D4.2 Reports of Assembly of Members (AoM) Assessments

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Executive summary

The Assembly of Members (AoM) is the board established by InfAct that provides a platform for European and European Economic Area's Member States (EU/EEA MSs) to give feedback and political guidance to InfAct's counterparts, and fosters dialogue for long-term projection of InfAct's activities. The AoM acts as liaison with their national research and public health authorities.

A total of 30 representatives of Ministries of Health and Research from 22 European countries gave inputs through 4 meetings that were held: Austria (MoH), Belgium (MoH, MoR), Bosnia and Herzegovina (MoH), Croatia (MoH), Czech Republic (MoH), Estonia (MoH), Finland (MoH), France (MoH, MoR), G. D. Luxembourg (MoH, MoR), Greece (MoH), Iceland (MoH), Ireland (MoH), Italy (MoR, MoH), Lithuania (MoH), Malta (MoH, MoR), Netherlands (MoH, MoR), Norway (MoH), Portugal (MoH, MoR), Romania (MoH), Serbia (MoH, MoR) Spain (MoR) and UK (MoH/MoR).

The First AoM was held in Madrid in March 2019, where the InfAct beneficiaries and stakeholders approved the Terms of reference for the Assembly of Members, challenges and needs of the current European Health Information Systems (EU-HIS), rationale and added value of the Health Information Research Infrastructures (HI-RI), the role of InfAct for improving HIS and the benefits and long-term approach of the ESFRI roadmap. The representatives engaged in group discussions on the strengths and weaknesses of a HI-RI at the EU level, and on how it could respond to the EU-EEA-MSs national needs. The most important recommendations raised from this first AoM were: (i) EU/EEA MSs need clarity on what kind of infrastructure and outcomes are going to be provided, (ii) there is a need of linking research and health management in order to increase evidence based health policy, (iii) funding such an infrastructure remains a concern, since for being useful in terms of EU-HIS most countries should be involved and provide national data in a standardized way, and (iv) to gather in one stop-shop research results and HI for health management and policies, will not be met if only few countries participate.

The Second AoM was held in Brussels (November 2019), where the beneficiaries and stakeholders from InfAct presented: The distributed Infrastructure for Population Health (DIPoH) (rationale, structure, services and business case), the Fact-Sheets (FS) including InfAct main outcomes so far, the conclusions of the first Technical Dialogues (TD), the composition of what was called National Nodes (NN), the Research Nodes and the strategic draft of the ESFRI application. The most important issues raised from EU/EEA MSs were: (i) alternatives for funding and design of the research infrastructure, apart from the business plan for ESFRI roadmap and the ERIC/DIPoH, were required, (ii) A more precise definition of expenses that should be covered by EU/EEA MSs and the location of the central office were needed, (iii) funding would depend on political commitment across EU-EEA MSs so countries must

assess the added value and potential benefits at national level, (iv) clarify the role of the European Commission (EC) in supporting the research infrastructure, and (v) the importance of the National Nodes (NN) and the Research Nodes was stressed, but further clarification was needed about their definition.

The Third AoM was held virtually in 25 June 2020. InfAct beneficiaries presented an update on relevant activities from the last AoM related to: InfAct and COVID-19, summary of DIPoH and DIPoH practical use case: Population HI-RI (PHIRI) for COVID-19. Finally, it was presented a new Joint Action towards European Health Data Space (THEDAS), and an update about DIPoH, including an explanation of its governance, management models and cost estimation process. Representatives from Ministries of Health (MoH) and Research (MoR) considered that the design of DIPoH had advanced positively after addressing some aspects that needed further development and also mentioned some country-specific barriers to support the infrastructure.

The Fourth AoM also took place virtually in October 2020. InfAct beneficiaries presented an update on the ESFRI application and DIPoH final budget, phases and timeline, the InfAct Sustainability Plan highlighting InfAct outcomes and recommendations from the Second TD and an update on PHIRI. The EC showed his satisfaction with the progress regarding the proposed DIPoH and stressed the importance of InfAct contributions in the future initiatives for strengthening HI across Europe. AoM's representatives raised some concerns on the individual financial contribution by country; EU/EEA MSs also wanted to know how DIPoH and PHIRI were connected, how were the interactions with existing research infrastructures, which role would DIPoH play in the European Health Data Space initiative and how data sharing and privacy would be managed within DIPoH. All countries agree with the InfAct's Sustainability Plan proposal.

Key points

- ✓ The terms of reference for the AoM were approved unanimously.
- ✓ All countries agree in the interest of setting up a unique infrastructure gathering research, HIS, best evidence to inform policies and HI systems for health management.
- ✓ Country representatives highlighted the work on setting up DIPoH, the importance of building the NN and considered that the proposal is well articulated at national and European level.

- ✓ 14 countries have already given their political support or sign the Memorandum of Understanding to the DIPoH infrastructure.
- ✓ Among the barriers to provide political support, country representatives mentioned: (i) some countries need also to guarantee financial support before signing the letter of political support, (ii) in others, the responsibility of funding belongs to the Ministries of Research, (iii) in some of them the internal process of application at national level was over so they should wait for the next year call and (iv) the remaining countries would support an enlargement of scope of ECDC rather than the research infrastructure.
- ✓ Country representatives welcomed setting up PHIRI as a practical use case of DIPoH, because it fills a gap of rapid data exchange between countries and recommended the linkage with other initiatives on HI at national and European level.
- ✓ DIPoH proposal was submitted to the ESFRI roadmap.
- ✓ InfAct is closely cooperating with international organisations (Eurostat, ECDC, EC, WHO Europe, OECD), research infrastructures through the Healthy Cloud (Elixir, EATRIS, ECRIN, BBMRI-ERIC, Euro Bioimaging), EGI-ACE (EOSC Pilot, EOSC Life, EGI) and the European Health data Space.
- ✓ All countries would like information to be involved in future initiatives as PHIRI and DIPoH and consider that the AoM is the most suitable way to inform the EU/EEA MSs on the advances in the development of DIPoH.

Reports of Assembly of Members (AoM) assessments

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I. Introduction

Following the recommendations of the Council of the European Union, the EC and EU/EEA MSs were invited to cooperate with the aim of establishing a sustainable and integrated EU HI system. More specifically, the Council Conclusions urged to explore the potential of a comprehensive EU-RI as a tool. The Joint Action (JA) on HI (InfAct) builds on previous work provided by BRIDGE Health and further develops collaborative action to set up a sustainable infrastructure for EU HI. InfAct started in March 2018, bringing together 40 institutions from 28 EU countries. InfAct is focused on: (i) providing tools and methods for HI support through innovation for public health policy development and research, and (ii) integrating population health and health care information systems in a sustainable EU-RI. It will contribute to reduce HI inequalities by strengthening country capacities and enhancing HI priority setting, methodologies and practices.
InfAct brings together HI players around Europe in an AoM. Representatives from MoH and MoR from EU-EEA are invited to participate in this AoM. The AoM will decide on a strategic vision for a sustainable infrastructure for EU-HIS. The AoM will serve as a communication channel between InfAct and the ministerial representatives.
This committee develops a shared vision about possible levels of commitment, ways of governance and types of organizational involvement of EU/EEA MSs for such research infrastructure. The AoM can set the basis for a permanent structure in a future EU HI infrastructure. AoM also acts by monitoring InfAct's activities, provide guidance for better coordination at national level for health data production and reporting and facilitates the integration of InfAct's tools, outputs and outcomes in national health systems and public health and research policies.

II. Aim

The AoM is the board established by InfAct providing a platform for MSs to give feedback and political guidance to InfAct's counterparts, and fosters dialogue for long-term projection of InfAct's activities.

III. Approach

Initially the Terms of Reference for the AoM were elaborated focusing on the composition and rules of procedure. Every country beneficiary of Infact was contacted to serve as a

liaison with their respective MoH and MoR to designate two representatives (titular and alternate) for each Ministry in the board. The Chair of the meeting was a representative from InfAct (Neville Calleja and Thomas Ziese) and the Secretariat was developed by ISCIII as WP4 leader.

Three meetings were scheduled to be held during the project, however due to the exceptional circumstances of COVID-19, it was decided to organise an additional AoM to discuss crucial aspects of the project as the ESFRI application and the setting up of PHIRI as a practical DIPoH's use case. The meetings took place in March of 2019 in Madrid, in November of 2019 in Brussels and two virtual meetings in June and October of 2020. In the last AoM it was decided to organize an additional AoM in April 2021.

The minutes of each AoM were shared one month after the meeting.

IV. Results

A. Minutes of the First Assembly of Members

1. Introduction to the Assembly of Members

Welcome by Dr.Isabel Noguer (IN), Leader of Work Package 4. Instituto de Salud Carlos III (ISCIII). Ministry of Science and Innovation. Spain

IN introduced the work package (WP) 4 (Integration in National Policies and Sustainability) of the Joint Action Information for Action (InfAct). IN informed that InfAct gathers 28 countries and 40 institutions with the aim to improve, and provide innovative advances for HI systems (HIS). She stated that the present AoM counted with the participation of 19 countries and 29 representatives from MoH and MoR from EU-EEA-MSs. She introduced Raquel Yotti as Director of the ISCIII and Prof Neville Calleja, as chairman of the AoM.

Welcome by Dr. Raquel Yotti (RY), General Director of ISCIII. Ministry of Science and Innovation. Spain.

RY gave a background review of the mission of ISCIII as the institution promoting health research and innovation, providing scientific and technical support for the national health system and giving general advice for policymaking.

RY also stressed the importance of the sustainability of health systems and underscored the relevance that research and innovation provided to accomplish this task. RY also highlighted the critical role of a solid HI system (HIS) in order to improve health performance. Finally, RY welcomed EU/EEA MSs representatives and invited them to discuss the main components that could facilitate the sustainability of HIS across the EU.

Terms of Reference of the AoM by Neville Calleja (NC). Chair of the AoM, Director of the Department for Policy in Health, HI and Research, Ministry of Health. Malta.

NC gave an overview of InfAct, as a project that embodies 20 years of methodological experience on HI in Europe, and that should be sustainable in the future. Based on his experience as HI producer and policy maker, stated that the demands of HI coming from MoH are progressively getting very complex and more specific. He remarked that the challenges, upcoming for HI producers, are to research and develop new methods to better answer policy makers demands and to assess the EU/EEA MSs needs. As health ministries need evidence to deliver better health and wellbeing to the population, the HI producers strive to provide relevant HI for policy makers. Thus, building a sustainable infrastructure could improve HI for a better evidence-based and health policy-making.

NC explained that the purpose of the meeting was to discuss the needs of EU/EEA MSs to make InfAct sustainable and adapted to the needs of the countries. He also summarized the Terms of Reference (ToR) and operating procedures for this AoM (*Annex 1*) and stated that the AoM is a forum of dialog for MS, which also had the attendance of international observers (DG Santé, and WHO, among others). He highlighted AoM's objectives as follows: to provide guidance to optimally shape the future HI infrastructure according to the national needs and to advocate for its sustainability. Thereby, this infrastructure will be designed to fit the needs of the countries. Finally, through the time fame of the project, the AoM is expected to have 3 meetings (two meetings in 2019 and one meeting in 2020).

2. Introduction to InfAct. Dr. Herman Van Oyen (HVO), Coordinator of InfAct. Director of Epidemiology and Public health, Sciensano. Belgium

HVO, asked representatives to reflect about the need of building a sustainable research infrastructure: How efficient are health systems in our own country? How are such systems compared to other European countries? As InfAct, expects to improve the structure of HIS across Europe, those questions could be appropriately answered. HVO outlined the gaps between and within EU/EEA MSs in terms of health status but also in measuring population health and presented the goals of InfAct to strengthen EU and national HIS: (1) establishing a sustainable research infrastructure (RI) which will support population health and health system performance assessment, (2) strengthening European HI and knowledge bases and HI research capacities, to reduce HI inequalities and (3) supporting HI interoperability and innovative HI tools and data sources.

He then focused on the conceptual framework of InfAct based on 3 pillars: (1) political support focusing on the development of a business case and a road map for the implementation of the RI, and the integration of HI into regional and (inter)national policies (2) capacity building based on assessing HIS through peer review, developing a flagship training to reduce HI inequalities, identifying relevant HI networks and prioritization strategies and (3) HI tools focusing on improving the quality of data, the development of

new ways of using existing data sources to derive indicators, the use of new technologies for HI, and the interoperability of health data instruments and sources.

InfAct is working on assessing the current status of HIS, strengthening HI capacity, assessing and piloting interoperability for public health policy, providing innovation in HI for public health policy development, providing optimum tools and methods for HI support, developing a proof of concept for a sustainable structure and finally facilitating the integration into national policies and sustainability. The project is organised in 10 WP whose main tasks are listed below:

- WP4: Organisation of the Assembly of Members with representatives from Ministries of Health (MoH) and Ministries of Research (MoR), fostering Technical Dialogues between technical national experts and WP leaders and the elaboration of the Sustainability Plan.
- WP5: Assessment of HIS through peer-review assessment, cataloguing of networks and projects and prioritization of HI.
- WP6: To design a roadmap for capacity building and a flagship training programme.
- WP7: Elaborate the application for the ESFRI roadmap, connection of EU/EEA MSs HI networks, connection with pan-European research networks, development of a business case and a roadmap and the creation of a web-based platform.
- WP8: Health monitoring data, collection methods and indicators. Elaborate guidelines on accessibility, availability, and reporting in HI.
- WP9: Sharing inspiring examples from EU/EEA MSs on emerging indicators and data sources to target priority public health actions and health care strategies, enlarging the set of morbidity indicators available across the EU.
- WP10: Mapping and analysing (inter)national inspirational case studies on public health interoperability, developing practical empirical work through case studies and its piloting.

The expected InfAct´s outcome is to build an EU RI that will allow EU/EEA MSs and the EU to improve health performance through: an advanced scientific knowledge, increased capacity building and research targeting, improved interoperability and innovation in HI, a more robust data collection and a better-informed decision making for research and policy that will enhance its sustainability.

Comment: Philip Roux from DG Santé highlighted the timeline defined for the project and remarked that the main purpose of the meeting is to make policy makers take the right decisions regarding HI and to define strategies to work together in achieving the goals proposed for the project in a timely manner.

3. The current EU HIS: challenges and needs. Linda Abboud (LA), Coordination of InfAct. Project Researcher. Sciensano, Belgium.

LA addresses the question from the representative of the French MoR about the meaning of HI for InfAct. LA defined it as all the data, evidence and knowledge on health and health system performance at individual and population level to facilitate research promotion, prevention, care and support policy-making. Additionally, a HIS could be defined as a complex, multi layered system, aimed at producing health intelligence. The steps relevant for population health monitoring from data collection to knowledge translation and policy making were underpinned by research and ended up in evidence for decision making as the most important output of the HIS.

Health and health care, are major policy areas that draw intense political and societal attention because of the increasing concerns to respond to the needs of the citizens, a higher notion of social justice and equity in Europe and therefore higher expenditures in national health. As a consequence, high-performing equitable health systems need to be guided by HI. Such health systems require up-to-date data and high-quality data, innovative and relevant research and good practices.

Regarding the EU HI sphere, the key players are international organisations, such as WHO and OECD as well as the European Commission, and also numerous individual and independent projects working on HI that are not included in the network of such key players.

The current situation of HI shows that there have been some successful projects that have incorporated their outputs into Eurostat and the Joint Research Centre (JRC), but in general, when funding finishes, the project is discontinued and then all the data is dispersed or this knowledge is stored but not used, and the networks of experts fall apart.

There is a lot of fragmentation, knowledge is dispersed and data are incomplete and difficult to access. HI activities are project based, therefore there is no long term planning; which produces duplication that causes a waste of resources. In addition, there are inequalities in terms of quality and research capacities across European countries. So there is a need for a HI infrastructure to bring all this together and to solve these challenges.

This problem has been discussed since 1998 and finally in 2013 the Council conclusion was *"to cooperate with a view to establishing a sustainable and integrated EU HI System, with the potential of a comprehensive HI research infrastructure consortium (ERIC) as a tool"*. Thus, the need for an infrastructure at European level was clearly identified and started with the BRIDGE project in 2015 and continued with InfAct in 2018.

4. The concept of the HI Research Infrastructures: rational, goals and added value. Petronille Bogaert (PB). Coordination of InfAct. Project Researcher Sciensano. Belgium.

PB explained the concept of a RI as an integrated structure that is capable of connecting networks in HI and overcoming fragmentation to enable top-level research for better evidence and more intelligence to support evidence informed policy making with the overarching aim to improve public health (population health and health care system). The

main goals of a research infrastructure are: (i) to make available and share quality data, information and tools, (ii) to strengthen scientific knowledge, promoting scientific cooperation and integration, (iii) to support expertise development, methodological innovation and the use of HI to inform policy. The scope of this infrastructure is to fill the gap in population health and healthcare systems.

A RI that has one coordinating hub (central office with a web based platform that delivers services) with different hubs connected around this central hub. There are 2 types of networks in this infrastructure: (i) a *domain specific network* is a group of collaborating researchers on a common health topic or method, and (ii) a *national network* that is a consortium of relevant national actors and stakeholders.

This infrastructure is organised in 4 main services: 1) One stop-shop for EU HI research: The idea is to have a place where anyone can find the HI that are looking for, not only data but also guidelines, tools and reports, 2) innovative research in HI: to support new methodologies and provide computing, interoperability and tool services but also ethical and legal support, 3) Capacity building in HI. As tackling inequalities in Europe is a crucial issue, this infrastructure will have an overview of professional training programs for public health specialists, statisticians and epidemiologists, and 4) Decision making based on evidence based research, focuses on engaging with policymakers and providing them the tools they need for a better prioritisation and translation into policies. The added value for research is to have EU comparative data (fair HI, data quality checks, large cohorts for research, enhanced data access flow, structured scientific exchange, produce quicker results and ensured ethical and legal compliance) and to build a collaborative network (organise and connect public health expertise and systems, create synergies between projects and HI activities, better access to existing knowledge and expertise). On the other hand, the added values for society is to have quality information on evidence based decisions for policy and decision makers, enhanced monitoring of health risks and health related problems to improve health and wellbeing, to optimize funds allocation for financers and to help administrators by providing an overview of international data collection so that duplication is reduced (*Annex 2 Policy paper)*.

In summary, the proposed RI plans to tackle the challenges of HIS

Table 1. Challenges of HIS

Problem	**Expected solutions**
Fragmentation	Connecting stakeholders and information, efficient use (reuse) of data
Inequalities	Capacity building, knowledge translation
Project based	Sustainable infrastructure, knowledge depot, return of investment

Comments and questions

Bertrand Schwartz (BSch), French MoR Representative: Some HI are already there, and has been checked for quality. Quality must be checked before collecting data. You must give figures and a quality insurance strategy must be presented at some level. What is the action of the proposed infrastructure? What are we supposed to do? Is it to work on quality? What is the overall purpose of the infrastructure in terms of future services and objectives apart from connecting data?

HVO illustrated the answer with an example of two levels on which you can think about data. The first issue is to ask a simple question to yourself: What do you know in France about diabetes? That is a simple question and I can tell you it is a very hard answer to find. First of all because there is no clear definition about what people do about diabetes, if the main treatment is getting people on diet and exercise, this kind of information is currently not integrated because we are focused on what it is done in terms of pharmacological treatment.

On one level, there is simple data that should be there. Burden of disease (BoD) is a very old indicator that was promoted by WHO and the World Bank and it is about combining years lost by early death and by bad health. Right now only very few EU countries are currently able to do this calculation, because they understand the mathematical modelling behind it and used it for establishing policy priorities. Thus, this is basic data that should be there and that is collected through the national bureau of statistics. At another level you can think about genomics because previous research have identified traits that are potentially linked with cancer but at the moment there is no clue on how to act medically when people have these traits. In addition, there is no knowledge about the causal link in people that have both cancer and these traits. Therefore, the question is how to introduce this knowledge about genomic and big data not only into clinical research but also at population level. In conclusion, it is not only about collecting data but to be able to use what is already there and to know which standards are necessary to do so. For a comprehensive HI infrastructure, it is important to bring researchers, epidemiologists, social scientists, health economists, and different professionals that are working in different projects to facilitate the exchange of knowledge and methods. Many things are established but they are fragmented. For example, if you ask about a particular health problem, depending on the data source you use (WHO, Eurostat, OECD) you obtain different answers.

5. Case study Euro-Peristat: research networks in public health. Marie Delnord (MD), Euro-Peristat and Sciensano. Belgium.

MD informed about maternal and newborn health in Europe (importance as a burden of morbidity and mortality, differences on mortality between and within countries, the crucial need of new technologies and limiting the iatrogenic effects) and why it is a priority for surveillance and research. Euro-Peristat project is an EU-funded initiative starting in 1999 with the aim of monitoring perinatal health in the EU and it is based on valid and reliable routinely collected indicators. In this network, 31 European countries are participating. It

uses population-based data during pregnancy, delivery and postpartum. Its data sources are vital statistics, medical birth registries, and hospital discharge data.

Monitoring maternal and newborn health in Europe is important because EU countries face common challenges: average increase of maternal age at delivery and higher prevalence of obesity among others. Moreover, the approaches to perinatal health differ greatly across Europe, many country level indicators are not comparable and key indicators are not available in the international databases (preterm birth rate, maternal smoking, etc).

In Euro-Peristat there are core indicators that are essential for each country to monitor perinatal health: newborn health (fetal, neonatal and infant mortality rates, birth weight distribution, distribution of gestational age), maternal health (maternal mortality), population and risk factors (multiple birth rate, distribution of maternal age, distribution of parity), health services and its provision (mode of delivery). Furthermore, there are 20 indicators that are recommended to monitor the percentage of women that smoked during pregnancy, distribution of mothers' educational level, distribution of parents' occupational classification, distribution of mothers' country of birth or distribution of mothers' pregnancy or body mass index (BMI). Translation from knowledge to action needs good research and evidence to sustain interventions and policies, which could improve maternal and neonatal health. Research outcomes need to be communicated in appropriate way through different channels (in Euro-Peristat such channels are Perinatal Health Reports, data on indicators that are available in internet and scientific conferences). In addition, publications in peer-reviewed journals add validity to all Euro-Peristat products and its results are used to inform clinical guidelines, policy briefs and to improve the quality of perinatal health monitoring. There is also a potential to generate revenue streams by leveraging data and expertise. Euro-Peristat data aid in the investigation on the population determinants of maternal and child health and the indicators are used to generate hypotheses about the reasons for differences in health, to identify high and low performers and to set benchmarks for policy. For example in the Netherlands the analysis of poor mortality rankings ended up in an assessment of quality of care and further reorganisation of antenatal care that had positive outcomes in maternal health. There is also a platform to develop better methods for cross-country data collection/analysis and to collaborate with other EU research projects. The impact of Euro-Peristat has been observed in promoting best practices among national professional societies through the development of the European Board & College of Obstetrics and Gynaecology (EBCOG) standards of care, on raising visibility of maternal and child health inequalities and to advocate for better outcomes by The European Foundation for the Care of Newborn Infants (EFCNI), standards of care for preterm births and fostering international organisations consultation to update reporting criteria, for neonatal and infant mortality data.

Building a European research infrastructure might have a strong added value for the Euro-Peristat network because research at EU level provides strength in numbers by increasing the capacity to detect population determinants with a small but cumulative impact on health. In addition, it is an opportunity to boost research by extending hypotheses to the social and environmental determinants of health for solution-oriented research.

In her concluding remarks, MD pointed out Euro-Peristat's vision for a sustainable perinatal health reporting. They support the idea of creating a European RI to facilitate participation in European research projects across domains, with regular collection of Euro-Peristat indicators and a pluridisciplinary network of experts who would meet regularly to analyse and interpret data.

6. Improving HI and HI systems through InfAct: what is in it for MS. Dr. Enrique Bernal-Delgado (EB), Senior Health Services Researche. Institute for Health Sciences in Aragon (IACS). Spain

EB started his presentation with a set of research questions that could be relevant for public health professionals

- Would it be possible to predict the attributable fractions of risk after a public health intervention, and to report them as quick as possible?
- Could I know the economic burden of a disease?
- Could I discover care pathways of chronic patients and to see whether different pathways are responsible for different outcomes?
- Can I access to open source data models and analytics to respond similar questions on public health research?
- Can I get advice on how to reuse existing datasets in public health research?
- Is there any training program that could help me to develop my capacities to conduct public health research reusing existing datasets?

These are questions that public health specialists are asking themselves to produce relevant and meaningful information for policy decision makers. Public health research is oriented to public decisions, and it is addressed to answer relevant questions to promote evidence-based decision-making.

InfAct is working on several case studies to demonstrate the added value of research for better health for the MS. The idea is to answer these questions and to assess if a potential ERIC provides the researchers an added value to respond to those questions. For example, when it comes to the economic burden of disease: could we know the cost of outpatient care in patients with dementia? InfAct in France has conducted a linkage exercise about individual episodes of dementia in different settings and tracked them down for a year. Then they allocated the costs derived from those patients and compared France with other European or OECD countries using the purchasing parity power. They assessed that the cost of dementia was much higher in France.

Another question for these case studies are: Would it be possible to predict the attributable fractions of risk after a public health intervention, and report it as quick as possible? This question is related to adding different data sources for predicting events on the basis of

machine learning algorithms. When you add information, you refine your prediction of the attributable fraction of such events.

A third important question is: Can we know how care pathways work and how they impact patients´ health? In the case study that we present, data sources from 6 different countries were mapped and compared. There were a variety of data sources and, as different institutions have different pathways of care, we could see that outcomes were different depending on the pathway of care.

