and then pulling their investment out as soon as possible, rather than staying for the long-term.
- The subject of the delay in reimbursement was mentioned by several participants, with the delay ranging from 4-5 months in the Netherlands to up to 24 months in Spain. It was pointed out that this length of delay before reimbursement made project planning extremely difficult. After discussion with the participant representing the European Commission, it was agreed that the delay in reimbursement was dependent on the managing authority in the Member State rather than the Commission itself.
- When participants were asked whether their project would have been possible without the European Structural and Investment Funds, there was agreement from each participant that their project would not have been possible.
- One participant noted that involvement with ESIF had helped her find out about other Interreg projects, and had led to other funding opportunities including with Horizon 2020.
- Another participant mentioned the difficulty of finding other EU-funded projects that corresponded to the theme of her project. She said that she would really appreciate being able to talk with other projects doing similar work to her own in order to share ideas and best practice, but that after searching she could not find any kind of centralised database. Other participants agreed that this would be a useful resource. It was noted that this is part of the work being done by the Consultant as part of the current project.

Annex 2: Thematic workshop presentation and discussion summaries (Day 2)

Presentations

Introduction and welcome: Rosa Castro, Milieu

- Dr Castro opened the event with a short presentation of the 'ESI Funds for Health' project, outlining the objectives of the project, its main outputs and the purpose of the thematic workshop.

Presentation: 'Research and Innovation: the role of EU Regions and the case of Research and Innovation in Personalised Medicine' by Gianpetro Van de Goor, DG-Research, European Commission

- Mr Van de Goor said that the focus for H2020 was on supporting the best research teams and ideas, and funds would not be awarded from a cohesion perspective.
- Previously there had been an impression that some investment in health would come back to the country. Now this is no longer the case; the focus is on excellence. This makes it difficult for some regions to get research funding because of weaker capacities and structures in their area.
- He said that the program is supporting collaboration; that is why a minimum of three countries are required in partnerships, making another challenge for putting projects together.
- Referring to potential opportunities for funding, Mr Van de Goor mentioned that the work program can often set where priorities lie for regions. He also said that opportunities for regional cooperation could be mapped based on smart specialisation strategies, and that there were 120 projects making reference to health, with investment particularly in personalised medicine, supported by digitalisation.
- The consortium of Member States on personalised medicine is an important platform to make sure that the agendas of different Member States have some commonalities.
- Mr Van de Goor said that ESI Funds could contribute to infrastructure and capacity building that is necessary to compete at EU-level for research funds.
- Describing the 'seal of excellence' approach, Mr Van de Goor said that this measure meant that projects that are submitted to Horizon 2020 and rated as fundable, but because of limitations are unbale to be funded, can be funded by other actors, for example regional or private. This is a way to support capacity improvement, so that the projects have a better chance of succeeding next time.
- For the next framework program, called Horizon Europe, there is a new will to collaborate across different policy sectors to set the agenda and work programme. Mr Van de Goor hopes that there will be a more balanced support for R&I that will make innovation better and more cost-effective and help to overcome specific challenges in the health sector. This would be something to work on with DG SANTE and DG REGIO.
- Mr Van de Goor highlighted the need to make regions aware of innovative projects in their territory, so that they can support implementation, for example in their hospitals and care systems. In this respect, networking to bring actors in a region together is very important.

Presentation: 'Policy developments and ESI Funds priorities related to research and innovation in health and the life sciences' by Loukianos Gatzoulis, DG-SANTE, European Commission

- Mr Gatzoulis mentioned that there is no single funding program that will cover everything, and therefore it is essential to combine financing instruments, for example using loans or equity

scheme, contracting and payment models, or social impact bonds to finance services, combined with loans.

- He said that it could also be helpful to bundle projects so that there are less small, isolated projects. Bundled projects are more attractive to investors.
- Referring to the relative roles of the private sector and the state, Mr Gatzoulis said that with a private-sector focus on physical infrastructure, it would allow redirecting of public funds to other areas, for example through public-private partnerships.