The ERIC services are aimed to answer these kind of research questions. The interoperable data model (IODM) that we are proposing is focused on the following aspects: advice on the definition of entities and attributes to build the indicator and confounders, available semantic and syntactic repertoires, available metadata from other projects or HIS and to deal with legal and ethical provisions to access raw data. There will be Extraction Transformation and Load (ETL) scripts to extract events and an IODM for data quality assessment. It will include also a self-contained analytical pipeline for the rapid cycle and a training for full application of such analytical pipeline.

InfAct also aims at capacity building. It will try to answer the following questions: What are our knowledge gaps? What are our needs? What we want to know? Are our HIS good enough to get the most out of the research supported by the ERIC? Am I prepared to design and conduct research reusing existing data collected and maintained elsewhere and to produce relevant policy-oriented research outcomes? Do I have the computing capacity to do so? InfAct hopes to pave the way for capacity building by carrying out activities such as developing a prioritization exercise along with EU/EEA MSs to understand how to link the research agenda with the policy making needs, performing a formal assessment to understand HIS current status and how they could size up to others in Europe; thus, to get the most out of the research supported by the ERIC, maintaining existing datasets from past and ongoing European projects of interest for the research and policy making communities and mapping out existing training programs on the reuse of routine health data to foster better research.

7. Questions and comments on HI Infrastructure proposals from InfAct

Jerome Weinbach (JW) from the French MoH: You are supporting an ERIC. Are there any other options in terms of the legal status of your activities? What kind of services do you want to provide at the EU level? How are you including existing opportunities that are supported by EC (ELIXIR, EOSC Hub, etc.)? Do you plan to design the RI from scratch or to use existing infrastructures, tools, complementary including environmental datasets, standards and computing resources?

HVO: There is a missing link in the puzzle if you look at the health domain. We will try to use what is already there. There are activities dealing with clinical and experimental design; although there are no activities on population health. We will work with key research existing communities. We need to think big and do little to accomplish a lot, because currently we are doing a lot and none of our investments gives a return of investments.

Aziz Naji (AN) Belgian MoR. This task entangles a lot of difficulties, because data is collected in different ways and it is not harmonized so we need to put it together to add another layer of analysis. It means creating a RI to safely store data that could be useful not only for ourselves because that is the issue with an ERIC. I do not think that this is already an infrastructure in itself, but a process. How would you go step by step towards a full grown infrastructure such as the one you described?

EB: The environment of networks working in Europe doing research are very likely based on a centralized infrastructure data and it is necessary to move forward. It must have flexibility and provide remote access to basic data to all users. Data could be in a cloud and to access to metadata and data with detailed granularity so if you wanted to get further information it would be necessary to provide the protocol and the purpose of such data. So it should be flexible not everything for everybody, centralized, or partly decentralized and maybe shielded. We are not starting from scratch but starting from the needs.

PB: We should not answer all questions today. We are in the application process and when you have the ESFRI application you are provided with the resources to develop this platform. What we have to do today is to show the way forward and how we are going to do this over time.

NC: The details of the technical issues about the platform will be defined after ESFRI application. What we have to do today is to know what we want this RI to produce.

Patrizia Theurer (PT), Representative from the Austrian MoH. Recommended to think about flexibility. It would be interesting to have 2 levels of participation because for instance Austria is just starting to link many data now and is not participating in the projects you have mentioned.

Lieven de Raedt (LdR) Representative from the Belgian MoH. Expert group on Health systems performance assessment (HSPA) started their discussions with the conceptual and normative framework. What is performance of a health system? They answer it first and then continued with the next steps of the project. I think here the conceptual and normative debate is missing.

NC: I am participating in the HIS assessment. It is giving us very rich information about local context specific landscape in Europe. We found weaknesses in which we perceived previously as strong information system and strengths in those that we previously perceived as weak information systems. So, at the end of the session we may have some answers to this question.

HVO: contextual framework can be driven by many elements. It is important to define first what the subject of study is: Air quality? Health system? So conceptual framework depends on the subject and when you work in a multidisciplinary group you allow different visions come together in a conceptual framework.

EB: Normative framework also depends on the subject and it is project specific. We cannot define it now because this project is unspecific at this point of time.

Ricardo Proença (RP). Representative from the Portuguese MoR. My question is about the future scope of the RI. I saw that one of the main objectives was to set up data collection networks at the European level and data standardization. The question is: if we have a health research project that produces a dataset and that is considered relevant, is the RI that you propose open to register that data?

HVO: Yes this is one of the main aims of this research infrastructure

Philip Roux (PhR): I think it is the outcome what is more important to think of. Two elements of reflection: 1) the scientific advice mechanism we have in the Commission (SAM). We expect the same here. The politicians ask questions and we expect the technical experts to give answers and 2) to identify financing mechanisms and institutions apart from the ESFRI application.

8. The importance of research for policy making: the health system performance example. Dr. Josep Figueras (JF), Director of the European Observatory of Health Systems and Policies. WHO Europe

JF started his presentation with the argument that the policy side is messy beyond belief so putting energies in knowledge translation is urgently needed. This does not mean that InfAct is not necessary, quite the opposite, without the quality, validity and comparability of data, there is no point in translating that data and deliver it to policy makers. We need information and research for policy impact. The idea is to be aware of the uses and misuses of Health Systems Performance Assessment (HSPA). There is no doubt that more HSPA is needed because EU/EEA MSs need to demonstrate transparency and impact of the health systems, particularly in time of crises. We want to learn from best practices. Moreover, in this times people don´t want to be in the Health System only as patients, they want to be more proactive.

When interpreting HSPA for policies a number of questions arise: What we want to measure? What is the domain? What is health system performance? It depends on who and how is being measured.

Several years ago WHO defined objectives of the health systems: Level of Health is the 50% of the performance, with both responsiveness and financial protection account for 25% each one. In turn, responsiveness is divided in equal parts by level and equity. However, what ministries of finance care about is Sustainability and Cost containment and three potential scenarios might appear: contain costs and increase efficiency, contain costs and decrease efficiency and contain costs and decrease health.

There are key questions on policy interpretation of HSPA: 1) What do we want to measure? It is related to the phenomenon and domain under assessment and to the framework to be used, 2) Are these the right indicators? Are we measuring them well? The indicators should measure the domain under assessment, have good data quality and a comprehensive

methodological approach (risk adjustment, composite indicators, roles of values and trade-offs and absolute and relative levels of performance); it is important to be aware of methodological complexities. 3) What the differences mean? How to interpret the data, who is accountable for this results? For example diabetes is a good indicator for effectiveness of primary health care avoidable admissions, it could be used for some insight into performance and country comparative position, as a starting point for further discussions on quality improvement and it is a good reflection of the overall quality of primary health care, 4) What can we do about? It could be oriented to different policy interventions at primary health care, hospitals, governance or access and to policy levers (public reporting, incentives, regulatory tools, consumer choice). At this point, it is necessary to be aware of perverse incentives, interpretational interests to resist change and complexity in changing clinical and policy behaviour.

To sum up, there are some lessons for policy: (i) Need data valuable for HSPA comparisons, (ii) variety of data sources, (iii) data is easier to be used for describing population health or health systems, (iv) measurement challenges (methodological comparability, conceptual clarity, consensus, common and good indicators), (v) ensure health systems contextualization, (vi) embed with health systems governance, (vii) link with levers of policy improvement and (viii) knowledge brokering across contexts and from evidence to policy.

9. Group discussions on Research HI Infrastructure options

Explanation of discussion guide and distribution of groups as presented below

Table 2: Discussion groups

Group	Countries	Facilitator
1	Norway(1), Croatia(1), Belgium(2), Spain(1)	Neville Calleja
2	Finland(1), Czech republic(1), France(2), Portugal(1)	Enrique Bernal-Delgado
3	Bosnia & Herzegovina(1), Estonia(1), Austria(1), the Netherlands(2)	Herman van Oyen
4	Lithuania(1), Luxembourg(2), Ireland(1), Italy(1)	Petronille Bogaert
5	Serbia(2), United Kingdom(2), Malta(1), Belgium(1)	Alicia Padrón-Monedero

All groups were asked to answer two questions:

1) Why or why not an EU HI research infrastructure (RI)? Identify strengths, weaknesses, opportunities and threats (SWOT analysis)

- What are strengths of having an EU HI RI?
- What are weaknesses of having an EU HI RI?
- What are opportunities and added benefits for setting up and EU HI RI?
- What are barriers or threats for setting up an EU HI RI?

2) How can an EU HI research infrastructure (RI) respond to your needs?

- What are your 3 most important needs for health policy?
- How can research accommodate your national needs?
- How can European research collaboration support these needs?

Answer from AoM to the **question 1):**

- Nobody questioned the need for a health infrastructure supporting HIS, thinking that "the more countries to follow this initiative, the better in terms of EU-added value and public health utility".

- What it is not clear is the need of a research infrastructure because this kind of infrastructure has to deal with very different needs: Health management, Health policies and Research purposes. Each one with different visions, timeline, objectives, professional profiles and horizons.

- Most participants are not sure whether an ESFRI roadmap or an ERIC are the best way of building up or financing it. They suggested that InfAct should demonstrate its benefit as compared with other options.

- The ERICs are financed by EU/EEA MSs; therefore, before going any further discussions about EU/EEA MSs commitment, it should be clear who will pay and how much. This question is one of the most important issues.

InfAct is not the only project looking for an ERIC. EU/EEA MSs could be unsure about in which initiative they should put their limited budget assigned to international research purposes.

- It is assumed that going to an ERIC means that not all EU/EEA MSs will join the initiative. This means we will not gather HIS from all countries, so that could put in risk the EU benefit and InfAct outcomes.

- EU/EEA MSs stress international organisations (WHO, OECD) difficulties in accessing an ERIC since its administrative framework is quite complex and inflexible for them. How does InfAct expect OECD and WHO to be part of this ESFRI roadmap or ERIC?

- There is a lack of clarity in the proposals. There is a need of a well-structured written business plan including: services offer, resources needed including human resources, funding scheme and funding resources, business model, EU/EEA MSs participating, timeline and articulation with current initiatives and stakeholders in the field of health data (DG-Santé, DG RTD, DG Connect, DG ECO).

Answer from AoM to the **question 2):**

- Providing evidence based for political decision is the most pressing need. Policy makers need urgent and performant response. For researchers a response could take years. Therefore, a concern is how InfAct is going to deal with different timelines and needs.

- This project and the future infrastructure should enhance data quality, data availability, common procedures and standardization in data collection, data linking and universal access to EU comparable data.

- Providing a network of experts, with credibility, bringing EU/EEA MSs inputs.

- Much diversity for data collection, purposes and utilities has been exposed today, but EU/EEA MSs need to clearly identify the domain of this project. We heard in your presentations, that you want to keep to different options, which is understandable on one side, but on the other side it is difficult to sell a project if you do not tell clearly what you really are going to do and which domains are you planning to address.

- The most positive response for this Infrastructure would be to provide available evidence-based information for decision-making process. Providing in a timely manner innovative, quality and comparable data and public health policies across Europe, would be an expected outcome.

- There is a need of linking researchers, policy-makers and patients.

- Common health care indicators and health population data for prevention activities would also be an asset.

- Besides the link between the public and the private sector should be engaged in collaborating and focusing on research questions related to efficiency and effectiveness

- For the future, we need a very clear proposal where decision makers could see benefit and progress for our future health challenges.

In summary:

- All countries welcome a unique infrastructure gathering research, best evidence to inform policies and HI systems for health management.

- EU/EEA MSs need to clarity on what kind of infrastructure and outcomes are going to be provided.

- EU/EEA MSs need one stop-shop to provide in a timely manner quality and comparable data for decision-making.

- There is a need of linking research and health management in order to increase evidence based health policy.

- Funding such an infrastructure remains a concern, since for being useful in terms of EU-HIS most countries should be involved and providing national data in a standardized manner.

- A research Infrastructure does not need many countries involved, but it is not able to gather in one stop-shop research results and HI for health management and policies

10. ESFRI Roadmap. Gonzalo Arévalo (GA). Deputy Director for International Research Programmes and Institutional Relations. Carlos III Institute of Health. Ministry of Science and Innovation. Spain

RI are facilities, resources and services that are used by the research communities primarily to conduct research and foster innovation_at EU and Associated Countries level. The

objectives of the EU approach of a RI are: to address collectively the complexity and cost of the design and development of new world class RI, to open access to the research infrastructures existing in the individual EU/EEA MSs to all European researchers, to avoid duplication of efforts rationalise their use, to trigger the exchange of best practice, develop interoperability of facilities and resources, develop the training of the next generation of researchers, to connect national research communities and increase the overall quality of the research and innovation and to help pooling resources so that the Union can also develop and operate research infrastructures globally. ESFRI is a strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach. The ESFRI roles are: (i) to jointly reflect on the development of strategic policies for pan-European Research Infrastructures (RIs), (ii) to prepare a European Roadmap (with regular updates as different areas mature), (iii) to act as an incubator for concrete RI projects with pan-European interest. It is important to note that ESFRI it is not a decision making body to boost Europe's competitiveness.

Since 2006 ESFRI established an updated European Roadmap for Research Infrastructures (new and major upgrades, pan-European interest) for the following years. ESFRI stimulates the implementation of these facilities, and updates the roadmap as needed. ESFRI is a self-regulated body, which operates openly and on a consensus basis. ESFRI Delegates are senior science-policy officials or equivalents, who represent ministers responsible for research in their country.

ESFRI Projects: are RIs in their Preparation phase, which have been selected for the excellence of their scientific case and for their maturity, according to a sound expectation that the Project will enter the Implementation Phase within the ten-year term.

ESFRI Landmark: are RIs that were implemented, or reached an advanced Implementation Phase, under the Roadmap. The Landmarks can be already delivering science services and granting user access, or can be in advanced stage of construction with a clear schedule for the start of the Operation Phase.

The European Research Infrastructure Consortium (ERIC), is a legal instrument, based in the EU Regulation 723/2009, to provide a legal framework for Pan-European Research Infrastructures. ERIC is a body with its own legal personality, recognized by all EU MS. Memberships of ERIC are countries not organisations. ERIC contributes to execute EU research Activities, offers scientific and/or technological value added at EU Level, facilitates and promote the mobility of researchers and knowledge through the ERA, disseminates and optimizes the use of the results and outcomes of the research and innovation activities.

In order to get the ERIC Status, there is a process for its application and it is re-evaluated every five years.

Questions about ESFRI Roadmap

Q: How often is opened for application? How many projects have applied already that have not been admitted to ESFRI roadmap?

GA: ESFRI is opened every two years. The amount of applications is considerable but I do not have the exact figure of the number of projects rejected

Richard Blundell (RB) Malta Council for Science and Technology, Malta. The last ESFRI Roadmap was launched in September 2018, and the next one is going to be published 2021. The process for a Research Infrastructure of entering the ESFRI Roadmap is different from that to become an ERIC because the application is not cyclical so one can apply at any time. An ERIC requires the political support and commitment of three Member States.

JW: ERIC is a legal status that do not provide any funds, what is the joint action doing in terms of advocacy for specific funding opportunities within the next 2021-2027 financial framework (e.g. Horizon Europe) ? How relevant would be to obtain a call regarding research infrastructure for public health data ? It is to note that some ESFRI landmarks such as ERHINA (the European Network of high security laboratories) have not opted for an ERIC legal status (but for an International Association under Belgium law in the case of ERHINA), while continuing to develop their activities and business models.

Comment from AN: There in an infrastructure pillar in the new program. They are not providing funds for routine operations but they might fund projects of developing or outreaching to new MS. There is another pillar for health that is project-based development that could be funded.

PhR: Although an ERIC does not provide any funds per se, you should have a legal status to receive funds and the InfAct project should follow this route.

Sandra García (SG): An ESFRI roadmap does not uniquely lead you to an ERIC. Could you elaborate more the other options?

GA: The ERIC is not mandatory is the gold standard but other options are being financed by external sources, grants, contracts with enterprises, etc.

Giovanni Nicoletti (GN): ESFRI application is a sort of softer way of taking time but regretfully not for us, because there is a national decision that might be official when the application will be opened. There is a national roadmap, and an application to the national roadmap. Those who do not pass the application are not allowed to support the applications from other countries.

MC: This came up with the discussions and is definitely a threat to all the countries

11. HI Research Infrastructure-The ESFRI roadmap application. Dr. Herman Van Oyen (HVO), Coordinator of InfAct. Director of Epidemiology and Public Health, Sciensano. Belgium.

HVO explained the ESFRI lifecycle approach and their phases: design, preparatory, implementation and operational.

Why applying for an ESFRI

- Stepwise and structured process to set up a European Research Infrastructure Consortium (ERIC) on HI.
- Stamp of scientific excellence, its Pan-European relevance, and the socio-economic impact.
- Opportunities for European funding.
- Engagement of EU/EEA MSs and collaboration of research institutions at operational level.

Steps within InfAct: connecting National Networks in EU/EEA MSs, engaging Domain Specific Networks and their research communities, situating of the RI in the HI landscape, setting up web based platform, fine-tuning the services to be provided and develop a model for their implementation, interact with relevant stakeholders in HI field and submission of the ESFRI application

Timeline: the project is in the design phase and it will apply for ESFRI roadmap in 2021.

Stakeholders in HI research infrastructure field (existing infrastructures, international organisations and potential research communities have been already identified).

12. Programme and objectives for the next Two Assembly of Members. Dr. Isabel Noguer (IN), Leader of Work Package 4. ISCIII. Ministry of Science and Innovation. Spain

IN presented the aim of WP4, which is Sustainability for EU HIS supporting country knowledge and capacities, health research and policy making. It has three tasks: 1) support integration of JA HI activities in EU/EEA MSs through an AoM, 2) technical dialogues and 3) Sustainability Plan. The second AoM meeting will be held on November 13th 2019 in Brussels and the third one in October 27th 2020 in Madrid. The AoM's objectives for representatives are: (i) act as liaison with the national Research network, National Health System, and National Public Health authorities, (ii) give feedback/policy guidance to InfAct partners regarding potential translation of outcomes into national systems, (iii) assess the ESFRI roadmap or structural alternatives for InfAct long term activities, and (iv) support the potential integration of InfAct main outcomes in EU-HIS and policies.

For the schedule of the second meeting, it is expected to have a progress of the JA and to present fact-sheets with main findings from each work package, a report from technical dialogues and the Memorandum of Understanding (MoU) on the way forward (ESFRI and ERIC). Finally, for the third meeting, apart from reports of progress of the JA, the Sustainability Plan will be presented for review and approval.

NC: The proposed agenda is not rigid and would be adjusted according to what have been discussed.

13. View from the European Commission. Dr. Philip Roux (PhR), Head of Unit "Country knowledge and Scientific Committees" DG Santé. European Commission.

PhR mentioned, that DG Santé is funded through taxes so, eventually, the European citizens money is funding InfAct. Thus, DG Santé´s main interest is that such money is well and usefully spent. He raised 5 points to take into account about the meeting

First, it is important to keep in mind that not taking any decision is already taking a decision; and representatives should take responsibility on that. It is in the representatives hands to have a tool to steer national policies on health. Before launching InfAct there were long discussions about the different options to address HIS and their challenges. Is important to overcome the discussions and start acting to tackle the rising health problems and challenges across Europe.

Second, a business plan is indeed needed, it was discussed before and the elements of such plan already exist.

Third, it is important to consider the vision of DG Santé about the purpose and the expected impact of InfAct that should be (i) reducing health inequalities between and within MS, (ii) translate research faster into actions, because very often the research results are not used, and (iii) adding better services to citizens at a reasonable cost for ensuring sustainable health systems. PR said that the AoM representatives encourage the EC-DGs to work together, he agrees but he also would like to encourage AoM representatives to cross-sectorial work between Research and Public Health at the national level and DG Santé will do the same at the European Commission level because the most important goal is the health of the citizens.

Fourth, it is necessary to take advantage of the opportunities offered by new technologies to improve the way of collecting and disseminating data and to explore brand new technologies such as artificial intelligence. Health data should travel with the citizens when they travel across Europe and it is necessary to work together at least in the interoperability of the systems within and between the countries.

Finally, the process should go fast, and going faster means progressing by doing. It would be desirable to put energy in starting fast and while working, to analyze what is needed and how to make it better.

B. Minutes of the Second Assembly of Members

1. Welcome by Sciensano: Joris Van Loco. Scientific Director Sciensano. Belgium

Joris Van Loco (JVL) (Belgium): As a scientific director in Sciensano I am pleased to introduce you to Sciensano, a Belgian federal research Centre on population health. We have already a century of expertise in Public Health Research. As a Public Heath Institution,

we support knowledge translation to policy topics for the Belgian government. Our “One Health concept” is a holistic view on Public Health. We try to combine different disciplines coming from technologies, data analyses, and chemistry and to apply this holistic view on Public Health and to combine different institutions to provide evidence in Public Health. Our slogan is "Healthy all lifelong", so we have programs in health and diseases monitoring, in Health and environment, Health food consumption, food safety, effectiveness and safety of vaccines, medicines and health products, quality of medical laboratories, quality of medical advisory and quality of healthcare. Today we are here for the Joint Action InfAct. Sciensano has the role to coordinate, and also to assume the lead of the 3 important outcomes: to coordinate the national node development, the participation in the peer review process of the Belgian HI system (HIS) and other EU/EEA MSs and the development of HI impact assessment index. Moreover, one service in our scientific health in Sciensano is health data assessment, and our health data mission is to facilitate the data exchange between healthcare professionals and researchers to increase public health knowledge in Belgium.

Comparative population health research is essential and, as a research Institute, we want to push for a more sustainable pan-European HIS that boost both the research and public health policy and practice at EU/EEA MSs and EU levels. The objective of today, the second Assembly of Members (AoM) meeting of InfAct, it is to discuss and agree upon the further development towards a Distribute Research Infrastructure on Population Health (DIPoH). The mission of this DIPoH is to improve the identification of data sources, the access, the assessment of the data quality, and reuse data for comparative health research. In name of Sciensano, I wish you a fruitful discussion and a fruitful stay.

2. Welcome and introduction by the chair: Dr. Thomas Ziese. Robert Koch Institute. Germany.

Thomas Ziese (TZ): Ladies and gentlemen, you are in the second AoM. You are coming from Ministries of Health (MoH) and Ministries of Research (MoR), as well from DG Santé, and beneficiaries/stakeholders from InfAct. I am from Robert Koch institute, which is, as Sciensano the counterpart in Germany. Related to InfAct, we are dealing with data, however, our interest is also focused on ageing populations, prevalence in chronic diseases, diabetes, dementia, and social inequalities in health among other challenges. These programs and our health data expertise and research could be of use for the European Union (EU). Health data gathering within EU started at the 90s. It was created for different projects financed by DG Santé, or joint field networks on health issues like injuries among others. Different projects were set up in top-down direction and are often not well interacting. So now we are facing that we have a fragmented data situation within the EU. Looking at this situation, Sciensano leads the Joint Action InfAct that is financed again by DG Santé. InfAct´s aim, is the implementation of a sustainable structure for HI and establish research for evidence based policies, which is InfAct´s most important aim. I have attended the first meeting of the AoM in Madrid, where representatives of both MoH and MoR were informed of the different aspects of InfAct, including goals, work packages (WP) and achievements. The intention of this second AoM is to exchange and clarify questions and suggestions coming from MS. The main conclusions of this meeting will be gathered and

integrated in InfAct activities. For MS, there is a need to link health research and public health more closely nationally and at the EU level. We also stress the right balance between research and public health. Also, EU/EEA MSs require information on the sustainability of the structure and, mainly, the financial activities, so in the first AoM they demanded the need for a business case. The coordination of InfAct will provide you the information required in this first AoM, including the development of the business plan that will be the main topic around this meeting. The objectives of this second AoM meeting is to discuss and clarify the strategies of InfAct.

3. The Distributed Infrastructure for Population Health (DIPoH). Business case Part I

The rationale, the structure, the services by Petronille Bogaert, InfAct and Sciensano.

Petronille Bogaert (PB): I am Petronille Bogaert, I work in Sciensano together with Herman van Oyen and Linda Abboud, in EU HIS. We decided to call this structure DIPoH because it extends on Distributed Infrastructure on Population Health. During the last AoM you required us to provide more details on why we choose to work in a research infrastructure, and why we are not working with any existing infrastructure in the EU. First I start with the rationale on why we need this infrastructure. We see that in the EU all data is fragmented, in very small databases and placed in different countries. The data is normally incomplete, dispersed and difficult to access. There are social inequalities, and knowledge is still dispersed, incomplete and difficult to access. Large differences can be found among different countries in terms of data quality and, as a consequence, in comparability of HI between and within EU MS. Why do we need a Health infrastructure? This is based on a discussion that international research institutes had. We need a European strategy on HI more coordinated or more collaborative than the current project-based initiatives. There is a lot of work in HI by different DGs in the commission, different agencies, and different projects, which do not integrate the information between them. Additionally there is a need for an interdisciplinary cooperation with non-health sectors and the civil society to allow as much information as we can. To improve the link between HI activities including research and development, and policy needs, we need decisions on common issues and to create synergies and sustainability between projects and HI activities. We need also to take into account the data harmonization, collection, processing and reporting. What we want to do in DIPoH is generating new data definitions, indicators and to harmonize them between countries. We aim to: use a standardized methodological approach to data collection with experts in specific topics, to facilitate sharing and exchange of harmonized data at population level, to harmonize EU wide health reporting, including data visualizations, to ensure sustainable data collections and data availability for evidence-based public health. We need an infrastructure because there is a lot of potential benefit after data has been collected, in the following aspects: These research opportunities can provide recommendations in public health policies to improve our future. Comparison and benchmarking among EU/EEA MSs and for Europe allows assessing the quality and the efficiency of health care systems, assess inequalities in Europe, to have a unified general picture of health situation in Europe and addressing health determinants that operate across national boundaries. And about the knowledge sharing and capacity building we aim to

diminish the HI inequalities between countries and to develop knowledge and expertise and to facilitate its exchange. We want to make sure that the data will be available, both for research and policy-making, using the research for evidence-based policy making, monitoring and planning.