Presentation: 'Stairway to Excellence (S2E): Options for Synergies between ESIF & H2020' by Nida Kamil Özbolat, Joint Research Centre

- Introducing the S2E concept, Mr Özbolat explained that it was part of the smart specialisation platform and focussed on less developed Member States and regions to help them to adapt to an R&I-oriented growth approach. Activities for the platform include analysis to map capacity and identify needs to be addressed, and collaboration with Member States to build capacity to allow them to successfully bid for research funding. This can be done through bringing key actors in the innovation system together to help them learn to use EU funding programs efficiently.
- Mr Özbolat then asked why this extra support was needed. He explained that there is a significant innovation gap in the EU, particularly between the EU13 and EU15. Horizon 2020 funding tends to go to already well-performing regions, and this is true for health projects.
- He suggested that it was possible to bring together ESIF and H2020 funds together to reach socio-economic goals. Whilst H2020 necessitates high-level researchers and processes to win funding from the European Commission, ESIF is allocated in advance of project proposals and is co-managed by Member States. Tools are planned to make combining the two types of funding simpler.
- Mr Özbolat described two potential ways in which the funds could be combined. In an upstream way – for example if there are good researchers with no equipment, ESIF could be used to build capacity-, and downstream – if research is already done and is close to market commercialisation, ESIF could be used to aid commercialisation.
- He said that examples of ways to achieve synergies were available on the JRC S3 Platform website, along with case studies. These included building sequential projects that build on the previous one; taking up high-quality H2020 proposals that have not received funding and implementing via ESIF; putting in place parallel projects that complement each other; and bringing together H2020 and ESIF money on the same project.

Presentation: 'Presentation of the project 'i-4-1 health' by Professor Jan Kluytmans, Amphia Hospital, Breda

Professor Kluytmans presented the 'i-4-1 health' project, as during the peer review the previous day.

Presentation: 'ESI Funds for Health: overview of statistics and findings from the project work' Rosa Castro and Agnieszka Markowska, Milieu

- Given that the previous interventions by the EU Commission had provided a very detailed overview of the challenges for R&I in the EU, the presentation focused on giving the main findings and statistics obtained during the desk research performed by the project team in 2017
- Ms. Castro presented the findings of the 'ESI Funds for Health' mapping of programming at Member State level, namely TOs, IPs and SOs selected by Member States in relation to R&I, as well as examples of relevant programme indicators.
- Ms. Markowska presented the findings of the 'ESI Funds for Health' mapping of health projects supported by the ESIF. She started by explaining the approach used for the collection and analysis of the project data and then summarised the findings from all health projects identified as of

August 2017. She then provided an overview of the research and innovation in health projects supported by ESIF and identified as of August 2017, this included information about the geographic distribution and budget of the projects.

- Ms. Castro concluded by summarising the spending trends identified by the 'ESI Funds for Health' mapping (i.e. many R&I projects have tended to focus on funding the development of innovative processed and products). She then outlined the key questions about the ESIF spending trends and the development of ESI-funded R&I projects that should be considered during the workshop.

Presentation: 'Challenges and opportunities for the use of ESI Funds to support Research and Innovation in health and the life sciences' by Joanna Lane, Health ClusterNET

- In her presentation, Ms. Lane provided an overview of the challenges and possible solutions to enable a more effective use of the ESI Funds to support R&I in health and the life sciences.
- She started by explaining the role of ESIF in closing gaps regarding technology and manufacturing capabilities across the EU, referring to how ESIF and other funds could help projects developing new products or processes (which were the most numerous according to the findings of the ESI Funds for health project desk research done during 2017). Given this, she further referred to the role of ESIF in the different phases that projects undergo in terms of TRLs.
- Next, she focused on the perceived challenges to the use of ESIF to support R&I in this area, bringing the example of research done within the INNOLABS regions (e.g. Campania, Pomerania, Berlin, Paris and Oslo). Among the challenges are the politics of health administration, barriers to innovation, framework conditions and the perception of SME owners.
- Ms. Lane then focused on some proposed solutions, which include: (1) integrated planning and risk assessment; (2) the use of 'plug and play' innovation platforms; (3) the use of 'white spaces' (e.g. 'smart homes' and 'smart cities'; and (3) the use of enablers and intermediation. She emphasized how these solutions go beyond the 'catch-up' logic and also take into account other important enablers for R&I such as the need to build an attractive environment to attract people (researchers and others).