Why we decided a research infrastructure? We handled the options:

1) To strengthen existing structures: ECDC (European Centre for Disease Prevention and Control), JRC (Joint Research Centre), Eurostat, DG SANTE. As well, we took into account the outsourcing structures: WHO (World Health Organization) and OECD (Organization for Economic Co-operation and Development).

2) To create a new independent structure, through an Independent new EU agency

3) To set up a Research Infrastructure, as the European Research Infrastructure Consortium (ERIC).

The strengths and weakness of these options were identified.

1) To strengthen existing structures:

- ECDC, will have an important strength because: all EU/EEA MSs can be involved, could have a mandate to lead, ECDC is knowledge driven and knows how to store data. However, the weakness, are that it would require an amendment of the ECDC founding regulation that is a great challenge. A decision of the European Parliament and of the Council would be needed to install a separate surveillance system. Looking into the structure of the ECDC, it is very complicated, because there are specific topic activities. The annual budget of the ECDC would need to be increased and would require a financial commitment by the Commission and a political support by EU MS. It would require appropriate resources at EU level that are currently not available and it is too orientated towards infectious diseases, so it should be very clear in their mandate that they have a task other than infectious diseases. However, we think that the ECDC has an all-in-one approach, which might be a model for a long-term solution.

- The strengths of Eurostat are that it is a statistical authority of the EU, so it has a lot of knowledge in development, production and dissemination of European statistics. Also, they coordinate statistical activities of Community institutions, they elaborate the European statistics, defined by the European statistical office and they establish legal bases in each country to share data with them. However, the weaknesses are that: it is statistically data oriented, their health activities are limited, they have no clear link with MoH or MoR, they mostly link with technical statistics institutions, and they do not have a public health thinking as a main objective.

-The Joint Research Center is an agent within the Commission with the mission to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle. It was funded by the Horizon 2020 by the Commission. Their strengths are that they have developed registries, they are currently working on European Cancer, and they are research orientated. However, it is not clear their priority setting. Also, they have limited population health knowledge.

-DG Santé has important strengths: their knowledge on HI and its background in public health. However, setting up a new unit means budget and staff reallocation, they could have a possible lack of continuity and political support, and there could be a conflict between strategic policy development and practical day-to-day routine work on HI. DG Santé is mainly focused on strategies and government policies.

-Outsourcing the task to the WHO and OECD. Their strengths are that they have experience and expertise on the international domain. They are influential to MS, and to concentrate the task in them will reduce reporting by MS. However, they are not focused on what HI needs in EU, they have their own agenda, they have a limited research and new data development, they have a limited funding, and their knowledge is moved to international organizations so EU/EEA MSs will not be part of a bilateral agreement.

2) To create a new independent structure, through an Independent new EU agency:

What are the strengths of creating this new agency? It is tailored to specific needs, focused on what you want, it has its own voice that means a better advocacy and visibility, it has a clear vision and goals, it is linked with international organizations, and allows MoH and MoR to work together. However, it needs to start from the scratch so that will require a lot of work and resources. It needs strong political support, and would take a long time to be settled up. Moreover, there is no legal framework.

3) To set up a Research Infrastructure, as the European Research Infrastructure Consortium (ERIC).

It is the most feasible solution in the current setting, because it allows responses to current needs and demands with high usability for EU/EEA MSs and EU institutions, so really focus efforts on aspects that EU/EEA MSs think are important. It has possible funding mechanisms through participation in calls of MS, EC and EU/EEA MSs contribution. Ensures linkage with the scientific community, national infrastructures and international organizations. Also, it is a flexible tool, so it could reduce or expand the activities based on the HI needs. It can provide relevant HI for decision makers and has the capacity to bring together different actors in HI. And finally, can ensure continuity of existing HI activities. At this time, we really think that the DIPoH is the most feasible solution.

Questions

Jerome Weinbach (JW) (Ministry of Health of France): I am coming from the French MoH. I have two questions:

1) How will you work with existing infrastructures?

2) You told us about an infrastructure not much where the data will come from. There is a trend to create in EU/EEA MSs national data hubs. How would you integrate them in this future infrastructure?

PB: We are going to work through different networks or nodes, so we are going to connect between countries at the national level and also based on topics. At the national level, we

called them national nodes (NN), and at the topic network level we called them Research Networks (RN). It is about combining what it is available, so both NN and RN will provide an overview of what exists. What the research infrastructure would do is to highlight these existing infrastructures in countries and also have other countries to identify a representative to be the NN. The aim of the research infrastructure will be to connect the different countries. For example France experience in creating a data hub will be very beneficial for other countries to learn how we do that. This could be an added value of DIPoH.

1) How do we work with existing infrastructures? I think we are able to extend, research infrastructures and also joint actions, into a plan to connect with them. We are not looking at the same type of data that they have, because a lot of the researcher infrastructures look at, for example, experimental data, so we are focused on different objectives. But we can cooperate providing services.

PB: To complement the presentation, I want to show you a video.

Video: *"In Europe, vast amounts of HI are being collected, processed and used. There are many kinds of HI: insurance data, vital statistics, hospital care data, guidelines and manuals, big data, disease registries, indicators, and survey data. Collecting, processing and use of HI in Europe should pulsate with connections, constant data sharing and new findings. But there is no infrastructure connecting HI sources, or health projects and initiatives across Europe. As a result, huge amount of health data and related information are not efficiently organized, leading to dispersed knowledge, incomplete data and difficult access. Our aim is to connect the different sources of HI, projects and networks, into a European HI Research Infrastructure. This infrastructure will provide and share quality data, information and tools, it will strengthen and promote research and scientific knowledge, cooperation and integration, it will support expertise and innovations and it will inform health policy. Our mission is to connect and advance comparative health research for well-informed international decision-making. Our vision is to create a sustainable infrastructure for the best health knowledge, improving population health and care in Europe. Join the European HI Research Infrastructure."*

The rationale, the structure, the services by Linda Abboud, InfAct and Sciensano.

Linda Abboud (LA): I am Linda Abboud, from the Sciensano group working at the HI unit. DIPoH, wants to bring together networks, stakeholders and experts in HI, focused on population HI. We will enable them to perform high level of research and, basically make research more identifiable, successful and interoperable. We want to improve health and other outcomes, and the achievement of outcomes at lower costs in Population HI. We are focusing on the topics: health status of the population, determinants of Health, and also for health care system, as very important aspects on population health. The uniqueness of DIPoH is that it covers the population as a whole, the healthy as well as the non-healthy population, so it is not focused on patients or the diseases. Moreover as it is focusing on non-communicable chronic diseases and its determinants there are not duplications with

the ECDC. DIPoH will also facilitate secondary use of data, where includes both individual and aggregated level data. We are not including experimental research or clinical research.

The current research infrastructures available in Europe are listed on the following

Table 3 List of current research European infrastructures

Acronym	Name
BBMRI ERIC	*[Bio banking]*
CESSDA	*[Social Science Data Archives]*
EATRIS ERIC	*[Translational medicine]*
ECRIN ERIC	*[Clinical research]*
ELIXIR	*[Bioinformatics]*
EU OPENSCREEN ERIC	*[Chemical Biology]*
ESS ERIC	*[Social Survey]*
ERINHA	*[Highly Pathogenic Agents]*
ISBE	*[Systems biology]*
INSTRUCT ERIC	*[Structural Biology]*
METROFOOD-RI	*[Food and nutritional metrology]*
MIRRI	*[Microbiology]*
SHARE	*[Aging (survey)]*

Many of them are focused on social sciences, microbiology, and social biology, so we think that bringing a research infrastructure on health of populations is needed. We will collaborate with these research infrastructures but we will offer different services focused in our topic. The objective of DIPoH is to support the development of a large-scale, integrated and sustainable data services for population health and health services performance research. We want to create a catalogue of information and knowledge to generate a critical and growing mass of European researchers and their international networks and strengthen the synergy in the EU by facilitating comparative research, efforts at data linkage, (re)use of data, methods, results and a better involvement of national experts. So, this research infrastructure will ensure that research is findable, accessible, interoperable and reusable, so we can create stronger research networks in Europe. We are going to operate with a central office, which will have a web portal, and a services support. This office will do all the management, the services and the governance of the infrastructure. We will also have the two types of nodes and networks, the national nodes (NN) (across EU-MS) and the research networks (RN) (topic specific). The services for the research infrastructure are summarized in four different services:

1) One-stop shop for EU HI research is basically to create a catalogue that includes also the way to find the different data that are available in Europe. It includes the information of the metadata available, and the different data models. This catalogue will also allow to find different experts and the methodologies and tools for the different topics related to population health.

2) Innovation and research. We want to promote new methodologies and research on population health.

3) Capacity building in HI. To increase the capacity of the EU/EEA MSs in the different topics of HI research (collection, analysis, reporting and transformation). We would provide different programs and registries or training that exist in Europe and also new ones provided by us

4) To help researchers to create a better evidence oriented to our policy-makers (methodologies on knowledge translation).

We developed this services into activity layers. We have core activities, support activities and strategic activities. Few examples of core activities are to catalogue collections of FAIR data, which is the catalogue or dimension how to find the research the data, the expert, and the tools on different methodologies in population health research. We will also develop and maintain repositories for: international comparative datasets, indicator sets, research articles and reports from the networks, standards, guidelines, methods and metadata. We will facilitate access to relevant classification methods and standards. We will map open access software solutions, literature searches and reviews. The advisory services we will provide are, for example, the guidelines to FAIR data and being in line with ELSI requirements, working with complex/big data and data model development, analytical pipelines, customized selection of data models, building a productive research network, writing hands-on guides on methodologies and tools for HI practitioners and researchers. Our capacity building service will support researches in EU/EEA MSs with a new domain specific areas (setting up registries, surveys, improving quality of registries and surveys, stimulate data provision, data management plans, metadata, …), to do a real world data reuse, develop federated data infrastructures, manage specific capacity building projects, facilitate learning networks for researchers, organize and support expert exchange and teaching options. The research development support helps with legal and ethical aspects; forms, standards, regulations, designs EU-wide data collection efforts- (Standardization, interoperability), finds matches for research and funds/pools, gives advice when drawing up project descriptions, provides general information and advice about European and other international research programs, courses and meetings, contacts and coordinates in relation to EC staff in Brussels about EU projects and across sectors.

Another service will be focused on methodologies for knowledge and how to make sure that the research is usable for policy and decision making.

The service about strategic activities, it is based on knowledge brokering, and linking collaboration with other ERICs by connecting though a European science cloud. This also includes horizon scanning, support for joint research agenda and priority setting.

4. Results from Technical Dialogues on InfAct outcomes

Objectives of the Technical Dialogues by Rodrigo Sarmiento (RS), ISCIII, Spain

On behalf of work package 4, I am going to present a summary of the purposes of the Technical dialogues (TD). The TD are aimed at achieving technical support from national experts and the integration of this InfAct outcomes into national and European HI policies. The national experts are nominated by the MoH and the public health institutes. They aim

to achieve technical support working as a forum of exchange between national experts and InfAct work package leaders. Also the TD assess InfAct outcomes and its added value, relevance and feasibility to be integrated into HIS. Two meetings were on the schedule, one was already held in Madrid last October 2019, and the other one is scheduled to take place in September 29th of 2020. The fact sheets (FS) are a brief summary of InfAct outcomes that are used as a road map for TD in order to raise awareness and acceptance in decision makers. The main InfAct outcomes that summarize these FS that were discussed last October in Madrid were: BoD, industrial pollution and cancer, both from work package 9, assessing and piloting interoperability, from work package 10, prioritization of HI, from work package 5 and health data collection methods, from work package 8. The main conclusions of the TD were:

1. There was a consensus about the added value of the proposals in terms of promoting EU/EEA MSs mutual learning and cooperation
2. InfAct outcomes should be relevant for defining priorities and for decision makers. That means how to translate knowledge into policies.
3. Integration of different data sources, accuracy and robustness of comparable data were considered important goals.
4. General Data Protection Regulation (GDPR) versus interoperability was a major concern but a way forward for the future, which means more data is available but the regulations are stricter.
5. Feasibility to integrate InfAct outcomes into National/EU HIS was considered complex, based on different challenges as data quality and methods, intellectual property and long-term projections. Many of this outcomes are ongoing, thus, more specific results are needed to properly discuss feasibility.
6. Participation and also direct implication of the national data providers were highlighted
7. There was a concern regarding level of EU/EEA MSs commitment in order to integrate initiatives into HIS

Questions

JW: TD are important in your presentation. They provide inputs about the technical aspects related to the data health interoperability but not much about the infrastructure of HIS. We would like to know if the infrastructure you propose connects existing data providers' infrastructures. So could you provide more information about both information systems that are involved, software and hardware?

RS: Thanks for asking**,** about your question related to interoperability, it will be presented later by my colleague from IACS in a FS. Related to the infrastructure itself, it is going to be presented in more detail in the next TD.

PB: We are going to provide more information about the infrastructure in the second presentation after the next one.

Fact sheet "Use of non- health EU databases for health surveillance. Case study in Industrial pollution and cancer". Dr. Alicia Padrón Monedero, on behalf of WP9, ISCIII, Spain

Alicia Padrón (AP): I am going to present three FS that were discussed on the last TD on behalf of work package (WP) 4 that leads Isabel Noguer. We work at the Instituto de Salud Carlos III (ISCIII). I will start with the first FS, that was performed by Dr. Pablo Fernandez, from the ISCIII, from Spain, as a co-leader of the WP9, that leads Santé Publique France. We are going to present specific technical outcomes that were asked from you in the last AoM. In this FS we are going to present an integration of diseases and their determinants from non-health data bases for Evidence Based-policy making. More specifically, we are going to assess the possible relation between industrial pollution and mortality and/or morbidity for different conditions. We are going to present the tool, that we have developed, that combines the municipal mortality or morbidity data, from a specific country, and the information from the E-PRTR (European Pollutant Release and Transfer Register) maintained by the European Environmental Agency, that is available at the European level, and it can be discharged for free. The European Pollutant Release and Transfer Register is available at the European level and has information of the type of activity of all the pollutant industries divided into 9 pollutant sectors. The En-risk tool could analyze the mortality and morbidity related to different pollutant industries, it is very user-friendly and needs a minimal knowledge to use it. The application works in the users´ computer. It downloads the geographic coordinates for each facility from the official web of the E-PRTR, while health data can be directly loaded into "*En-risk"* by the user. This way, HI is always stored and managed in the computer of the user in order to guarantee data protection. You only need to additionally include the following minimum data: Shapefile (cartography) of the country (spatial unit = municipality), annual observed deaths (for mortality) or cases (for morbidity) and population figures broken down by age groups (18) and by sex per municipality. Optional information that could also be uploaded by the users is: social and economic environment information at the municipal level. We also need to specify our chosen distance to the exposure of the source E-PRTR. The statistical analysis is complex with Bayesian methods and I am not going to describe it here, but the tool makes this analyses without any effort from the user. It is very easy to use, it does not require statistical knowledge. However, the interpretation of the results requires a public health expert. In short, En-risk merges the information of the pollution industries with the morbidity and/or with the observed deaths, and the population broken down by 18 age groups and by sex. With this information, the program calculates, as you can see, the increase of risk of a specific pathology. This tool gives a screening-like information, it suggests the presence or the absence of excess risk, and you must further analyze it from a public health perspective. Currently we are using this instrument in Spain, with cancer, and we are going to include now in the analysis data from our partners from Portugal and France. This is going to be the next outcome.

Fact sheet "Two-round Delphi study of methods for prioritizing HI at national level". Dr. Alicia Padrón Monedero, on behalf of WP5, ISCIII, Spain

AP: The second FS was developed by partners from the Robert Koch Institute from WP 5, that leads Dr. Thomas Ziese. The keyword of this FS is prioritization and in the last TD was considered a very important subject for public health. The prioritization methods at the national level and at the EU level are very scarce in the literature. So, our partners from Robert Koch institute have performed a two-round Delphi survey with the prioritization methods collected to try to organize, analyze all the prioritization methods and give a toolkit or platform to collect good practices of prioritization that is the final goal of this ongoing process. They have completed the first level of the Delphi process, about collecting the first round of the information about prioritization methods from different stakeholders (universities, public health institutes and the statistical officers). They have also documented the national good practices into a framework of good practices to structure and facilitate the prioritization of HI at the national and international level. This framework, is going to be published and distributed as an InfAct document and it is going to be accessible to everybody. This document could help to lead the agenda of the politicians on the prioritization process on public health and also to detect ongoing public health increasing problems and emergency risks.

Fact sheet "Questionnaire for EU/EEA MSs regarding health data collection methods and procedures". Dr. Alicia Padrón Monedero, on behalf of WP8, ISCIII, Spain

AP: The last FS it was developed by the WP 8, leaded by our partners from the National Public Health Institute from Italy. The aim of this FS it is to identify and summarize existing health data collection methods that are not included in the ones at international level that we all know (WHO, ECDC and Eurostat). In Europe there are a lot of databases at different levels that are fragmented and that are no included and integrated in the international data sets. In this FS they have reviewed and identified standardized data collection methods by assessing the quality assurance procedures with the aim, to elaborate a guidelines of good practices for accessibility and availability of HI. Now they are in the pilot phase of the survey. They have collected information from 11 European countries, and now they are in the process of analyzing all this data collection methods and perform their quality assurance. Some of the databases are at the national level, some of them are integrated at the European level or in another structures, and some of them are just on development. One interesting thing of this picture, is that only one project uses metadata reporting standards, in particular DDI (Data Documentation Initiative). So the aims of this task are to generate knowledge on standardized health data collections and their quality, and also assure its sustainability by creating a guidance for good-practices in health data collection to be distributed for everybody to use it on the data collection protocol.

Fact sheet "Burden of Disease". Dr. Romana Haneef, WP9, Santé Publique France

Romana Haneef (RH): My name is Romana and I am working for WP9 at the Santé Publique France. WP 9 is focused in innovation in HI for public health policy. Some information resources have some problems such as a high cost of data collection, the low participation rate in the surveys, and also the self-information bias in self-reported surveys. Considering this facts we have 5 objectives in WP9: Identification of the innovative use of existing data sources; application of new techniques and methodological approaches for population health research; development of the guidelines/recommendations for using new methods to estimate health indicators; identification of the best practices for innovation in HI; development of composite indicators at EU level and comparability between EU/EEA MSs. Today I am presenting one of the outputs of WP9, about burden of disease (BoD). BoD it is a systematic, scientific effort to quantify the comparative magnitude of health loss due to diseases, injuries, and risk factors by age, sex, and geographical distribution for specific points in time. Unfortunately the BoD approaches are not a part of routine public health activities in Europe. The main reasons for lack of use of BoD estimates are the unequal level of knowledge, experience and capability to apply BoD methods and to use BoD estimates to translate them into health policies. During this project, we required from the National Public Health Institutes, two simple questions "Do these institutes have any experience to carry out a BoD study?" and if no, "In which areas they would require the BoD network to support them?: Developing a BoD methodology, estimating the BoD with practical exercises interpreting BoD data or translating of BoD data into policy". The answer of these two questions was that only 7 EU/EEA MSs had experience in using these approaches in BoD studies. They highlighted the need to have support in applying the methodology, also for practical exercises to interpret BoD data and also in translating this information into health policy. These results confirm that EU/EEA MSs need guidance and training to adopt and integrate BoD approaches in their public health systems. Among 25 MS, only The Netherlands is pioneer in applying BoD approaches. Moreover, this initiative is needed because BoD approaches have an added value to improve knowledge. The BoD could be used in different ways: to provide insight of a country's health status, provide comparable results in different country contexts and define and monitor trends in disease burden and risk factors. Also, BoD estimates could be used in different areas, for example: the national priority setting and resource allocation with potential economic impact, to assess the impact of interventions and policies, to provide a framework for quality improvement, and to target interventions to populations that need them the most. There is also an indirect benefit of performing a BoD study: to develop the capacity building or the skills in a MS, to identify data gaps and improve data quality and completeness of information, and to guide investments to improve HIS. Finally it is important to emphasize the potential role of BoD measurements that should provide population HI for action across Europe. This was the target and there were 5 specific objectives: to raise awareness about BoD concept, methods and implications in health policy across EU/EEA MSs; to share knowledge, experience and good practices; to provide mutual support to integrate BoD indicators in the public health policies across Europe; to provide the networking opportunities to collaborate with each other; and to improve the competencies and skills to perform a BoD study. So, we had organized two workshops on BoD, the first one was about the concept and methodologies of

BoD across EU/EEA MSs, and the second was about the use of BoD estimates in public health policy and practice. For these two workshops there were 40 participants coming from 25 EU/EEA MSs, 16 BoD experts from different countries and two of these experts are here in this meeting as well. These experts came from Belgium, Germany, the Netherlands, Serbia, Sweden, UK and US. It was an excellent group, sharing of different experiences. There were also experts from the Institute for Health Metrics and Evaluation (IHME) and also from the University of Washington. The key results of the BoD workshop I & II Were: The need for improving methodological trainings to strengthen their skills in how to calculate and interpret the BoD estimates across MS; also there is a need to encourage more collaborations across EU/EEA MSs to share or exchange good practices and knowledge for the BoD; to highlight the importance of the implications of BoD data to guide health policies across EU/EEA MSs; and to highlight the quality of data sources and the choice of indicators. At the moment we are planning for the III BoD workshop next year, with three specific objective: to interpret BoD estimates in comparison to the GBD metrics and to highlight the differences by taking into account various factors (i.e., technical, public health changes, etc.); to comment on country health profiles developed using GBD metrics; to develop a rational approach to conducting a BoD study in a given MS, to develop an InfAct BoD Toolkit. In the workshop that we are at the moment preparing, a background document will be shared, and it will include two main subjects: Four case studies as a narrative overview from those EU/EEA MSs who are developing BoD studies (Belgium, Germany, The Netherland and UK-Scotland); country profile of 28 EU/EEA MSs (constructed using routinely available GBD metrics). The next perspective of the BoD in Europe is a COST Action- European Burden of Disease Network (28/10/2019 –27/10/2023), from Sciensano. This COST action on BoD would provide networking opportunities for researchers and innovators in order to strengthen Europe's capacity to address scientific, technological and societal challenges. There are 27 EU/EEA MSs involved. This action has the similar objectives than the InfAct project: to promote and emphasized the initiative of BoD. Other perspectives of BoD are to highlight that we are also developing an application of Machine Learning Techniques to available data sources with a comparative approach at the EU level, to estimate incidence, prevalence, relative risk in different EU/EEA MSs and we will share this information among EU/EEA MSs. Finally there are three points that I want to highlight: in the future we will need a research infrastructure that will provide national information about BoD estimates; second, we need stronger skills to deal with how to use a new technology and also we need a strong collaboration within each other to face all this challenges. I would like to especially thank the BoD experts, especially John Newton from Public Health England and Henk Hilderink from the RIVM, Thomas Ziese from Robert Koch Institute, and Brecht from Sciensano, for being able to perform this BoD action.

TZ: Thank you Romana for this very interesting overview of BoD activities within InfAct. This is a good example of the usefulness of a network in the field of development and the collaboration in research activities.

JW (MoH of France): The discussion of the work at national level for estimate the BoD, may be sometimes misleading because figures could improve globally but you need to focus on population groups where the figures in the EU are not satisfactory. So my question is what

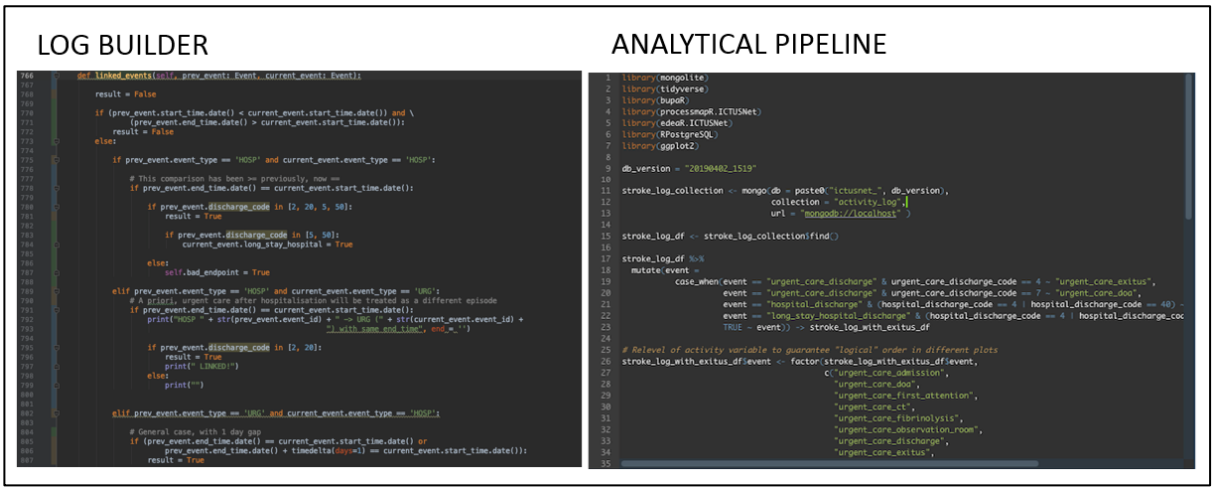
is the approach with this COST action and how will you work on specific population subgroups?

RH: It is a very important question. At the moment we just want to assist EU/EEA MSs to be able to perform the national BoD study. Then we can think about making estimations at the EU level. So, we must start at the national level and then to address these inequalities. In the future, most of the EU/EEA MSs would like to joint because in this workshops we create capacity building so EU/EEA MSs would start their national BoD analysis.

Fact sheet "Assessing and piloting interoperability". Dr. Enrique Bernal-Delgado, Institute for Health Sciences in Aragon (IACS). WP10, IACS, Spain

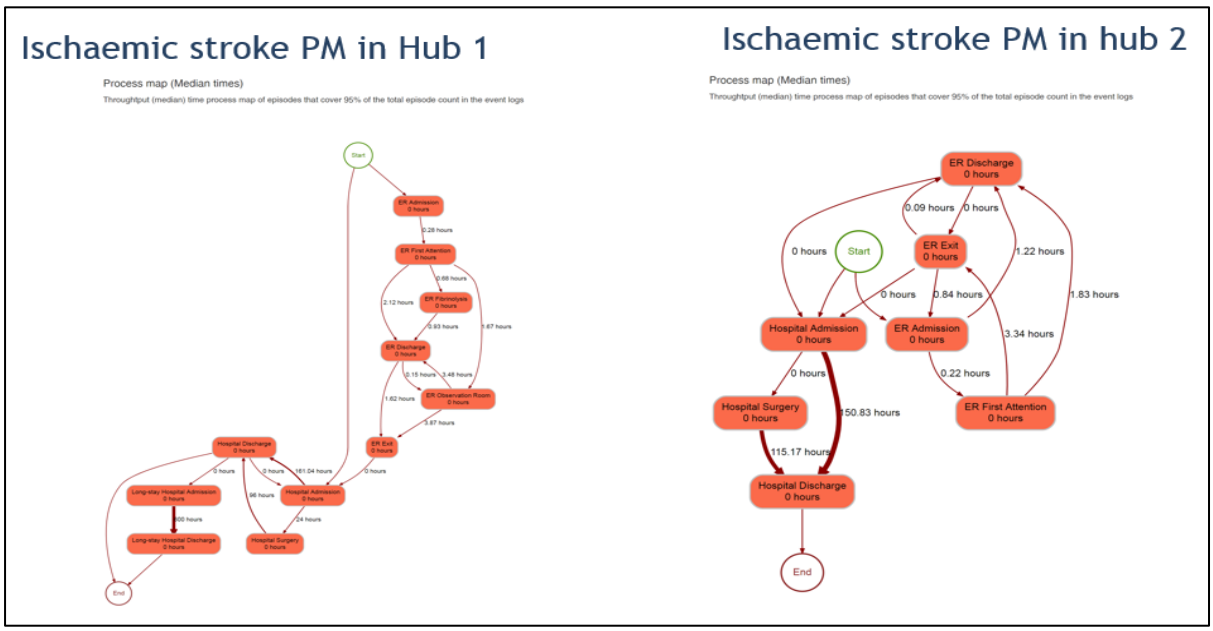
Enrique Bernal (EB): The main objective of this WP is making operational all the concepts that were presented early on the morning, about DIPoH. The foundation idea is to reuse existing data focused on population health research based on routine data (surveys, electronical records, mortality statistics...). The second foundation idea is that if you are collecting data from many data sources you need interoperability: semantic, technological and organizational interoperability that are present in the European interoperability framework. We focus on reusing data respectfully with the principles of the European interoperability framework, which means, for example, that we have taken into consideration the GDPR and, of course the national legislation. As a solution, we do not want to move data from the national data hubs to the centralized infrastructure because there are details, legal questions, ethical questions, and organizational impediments. The idea of this infrastructure it is keeping data at home and just move other things, just distributed other things. What we want to do is to catalyze the development of research network and the exchange of data hubs. We want to link research networks and data holders. The final output of this exchange will be research outputs actionable for policy proposes. WP 10 is focused in three topics based on the need of European policy makers: the first one is monitoring resilience, the second one is the spending in patients with dementia and the third one the variation in care pathways for acute ischemic stroke. Let me show how this distribution in the model for the analysis of the care pathways in acute stroke in Europe. Emergency departments are different across Europe, so you have first to agree on a common definition of stroke and the services provided to the stroke patients then you work on how data sources link. Then you built the data model. The second step of this distributed infrastructure is semantic interoperability. Depending on the country you should use ICD9 or ICD10. This is the second stage in defining the research infrastructure. The third one is about moving scripts, moving software. We are going to use open source software for every exchange. In figure 1, on the left, you can see the actual code program to link different data sources that were present in the data model and on the right once the data are collected, this is the software for the analysis.

Figure 1 Data model scripts



and then you get in the figure 2, the actual results in two different hubs with the same data model and the same program.

Figure 2 Data model outputs



We are now replicating all this analysis in other countries. This is the example of the feasibility of this kind of approach. The goal of this distributed infrastructure is to support and maintain existing research networks, the continuous mapping and distribution of open software solutions, training and capacity building and to provide advice and/or expert support on interoperability for integration within DIPoH.

Questions

JW: What kind of infrastructure is the DIPoH project planning to prepare?

EB: This is part of the challenge when you develop a distributed infrastructure. We are looking at the common data model that we may use to cover the whole research and the particular domains. With this model we are trying to demonstrate that this is feasible.

HVO: I agree that we are discussing a very important subject. In this regard we put many attention in NN. We have to reuse data also to reuse data sources, working on enable design which means also look forward several setups and exercises with different complexities and also different topics, looking for different challenges, and handle different options. If you have already a data hub centralized, you could also re-distributed them. If we work in the same way, all the experiences will increase knowledge and research. On the next stage of the development our knowledge provision could be translated into guidelines to develop those analysis.

Eric Guittet (EG) (MoR of France): You made a strong case on research networks as a key player. Are you using scientist networks as an input of InfAct?

HVO: We are not redefining networks, networks are a concluded and are involved in the process. What we already did was, to define some criteria about networks. A lot of networks are now existing, we all know that, but it is not limited to one city, to one country, you should have also a European approach.

EG: Individual researchers should have also access to their data.

EB: A group of individual researchers, from my perspective, is a network.

TZ: Networks needs not a presentation but a definition.

PB: In the second part of this meeting we will include such clarifications. The criteria that we think is important for research networks to have.

5. The Distributed Infrastructure for Population Health (DIPoH). Business case Part II

The national nodes and research networks by Dr. Hanna Tolonen, National Institute for Health and Welfare, Finland.

Hanna Tolonen (HT): I will talk about the development of National Nodes (NN) within InfAct taking Finland as an example of such initiative. The DIPoH structure is composed by: NN that are units within EU/EEA MSs representing national network, Research Networks (RN), a Central office, a Governance Structure and a Web based portal as a gateway to data, services and tools on population health.

The NN functions as an organisational entity that liaises between the research infrastructure, national specific research networks and the national HI stakeholders. The NN

oversees and supports the cohesion of the national HIS by: connecting with relevant national actors; exchanging national expertise at the international level and connecting to MoH and MoR.

The NN aims at bringing together the regional/national stakeholders that make possible to: share expertise on regional/national level, share ongoing activities on regional/national level and update on initiatives, meetings and expert groups at EU level.

19 countries have reported their progress within InfAct and most countries already have an existing format that brings together important HI stakeholders. In many countries, the coordinating organization is National Public Health Institute. Among the difficulties reported to organise a NN meeting were the identification of relevant stakeholders

- Example of NN (Finland)

In Finland the key stakeholders for HI were: the Finnish Institute for Health and Welfare (THL), Statistics Finland, the National Social Security Institution (KELA) and Research groups in different Universities.

There is no formal National Node but there are several joint activities of key stakeholders: a collaboration forum of governmental research organizations (TULANET), meetings with the heads of THL, Statistics Finland and KELA in routine meetings related to the use of data for both statistical and research purposes and the development of a new legislation 'the Act on Secondary Use of Health and Social Data (552/2019)' that will further facilitate information exchange. With this Act a new organization was established (FinData). FinData will be operational in 2020 and will ensure a one-stop shop for the secondary use of social and health data. FinData grants data permits when data are requested from multiple registers and provides the data in a secure IT-environment for data users. The goals are: (i) enable effective and safe processing and access to data, (ii) enhance data protection and security, (iii) eliminate administrative burden and (iv) improve register data quality. There are two types of uses of health and social data, the primary use for patients and also the national registers and the secondary use for scientific research, statistics, innovation, teaching and knowledge-based management, among others. There are many different data sources that are incorporated in Findata as disease registers (THL), prescriptions (KELA), causes of death (Finland Statistics), population data (Population Register Center), occupational illness (Finish Institute of Occupational Health), benefits and incomes (Finish Centre for Pensions).

How to access data sets? For individual data the direct identifying data will be removed and for statistical data it will be granted free use for the purposes specified in the Act. The secondary use of data will benefit the entire population as it is intended for public health purposes.

The operation will start by November 2019 in a stepwise approach and will work together with data owners. A centralised system issuing data permits for accessing to social and health data from the registers of several controllers that will offer electronic tools for data permit applications, information requests and access to data.

The national research infrastructure roadmap in Finland is updating in 2020. Their main components are: Finnish Microdata Access Services (FMAS) for routine data collections, the Population Based Surveys (FIRI-PBS) for survey data and the Finnish Dietary Information and Research Infrastructure (FINDIRI) for nutritional information.

There is a connection between NN and RN you cannot separate them because NN are providing data to RN, and there is of course a link within the ethical and legal framework (GDPR and Helsinki declaration).

Research Networks (RN) represent a group of collaborating experts that collect, exchange, harmonise and analyse data and information on a shared health topic. RN generate new data and research outputs, improve research methods and tools, develop standards and guidelines, and contribute to international research capacity building to support health policies and healthcare management. Examples of RN are: ECHI-European Core Health Indicators, ECHO-European Collaborative for Healthcare Optimization, EHES-European health examination survey, EHLEIS-European Health & Life Expectancy Information System, EuroPeristat, EuroSafe Injury Database and Burden of disease Network.

Soma data harmonisation/protocols are: EHCI indicator definitions, ECHO handbook for methodological issues, EHES standardized measurement protocols and survey guidelines, EuroPeristat indicator definitions, EuroSafe IDB-manual and coding instructions.

Aggregated data are freely available in every portal bur for individual level data under GDPR is not freely available. Available data include: ECHI data tool at EU/DG SANTÉ on health indicators, ECHO Atlas, EHES data hosted by countries conducing national HES, EuroPeristat reports and EuroSafe Injury Database.

Which information is available from NN (national data providers)? Routine administrative data, registers (mortality, disease register, medical prescriptions, etc) and survey based data.

Regarding capacity building on HI there are already different tools available: EHES has online training materials, training seminars, provides personal consultations and mentoring; EuroPeristat organizes thematic workshops on different aspects related to collection of data; EuroSafe provides assistance to countries providing data to IDB, and organizes training events.

We are not starting from scratch, we just have to work with existing building blocks from NN and RN to build a Research Infrastructure.

At the national and EU level DIPoH will pool existing resources and enhance and support the secondary use of such resources to build an effective health research and innovation environment to better health and social care solutions for the people, to develop tolls to identify and tackle inequalities and support health technology innovations. All of this will help to improve national economy through a better population health.

Questions

JW: Could you elaborate a bit more on the resources you have and the figures to establish Findata? In France we are establishing a new data hub, the French government has given 72 million euros for the next years and it would have a team of 40 people to start with. So it really reflects the huge effort that is behind establishing a national data hub, having in mind that France and Finland are somewhat different. We are not collecting the same data, because you are using your social data so we are different in the data we can provide to the DIPoH project. My question is, because it is up to you at the national hub. How would you manage a request coming to the DIPoH and especially a request about expertise? I am wondering how your networks and an infrastructure such as DIPoH get easy access to the expertise you need to fulfill your needs as it is difficult to mobilize the experts.

HT: There are some resources for the Findata we will have 20 to 25 persons involved full time for each year to work on the activities. I do not know the expenses. How THL as an expert responds to requests coming from DIPoH? For example in ECHO we can work in research networks on specific topics, which can then apply for additional funding from different resources. We would provide some funding also from the national actors to be part of the specific domain research network and then they would be actively involved. We do not have endless resources within countries, so it will be built within domain specific research networks.

EB: Some regions could ask for a strong national grant program or international 2020 Euro and get specific funds for this kind of things so the exchange of the fee for service might work.

TZ: I have one question about the definition of the national hub power. Keeping in mind that there is a lot of diversity, how do you plan the different countries to fit in this format?

HT: We cannot say that a NN need to have a certain format, we have 28 EU/EEA MSs that operate differently. You need to bring together stakeholders and actors working on HI and have an open dialogue with them and as a result select what it is best for your country, and how to be part of the DIPoH. They should consider the main issues within their country and the level of collaboration they can engage with.

JW: For those countries that are in the dynamics of setting up a NN, as France, it would be important that you organize a meeting with them, explaining your model proposal. I think they could be very interested in having a platform and an infrastructure; but it should be coordinated at the EU level. At this stage there are bilateral meetings, for instance Belgium is visiting France before the end of the year, Findata has contacted us, interested in HTH but if you as a group, mainly of researchers and public health specialists are not presenting discussions at the EU level, a strong support will be missed.

The finances by Dr. Mariken Tijhuis, Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands

Mariken Tijhuis (MT): This presentation is about options & models for creating a financially healthy RI. What we cannot offer today are exact figures and a detailed financial plan because we are still developing our structure. There are 3 main components of this business

plan: 1) defining the research infrastructure, 2) organizing the research infrastructure and 3) financing the research infrastructure:

1) For defining the RI, we have to count on the users and services. In relation to the users we have on one hand, the research networks and researchers that are those who provide the data and have the data expertise and in the other hand the EU/EEA MSs and the policy makers that are those using the data and having the policy expertise. When it comes to the services there are three types of activities in a one-stop shop: basic services (available to everyone), membership services (only for Research Infrastructure members) and fee services (available only by contract).

2) The RI is organized in RN and NN with a Central Office in charge of the management, the services support unit and the web platform.

3) Financing the RI: We are estimating expenses and identifying different funding options throughout the different phases, from developing and setting up to maintaining and expanding. The ESFRI roadmap will last ten years but we think we could develop it faster. The revenues for now are the revenue of sources. In the next phase we will dive into how much are users willing or able to pay. The question now is how do the funding streams relate to each step and develop over time. Income will depend on the final structure of committed partners and types of membership (individual, network, organization), which still needs to be decided.

The expenses were calculated with a central office (management and web platform) being developed with the support of 10 EU/EEA MSs in the first development phase and with the support of 30 EU/EEA MSs in the implementation phase. Simultaneously, RN will support integration, criteria fulfillment and quality assurance of the RI in the development and the implementation phase while NN will support the establishment of the RI in the developing phase.

The expenses for the central office were estimated based on the activities that are summarized in the figure 3

Figure 3 Expenses of the Central Office

Central Office	Development Serving e.g. 10 MS	Operational Serving e.g. 30 MS	Activities
Management	FTE (Senior, Junior, Admin) Overhead, Travel, Meetings	FTE (Senior, Junior, Admin) Overhead, Travel, Meetings	Manage RI governance and control; Develop Strategy; Evaluate functioning; Provide administrative support Prepare & support committee meetings; Advocate; Organise RI communication/PR;
Web platform	+ICT +hardware, software	+ICT +hardware, software	Handle web-data; Host website; Manage servers, software, updating; Develop & maintain repository; Set up communities, webinars, etc.; Implement RI services, in liaison with Services support
Services Support Unit			Manage, support and evaluate the services that the RI is offering (open access, to members and by contract), in liaison with *Web platform*; Liaise with stakeholders; Knowledge brokering
Total/yr	2 M?	8 M?	

The costs of RN will depend on participation rate and type of data collected and example of RN for EHES is presented in the figure 4

Figure 4 Cost of the Coordinating Centre over 5-year period

Cost of Coordinating Centre over a period of 5 years		MS n=5	MS n=16-20	MS n=28
Staff	Coordinator, IT-expert, Statistician (reporting, sampling), Epidemiologist, Lab person, Assistent			
	Overhead			
	Total	2.5M	4.1M	5.5M
Operational	Training seminar (planning, fieldwork, reporting)			
	Lab materials			
	Overhead			
	Total	50k	75k	140k
Travel	Visits (site, consultation)			
	Overhead			
	Total	70k	335k	600k
Total	5-year cost of Coordinating Centre	2.7M	4.5M	6.2M
	Annual cost of Coordinating Centre	540 k	900 k	1.25M

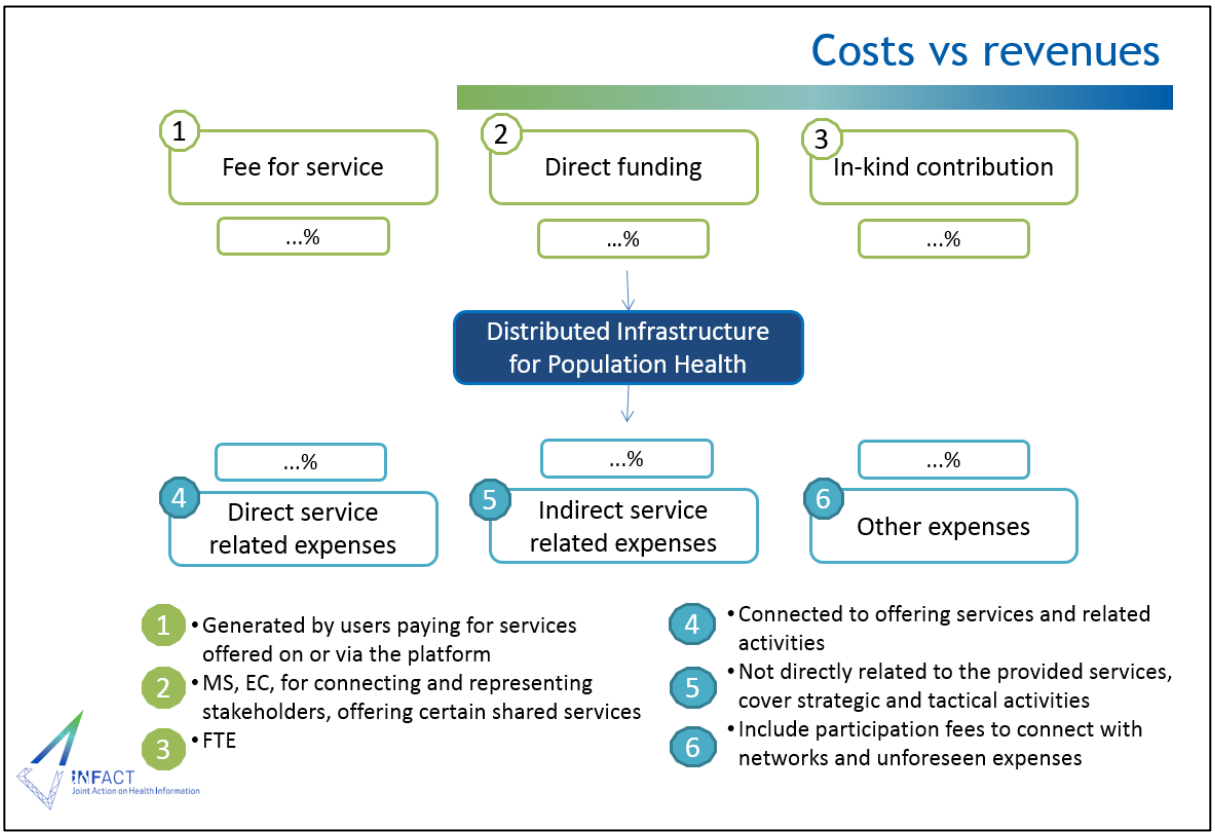
The NN may be existing structures so the expenses will depend on the extensiveness and previous characteristics.

Among the funding contributions are 1) Grants like the Horizon 2020 that supports for ESFRI roadmaps on European Research Infrastructures. 2) Other DG as DG Regions could be funders as well. 3) The memberships. The income from membership contributions will depend on the final structure of committed partners and types of memberships (individual, network, organizations), which still need to be decided. A precise contribution model still has to be developed. 4) The fee for service, the contributions will depend on the estimated costs of the services and functions and the de facto net revenues of the services. Besides the possible income as contributions from membership fees, there are possibilities for income from contracts (projects) by for instance, the European Commission, charities and the private

sector. The most important aspect is that the core of the infrastructure needs sustainable funding, to guarantee functioning of basic supporting facilities and governance.

In figure 5, the framework of the costs and revenues of the DIPoH services is summarized, taking into account that absolute numbers and percentages will change through the different phases.

Figure 5 Framework of the costs and revenues of the DIPoH services



Questions

Patrizia Theurer (PTh): Thank you, for addressing some of the questions from the First AoM meeting in Madrid. I understand that is difficult to find out the cost and what is difficult for me is to get an idea of other options we could have to set up HIS. For example ECDC could be a partner and could get the mandate. Would the costs be approximately comparable or they would be very different?

MT: I know that the cost would be very different but I do not know the exact amount.

HVO: It is a very interesting question and even more difficult to answer, for the simple reason that ECDC two years ago proposed one sheet in which they also proposed services but it was not accepted first of all by the European Commission and then by the MS. The services they were offering were totally different. What we are offering applies for risk factors, lifestyle, burden of disease, etc., so they have totally different approaches.

On the other hand, I think that as we are working with national hubs and also RN creating this group of expertise, it is not so different as how ECDC has been taking over national expertise and also international research networks on infectious diseases and setting up a central hub. That is the way they initiated their work.

JW: Could we come back on the slide of the central office?, because still for the second line of activities on the web platform ICT you are missing many cost items and resources that have led to the infrastructure itself, because the cloud even if you work in open source, has an extra cost and the infrastructure is very costly and you have also to take into account the cost of the IT service providers. It is very complex.

MT: During the study design we had the chance to dive and work with the web platform

JW: Yes, you have to annex something regarding that on the finances of the central office in your proposal, but my question now is about the fees, the fee for service, because by now it is the most tricky and sensitive issue. I think the real question behind this, in real life is, how you make sure that existing RN and national data hubs do not perceive you as an intermediary taking money sources from their own business and plans. They could organize them directly with the clients and other partners, other networks, they could organize the answers, so how do you install a kind of trust and confidence explaining that you have real added value compared to others?

MT: That is a very tricky thing. We have to make sure we have incentives for RN to join the project and other type of services that we actually would be selling. We plan to make a good market analyses about the networks in EU.

PB: I think also we can add that we have a competent huge network. We know people in different countries that have specific expertise that is one of the added value that DIPoH can offer. Why would researchers want to join the infrastructure? Because we have actually seen quite a while that research joints and research infrastructures are much more successful at obtaining funding because you become stronger

HVO: One thing is the certainly total set of services that we would provide as infrastructure. On the other hand people would like to be part of the infrastructure. It is not a competition. I think you are currently thinking moneywise but people can also get the return of their investment by getting better expertise and becoming part of the community. That is the way you have to think about, so that return of the investment is not only moneywise but has other impacts.

Giovanni Nicoletti (GN) (MoH of Italy): Sorry to intervene, I am not a scientist, but I have been waiting until the afternoon to make an intervention because we are rounding a bit in circles, because we are trying to give technical answers to questions that are mainly political. I would like to step back a bit and have an idea on how a group of researchers decided to organize and invent a service for potential clients somewhere in Europe. Why the perspective should be out there? Imagine that the EU/EEA MSs are not participating. I appreciate that you had time to do technical developments as the business plan and all their content but at the end of the day the question is how much do we want to put in this idea, and if I were to give a rough answer from my country perspective, which has not yet been

decided, I would say that if the idea it is to invest more in our country concerning the activities that you have described probably there are a lot of chances. If we have to invest a lot outside of our country probably it will not be accepted. So, within this 2 straightforward alternatives there is the negotiation among EU/EEA MSs every time and for everything. I think however, that it is important to have a group, to have a table of discussion with members and the payers, and it is important that the payers will decide, who is going to pay, how much they will pay, with which rules, and know all this in order to making a decision, otherwise you get lost. We have to rebuild something that looks like a negotiating table for the financial aspects, because otherwise when you are ready with the technical aspects we will have five years to discuss. For the negotiation, it is better to start now, start with some minor features, a sum reasonable that everybody would be available to pay and then decide what we can do with that model, designing the best outcomes possible and asking maybe some money to the MS. There is another part that I do not see here today that is the European Commission and sorry for that, but we just need to see if the EC (DG Santé, DG Research or the Commission as a whole), is still interested because their inputs started all this difficult task force to stay together. So, if they do not want to be involved I think we have a problem because the scope it was to create a monopoly, something decisive; not a group of researchers or good researchers to stick together, but a monopoly of the best researchers in public health institutes to offer European perspective, and clearly the EC must be a client of this initiative. If the EC is not part of this European infrastructure clearly there are several potential alternatives to do the same as MS, maybe not different but with different organization that would be not European standard, which could be multi country or could be country based, but let us be clear that country based is not European based. This is clearly a political issue. Sorry to bring this but this is an AoM. This is not a forum to re-discuss things that you have done in different tasks because you have done a great work and also you have done an even more excel work on financing it could be helpful to clarify different activities and how to calculate individual elements but at the end of the day it is the grand total that might frighten or encourage EU/EEA MSs to participate in this structure.