Summary of the peer review discussions by peer review participants

Participants in the peer review each gave a very brief summary of their project for those who had not been present on the previous day. This served to give concrete examples of how the ESIF are being used and fed into the break-out sessions that followed.

Discussions

Key questions and discussion points:

- The question of how projects are assessed came up, with one participant asking whether potential impact of research is assessed in proposals, as well as their research excellence. Mr Van de Goor replied that researchers should have an idea of what the impact of their research could be and that this would be evaluated. Nevertheless, deployment itself would not be funded.
- Also coming up was the question of private investment and intellectual property rights. This issue had also been raised during the peer review. A participant mentioned that in his experience investors do not want other people to be able to have access to the results that they are investing in, and therefore it is difficult to convince them to invest. Mr Van Goor replied that given that it was public money, it was not appropriate that a grant should subsidise private interest. In this situation a loan could be more appropriate. He pointed out that the European Investment Bank gives out loans which the Commission guarantees to turn into a grant if the results are not investible.
- The topic of relations between academia and business was mentioned again, with a question about the issue of transparency for the bidding process. How could a context be built where academia

and business could interact in a transparent way, not just for ethical reasons but also for capacity building, helping professionals to improve their approach to innovation? Mr Özbolat replied that the smart specialisation platform was considering the case of health because it clearly needs a tailored, specific approach.

- One participant who was involved in projects receiving ESI funding asked about how projects could receive funding to bring them to market once the innovation part of the project was completed. He said that the ESIF only fund innovation and there are no other options once the pilot project is finished. Mr Özbolat said that there were other options and that under the next funding period there would be new funding sectors that could apply to health that could offer opportunities.

Breakout sessions

Participants were split into two groups for the breakout sessions. Each group gathered approximately half of the participants present in the plenary session from a range of different backgrounds, including ESIF funded projects and managing authorities, as well as representatives of the European Commission. Each session started with a short presentation of each participant, indicating their country and their experience in working with ESIF in R&I.

Next, the following general questions were raised, and each participant shared their opinion as well as gave other comments and suggestions linked to the event:

- Based on your experience, how are the ESI funds contributing to work in research and innovation?
- What challenges have you encountered in your work with ESI funds and what solutions have you found?

Breakout Group 1

The discussion largely centred on overcoming obstacles that participants had encountered when using the structural funds. The following points summarise the discussion:

- The difficulty of administration of the funds came up during the break out session, as it had done during the workshop and the peer review. It was pointed out that there was a large burden for reporting that meant that researchers did not have sufficient time to spend on research.
    - One participant suggested that one solution for this could be to use a private service to directly manage the funds obligations for the project. This would mean that researchers do not have the burden of reporting.
    - However, another participant questioned how this would be compatible with regulation on the protection of patient data.
- 'The public procurement approach offers possibilities. This could help innovation where it is needed, but also give public authorities the lead, for businesses it is important that it is not too difficult to join up with other regions and countries. At the moment, there seems to be too much competition on price between countries. The facility offered by H2020 under Euro innovation Council could help. Late stages of dev and early deployment, that's where funding gap could be bridged.'
- Another participant said that in his experience there is a lack of highly skilled project managers involved in the projects, and that this is problematic. People need to be trained. He said that he is aware that the European Commission is looking at public procurement, but in many countries and regions the culture in the administration is not necessarily there. This was seconded by another participant from a different country who said that he also sometimes had difficulty finding the right human capital for projects.

- In some regions there is not a strategy for the healthcare system to buy into innovation. The system is based on a bottom-up approach where one researcher proposes something and asks for funding. At national level this is sometimes the case; other times there may be a strategy, but it is not implemented properly at regional level.
- The effectiveness of the smart specialisation strategy was questioned, with the comment that in some areas what is termed as a specialisation is not really one, and essentially boils down to a means of getting funding. Participants from different regions had different opinions on this. Some agreed that the specialisation was far too wide, meaning there was no critical mass of funding because the funding is too widely spread, so does not have enough impact. Others said that in their region there were real accents developing supported by strategic calls.

Breakout Group 2

The following points summarise the discussion in the breakout session 2, which were grouped in problems and opportunities.