MT: Thank you very much for your comments I would like to invite the Commission to reflect on how they would like to contribute to the infrastructure, and maybe to express your commitment.

TZ: From the EC we have Anne Marie so you can share with us your views about it

Anne Marie Yazbeck (AY) (European Comission): My name is Anne Marie Yazbeck, I am only an officer so I am in no position to define the future of health data so all I can do is to pass your concerns to the people responsible.

JW: As a complement to Giovanni comments, I would like to explain that maybe you have been working within a Ministry, either of Health or Research. I think a Ministry is not working in the way you are designing your strategy. A Ministry, first of all will think to adopt an idea and then think on the cost of it. That is why my recommendation is to work with national health data. The first question is: If you would come to offer services to the Ministries, why you guys and why not others? What makes you the bests? Who are you? I think a Ministry would prefer a competitive core to see how the committee responds to specific quest or to choose between different options. I think it is very good that you produced the business

plan, but you are in a competitive environment, if you go directly to the Ministry with your proposal you would need some documents but still you have to explain to them why you and no other person that could have the same idea that you have.

MT: Yes, I agree that priorities to HI are not easy to sell. It would be easier if we were a research infrastructure, because when you have together a NN the parties will see an added value of some structure being established on this topic. The need is there, the MoH and MoR may not see it as a priority but we are creating commitment and engagement on it.

JW: I think that you need to move the focus. You should not need to focus on the need of an infrastructure to manage health data and provide new information, because is quite obvious. Where you should focus more is on other issues, for instance: if under Horizon 2020 it would be a call proposing to fund this kind of infrastructure in euros, do you think that you would be the only one to submit the proposal?

TZ: I would like to come back to the presentation of Marieke who mentioned the crucial role of having research to make good evidence for informing policy. To have the national public health institutes on board could be an added value because these should be the ones having the better understanding on how to translate research into policy information. This is an argument to be made on supporting the funding decisions.

HVO: I think that some important elements have been presented. One of the key elements of research in Europe is to know the citizens and what we do for citizens, so one of the elements we have to deal with is to think better on how what can be useful to people either working in clinical practice, on health authorities or for policy makers. That element I think is unique and it would trigger researchers to focus more on this knowledge translation research into health problems, which is something very complex.

Hana Marie Broulikova (HMB) (MoH of Czech Republic): My comment is on Petronille´s presentations. What you can do to distinguish yourselves from DG Santé and to show that you are a really good option? What you can offer additionally to the national Ministries? I guess that having projects is necessary to recover the costs. I could not agree with the budget you chose and I see why you want your own infrastructure but you think the network that exists and the partners give credit to you as well?

EG: At the end what you need? The commitment of EU/EEA MSs? The commitment of EU/EEA MSs relies on the priorities of the research, so if you have a look to the national procedures, there are some aspects to be followed, accepted and funded by the MS. Country support depends on specific purposes. To be supported politically and financially in France two cost evaluations should be positive, so you have to care for the national procedures.

TZ: Some comments and ideas keeping in mind the concerns that have been raised here?

JW: Have you done something to submit to Horizon 2020?

HVO: We have done one task about the HI cloud, and also to advice other people that want to join that task.

JW: If you look at the ECHO hub it never received the push button of the Ministries and EU/EEA MSs to exist. It was pushed by the Commission from the discussion with civil societies, the researchers and so on. You could imagine in research to have a project funded with the participation of this distinguished networks, even national hubs, if they agree to participate with funding, and then within 5 years of experience, the Ministries will commit because they will assess that it is working

HT: It is true that we all belong to Horizon 2020 because they are preparing the 4-year program, and our task must be prepared by February or March. We are now actively putting on ideas for that period. Usually when the call officially opens, you have 2 days for making comments, but we can circulate the current information now within the consortium and each of could go to our national representatives to give opinion on that. That is the only way to get topics on the agenda to be applied in upcoming years

Miriam Azzopardi (MA) (MoH of Malta): I would like to know how were calculated the expenses of each MS? You presented that about 10 EU/EEA MSs decided to contribute, how you come with that figure? And also I would like to know where the central office would be located.

Mariken Tijhuis (MT): That was just only an example. For the contribution there are many options. I just showed you different ways in which this could be establish, it is not decided yet. About the central office, nothing is decided about it, either location or affiliation.

Richard Blundell (RB) (MoR of Malta): I want to turn back on the question of my colleague, regarding the ERIC. Where will be based? Is there is any country or EU/EEA MSs which is ready to host this office? Now, I would like to talk about the Horizon 2020 in Europe. Under the current circumstances in Europe, from a policy perspective, under the pillar 2 of Horizon 2020 to follow to this cluster would be appropriate. So I suppose there will be enough burse of funding under that cluster to develop the functional areas of an ERIC project.

MT: We have not decided yet who will be in charge.

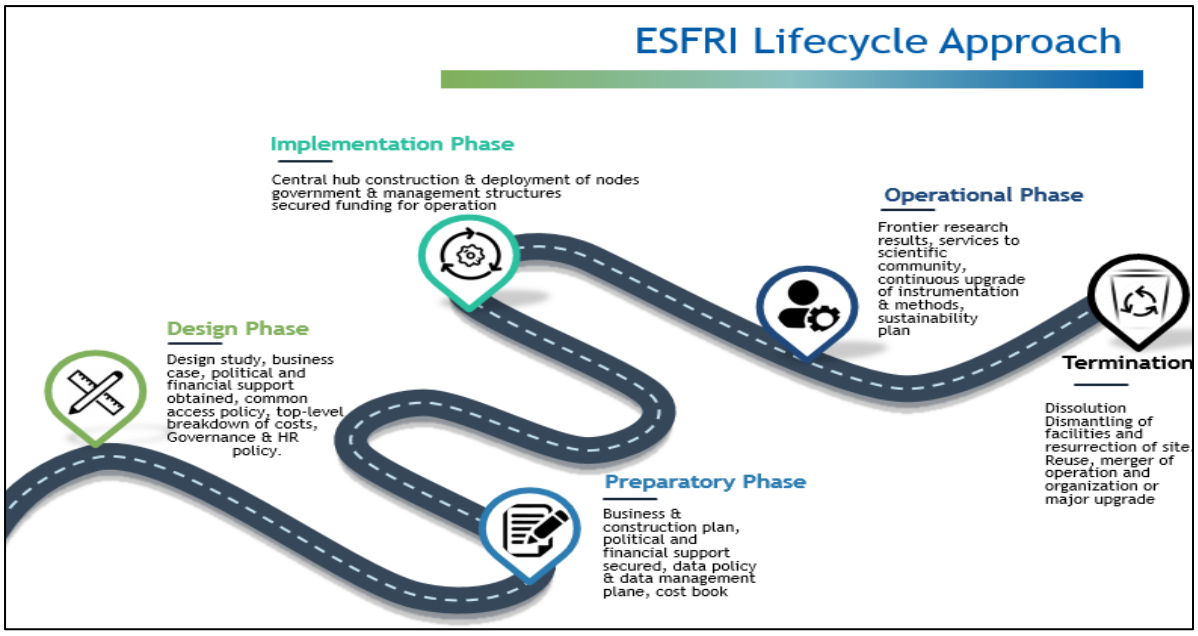
HVO: As we develop our case study, we need to decide the financial terms but we must also assess the different services that we can give. The platform does not necessarily need to be in one central office. The central office will provide necessary elements for training capacity, and the promotion of health, making services available. At the end it will require investments hopefully from the MS.

6. The ESFRI application by InfAct. Herman Van Oyen (HVO), InfAct and Sciensano, Belgium

HVO: The ESFRI application should be a planned by the middle of this year. It is a stepwise and structured approach to set up a European Research Infrastructure Consortium (ERIC) on HI. This application could be also a scientific excellent bitmap. It gives you high priority within the European research domain, scientific excellence, and Pan-European relevance, so it is very important for our research networks, and for the socio-economic impact. Also allows opportunities for European funding. It will also stablish engagement of MS, and collaboration of research institutions that will work together at the operational level. They

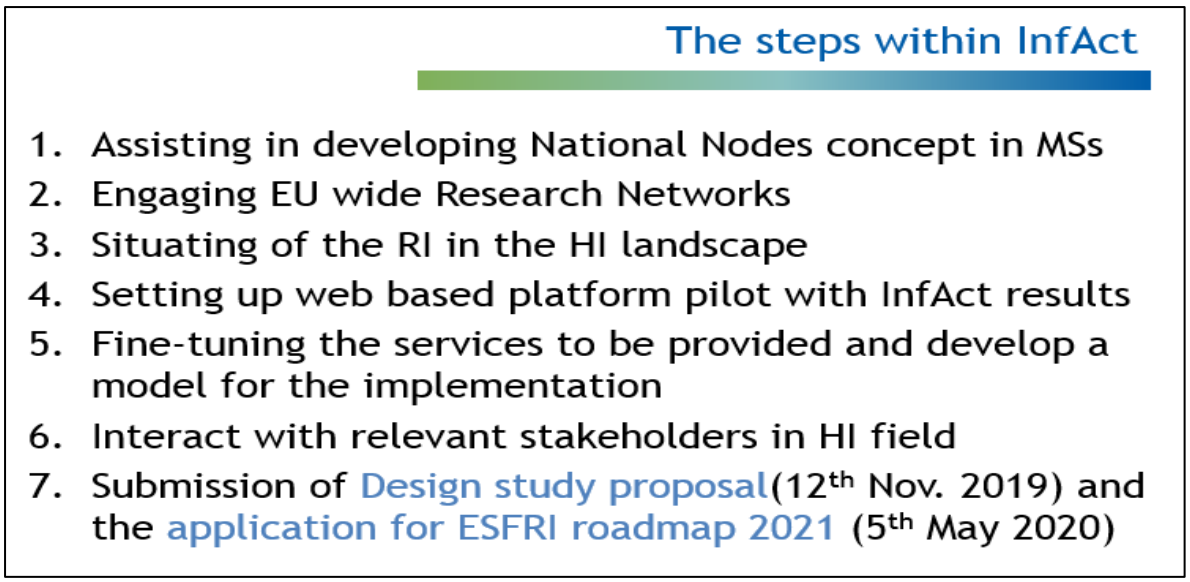
have the recognition as an EU priority. The ESFRI roadmap is more a cooperation and agreement between institutions in EU/EEA MSs, and there is no financial obligations for EU/EEA MSs. The end point of the ESFRI is to develop into another structure that could be an ERIC. So, supposing your candidate will be ERIC, you create an institution under the European law, and, the financial commitment will be upfront by the different EU/EEA MSs for at least, three to five years. We are ready and able to submit InfAct application for the design phase. You have to go deeper to that and re-explore the opportunities or possibilities that you have, and propose recommendations (Figure 6)

Figure 6 ESFRI lifecycle approach.



What we are already doing in InfAct is working on some of the elements that we think are useful for the future. You have been speaking about the development of this NN that seems to be a particular update. One of the elements that InfAct has is the development of HI capacity within EU/EEA MSs bringing together in the NN people from different institutions. That is why we have this NN, they are useful because allow EU/EEA MSs to interact. The steps within InfAct for an ESFRI roadmap application are showed in the figure 7

Figure 7 Steps within InfAct.



This slide shows the requirements for this roadmap application including the political support. The expression of financial commitment is mainly for the lead country to express that they will contribute to both preparatory and implementation phases for a period of 3 to 4 years. It is also necessary and most important, an inter-institutional and multi-lateral agreement by lead institutes identified within each country representing all national research institutes involved in the RI. On the other hand, our research networks came from different institutions so there are several of this research network offices involved. Either countries or institutions could contribute, either in cash or in kind, to the stage that they choose. The most important is that we need to have a discussion on how many countries will be currently involved. The AoM, at least by April next year, should express which are the countries that agree to contribute to one of this phases It is essential that we have this political commitment and we will contact you again to discuss all the things you need in order to meet your desires. That is the point I want to discuss with you, that is why we met together in the AoM to assess what are your minimums because this essential for this mission, that we have support from institutions from many European countries and from networks that we have been working across Europe. We want to facilitate access, within InfAct, between the researchers and the data owners and see which the routes that they have to take are. To facilitate that, also the data owners should facilitate and sign consensus related to data quality by bringing the standards that should meet data collection and the using of data.

Questions

GN: My first comment is about the view of the MoH. I am concerned because based in the Italian rules, I am not sure if we can subscribe this letter, so I guess we will follow the rules of the MoR. If I have to make an advocacy to the MoR, I should achieve something more than the paper that we have in the documentation. I have to submit something as an official proposal not a draft of a working group because we ask the ministry to decide and he will need a formal request by some of you. 1) The first suggestion is that you write a much simpler proposal, to present to the MoR. 2) The second suggestion is mentioned by the

countries about the proper official procedure in the different countries and in Italy in particular. I checked this morning and there is still nothing on the MoR website And clearly I do not know a real timetable, or time limits but I think it would be a bit shorter that what you presented today.

HVO: The proposal would be a starting point for discussion, because it raises the way we want to go and what we want to develop exactly. If you think that there are other elements that should be added, we will discuss them and include them. For the second point, of course we have to discuss about policy in Italy.

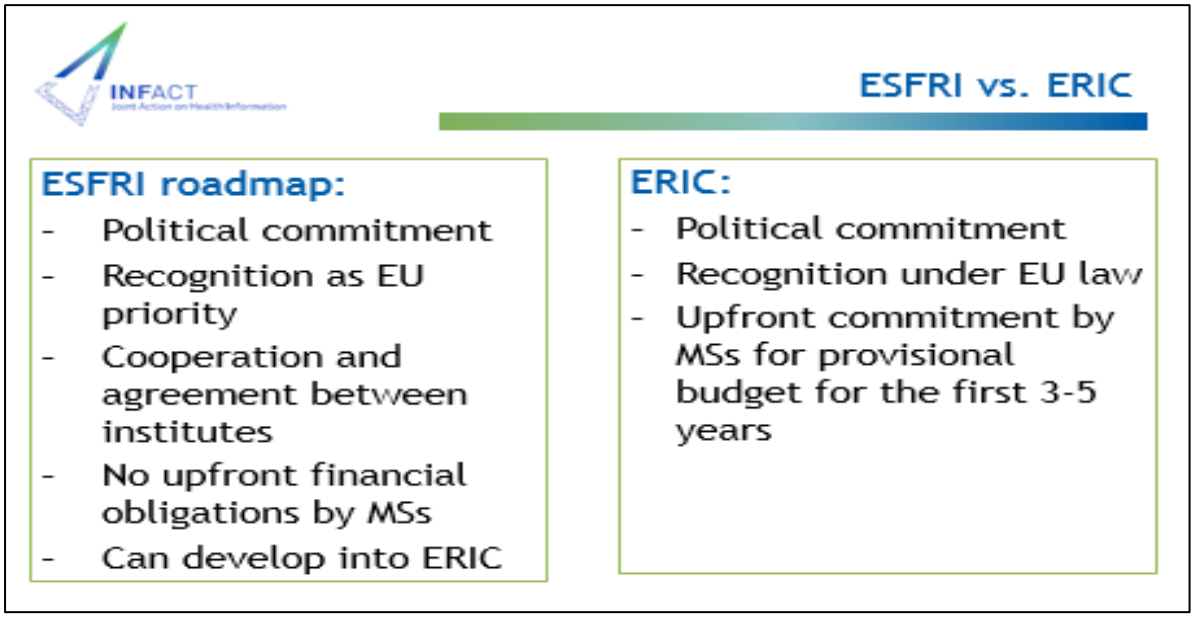
GN: I am sure that the study design is the global concern of the technical experts. But the proposal should respect some formality on the application, in order to be submitted to the Italian authority.

HT: I just got a message this morning from our national ESFRI representative. About the timeline we should have ready a proposal by the end of January to be considered for the next ESFRI committee in April.

HVO: So we have a short timeline.

RB: I would like to make one clarification about that. Could you go back to the slide (see figure 8), ESFRI and ERIC can complemented each other

Figure 8 ESFRI vs ERIC.



HVO: Can you either say, ok, I get the ESFRI roadmap and then we go for the ERIC?

RB: Yes, and if the structure of an ERIC does not fit your needs, or you like another structure with different rules like other level company, or like an NGO, you still can be in the roadmap for an ESFRI.

HVO: We are ready to write the proposal and make it available to the different EU/EEA MSs. Now I want to invite to a Spanish colleague, to speak about the next AoM.

7. Programme and objectives for the next Assembly of Members (AoM), by Dr. Isabel Noguer, Instituto de Salud Carlos III, Spain.

IN: Thank you Herman. I am going to be really short. I would like to start by thanking the contributions from all EU/EEA MSs in the last AoM. We have integrated all your comments and suggestions. And I would like also to thank the coordination since they have supported this second AoM that the WP4 could not cover. I think it is really important to have more than two AoM discussions, that have been really interesting and we have discussed about proposals, options and many issues that need to be into account for the last AoM. We would propose to organize the TD that would feed this last AoM to focus on the French proposal. We propose to split this TD in two different parts. 1) The first one, to discuss about the outcomes from different WPs, that will be presented in this second TD, 2) The second part to focus on the DIPoH discussions, the final proposal with your comments already integrated and this final proposal to be approved o discussed in the last AoM. So, we will exchange e-mail messages to look for suggestions and comments for this second TD that would feed the last AoM. We will send the minutes of this AoM, as soon as possible, and our proposal for the last AoM will be: the recommendations from the TD, the last FS proposed by our colleagues from different WPs, the ESFRI roadmap progress, depending on the recommendations and conclusions from the second TD, and finally, we have to discuss and propose the Sustainability Plan for this Joint Action. We expect to have as much comments, from your part, as national experts as possible in order to perform the best possible Sustainability Plan.

TZ: Thank you very much Isabel for this advance of the next AoM.

C. Minutes of the Third Assembly of Members

1. Welcome and introduction by the chair: Thomas Ziese, Germany. Robert Koch Institute, Germany.

Thomas Ziese (TZ): Well I think the board is more or less complete. Dear colleagues and representatives of ministries of health and research, I am very pleased to welcome you to this additional virtual Assembly of Members of the Joint Action InfAct. Briefly to introduce myself, I am Thomas Ziese, I work at the Robert Koch Institute in Berlin, and I am the head of the area of National Health Reporting. I am engaged in European Health data for 20 years and I am one of the package leaders within the InfAct project, so it is a particular pleasure to me to chair this meeting today. There have been two previous AoM meetings last year, one in Madrid and one in Brussels. In the last one in Brussels we had more than 22 member's representatives of MoH and MoR and we gave an overview of what is InfAct about, what is the philosophy and what is the final goal of InfAct. We explained the different options we have for sustainable infrastructure on health data, we considered for example a union with ECDC and JRC, and considering those different options we concluded that we would prefer

a research infrastructure, which was discussed at that time. Then we informed about the DIPoH, the Distributed Infrastructure on Population Health, which is connected to the ESFRI; we discussed the importance of HI in general, policy making and we introduced the concepts of national nodes and research networks. Furthermore, we discussed several options for sustainable financial structures, discussions that were very fruitful and we took your comments and suggestions and incorporated them as much as possible. We would like to thank you for your input and clarifying discussion at that time.

This virtual AoM is not a face to face meeting due to coronavirus, it's no useless to say that coronavirus has an impact on almost any aspect in life, and of course drives the priority of public health and research. This is also reflected in the priorities of the German EU presidency that it is starting next week for the second part of this year. The coronavirus pandemic has clearly demonstrated the importance of cooperation and coordination within the European Union, also and especially, in the area of health policy. Keeping in mind this headlight the coronavirus importance is reflected in the goals of the German presidency: two of them are 1) European public health organizations such as ECDC must be strengthened, and the other one, which is relevant for us is 2) Europe must become more attractive for research, this requires data, so the Minister of Health therefore wants to drive the creation of the European Health Data Space. Keeping this momentum in mind we are happy to discuss with you the next steps of the sustainable infrastructure for population health.

The aims of this meeting are:

1. To update the Ministries in the work of InfAct in the Distributed Infrastructure of Population Health (DIPoH), which we already focused on last time.
2. To update you on the ESFRI application.
3. To inform about the idea of the DIPoH for COVID-19, which is an interest of the European Commission.

We have two sessions and time for questions, discussions and suggestions from your side, which we are happy to take and discussed again. Besides information and exchange of ideas, this meeting has another goal, to seek support and more active participation for the project in its different aspects.

We would like to record the meeting mainly for documentation processes so I would like to ask you, if you do not agree please wave your hand or leave a comment in the chat. I take this as a silent consensus and thank you very much for this. Then I would like to start, I will give the floor to Petronille who will give us an update on InfAct activities.

2. Updates on relevant InfAct activities: Petronille Bogaert, Sciensano, Belgium

InfAct and COVID-19

Petronille Bogaert (PB): All slides are available on InfAct website https://www.inf-act.eu/assembly-members

We wanted to do an update of what we have been doing within InfAct. First, it is the issue of COVID-19; back then actually partners came to us and ask us to stay more actively involved to support countries in the COVID-19 crisis. Initially, we thought that our partners were really busy, they really need the time a bit of a break in InfAct to address the crisis but it was a bit of the opposite, our partners came to us and ask if we can really use the InfAct network to create some kind of rapid structured exchange between the partners. So, we had quite a lot of partners that came to us to ask specific questions and thus we organized two monthly meetings to cover such questions that we have received during the week, but also to cover other topics that came up. I am going to be more specific about the topics we covered, which might also be interesting for you in the Ministries of Health and the Ministries of Research:

- **Exchange and provide overview of on-going or planned Covid-19 studies.**

– What data should be collected to the analysis of impact COVID-19 on NCDs? Our partners were interested at the start of the crisis on how they can monitor COVID-19 during the crisis but also on a long term what will be the impact of COVID-19 on chronic diseases. For example for the care that has not been provided during the COVID-19 crisis due to that fact that hospitals were focused on the COVID-19 treatments and did not carry out other essential care or emergency care.

- **Exchange relevant regional, national and international data sources.**

– Which data sources are available at sub-regional level? This is important because when the borders were opened between the countries, how to access to regional data was really important.

- **Discuss and exchange on latest developments, recently validated tools, approaches, standard operating procedures, protocols and guidelines.**

– How are you counting COVID-19 deaths in your country and who is being tested? Apparently this is very different between the countries and has a huge impact on how the deaths are counted. For example in some countries is only based on PCR testing whereas in other countries is also based on clinically positive cases and also on CT scans. We have seen huge differences between countries even those that are similar on population density, etc. It is really important how the countries do that and we are keeping track on this.

– How are you carrying out contact tracing in your country? We are also keeping track of contact tracing in countries. We know ECDC is doing some of these things but we noticed that not all questions are provided by ECDC so we also give some support there, and this is key because there is a trust between partners and we were able to provide quick answers. So, it really connected the people and the experts in the field that are working on COVID-19 on this specific question.

- **Exchange policy and impact measures**

- Measure/guidelines about re-opening of schools and data indicating the consequences of the re-opening?

- How are hospital visits and visits to long term care facilities organized in your country?

- Impact on mental health through health surveys.

So I think that based on our experience we can conclude that:

- Many questions, that the countries had, remain unanswered by existing institutions and important data gaps were persistent, especially for COVID-19.

- Partners are looking for mechanisms for structured exchange, making sure there is a platform where they can exchange quickly, pragmatically and also in a trusted environment.

- InfAct built up trust between the partners to share and exchange. InfAct provided some sort of safe space. We actually shared protocols, there were questions that we shared and that was highly useful. I think we can really say that there is a need to develop this more structurally and in a longer term within Europe. It is clear the need for a Research Infrastructure on population health, in order to support future crisis for which DIPoH can provide the basis.

Now I would like to give the floor to Neville Calleja to pick up on that because I think it would be nice if someone can share his experience on how this crisis impacted his country and how InfAct was able to support this.

Neville Calleja (NC) (MoH Malta): Hi Petronille, good morning everyone, indeed the Ministry of Health in Malta was one who actually benefitted of this impromptu, that put the project in practice. For those of you who are not actually participating in this, especially in the Ministries of Health, there was little coordination coming from international organizations, they seem to not have been able to cope with the requirements typically from the policy side. I think never before this period we have we seen a fast changing policy landscape which was highly dependent on HI, and this is why the proposal was created and fill the gap of exchange space. In fact, as you are probably aware, I am also the chairman of the European HI initiative within WHO and those needs have also been raised. So, I noticed many of the people from the participant list must have been even more active than me. We had a situation where there was a lot of secrecy between different member states, so it was good to have such a safe space where we could frankly ask questions to each other like a big club: How are you doing this? How are you doing that? And for this questions we get an answer right away, because if we get them a week later that would be maybe too late. We must thank InfAct for occupying that space. As a last point, there is a paper circulating in Policy within Europe that has been signed by a number of countries on the need of setting up a pandemic preparedness plan at the European level taking into account health and non-health issues as food supply, energy, etc. This is something that should be supported. I do

not think that the European Union was prepared for this pandemic and we need to learn lessons from this. This storage information is key to any pandemic plan that why is very important to support this initiative.

Distributed infrastructure on Population Health (DIPoH) summary

PB: I want to give you an update, a reminder of what we are doing with DIPoH.

Just to give a bit of history and composition: the previous project was BRIDGE health in which we brought together mostly research networks across Europe, that included among others: Life expectancy, European Core Health Indicators, Health Examination Surveys, environmental and chemical networks (31 partners in 16 countries representing 14 population health research networks in 9 population health research domains).

We investigated how we can set up a more structured and sustainable HI infrastructure at the European level. We came to the conclusion of the need for a Research Infrastructure (RI) on population health research.

This was confirmed with InfAct project, with 40 partners working together providing a proof of concept by piloting RI elements and preparing for the ESFRI application for this RI.

So what is the aim of this RI? The aim is to facilitate the identification, access, assessment, and reuse of population health information data across Europe.

It is about connecting networks to enable top level research. This will have an impact on policy, practice and technology. Overall, it is based on improved health and other outcomes and the achievement of those outcomes at lower cost. What we see right now is that HI systems very much function in silos, which leads to duplication of activities, and another inefficient aspects.

What will be covered in this HI framework? We cover the domain of health status, the determinants of health and health care systems. We received many questions to be more specific of what we cover. We cover health behaviour, personal risks and resources, socioeconomic factors and physical environment; and in health systems we cover expenditure, accessibility, utilisation, quality, effectiveness and safety.

So what is unique about what we want to offer of this DIPoH? ,

- There is not structure, at the moment, which covers the population health as a whole; we cover not only sick people but also healthy people.
- It is focused on non-communicable diseases (NCD).
- It provides a comprehensive view on health data: population health (administrative data, vital statistics, health surveys, longitudinal studies) and health care (e-health records, hospitalisations).
- It facilitates secondary use of routine data sources.
- It includes individual and aggregated level data, it does not include experimental research (covered but other infrastructures we are in contact with) and it boost national population health research.

Being more specific about the services we would provide:

The first one is to set up a one stop shop for EU HI, that allows you, as policy makers, to find the necessary supporting documents that you need and it allows the researchers or the public health specialists to find data, experts, networks, guidelines and the tools that you are looking for (provide an overview of available data sources in a country) through a web based platform, which is under development at the moment.

The second point is innovative research in HI. In many countries there are health data hubs and data spaces and we have a centralised cloud on HI but there are many steps that are missing and this something that DIPoH wants to invest in: to allow countries to make queries, searches, to ask questions and to get federate access to data and to be able to get real life answers to this questions. But also what we doing in InfAct right now is using artificial intelligence and to investigate how this is used in countries for data linkage so we are quite active in terms of innovation.

The third pillar is capacity building. In your countries you have experts working on specific fields but you might have other fields that need to be strengthened and in our network we have experts all over Europe, which have specific skills in different topics. For example: how to set up a health examination survey but also to provide support on how to set up a health data in your country. So the idea is to provide support in training and exchanges.

And finally, our fourth pillar is knowledge translation and is to provide tools in knowledge translation that exists, to provide support for researchers to make sure that their outputs are streamlined to what policy makers need and to pool also some types of policy reports that are relevant to population health (Figure 9)

Figure 9 Services of the Distributed Infrastructure on Population Health.

DIPoH Practical Use Case: PHIRI for COVID-19

PB: Based on the activities that we are doing with DIPoH, this has gotten some attention at some levels and also at DG-RtD, where they are very interested in the activities that we have been doing. As you know various calls are opened up both in Horizon 2020, COVID-19-specific calls but also at the level of DG-RtD. The Research Infrastructure Work Programme has been amended and in these amendments there is a mention of a set-up of a Population HI Research Infrastructure for COVID-19, which builds on the work of InfAct. Of course, this is something we really want to pursue. This would be an ideal practical pilot of the activities that we do that we called PHIRI (Population Health Information Research Infrastructure). What have we foreseen? At the moment the amendment has been published last week and in Friday we will have a meeting with the different partners of InfAct, but I invited many of you to participate. We will discuss with the partners, what exactly we want to do but we already have a draft outline of the activities that are possible. Of course this is open for discussion. We are still moulding this so any feedback is more than welcome. If you are interested you are more than welcome to participate in the meeting tomorrow. So the idea is the same as DIPoH, only it will focus on the impact of COVID-19 on population in general, as an holistic view of the impact of COVID-19.

As in DIPoH, in PHIRI the identification, access, assessment and reuse of HI for research, covers population health and non-health data in EU/EEA MSs and across EU/EEA MSs and can underpin public health policy decisions relevant to COVID-19. The four content pillars are very similar to DIPoH. It will provide: 1) a one-stop shop platform with Findable Accessible Interoperable and Reusable (FAIR) catalogues, 2) tools for population health research for COVID-19, 3) an overview of capacity building and training that are currently on-going for COVID-19 in order to prepare for upcoming waves or other crises that come up in the future and 4) to assist the health research community in knowledge translation.

The main focus of PHIRI is to set up this platform with FAIR catalogues in similar way to DIPoH. The idea is not to host data centrally but to provide an overview of different types of data that are available in the country in the format of FAIR catalogues: 1) to prepare a FAIR catalogue with metadata repository on population HI with information on how to access to different data, 2) to facilitate real-time data exchange and data requests by securely make available federated data sets and variables in countries to monitor population health with controlled access policies, by respecting GDPR, 3) to allow tools for analysis and queries searches, 4) to provide an overview of studies and trainings in population health and contact points in countries, and finally, 5) to provide an overview of policy and impact measures.

About other organizations, we know ECDC is doing many things, we also know that the Observatory is working on policy measures, we know there is a Joint Action on European Health Data Space and there is also the EU COVID-19 data platform; but the idea is to work very closely with them and what it is already done not to be duplicated but to share the information.

What will be the added value for Member States? This also can be extrapolated to the activities of DIPoH: 1) to have easily findable data and information needed for research and to underpin policy decisions; 2) to facilitate exchange and access data, helping to cope with multitude of research and evidence (which for COVID-19 is very relevant); 3) to provide a rapid response to research and policy questions; 4) to provide access to a network of COVID-19 HI experts to retrieve information from, but also to feed information to, so whenever this information that is relevant comes up in a country is very interesting to share; 5) to identify quick wins by identifying good practices in countries and exchanging approaches between countries such as sharing key indicators, protocols and tools to monitor the wider effects of Covid-19 pandemic; 6) to have an overview of available training materials and training staff; and 7) to provide a pragmatic support to countries in preparing for potential upcoming COVID-19 waves or other epidemics.

How we interact with other organisations, platforms and other initiatives? It is one of the questions that have been raised in the past. InfAct has been collaborating with Eurostat, ECDC, European Commission, WHO Europe and OECD. This has been done in the past with the European Commission Expert Group on HI but we also participate in the European HI Initiative from WHO Europe and we have been very active in submitting new proposals both for the Health Research Innovation Cloud but also for the European Open Science Cloud. InfAct is actually taking the lead of the Health Research Innovation Cloud working with other organisations and research infrastructures such as BBMRI, EATRIS, ECRIN, ELIXIR and EuroBioImaging. You see how we are connecting with other initiatives and enacting with other research infrastructures since the last AoM. Lastly, the Health Data Space (THEDAS) is a new Joint Action, which InfAct is connecting. As you can see there is quite a lot of initiatives happening at European level because I think is really important to bring everything together, again because we need to prevent duplication.

I will give to floor to Markus Kalliola, which is the coordinator of the Joint Action on Health Data Space and shortly intervene to present in a few words the European Health Data Space.

3. Joint Action Towards the European Health Data Space (TEHDAS): Markus Kalliola, Sitra, Finland

MK: Thank you for inviting me today to present the Joint Action on European Health Data Space. What is the Finnish Innovation Fund? It is an independent organisation under the Parliament of Finland that was established 50 years ago as a gift to Finnish citizens. The public future oriented organisation was given the mission to build the successful Finland of tomorrow. We operate with our own endowment capital, which is currently 800 to 900 euros and it is invested around the world in stock market and other investments and obtains yearly returns of capital for investments and activities. In the last fifteen years it is more involved in health projects especially in health data.

We start with the mission letter of the European Commissioner of Health from November, where Health Data Space was mentioned as one of the priorities for this Commission. So, this Joint Action was added to the work program last year and the process was started for this action.

It means that other sectors have data spaces. We are here for give options to the Commission and EU/EEA MSs to operate and to build sector specific health data space.

What is the European Health Data Space about? Is to use health data for better health care, better policymaking and better research and innovation. It has 3 pillars of action data: governance and rules, data quality and interoperability and infrastructure and technology. More specific details of this Joint Action can be found in the European Commission website.

Our administrative timeline: the deadline for nominating competent authorities was at the end of May, at the 3rd of June we had a kick off for all competent authorities and we were nominated as the coordinator for this Joint Action in the break out session and our deadline for application is October.

The mission statement is that the Joint Action helps EU/EEA MSs and the Commission in developing sharing of health data for citizen´s health, public health, treatment, research and innovation in Europe. Of course in the future Europe citizens, communities and companies will benefit from a protected and secure access to seamless health data available regardless where it is stored, which is basically the meaning of the European Health Data Space.

There are 26 countries interested in participating. This is the provisional structure for TEHDAS, which consists of 8 work packages (WP), 4 mandatory (Coordination, dissemination, evaluation and sustainability) and 4 thematic WP. For the thematic WP we have WP5 sharing data for health, WP6 European Excellence, WP7 Connecting the dots and WP8 iCitizen. On the sustainability side I want to underline what Petronille said regarding connecting different activities. When CHAFEA presented the Joint Action on the 3rd of June, they really highlighted the need of looking into other on-going activities, which interlink with project deliverables, with what is happening elsewhere so they did not create their joint actions in a silo and not understanding what others are doing.

The European Commission has asked certain deliverables for this Joint Action, related to provide actions for them to go onward the European Health Data Space. This means we do not make the decisions in this Joint Action so we provide options for others to operate. What this Joint Action is not about? It does not develop IT applications or IT infrastructure, we do not fund other projects and we are not the final decision-making body but instead we create options for others (MS, European Commission).

Our WP and deliverables are built on the needs of the Commission and EU/EEA MSs for better health and better policy-making and better R&D&I.

The WP5, sharing data for health is probably the most important WP that we have, and in the survey of 26 EU/EEA MSs everybody wanted to participate. In this WP we think how the different organisations and entities in Europe work together so the needed skills to work in this WP are legal and organisational. In this WP, the deliverable 5.1, and again this is provisional, is something that the Commission want to receive in quite an early phase when we start the Joint Action, it is about to provide options for governance models including functions and responsibilities for cross border collaboration in the secondary use of health data taking into account use cases (especially the upcoming one-stop shops to secondary

use of health data). There is one in Finland and one in France at the moment, the Finnish is called Findata and the French is called Data Health or something like that. How do they work together? How this upcoming one stop shop for health data and specific MS, how could they share data, what are the guidelines for them to operate? Of course we need to build more on that, on what is asked to do. The deliverable 5.2 (Options to harmonise GDPR implementation) is something that we do not do because it is something currently being doing with a series of working groups working for the Commission and they are still working on this specific task so at the end of the planning we might drop this.

On European Excellence we look more into quality and semantics. The key question is how to incentivize quality on source, and this is in D6.1 Data quality framework. In D6.2 we also analyse economic models of data exchange and data sharing on secondary use cases. When the registry or whenever is a hospital or whatever it has the health data when it starts sharing the data there are also cost for that action. So, how you compensate for participating in different kind of activities? The European Commission cannot fund for each activity so we need to understand that part. Another thing with this WP and also with the next one is about the infrastructure. It is pretty much as Petronille described about the distributed query. There are quite a lot of projects that are thinking that kind of infrastructure at the moment as Darwin, DIPoH for public health an so on. There are a lot of activities like that on-going. One of the things wehave been looking at here is: How to give guidance for these registries? What actions they take when they receive a request from this kind of distributed access to their data? Everyone has their own plan on how to create those.

Moving on WP7, connecting the dots is also linked to that idea and, as Petronille said, there are some many on-going activities at the moment. In the next health program we have more money, that means we have more Joint Actions and how do we make the investments wisely when we have more money? At the moment we have a bit more than in the 3rd program, in the 4th program we have 9.4 billion euros. I think we do not have working infrastructures at the moment to invest that money in the European environment. So we need to think about that, this is something to look at and something that has been asked for us as: What would be the investment framework to go forward?

The last one (WP8) is the iCitizen, which looks more on the consumer data, what the consumers are and the data they are gathering. There are going to be much more data about consumers and citizens, so how do we link that with secondary use of health data?

PB: Thanks you so much Markus, we will only circulate the slides among the participants. I think we have commonalities and similar aims but at the same time DIPoH is already a bit of a step ahead because we are already setting up an IT structure, and we already are developing services. We are looking forward to working together. We also talked to our partners within InfAct to know whom within the country is working in health data space. We are going to be able to work together much more in the future.

Questions and comments

Alexandra Cucu (AC) (Romania): I am Alexandra from Romania, one of the countries not joining the project, unfortunately, it is the first time we found out about this project. Is it everything closed? Do we still have the chance to join now, to catch the train?

MK: That is not up to me; you should contact European Commission and CHAFEA and ask them what it is the nomination process. We have of course started the work, and for me I would welcome you to the project if it were up to me, so please contact the European Commission and CHAFEA as soon as possible.

AC: I will do it through the Ministry of Health, they are the contact, the focal point for Romania, I will try to catch the train if possible

Claudia Habl (CH): I can add that Martin D. is the person in charge, I think.

MK: I can put the contact details in the chat for the people who are responsible for the Commission from a certain point of view, to contact them directly.

PB: If you have any question, please write in the chat and I will give you the floor. Meanwhile I will continue my presentation. I have to slides left and then we will go back to Thomas. TEHDAS is one of the initiatives and when we think about COVID-19, they are a lot of initiatives also on-going, which were initiated by other research infrastructures such as ELIXIR and so forth, so some of you might have already heard about the COVID-19 data platform and also here we are not aiming to duplicate it. But as you can see they cover mostly the SARS Cov2 virus biology and the human COVID-19 biology aspects and we are interested in population dynamics; they are doing most the genomic profiling and we would cover national health institutes and infrastructures, clinical research but also other elements, so what would be the added value of PHIRI? This is really to look into the population dynamics of human and the virus so look at the whole public health in a societal aspects, which is maybe a little bit different of what it is currently investigating the European COVID-19 data platform. You can see that we will covered disease states and risk factors so why is somebody not showing any symptoms after being infected by COVID-19 and others become really sick? How COVID-19 has an impact in the burden of disease? And also in vital statistics so as mentioned earlier, how are countries counting COVID-19 deaths? When the countries are going to readjust the counting of deaths? There will be some changes in the number of deaths in countries when they correct for the past few months. We will also look at epidemiological data and then the idea is to give a much bigger assessment of the impact of determinants of health. We know than in many countries, people in precarious positions, people from low socioeconomic status have been impacted much harder from this crisis. The idea is to have a better overview of the details about this, to look at this socioeconomic factors and inequality data but also at the physical environments. You can think for example about the impact of going back to schools, the impact of going back to work and also the impact on mental health. Finally, the impact on health care systems, to look at administrative data, individual health records, for example. We still have a lot of questions in Belgium and we do not know if it is similar in your countries but in personnel, infrastructure and technology, we have questions like how much do we need to invest in infrastructure for COVID-19? What do we need to do with our personnel? How do we need to organise within the country? Should we need to invest buying protective material?

TZ: Thank you so much Petronille and Markus for giving us such a comprehensive overview of InfAct and TEHDAS, it is very helpful. One of the questions is from Spain, Gonzalo could you pose your question?

Gonzalo Arévalo (GA) (Spain): Good morning to everyone, my name is Gonzalo Arévalo, I work for ISCIII but I am here on behalf of the MoR. My institution is also part of this Joint Action and I am speaking from the national perspective of the MoR. My comment/question is double, how do you foresee that PHIRI will connect with the national repository that some countries -and this the case of Spain-, have launched for gathering information of research projects, we are not only speaking about health records but also about epidemiological information we gathered from research projects we are funding with the national data specific for COVID-19, and this is similar in some other countries? And on the other hand recently there was a call, launched by the Commission for the creation of a Pan-European cohort on COVID-19 that gather this kind of information. On this matter there were several proposals, I think more than 20 countries are competing for this and we were leading one of the activities. We are interested in seeing how the cities interact with the final Pan-European cohort that will be starting soon.

PB: Yes, thank you so much Gonzalo. Of course I did not mention all the projects because they are proposals and we do not know whether they are going to be accepted or not. Of course we know SECURE and, actually in Sciensano we are participating as well, so InfAct also participates in the aspects of connecting with different initiatives and we have in Sciensano a department on patients involvement that are participating in SECURE. Of course I think we have to wait a little bit for this proposals to go through the process of the selection by the Commission. They will approach different proposals and see how we can work closely together in the ground with these initiatives. There are 5 calls and we are participating in quite a few of them so we look forward to hearing from the Commission, which one will be selected. What you said Gonzalo is truly important, thank you

TZ: Any other questions or comments? There is something from Jerome in the chat. Jerome would you like to rephrase it?

Jerome Weinbach (JW) (France): Do you think the current content of the proposal for the EU4Health program 2021-2027 is satisfactory enough to secure support for the InfAct Sustainability Plan? What about your connexion with DG CONNECT (Digital Europe, EOSC Hub)?

PB: Thank you for that question Jerome. Indeed, the new EU4Health programme has been published a few weeks ago and we saw that health data and exchange of data also has a role in this. For InfAct we think in terms of the data aspects. We would really like to apply for calls that come forth from that. About your second question, what about your connexion with DG CONNECT (Digital Europe, EOSC Hub)? The EGI as I showed in my last slides, is also submitting a call, specifically setting up and piloting from the services at EOSC, and for EOSC we are participating in one of the calls. There are also some the services that would be provided with DIPoH and with PHIRI will already be piloted through that. We have submitted a proposal with them, so you can see that we have a close connection with EOSC.

TZ: Are there any other questions? I would like to ask one question, which is a bit down to earth, anyway. You mentioned PHIRI, which obviously fills the gap, fills the information needs that we have. What are the steps to get involved with PHIRI? You mentioned that there will be a teleconference tomorrow but if any of us will not have the chance to join tomorrow which are the other ways to join PHIRI?

PB: Yes, PHIRI is meeting tomorrow. We will discuss preliminary the work packages. We will work very similar to the approaches that Markus is having in TEHDAS. Tomorrow we will present preliminary work packages and some of the ideas on how to address the call and then we will give all the countries the time to fill in a survey on how would we like to participate and they would like to see any changes in the work packages. So, if you cannot participate tomorrow, just let us know if you would like to be involved. I think I invited everyone that is a partner in InfAct, but also we could reach out much further. So, If you could just reply to the email and get back to me, we will keep you in the loop and make sure you can participate. Just get in contact with InfAct coordination and at the end of Linda's presentations we will have a slide again with email address see you can contact us anytime. Thank you. Back to Thomas

TZ: Thank you Petronille. Thank you Markus again. So, we are going to proceed with the agenda, the next section is the update on the Distributed Infrastructure on Population Health (DIPoH) and more information's on the ESFRI application by Linda.

4. Updates on the Distributed Infrastructure on Population Health (DIPoH): Linda Abboud, Sciensano, Belgium

Planning

LA: As you know the deadline for the ESFRI was supposed to be in May, but due to everything that has been happening lately, the Commission has decided to extend the deadlines till 9th of September 2020. That is one of the reasons we wanted to set up this meeting with you, to be able to give up update before our last Assembly of Members which will be then in October after the deadline has past. So we wanted to give you an update also, about what has been happening in last few months with regards to setting up a population health research infrastructure as well.

We are in the last stages of the preparation for the ESFRI application. We are aiming to finalize the draft, the final draft, by in this month and we will send it out to InfAct partners for review. If anyone would like to have a draft, if this needed for gaining more the political support, you can get in contact with your country InfAct partner.

Ongoing work on DIPoH Business Case: What we have done so far in the business cases for DIPoH, is that we have identified the user groups. We have also added to our applications what the added value is for these different users groups. We refined a bit our services and we specified them. We analysed the HI landscape. We also developed the management and governance structures for the different phases of DIPoH, which I will briefly present lately.

We also went more into detail for a sustainability strategy and users strategy; and then in the end we have spent quite a lot of time on the cost estimations expected for DIPoH.

DIPoH Governance and management models

LA: Shortly, on the governance and management models that we have prepared for DIPoH. ESFRI application, as we presented previously has different phases. We started with the design phase, to preparation phase and then we will develop the implementation phase and operational phase.

What we have been doing in InfAct is counted as the design phase, because we have done already a lot of the background, the work needed for such an infrastructure. Then, once we apply for the ESFRI roadmap we will go into the preparation phase. That phase will start in 2022, hopefully then we will have the implementation phase so for these models we count the preparation phase and implementation phases as interim phases. In the implementation phase DIPoH is supposed to have support, a legal structure and then it will become operational.

Interim governance and management model: The interim governance and management models cover the preparation and implementation phases, meaning that starts from the beginning until the moment that it becomes a legal entity. For these phases, the tasks and activities will be project based, and you can see we have already been busy for different calls as well. The governance bodies are also responsible for further refining the processes and the governance, the statutes and different participation models in the operational phase once DIPoH becomes operational.

We have a general assembly, which constitutes all the partners that had signed the memorandum of understanding, which I will show later on. We have the Interim Coordination Office (ICO) and that one is supported by external support teams. We also have a Scientific Advisor Board, an Ethics and Privacy board and a Technical Advisory Board. They are in contact both in the Assembly of Member as well as with Interim Coordination Office. Of course, as I mentioned before, the interim phase would be more project based so there would be work packages that would be led by the coordination office. Also we find very important to keep the stakeholders and users involved to make sure that whatever we are preparing and implementing for DIPoH to become operational is in accordance to what the stakeholders users need.

Transition: Then, we have a transition phase. Once we become a legal entity we have to go into an operational phase for DIPoH. In the table you can see what the different bodies and that the interim phase will become in the operational phase. So, for example, the ultimate decision-making body, which is for us the general assembly, will become the Assembly of Members, with representatives from the ministries of health. Then, we will still have a central office so we will have a central executive management office, and a general director of the infrastructure with the core supporting team. We will keep external support bodies like the scientific support advisory and ethics and privacy boards. You can see we kept up the technical advisor board because at that point it would become an essential part of the central office, and hopefully everything, by then, would be set up. Then we will keep the

interactions with stakeholders in a consultation platform and our operational elements would be the network committee that would be composed by our national nodes and research networks.

Operational governance and management model: You can see how this comes together. We have the Assembly of Members with the full decision-making powers that can be constituted as members or observers. We have the two supporting bodies, the Scientific Advisory Board and Ethics and Privacy Board; and then we have the executives layer, which are the central office with the consultation platform that will keep us in contact with the HI landscape. The operative layer is composed by the national nodes and the research networks.

DIPoH Operational elements: We have provided information in the last Assembly of Members when we went more into detail to the national nodes and research networks.

National Nodes

The central office that will be a web-based portal and the one-stop shop and the services support centre, will be connected to different national nodes that are country based. Then we have the research networks that are cross border specifically oriented research networks.

How do we see the national nodes? It is an organisational entity that liaises between research infrastructure (DIPoH) and the country with the different research networks. We see it as basically bringing together the different stakeholders within the country that are working in population health to discuss different topics together, to share their experiences together, to connect with the relevant expertise as well and then connect to DIPoH that will connect them at European level. We also saw this in the past few months with this pandemic that has overcome the MS. It is really important that the stakeholders, within the country, really talk together so that a policy-makers can make decisions that are based on evidence from the different stakeholders inside the country.

Aim of National Nodes: The aim of the national node is to share expertise on regional and national level as well, to share on-going activities, to update on different initiatives (this also include initiatives at EU level) and to provide overview of national data sources. So we see that national nodes have two roles: coordinating whatever is happening on HI in the country but also managing the data that is available and being collected at the country level. This is already starting in InfAct. In this web platform that we are starting, were setting up a sort of format on how these different national data sources can be presented in a sort of profile, so that the different users of DIPoH will be able to see where o which stakeholder does what in a country. We are already taking the steps into the development of the national nodes within InfAct so in DIPoH we will take that further. We find very important that within InfAct we also receive support from our different partners to provide the overview of national data sources and put it in this web-based platform that we are setting up.

Nodes in the framework of InfAct: In InfAct we have taken quite a few steps setting up these national nodes. We started providing a survey to see which country already have an on-going, kind of body that could serve as a national node. We also stated which were the benefits for the countries who do not have it yet, what are the different barriers and we set up some guidelines. We had meetings with our InfAct partners to try to support different countries on setting up such national nodes.

We have been keeping an update since the last year of what has been on-going in different countries, so we can see that:

- 19 countries have been giving us regular reporting of what has been happening in the national node. Whether there is already a body and if not whether there has been already a meeting that brought together the stakeholders.
- 12 countries have already somewhat an on-going format that can bring together HI stakeholders. And,
- 7 countries initiated first meetings in the framework of InfAct,

Most of these meetings have been organised by the National Public Health Institutes and the InfAct partners. It is important to know to that we will continue supporting the setup of the different National Nodes within different InfAct countries, and we have also realised developments and there is a very large interest from the Commission to build further on these National Nodes with different initiatives and they are now upcoming.

DIPoH Cost Estimation

I am going to present more of what are the steps and strategies for calculating this cost estimation. I do not have specific numbers yet, so if there any questions of course feel free to ask and I will try to answer as best as I can and with my colleagues. We are developing the cost estimation in accordance to ESFRI guidelines. One of the ESFRI steering groups has developed a document with guidelines for the cost estimation for different research infrastructures whether is distributed or not so we are following those. We have divided the estimations into investment costs and operational cost. For the investment, we are looking specifically into the interim phases, which I already mentioned are the preparatory and implementation phases. Then, we have yearly operational costs once DIPoH would become a legal entity.