- The following problems were identified by participants in this breakout session:
  - Disconnection of national and regional priorities, bad cooperation between different ministries
  - Lack of capacity at regional levels to administer the ESIF
  - Lack of one-stop shop to receive guidance for potential beneficiaries, need to consult various institutions
  - Health does not seem to be high on priority lists
  - Lack of standard rules in administering the funding
  - Lack of knowledge about what is needed, insufficient applied research, testing and dissemination of results of projects
  - Need for indicators capturing ling-term impact in terms of health
  - Misconception that ESIF are for funding infrastructure
  - Lack of strategic thinking how to combine different funding sources
- Advantages
  - ESIF project allow combining input from different stakeholders, networking
  - ESIF provide opportunity for international cooperation, joint actions, partnerships
  - ESFIF provide access to small grants
  - 15% of OP budget can be spent outside the territory of the region to which the OP directly relates – this opportunity is, however, not used sufficiently
  - ESIF can be used for projects focusing on screening of the diseases
  - ESIF allow increasing specialisation – the benefits are broader than the regions in which projects are implemented

Annex 3: List of participants

Peer review/Day 1

	First name	Last name	Organisation
1	Giuseppe	CARBONE	University of Cassino /Technical University of Cluj-Napoca
2	Marisol	FRAGOSO	Navarrabiomed
3	Alex	FRIEDRICH	UMCG
4	Corinna	GLASNER	UMCG
5	Sonja	HANSEN	Center for Asstisted Living Technology, Health and Care, Aarhus Municipality
6	Katarzyana	KIELAR-KOWALCZYK	European Commission
7	Jan	KLUYTMANS	Amphia Hospital
8	Marjolein	KLUYTMANS	Amphia Ziekenhuis
9	Cinzia	MAMBRETTI	Fondazione Politecnico di Milano
10	Lorenzo	MORONI	Maastricht University
11	Nida Kamil	OZBOLAT	European Commission (DG JRC)

	First name	Last name	Organisation
12	Mariana	Postolache	Ministry of Health Romania
13	Vojtech	PRIBYLA	RECETOX - Masaryk University
14	Diana	Vîrtaci	Ministry of Health
15	Jac	WIJKMANS	Inntrest
16	Ina	WILLEMSEN	Amphia Ziekenhuis
17	Rosa	CASTRO	Milieu
18	Agnieszka	MARKOWSKA	Milieu
19	Matthew	JONES	Milieu
20	Joanna	LANE	Health Cluster Net

Thematic workshop/Day 2

#	First name	Last name	Organisation
1	Emanuele	Arca	Pharmerit International - Erasmus University

#	First name	Last name	Organisation
2	Stefano	Benvenuti	Fondazione Telethon
3	Natacha	Berbers	Correlation Network
4	Giuseppe	Carbone	University of Cassino /Technical University of Cluj-Napoca
5	Marisol	Fragoso	Navarrabiomed
6	Alex	Friedrich	UMCG
7	Loukianos	Gatzoulis	European Commission, DG Health and Food Safety
8	Corinna	Glasner	UMCG
9	Annejet	Goede	Erasmus University Medical Center
10	Jonathan	Gomez-Raja	FundeSalud, Government of Extremadura
11	Natalija	Hamandikova	Health Ministry
12	Sonja	Hansen	Center for Asstisted Living Technology, Health and Care, Aarhus Municipality
13	Victor	Haze	Health Valley Netherlands
14	Maddalena	Illario	Campagnia region Italy

#	First name	Last name	Organisation
15	Angela	Ivask	Ministry of Social Affairs (Estonia)
16	Kristine	Karsa	Ministry of Health
17	Katarzyana	Kielar-Kowalczyk	European Commission
18	Jan	Kluytmans	Amphia Hospital
19	Cinzia	Mambretti	Fondazione Politecnico di Milano
20	Aurel	Marin	Viata Medicala
21	Joao	Marinho	Hitachi Ltd.,
22	Mariska	Mooijekind	European Oncology Nursing Society (EONS)
23	Virginie	Mouchel	ANR
24	Bregje	Mutsaers	Amphia hospital
25	Nida Kamil	Ozbolat	European Commission (DG JRC)
26	Olga	Pervusina	Medical Grants Pervushina & Partners
27	Mariana	Postolache	Ministry of Health Romania