For this cost estimations we are looking into what kind of costs need the general functioning and the service development at both the central office and the operational elements (which are the national nodes and research networks). This includes different human resources, travel and other costs for the development of the services, but this also includes quite a bit of cost estimation for different technical resources that are needed for the distributed infrastructure. DIPoH will set up governance structures, but we really want to DIPoH to start with technical aspects of this queries, that will then be able to go through a research infrastructure to provide the data needed for different research questions. To set DIPoH up there is a lot of back and technical expertise needed and we have included it in our cost

estimation. We want to enable semantic and technological interoperability across different national nodes and research networks, so this is specifically for national nodes and research networks that serve as data hubs. They have currently national data in house, then they can be interoperable connected to the central office.

DIPoH Contribution model: What I just said were the cost estimations. The contribution model is about how we are going to pay for all of this. It is important to know the contributions models will come into effect once DIPoH is a legal entity and it will depend on actual costs and the *de facto* revenues of the different DIPoH services that will become operational in the last phase. And also this depends on the different types of memberships and this is something that still needs to be developed in the preparatory and implementation phases of DIPoH; once DIPoH is on the roadmap.

Operational DIPoH - Contribution model: The contribution model as a distributed infrastructure will have different funding models, again when it is operational. Now we are competing in different EU grants under Horizon2020 and hopefully in the Horizon Europe. The Central Office will be funded through membership fees paid by Member states. When we have the Assembly of Members, once DIPoH is operational, there will be an annual membership fee that will be paid by of members of the infrastructure. There will be fee for services options and that will be paid by DIPoH users. And then, for the elements we have the National Nodes and Research Networks. National Nodes are typically funded through national-level investments and the international founding for research as well. And the Research Networks are also funded either through national-level investments or international funding.

I can add here that in the cost estimations we have different ideas also for the previous phasesIt is important to know that we do have allocated budget for different National Nodes and Research Networks, to set things up and running to be connected to the DIPoH distributed infrastructure.

Political support

The next point is the support, which is also one of the reasons we have all you here and we really wanted to update on what we have been doing. For DIPoH we need a three types of support. We need: 1) An expression of political support (EoS): this is mainly by national ministries to sign. 2) An Expression of Financial Commitment (EoC) signed by any legal entity or authority within the country can sign this letters. 3) Inter-institutional and multi-lateral agreement, which we are calling a MoU and that is signed by the core partners in the DIPoH consortium, mainly national organizations or institutes that sign this memorandum of understanding to prepare to go forward in the implementation and preparation phases of DIPoH. Also, I have to mention that Political support and Financial Commitments are for the preparatory and implementation phases. And you can see in this slide for this MoU is possible to sign this agreement as an institute without having the political support of that country

Expression of political Support (EoS): For the expression of political support we have received or expected the letters from:

- Belgium: Two different Ministries
- The Netherlands from of the Ministry of Health
- Portugal: the Ministry of Research
- Romania
- Croatia
- Finland is still expected

Pending: We have 6 countries that are still working on getting the political support letters, so this still are pending. The pending countries I can mention here are: Ireland, Spain, France, Italy, Malta, Slovenia and Serbia as well.

For the financial Commitment, we already have received the guarantee for financial commitment from the leading country, which is Belgium. We have the commitment from two institutes, from Sciensano and RIZIV. This will basically cover the central hub or the coordination for the first two phases of DIPoH. And, we have also reach out to different Research Networks that will become an important element in DIPoH. So far we have letters from 4 different research networks (EuroPeristat, EuroSafe, ECHO, EHLIES) and we are still trying to get in contact with additional different networks as well. I have here a few examples of how the letter of political support looks like but I think it is important for us to know also from you, who are here, whether or how you stand with this project and if you think if you can provide still political support for this project. Maybe we can do a round table to see the different countries that we have in this meeting. Maybe you could answer whether you think an additional political support in your country is possible.

Round of table on political support

Do we have anyone from Austria?

CH (Austria): We received the memorandum. But, the political support for ESFRI is the responsibility of MoR in our country and not of the MoH. In the MoH basically there are people that are supportive and people that still do not need to be convinced. So, I do not know about if we can do it until. I think the situation is good but as I said it correctly is the ministry of research that must take note on that. This is exactly what we have to talk to the people in charge of ESFRI, but I am not sure we are still debating if I can do it on my own, as the public health institute or if the Ministry of Health has to decide. The problem is that one decision-making person is not very positive; do you know what I mean. There is still the chance of coming later if necessary? Or is it October the hard deadline?

LA: September 9th is the deadline for the application and by then we need letters. In our application we can say whether is still expected to come in, I think in previous applications they did that as well.

CH: I think mi colleague Patrizia, said it last time, and I think I said it more than a year ago. My problem is I that cannot go there and ask for money. For the money they will ask probably for a business plan, and there are still no cost estimations. I know this is the big problem. I am interested in how those countries who signed already, Netherlands, Belgium, and so on, how did you make your ministries signed such a letter, if they were not able to give a concrete budget number? This is the main problem, they will ask me how much money we would need and I ca not tell them. That is my problem.

LA: Just to clarify we have two different letters. For the political support you are not putting any money yet, you are providing political support meaning that you are in favour of such an infrastructure. The preparatory and implementations phases are not legally binding, it is not saying that you are putting any money yet.

CH: It is good to hear that, but still I think in my country to provide political support go hand to hand with the financial commitments. It is not my opinion. I am just telling how the situation is. I am happy to share this information with others, saying other countries gave political support, and that does not mean anything. But for me in practice I have learnt in the hard way that this perhaps not sparks interest in your government or whatever. I will work on it, but I cannot promise anything until September, so is good if you do not list Austria.

LA: All right, ok. We will keep note of that. Thank you Claudia. The next country we have is Bulgaria, but I do not know if there is anyone from Bulgaria at the meeting. We have Cyprus and Czech Republic's.

Hana Marie Broulikova (HMB) (Czech Republic): I have worked on that, after the last meeting in Brussels, I forwarded all the documents, the issue now of this, is that the ministry does not have a person dedicated to do that. What I can do is basically remind them there is a deadline. I think there are same similar cases but they provided the letter of political support, so I would say that it is a matter of time and effort to explain on what is DIPoH. I will try to do it again. I cannot promise, but I am hopeful they will align. The personal at the Ministry now are busy with different things and unfortunately the structure is not a department dedicated to such things now.

LA: All right. If you need other documentation or if you have any questions for explaining DIPoH, please contact us, and maybe we can help. Then we have Denmark and then we have Estonia.

Angela Ivask (AI) (Estonia): I do not know if Eleri is online. I am from the same ministry where Eleri is from, the Ministry of Health. I would say that we have a similar case than Austria and Czech Republic's. We cannot say at the moment for sure, because joining the ESFRI object is a shared responsibility or actually is responsibility of the Ministry of Education and Research. But the thing is, the national or official application process for ESFRI is every two years object, we first have to obtain a national agreement to join an international ESFRI. We past the deadline a little bit, because our deadline was last autumn, so now we should make an exception if we would like to join another object, thus, it has to have a strong political support. As said by Austria our Ministry of Education and Research we only give political support if we are sure about our financial support later; so we still have to

discuss about it, especially now, where the budgets are really tight related to COVI19 mitigation. They will probably provide you a written feedback a little later.

LA: All right. That will be great. Thank you Angela. And then we have Finland and then we have France.

JW (France)**:** **A**s you can imagine, and I think this is the case for all of us, this is a very demanding period regarding commitments for to the future, for the recovery plan whether is at the national level or at the European level. Also we are at the turning point between two European programs, so it is going to be difficult at this stage to request a kind of support or commitment letter to my Ministry. Maybe my colleague from the Ministry of Research is online, I do not know if is Bertrand or Eric. We will try of course and I think the work you have done since the last time we met is excellent, so that made things clearer. It is also well articulated with many on-going initiatives so it would help for health, but, I cannot guarantee we will have the audience right now, considering the current context. As you know, we were asked to invest a lot in vaccination, in a recovery plans, etc. Maybe the period is not ideal, I would say, but let us see what we can get in few months or few weeks' time before the October meeting.

Eric Guittet (EG) (France): If I can comment from the Ministry of Research, in fact, the Ministry of Research is the entity that delivers political support, and I mentioned that back in November. The process is initiated quite early, we would have needed the entire set of documents by December, the beginning of January the latest. Since we did not had the elements at that time, it will be impossible to get political support from the French Research Ministry. I will not tell you anything about the rest in terms of financial support that could be given by the Ministry of Health for instance. But for the political support it would be the French Ministry of Research but we are out of date for that.

LA: I remember that in November the deadline was very soon for the national program.

EG: Probably too soon, but France is a very bureaucratic entity, so, it does not mean that we are not following the evolution of the project over the months and as you mentioned we have seen a nice evolution of the project. Probably we will keep on participating but we will not be able to provide political support by September.

LA: That is too great to hear and I think also our colleagues from InfAct are trying to get this Memorandum of Understanding from Sante Publique France. So France still will be engaged in a way that hopefully once the research infrastructure is on the roadmap, is still possible to receive political support in the following stages. We hope that in countries where we have missed the deadline for the national roadmap we can still try to receive some support afterwards.

EG: Yes,, the building of National Nodes is a very important step for us.

JW: I think the political support is also strictly dependent on the on-going evolution in France. There is a newcomer, a new actor on the field of health data, which is the national health data hub. It did not existed at the time InfAct and when the former projects were launched. The French health data hub is involved in the future joint action as the competent

authority, so it is good news, and of course, a political support will depend on its view as a competent authority in that field. I think this is a new path for the France decision, that it is would be extremely important for gaining the political support from all authorities.

EG: Again, political support belongs from Ministry of Research and all steps will be behind us.

LA: It is fine. But, we are aware of the importance of the National Nodes and we really hope to work with the French data hub and also with the THEDAS, the new joint action and keep the interactions going also for DIPoH as well. Now, we have a Germany.

TZ (Germany): Thank you. It was a decided from the Germany Ministry of Health last year, that we would go into an enlargement of the scope of ECDC rather than a research infrastructure. Then coronavirus happened and things are changing, this true for persons and this true for decision makers as well so we are now in contact with new people at the Ministry to see what we can do but nothing is finalised or decided yet. It is still in the process and the Ministry is step by step back from coronavirus mode to the normal mode, and for the time being there is no support yet but we are trying to get it, for the time being we do not have it.

LA: Thank you very much Thomas. And now we have a Greece, Hungary and Ireland.

Alan Cahill (Ach) (Ireland): We had an election in February. At that time we had government conformation talks but they were obviously delayed due to COVID-19. Now they are already finalised so we expect new government to be in place on the next few days. We are essentially waiting for the new set of Ministers. I guess that until that happens we will not be able to get political support. That is largely the reasons why we have not signed the letter yet.

LA: Thank you very much for the information. Then we have Latvia. And Italy, is Giovanni there for Italy?

Grazia Pavoncello (GP) (Italy): Yes, I am Grazia Pavoncello for the Ministry of University and Research. You know the bureaucracy in Italy it is not famous for being fast, but we have another internal deadline. The deadline for submissions of political support is 9th of November, but internally in Italy it is finalising these days (the last days of June our political and financial support for the proposal). I think that it is just a matter of time, but unfortunately our scientific committee is overloaded at the moment. Our main issue is related to the internal deadline of the submission.

LA: All right, but that is the Ministry of Research, it is correct?

GP: Yes.

LA: ok. Thank you. Then, we have Lithuania. No Lithuania, Luxembourg? We have Malta.

NC (Malta): We are currently hands up with COVID-19 at the Ministry. I will try to get political support from the Ministry of Health on the next few weeks.

LA: Ok. Thank you Neville. We have Poland. Portugal is on the way, Romania we have, Slovakia anyone? And Slovenia.

Metka Zaletel (Slovenia): Slovenia is one of the pending countries. We have experienced a new change in the Ministry and I have already spoken with the new Director General at one of the Directorates at the Ministry of Health. She is quite eager to be part of this ESFRI, so we will have a meeting next week and I will present what you presented today. I think we can manage to provide an answer before the deadline at the beginning of September.

LA: Ok. Thank you Metka. We missed Norway, and Hakkon just informed us that the letter is pending. We can go with Spain.

Gonzalo Arévalo (GP) Spain: I am the representative of MoR, although I work for the ISCIII. It is good to be speaking at the end because our issues are a mixture of what it has been commented by our colleagues. On one hand we faced the same problem that was mentioned by our Austrian colleague that by signing this political declaration we know that later on, a few years hopefully there will be a financial engagement and this make things difficult. And on the other hand the internal process for this application was very early in this year where we should have had this information. Nevertheless if we can get the updated information we can try to see more properly what it is and check if we can get it, but I do not promise anything

LA: Great. Thank you Gonzalo. The last one is Sweden.

I will go back with my slides. So, I have some example of different letters if anyone would like I can send them as well.

***Example** EoS:*

Subject: Letter for expression of political support (EoS) for the construction of the research infrastructure for population HI.

Through this letter, we would like to express the interest of [name of country] to be involved in the process towards the construction and implementation of the research infrastructure on population HI.

The ministry of health/research recognizes the Distributed Infrastructure on Population Health, (DIPoH) as an important research infrastructure and encourages the participation of national institutes to the preparatory phase consortium, subject to further assessments and bilateral agreements.

This "Expression of Political Support (EoS)" does not constitute, in any aspect, a decision on the financial contribution from the government of [name of country] to the construction of the research infrastructure.

The ministry recommends [lead institution in country] as coordinator, as our representing organization to the research infrastructure on population HI.

Example EoC

Subject: Expression of Commitment

[name of lead institution in the country] expresses its financial commitment towards the preparatory and construction phases of the research infrastructure on population HI as a pan-European research infrastructure.

[name of lead institution in the country] will participate in the development of this important research infrastructure through [in cash and/or in kind contribution],the size and manner of out financial contribution will be proportionate to the budgetary needs of the research infrastructure on population HI and our financial capacity.

It will be further calculated based on (i) modalities described in the consortium agreement signed by all participating organizations (ii) subsequent agreements of the board of the research infrastructure on population HI.

HMB: Can I ask a question? I want to ask because, from the Czech Republic I will probably negotiate with the person who is also involved in the negotiations about the National nodes. I saw in the slides that Czech Republic is one the dark blue countries there, so I wanted to ask you a bit about your experiences for Czech Republic regarding this National Nodes negotiation, so I have more information from your side than from the person at the Ministry.

LA: Our partners from InfAct are Ondrej and Sarka (Sorry, I do not remember the last name). They said they still were trying to set it up a National Node and that was last year when they were in Brussels but tomorrow we have another meeting and we will ask for updates regarding that. So I will ask them and if that is OK with you and also tell her to communicate with you and then she can give an update.

HMB**:** I think is Sarka Dankova**,** it is perfect. We will be in touch I was just wondering how it is going so now I will use this information in the negotiation, thank you. We will be discussing this information and going to organize your information and organization.

LA: Thank you, perfect.

Inter-institutional Memorandum of Understanding: This is the last Memorandum of Understanding. This Memorandum of Understanding could be signed by the institutes that will become core partners in the setup in the preparatory and implementations phases. We have already received four letters, well five, Belgium is also included. We have quite a bit few expected as well. You can be in contact with InfAct partners and see how to proceed with that this signature as well.

Upcoming meetings: So, to end of this meeting we have three minutes left, just to inform you about the upcoming meetings. We have:

1. PHIRI for COVID-19 meeting with InfAct partners tomorrow June 26th (13:00)
2. Then we have an InfAct National Nodes meeting with our InfAct partners, to update on National Nodes status and discuss further work. June 26th(15:00)

   If you want to join this meeting please send an email to infact.coordination@Sciensano.be and we send the webex link to joint.

3. Last reminder our **third Assembly of Member Meeting** scheduled in October 27th. So far the location is still Madrid, and we will have a plan B. In case Corona Virus has a second wave at that time we will need to have the meeting virtually.

5. Concluding remarks: Thomas Ziese, Robert Koch Institute, Germany

TZ: Thank you very much Linda. Thanks everyone to the *tour de table* for keeping us informed about the progress. I would like to advertise again the request, the uses of these different opportunities that have been shown by Petronille and Linda today, using or joining the DIPoH in different levels, then joining the PHIRI, which may show some practical aspect how is the DIPoH working to give a practical example in the real world. I think this is the opportunity for promoting the whole idea of HI systems within our ministries again. And also with the institutions by signing the memorandum of understanding to support the DIPoH. So, would be great if the outcome of this meeting would be some letters this way or the other, to help the whole process. I would like to close the meeting.

PB: One more question, sorry Thomas. I just wanted to say that we can now present the strategy where we included and discussed the estimation of the costs. Clearly, some countries really want to see these figures. We have an Excel sheet we are working on, still is work in progress but we can share it with partners if people would like to use it for gaining more support.

HVO: Then, I just would like to apologise that, I was planned to be in the meeting from the beginning but I had another COVID-19 activity that interfered, and so Thomas I want to thank you in fact for chairing this meeting for us. Thank you very much.

TZ: It was a pleasure, actually and thank you Petronille as well for this information that you could make some figures available if needed. Maybe that really would be helpful for negotiations.

Isabel Noguer (IN): On behalf of Work Package 4, I just we wanted to thank all the participants that we have in this extraordinary Assembly of members. We will draft the minutes of this meeting and we will distribute them to you. I will like to remember to you that we have a Technical Dialogue already foreseen by September. In this Technical Dialogue we will invite experts from different countries in order to discuss about the last Fact Sheets provided by our InfAct partners. I invite you to promote National Experts working in your countries and involved in HI systems to participate in this Technical Dialogue foreseen by September. Thank you very much Thomas.

TZ: Ok. Thank you Isabel for this view into the future, I am looking forward to seeing all of you in the next AoM, hopefully in Madrid face to face, and I wish you a pleasant summer. Thank you and goodbye.

D. Minutes of the Fourth Assembly of Members

1. Welcome and introduction to the 4th Assembly of Members

Welcome to the 4th AoM. Gonzalo Arévalo, Deputy Director for International Research Programmes and Institutional Relations. Carlos III Institute of Health. Ministry of Science and Innovation. Spain

GA: I will just say a warm welcome to all of you, we are very pleased to host this meeting, and as part of this Joint Action. I would like to apologize for Dr Emilia Sánchez Chamorro. She is the maximum responsible for the Spanish Public Health School, which is the place were Isabel's team currently work and where the meeting would have been held. From my side nothing more because we are short of time and you already know us, our institute and you also know me because I am part of this board as the delegate of MoR, so thank you very much.

Introduction to the 4th AoM. Neville Calleja (NC), University of Malta. Chair of the AoM

NC: Welcome everyone to this AoM. Thank you to the Spanish team for organizing and delivering the Sustainability Plan for this meeting. I could not join personally last meeting but I followed what had been discussed. In the meantime, some of you might be aware that the application for the DIPoH indeed have been completed and submitted to the ESFRI roadmap. Moreover, even a spin-off of DIPoH, called PHIRI, which stands for Population HI Research Infrastructure has been developed and which it is the practical use case for COVID-19, which would be looking at practical issues regarding COVID-19. The team has also completed the Sustainability Plan so those are the 3 main achievements I would say.

I am Neville Calleja from Malta, a partner of this project. InfAct is already reaching its end of life but definitely it has siblings that are poised to be even more successful. Just to take you quickly to other AoMs, to refresh your memories, the first AoM was held in Madrid around 18 months ago and we basically tried to shape the concept of DIPoH, it looked at the challenges and the needs of the current EU HIS, existing research networks (in InfAct we looked at one Europeristat case study) and we tried to tease out as much as possible what is in it, what will be in it for EU/EEA MSs, so we tried to focus on teasing out from you the expectations and benefits from MoH and MoR. Obviously there was an extensive discussion around why or why not it was needed an EU HI Research Infrastructure. The 2nd AoM was held in Brussels. The business case was presented with the rationale, the structure and the services being planned, with NN and research networks. We also had the explanation of why we decided to go for a Research Infrastructure and why we decided not to go for other models like and extension of the ECDC, to the GRC or to DG Santé itself. We also discussed the importance of HI for policy-making. We have now a very case in point because I never have seen in my career HI mainstreamed as much as it is now during the COVID-19 epidemic and the challenges we have face to deliver information and deliver it in time. We also look at models and options for creating a financially healthy infrastructure, which is also a

discussion we continue today. Finally, there was an interim meeting last June, when there was again a presentation of the COVID-19 activities that InfAct was doing, this was a new development over the previous meeting and the concept of PHIRI was introduced, and also an update of DIPoH was discussed. That was a brief summary of what we discussed in the previous 3 meetings and at this point I think I will also give the floor to Petronille to explain something that we planned to use during these 3 hours to try to capture your feedback.

Petronille Bogaert (PB), Sciensano: We would like to have your live feedback during the meeting so if everyone could take their phone of if you prefer do it with your computer I will show you in a minute. If you scan the QR code it will say Mentimeter, and you will see the question. What topics would you like to hear about during this meeting?

Mentimeter questions

- How are PHIRI and DIPoH connected?
- Any plans for DIPoH to work closely with the European Health Data Space initiative?
- Data sharing and privacy of health data in EU countries, sustainability of EU HI infrastructure for population health research.
- Interaction with existing RI
- How will coordination of DIPoH and EHDS initiatives be reached and maintained?
- Link to research data and EOSC-Life.

Welcome from InfAct coordination. Herman Van Oyen, Scientific Director, Sciensano, Belgium.

I just want to remind you what is the objective of the DIPoH and the framework of HI because HI is now there as it was already mentioned, in fact it needs not only to be there but it has also to have a certain purpose. DIPoH can play a major role as the platform that should facilitate the finding, the access and the assessment but especially the reuse of existing health data within Europe, which clearly links to the European Health Data Space, and the reuse is important both at the level of research and at the level of policy development. That is why in InfAct we have these 4 pillars that we proposed as our services: one is about innovative research methodologies; another one on capacity building; we have especially stressed the importance of the pillar about knowledge translation research for evidence-based decision making, and as DIPoH we want to strengthen this type of research activities that better interact the integration of knowledge on population health into evidence-based policies. I think in this meeting we will try to answer some of the questions and critiques that were put forward in the previous meetings. One of the major points I want to stress is that in InfAct we are being very successful in the preparation of DIPoH to interact with existing research infrastructures from the Life Sciences and it was clearly showing that population health has an added value to other people that either work in lifecycles like ELIXIR or work with more clinical and experimental health data, so it shows the type of interaction and the success in submitting together a project with them and we are also working in other projects that will contribute to the European Health Data Space. Based on that we have now submitted the ESFRI application and I think is very important that all people around the table within the different EU/EEA MSs should meet the ESFRI

representative to speak about DIPoH so it facilitates the process and enhances our position in this type of evaluation that we will have. Thank you

2. Comments from the European Commission (Philip Roux, DG Santé)

Philip Roux (PhR): Thanks and as you said before Neville, we are in difficult times. I am recently impressed about our capacity to overcome many difficulties on daily basis and that we continue to show as the situation evolves. I want to thank you all for your involvement and for the involvement of your teams. The work in the Joint Action all along the way reaching today's meeting and for the tangible contributions, including those that you have mentioned Neville and I know it is not a complete description of all the achievements but you have mentioned the key one's of great importance to us.

First, we have a new Director General in DG Santé (Mrs. Sandra Gallina), she is new but full of energy and I am sure she will be a key person in the future, as HI is taking a big share in the work of public health and that is also true in the EC.

Second, we are progressing towards an EU health program, which right now is in discussion, the envelope that is foreseen at the moment is for 7 years, of course a period of 10 years have been proposed at the EC level; it is less than we proposed but is still more than what we have with the previous programs. The discussions are not finished yet and of course we are working in combination with other programs of the EC. The Research Program is huge and it is an extra-source of means for future activities, which was aided by InfAct.

And third, the unit that is hosting the Joint Action, it is now named **Health Information and Health Integration in All Policies** so that is not just a cosmetic change, is a drastic change, in essence we will have the capacity to look more wider into the EC activities and more involved in the key one's such as the EU Health Data Space. This fact has a close link with the work that you have been developing, and that for me is excellent new because It means that even if the Joint Action is reaching its last chapter, it is not the end of the story it is just the end of one period of work and it opens to a number of other initiatives. All the work that has been achieved will be more than instrumental in the future development and that for me is very important. I think we progressed a lot in the last years and I hope that the elements that have to be discussed and exchanged today as a wrap up of all achievements will be very instrumental in the future. Many thanks and I am very sorry for not staying but my colleagues from the agency will continue with you a bit longer and they will report back and of course I have opportunities to re-discuss with you to make fruitful use of the results of the Joint Action. Thank you very much.

3. Update on the Distributed Infrastructure on Population Health (DIPoH). Linda Abboud (LA), InfAct coordination, Sciensano, Belgium

LA: Good morning, I will have a presentation to go over everything we have done until now, about DIPoH and our ESFRI application. I will go quickly to the things that we are done and then I will give you some aspects of points that we could not answer yet in the previous AoM

as: 1) whether go for an ERIC or not, 2) what type of data we are using, 3) how are we going to get the support of different EU/EEA MSs, 4) why DIPoH, 5) why a research infrastructure.

The road to DIPoH

We explained in the very beginning what are the challenges of HI, the fact that there is a lot of fragmentation at the moment, there are inequalities and a lot of HI activities are project-based, which leads to duplication, waste of resources and long-term planning. As a consequence, we identified that there is a need for a HI infrastructure.

Why a research infrastructure? Because it allows responses to current needs and demands with high usability for EU/EEA MSs and EU institution, builds bridges between research communities and with decision-makers, facilitates innovation and knowledge sharing and can ensure continuity of existing HI activities. And, as Neville mentioned, in BRIDGE health other options as an extension of the ECDC were assessed and the research infrastructure was the most feasible solution in the current setting.