#	First name	Last name	Organisation
28	Vojtech	Pribyla	RECETOX - Masaryk University
29	Barbora	Prokesova	Recetox - Masaryk University
30	Andreja	Rafaelic	University Ljubljana
31	Agnė	Raukštienė	Ministry of Health of the Republic of Lithuania
32	Heather	Rogers	BioCruces Health Research Institute
33	Miran	Šolinc	Association ŠKUC
34	Gianpetro	Van de Goor	European Commission (DG RTD)
35	Ilze	Vērdiņa-Lāce	Ministry of Health of the Republic of Latvia
36	Diana	Vîrtaci	Ministry of Health
37	Jac	Wijkmans	Inntrest
38	Jayne	Woolford	WERC
39	Joanna	Lane	Health Cluster Net
40	Rosa	Castro	Milieu

#	First name	Last name	Organisation
41	Agnieszka	Markoska	Milieu
42	Matthew	Jones	Milieu

Annex 4 Event agendas

'Research and Innovation in health' Workshop

Agenda: Peer review

June 20, 2018

Amphia Hospital. Molengracht 21. Breda, The Netherlands

Time	Agenda
09:30-10:00	Welcome and introduction *Amphia Hospital & Milieu*
10:00-11:00	Presentation of the host project 'i-4-1-health *Professor Jan Kluytmans, Project coordinator i-4-1 health project*
11:00-12:00	Peer project session 1 – presentation and short discussion of projects related to products and processes in health and the life sciences and clinic-industria-academia collaborations: • Health-i-care (Interreg DE, NL) • BONE-Bio-Fabrication of Orthopedics in a New Era (Interreg FR-CH) • Fast breast check (IT Region, tbc) *Facilitator: Joanna Lane, Health ClusterNET*
12:00-13:00	Lunch
13:00-14:30	Site tour: on-site demonstration of the IRIS scan *With the participation of Professor Jan Kluytmans*
14:30-15:00	Peer project session 2 – presentation and short discussion of projects related to research infrastructures • COILED (NL) • REFBIO II (Interreg Spain-France-Andorra) *Facilitator: Rosa Castro, Milieu*
15:00-15:30	Peer project session 3 – presentation and short discussion of projects related to research infrastructure and capacity building • AgeWell (RO) • Cetocoen Plus (CZ) *Facilitator: Rosa Castro, Milieu*
15:30-15:45	Coffee break
15:45-16:15	Open discussion
16:15-16:45	Summary of key lessons learned *Milieu*
19:00	Networking dinner **Restaurant Zuyd, Ginnekenweg 35, 4818 JA Breda, Netherlands**

Agenda: Thematic Workshop

June 21, 2018

Boven Breda. Schoolstraat 2. Breda, The Netherlands

Time	Agenda
09:30-09:45	**Opening** *Amphia Hospital and Milieu*
	Part 1: Plenary
09:45-10:15	Research and Innovation: the role of EU Regions and the case of Research and Innovation in Personalised Medicine *Gianpetro Van de Goor, European Commission, DG-Research*
10:15-10:45	Policy developments and ESI Funds priorities related to research and innovation in health and the life sciences *Loukianos GATZOULIS, European Commission, DG-SANTE*
10:45-11:15	Stairway to Excellence (S2E): Options for Synergies between ESIF & H2020 *Nida Kamil Özbolat, Joint Research Centre*
11:15-11:30	Coffee break
11:30-12:15	Presentation of the project 'i-4-1 health' *Professor Jan Kluytmans* Panel with beneficiaries from exemplary projects and summary of the peer review discussions *Moderator: Rosa Castro, Milieu*
12:15-13:15	Networking lunch
13:15-14:00	ESI Funds for Health: overview of statistics and findings from the project work *Rosa Castro and Agnieszka Markowska, Milieu*
14:00-14:30	Challenges and opportunities for the use of ESI Funds to support Research and Innovation in health and the life sciences *Joanna Lane, Health ClusterNET*
	Part 2: Breakout sessions
14:30-15:30	Parallel breakout sessions discussing the challenges, opportunities, lessons learned and key messages about the use of ESI Funds to support research and development related to innovative products and processes, clinic-industry collaboration and research infrastructures
15:30-15:45	Coffee break
15:45-17:00	**Summary and conclusions of the event** *Joanna Lane, Health ClusterNET*

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