We also presented our framework that is focused on population health, including health status, determinants of health and health care system, and then we presented the concept of DIPoH, which is connecting the different networks and stakeholders that enables top level research and hopefully spurs policy change, practice change and technology change to improve health and other outcomes. Then we presented the uniqueness of DIPoH focusing on population health, which are: 1) it covers population as a whole, 2) facilitates secondary use of routine data sources, 3) includes individual and aggregated level data, 4) boosts national population health research and 5) does not include experimental research. We also showed the landscape analysis that we have done on the different RI that are on the ESFRI roadmap and the need to fill this gap of the RI focusing on population health.

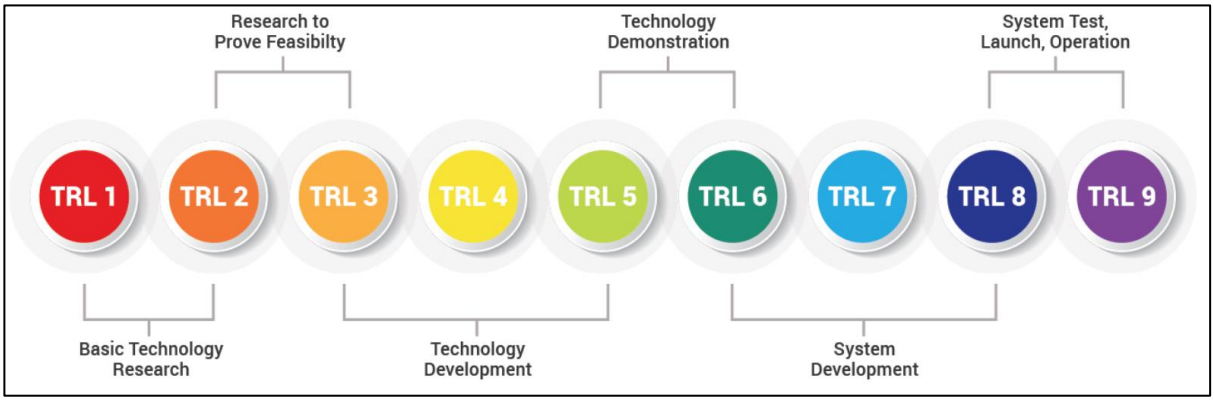
The structure builds on the central office, different nodes as the NN and the research networks and finally the HI portal, which is a gateway to data, services and tools that will be provided by DIPoH as a RI. As you remember in Brussels and Madrid, we presented some examples of the NN and research networks and the importance of bringing them together in a RI. The services, that Herman already mentioned for DIPoH: 1) a one-stop shop for EU HI research, in a form of a web-based HI portal, this bring together metadata of the different data, experts, networks, guidelines and tools across Europe, 2) innovation in HI research focusing on population health and different developments, 3) capacity building improving skills for population health research across Europe to reduce health inequalities as well, and 4) knowledge translation to bridge the gap between researchers and policy makers. Finally, we explained why the need to apply for the ESFRI, because is a stepwise and structured process. It is a stamp for excellence with Pan European relevance and provides opportunities for European funding engagement of EU/EEA MSs.

DIPoH progress

That is what we have done so far and I would like to resonate what Philip said, and thank you for all the feedback received in the previous meetings. We are happy to say that we submitted the ESFRI application the 9 of September of 2020 and to give an idea of what timeline we are expecting, we hope to have a decision somewhere next year. Within the progress that we have done within InfAct through the ESFRI process there are some aspects that were refined from the feedback provided in the previous AoM: 1) the need and expected impact of the infrastructure, 2) the landscape analysis, 3) the services, 4) the user communities, 5) the structure and federated infrastructure, 6) the management and governance models, 7) the planning and the costs.

Highlighting the different aspects that we have already achieved during the past years in the work towards DIPoH. We have achieved from BRIDGE and InfAct Technology Readiness Levels (TRL). The TRL is a classification widely applied in EU research and innovation projects that goes from level 1 to level 9, which means going from the basic concept proving the feasibility of DIPoH and then demonstrating it and launching it at operational level as it is shown in the figure

Figure 10 Technology Readiness levels



For the one-stop shop we developed a catalogue with metadata for both of existing HI projects and networks (TRL 7 consists on a prototype of the metadata catalogue of an initial set of network that is being set up in InfAct and tested in an operating environment, the HI portal) and HI data sources (TRL7 a prototype of the metadata catalogue of data sources has been set up and tested in operating environment). Adding up to this, ELSI and FAIR guidelines are demonstrated in the different settings and made available in the portal prototype (TRL 7)

Comment from PB: I would like to go back to the previous slide because one of the questions in the Mentimeter was data sharing and privacy of health data in EU countries. These ELSI and FAIR guidelines were looking into that, so, within InfAct, we already tested how to make it possible for data to be available and to be accessed centrally without affecting ethical and legal aspects. It has been tested because the fact is that data does not have to be moved from one country to another, and the central office will only answer the queries.

This is the way you respect all legal and ethical issues and I think that is the answer to the question that what poised before.

LA: The second service is innovative research in HI, with leading-edge study designs and analytical methods, with machine learning techniques and developing methodological guidelines. In WP9 they have done a couple of case studies using machine learning techniques and developing a practical examples for using it in population health research (TRL 5). There is also semantic and technical interoperability across datasets, within and between countries. By using cases studies we will demonstrate the feasibility of using common data models in distributed infrastructures implemented in real-life environments (TLR 6).

Regarding capacity building, in InfAct we are trying to come up with some standardised protocols and guidelines. We did a European Capacity Building strategy in WP6 and now they are piloting the first flagship course for health population and so far it has received a positive feedback and this is something that DIPoH could provide as well (TRL 7). We have also done HI systems assessments across 9 nine different countries and we have developed a protocol to do this in a peer-review manner, which also performs a mapping exercise to assess national HI systems and establishes an information base where stakeholders can contact international expert networks, projects and organisational bodies collecting comparable health data (TRL7).

The last service is knowledge translation research. Within Sciensano we developed the HI impact index, a review of existing tools. A prototype of the index has been developed to assess knowledge translation processes (TRL3) and what we are doing here with WP4, with the technical dialogues is to foster the integration of outputs of InfAct into different national policies and talking with national experts about these outcomes and how they can be integrated in a national level (TLR5). The European HI training course, also provided a test for the use of knowledge translation research in HI (TLR6). In addition, we identified inspiring examples from EU/EEA MSs with regards to innovation of data sources (use of data linkage and/or applying artificial intelligence) to estimate health indicators, which could be potentially useful to target priority public health actions and healthcare strategies such as the development of best practices and guidelines to enlarge the set of morbidity indicators available across the EU using innovative techniques (TLR5). Finally, we piloted interoperability for public health policy in WP10 (TLR2). All of this, you can also read it in the Feasibility and Design study report that you have received before this meeting. In the Sustainability Plan all this information is explained better and more in depth. My colleagues from Spain will also go over through this and you have also received the document if you want to check a more specific aspect of the project.

PB: just to add that the HI portal is being developed at the moment. We are working together with ICT to develop the whole platform and I think that it will be very useful for MoH and MoR, and also people working on public health institutes and any other stakeholder that use HI across Europe, because what is being done at the moment is to make inventories and catalogues to describe the different types of health data sources that are available across Europe. In PHIRI which we will present later we will show you what this means for COVID-19, because we also provide information of the health data sources that are available

for COVID-19, which are very useful during this crisis. So, the HI portal, will already be launched within InfAct project and then it will be further taken up during PHIRI and DIPoH. I think also that the European HI School is worth mentioning, because it is unique and InfAct has already taken forward. Unfortunately, we had to switch from face-to-face to virtual lectures, due to the COVID-19 situation. On the other hand we had a lot of applications across Europe so we had to make a selection and for this success we will try to organize another one within the framework of InfAct.

DIPoH phases planning

LA: I will go further into some aspects of DIPoH that were not clearly answered in the previous meetings and have been developed during the ESFRI application. The design phase started in 2015 with BRIDGE Health and went through InfAct. Then we planned a 3-year period of the preparatory phase, another 3 years for implementation and then in those phases the research development and technical construction will be further developed. The agreements between different partners and stakeholders will also be agreed upon, and will be made legally bounding. In the preparation phase the focused will be achieving the **legal entity of DIPoH**. In the implementation phase, we will deploy this legal entity as soon as possible, we will have a business plan and the budget agreed upon among all the members of the DIPoH and then also this time period will be for further development of the federated infrastructure of DIPoH, the HI portal and the different services that will be provided through DIPoH.

During these phases we will work together with the NN as well as different research infrastructures to connect them with DIPoH. Once the preparatory and implementation phase are done, DIPoH will go into the operational phase and then it will be delivering its full set of services. It will continue networking and collaborating with different international organizations and prepare for an upgrade. The ESFRI roadmap an operational phase takes a maximum 10 years, and after these 10 years there is an evaluation of the RI after which hopefully an upgrade will happen.

DIPOH Cost book

I will go into the most wanted question, which is the cost book. We shared with you the document but if there are still questions please put them in the chat and I will answer them as best as possible. The costs were estimated in accordance to ESFRI guidelines separating between initial investment costs (including design, preparatory and construction phases), and the yearly operational costs. Costs estimations are themselves divided between general functioning, service development of Central Office and DIPoH's Operational Elements (NN+RN), which include human resources, travel, other costs and also the cost estimation for the technical resources for the set up of a distributed infrastructure to enable semantic and technological interoperability across NN and RN (as data hubs), with the Central Office.

The summary **cost estimations for DIPoH** are: 7.6 million € for the design phase, 14.1 million € for the preparatory phase, 29.4 million € for the implementation phase and the average annual operation of 10 million €. In the document there is more detail of what we have

considered. For example about human resources for the different profiles that we think are necessary in the different aspects such as our central hub and in the different nodes we have also taken into consideration the fact that we need to be able to connect and have a focal point in each NN and a coordinator in each research network. The technological resources also include the different materials and the licenses that have become very costly, and are needed for the federated infrastructure. We have received the financial support from our partner in Belgium so it will allow covering the coordination and management of the central hub.

As a distributed infrastructure, DIPoH will have a mixed funding model with the following contributions: (i) the Central Office is funded through membership fees paid by Member countries, (ii) fee for services paid by DIPoH users, (iii) NN are typically funded through national-level investments, supporting national coordination, the development and operation of services, (iv) research Networks are funded through national-level investments and international funding, and (v) DIPoH collectively competes for grant funding from the EU under Horizon 2020 and Horizon Europe. So, these are the different funding models that you can also find in the Cost book in more detail. These are the options but this will be decided upon in the preparatory phase, with the members of DIPoH, on how much will be expected from the membership fees.

DIPoH support

ESFRI application was submitted with the support of 14 countries, which have provided political or financial support and/or signed the Memorandum of Understanding (MoU), which will provide some in kind support once the actual work starts in the different phases. During the ESFRI application, we also managed to receive support from the different EU infrastructures and beyond Europe as well. But the work has not stopped here, we still need to get more support from the EU/EEA MSs, we still want to get in contact with every one of you whether it's possible to get political support or financial support or the national institutes would like to sign the MoU for the membership of the first two phases of DIPoH. If you still want to get in to contact with us, please e-mail us. We know from our previous meetings that in many of the cases, the countries to get their political support, they will need to apply for the national ESFRI roadmap, and in some cases the deadlines have already passed. Although, in the upcoming cycles we can still be able to apply for it. Please let us know and we will try to contact you to get the political support for DIPoH.

Questions

GA: When would be expected to have the ESFRI started?

LA: We expect to have the answer for the ESFRI around this time next year and that is why we put the preparation of the Preparatory phase at the beginning of 2022, so that we cover the gap waiting to know if we are on the roadmap or not, and then hopefully we will go into the preparation and the implementation phases

NC: I would say that Health Ministries cannot express political support usually without the input of the Ministry responsible for Research, I am not sure for other countries but this is my case. I definitely have to pass through the competent authority here, which is the Malta Council for Science and Technology

LA: True, in each country is different. It can be the Ministry of Science, or Social Affairs or the Ministry of Health so if we can help with these discussions in different countries please contact us and we will provide the necessary documentation to be able to have these discussions.

PB: The next question on the Mentimeter is how do you anticipate your future involvement? And the options are: provide political support, provide institutional support (MoU), make use of DIPoH services or I need additional information. If you click on the final option, we would like to know what kind of information that is, so please clarify that via chat.

Catarina Carreira (CC), Ministry of Science, Portugal: More information about the costs is needed. How each country is supposed to contribute? Is the contribution/fees the same for each country? Or is it according to any criteria?

NC: In view of the lack of representation of Malta separately, if I can take my chair's hat off for a second, I would echo Portugal's question for Malta too. It would be key for us to start discussing financial support locally.

LA: We have developed a model with regarding to the contribution of the countries, this takes into consideration GDP of countries. However, this will be finalised in the preparatory phase. It is important to remember that the political support provided now is not legally binding and is only applicable for the preparatory and implementation phases. The membership fee will come into effect when the legal entity has been established, by that time the contribution model will have been agreed upon and finalised in the prior (preparatory and implementation) phases. This is in the page 28 of the Design and Feasibility Report if you would like to check it. We will assess again this model we have developed in the preparatory phase and decide how to proceed in the future

GA: GDP can be an option, but not alone. It is better a mixed model between absolute values as GDP and relative values (Total Inhabitants, number of researchers, etc). Otherwise big countries are penalised.

PB: Thanks for your comment Gonzalo, we will take this into consideration when we review our model and we can make this as the main topics for the next AoM.

HVO: I just want to add that the fact that a distributed RI, makes the central office a minimal setting and if you look at the proposed cost you will see that we clearly foresee the level of development of the NN. On the other hand, the main aim is in fact to use the infrastructure to support the investment done in Finland, France, and also in Belgium to create a national data hub and the contribution that DIPoH will have to do is to be able to make the connectivity between those different systems. Distributed functioning can be there so people for example can launch the syntax, the script so data should not be moved, etc.

4. InfAct Sustainability Plan: Alicia Padrón-Monedero, WP4, National School of Public Health, ISCIII, Spain

AP: The European Council urged to look into an EU HI Research Infrastructure as a tool, so EU/EEA MSs and the European Commission aimed at establishing a sustainable infrastructure on EU HI through improving the availability of comparable, robust and policy-relevant HI on population health and HSP.

The InfAct strategy to develop a sustainable infrastructure is based on 3 tasks: (i) supporting sustainability and integration of JA HI activities in EU EU/EEA MSs/EEA through an AoM, (ii) raising awareness and acceptance on feasibility and added value of innovative actions to improve EU HIS via Technical Dialogues (TD), and (iii) providing a Sustainability Plan to integrate the findings of InfAct in EU EU/EEA MSs/EEA protocols.

Technical Dialogues: Two TD have been held with the participation of National Technical Experts (NTE) from 15 EU/EEA countries. The most remarkable aspects were: (i) consensus about added value of InfAct outcomes: considered relevant for defining priorities and for decision makers, (ii) Integration and access to different data sources (adequate level of quality, accuracy and robustness) are important goals, (iii) GDPR versus interoperability a major concern but a way forward for the future, (iv) feasibility to integrate InfAct outcomes into National/EU HIS considered complex NTE asked for more specific results, (v) NTE highlighted the need of involvement of national data providers to translate these results into policies, (vi) NTE provided insights about capacity building experiences for stronger EU/EEA MSs involvement, (vii) Highlighted the need of a EU HI infrastructure so DIPoH proposal has an important added value. The concerns were its feasibility and level of country and EU involvement, (viii) Setting up NNs on HI was considered crucial for the DIPoH and asked for more involvement from European institutions, and finally, (ix) there is a need of strong EU-EU/EEA MSs coordination/collaboration to achieve/sustain main InfAct outcomes.

Assembly of Members: Three previous AoM have been held with the participation of 26 representatives from MoH and MoR from 21 EU/EEA MSs. The main recommendations from the AoM board have been: (i) AoM has highlighted the work of setting up a DIPoH and the value in building the NN and considered the proposal well-articulated at national and EU level, (ii) AoM have welcomed PHIRI as a practical use case of DIPoH, (iii) AoM have received wide country support: (13 MoU, 10 letters of political support, 3 expressions of financial commitment, 8 letters of intent from Research Networks). Among the Barriers for political support, EU/EEA MSs representatives have mentioned: 1) financial issues 2) organizational aspects 3) other positions: some countries support an enlargement of ECDC mission

Sustainability Plan: The plan was designed focusing on InfAct outcomes and based on knowledge translation and sustainable criteria: 1) A new Research Infrastructure: The Distributed Infrastructure on Population Health (DIPoH), 2) Capacity building, and 3) HI tools and innovative proposals.

- A new Research Infrastructure: The DIPoH. InfAct developed a business plan and proof of concept for a sustainable EU structure for HI. The core elements of DIPoH

are: 1) the set-up of 19 National Nodes on HI, 2) coordination with key Research Networks, 3) Business case describing the whole RI to be implemented, 4) the governance structure and the HI portal as the basis for the future DIPoH, that will be maintained after the project. MoH and MoR provided feedback and some of them expressed interest in joining DIPoH for the ESFRI Roadmap 2021, which was submitted in September 2020.

- HI tools and innovative proposals ready to be implemented in EU/EEA MSs: Among these proposals, InfAct has come up with: guidelines on data collection and data sharing methods, a catalogue of international HI collection networks, projects and indicator/data sets, guidance on good practice for health reporting (to fill the gap in public health science between gaining new knowledge and its translation into policies), a roadmap for innovative use of data sources and methodological guidelines to estimating health indicators using data linkage and machine learning techniques, inspiring innovative indicators (non-health databases on environmental health determinants for public health surveillance "en-Risk"), and the development of a composite health indicator for monitoring Non Communicable Disease, a report on assessing and piloting interoperability at the EU level and a sustainable European Core Health Indicators (ECHI), updating its technical content.
- Tools on capacity building ready to be implemented: a manual to carry out HIS´s assessment in peer-review format that was already piloted, guidelines of good-practice-approach for prioritising HI at national level, promote the integration of BoD indicators in public health policies across Europe by raising awareness, sharing knowledge and experience, and provide mutual support, and the implementation of the First European Training School on HI (HI Training Program) designed to improve EU/EEA MSs capacities in population health and HSP analysis, both addressing inequalities https://health-information.primarycareinnovation.org/

InfAct is also contributing to new initiatives as Population HI Research Infrastructure for COVID-19 (PHIRI). Starting in November 2020 funded by the EC Directorate Research and Innovation. The aim is facilitating and supporting open, interconnected, and data-driven research through the sharing of cross-country COVID-19 population HI and exchange of best practices. PHIRI is a spin-off project of InfAct. PHIRI is a practical use case of DIPoH, within the COVID-19 crisis. It fills a gap of rapid data exchange between countries and links with other initiatives on HI at national and EU level.

InfAct actively engages in other relevant projects on HI as European Health and Innovation cloud proposal by Healthy Cloud, uncover, EGI-ACE and the Joint Action TEHDAS.

The limitations for InfAct's outcomes future translation into National and EU health policies are: 1) structural and functional country variability that affects: feasibility and delays in the inclusion of innovative approaches in national HIS, 2) resources at all levels to deal with innovations, 3) exceptional circumstances as COVID-19 and 4) additional EU/EEA MSs political support and EU institutional involvement is needed to achieve InfAct goals.

The key points of the Sustainability Plan are summarised below:

- DIPoH for the ESFRI application submitted (September 2020) and supported by many country participants.
- New tools for improving population health data available and ready to be implemented.
- InfAct outcomes oriented to better inform policy makers.
- A capacity building program designed and flexible to face current and future needs.
- Need of strong EU and country involvement to achieve wide and systematic implementation in order to better support health decision-making, EU population health and EU added value.

NC: Thank you to the Spanish team for this comprehensive presentation and all the members for their inputs, and indeed having seen the Sustainability Plan is an excellent toolbox and give us an opportunity to explore new directions but again it needs feedback from EU/EEA MSS to keep this project going in the long term.

PB: The next question in the Mentimeter is; Do you think the AoM is the appropriate platform to engage with Ministries? Yes, No or Undecided

5. PHIRI Update and next steps: Petronille Bogaert, Sciensano, Belgium

PB: I am very pleased to talk to you more about the Population HI Research Infrastructure (PHIRI), which is actually a spin-off project that came to its existence during the COVID-19 crisis and basically is what we are aiming to do with DIPoH and already kick-started for COVID-19.

How can we come up with creating this? The Covid-19 response teams have indicated, a strong need to structurally exchange between countries. InfAct facilitates exchanges between partners and with international organizations, by the rapid exchange with InfAct connecting experts and expertise, with two meetings a month with specific questions and with the storage of relevant information. What kind of questions came up?, I can mention the question of last week regarding the face shields, whether the rules of the countries have recommended their use or in other countries they are actually prohibited. It is actually useful to learn what other countries are doing, and this the whole key idea of what DIPoH wants to do with PHIRI, to facilitate the exchange of data, information, guidelines and tools but also expertise available in countries.

After a period of meetings it was clear that many questions remain unanswered and data gaps were persistent. In addition, partners were looking for mechanisms for a structured exchange. InfAct provided a safe space. In conclusion, the need for a Research Infrastructure on population health was also reflected during the COVID-19 crisis for which DIPoH provided the basis as the practical use case.

After the interim AoM, we got the attention of the Commission and in July we drafted together with all EU/EEA MSs a program on how we can build the Population HI Research infrastructure for COVID-19. Starting next week we are going to help the countries to address the COVID-19 crisis. PHIRI will probably start the 1st of November and will run for 3 years, we have 41 partners in 30 countries participating in this project, which are InfAct partners plus other partners working specifically in COVID-19 area. We have 9 work packages and 3 transversal topics and as you see in the chart of the bottom, what we aim to do is not focus on immediate morbidity and mortality, although is something we facilitate research about, but we will be looking at the wider impact of COVID-19 on population health: 1) what is the impact of interrupted care on chronic diseases, 2) impact on vulnerable populations, 3) mental illnesses and 4) other aspects.

The aim of PHIRI is the identification, access, assessment and reuse for research, population health and non-health data in EU/EEA MSs and across EU/EEA MSs that can underpin public health policy decisions relevant to COVID-19. This project will be carried out in close interaction with key stakeholders in the HI landscape (ECDC, EUROSTAT, JRC, OECD, and WHO). What we are doing at the moment is to be embedded in routine activities, with ECDC combining surveillance data with population health data, we also work together with Eurostat and JRC. JRC has been working on setting up federated access to data, they work a lot with National Nodes and outreach. We are also collaborating with ECDC and WHO. With WHO we are collaborating with the unit of HI, which is EHII (European HI Initiative) but also with the unit of Digital Health that is working on infodemic.

Coming back to questions that you raised at the beginning of the meeting related basically of the interactions between DIPoH and InfAct with other existing infrastructures, and as I mentioned we are in permanent contact with ECDC, EUROSTAT, the EC, OECD, and WHO. Other initiatives are Healthy Cloud, which is run by DG RTD that has been accepted by the EC and is called Health Research and Innovation Cloud and it brings together all these different networks working on population health and also those networks working on more exact sciences (BBMRI, EATRIS, ECRIN, Elixir and Eurobioimaging) that with the partners of InfAct we submitted a proposal that now has been accepted. That shows that we are able to interact, we know these partners. With Elixir we discussed PHIRI and DIPoH and see how we further interact with them. With EOSC Life they have a few calls coming out, in which DIPoH and PHIRI can showcase some of the services through the EOSC Life platform. EGI-ACE is the EOSC pilot and we are also present because some of the services of PHIRI will be tested. We are also very active in the European Health Data Space Joint Action, which prepares actually all the conceptual options and framework developments for the European Health Data Space regulation that will be set up in 2 years time. In TEHDAS we will be work package leaders on sustainability, engagement and outreach, ideally placed, because it means we will make sure as representative as TEHDAS that we reach out all of these different projects that are currently ongoing at European level, including DIPoH and PHIRI, because we represent these institutions as well and we will make sure that those projects are building blocks of the European Health Data Space. In that sense DIPoH and PHIRI will be a cornerstone within this European Health Data Space, and in the future we foresee a strong engagement and the productions of what we are doing within PHIRI will be part of this European Health Data Space. We also are a work package leader in Healthy Cloud and

we make metadata, sheets and templates for catalogues, in which we will include both population health aspects and see how we can combine with existing infrastructures as EATRIS, etc

The objectives for PHIRI are very similar to DIPoH, as you can see: 1) to provide a HI portal for COVID-19 with FAIR catalogues on health and health care data for structured information exchange across European countries. The idea is to link different data sources and to use Pan-European data in a GDPR compliant and federated way, 2) to provide structured exchange between countries on COVID-19 best practices and expertise (it allows researchers to provide relevant and evidence based information ready for use in research, and decision-making processes) and 3) to promote **interoperability** and tackle HI inequalities (PHIRI supports researchers and public health bodies to research queries related to COVID-19 and also provides capacity building for management of COVID-19 relevant population health and healthcare data).

The structure of the project has 2 transversal layers: training and support for policy makers. We have 6 core WPs: 1) research methodologies to assess the wider impact of COVID-19, 2) testing use cases in which we want to really measure the impact of COVID-19, 3) set up the HI portal, 4) the actual federated research infrastructure to allow real-time exchange between countries, 5) a rapid exchange forum to respond to questions and foresight and, 6) modelling scenarios.

From every WP I selected a key points on what PHIRI can offer you that would be of interest for MoH and MoR. PHIRI is stronger than InfAct because it will try to respond to your needs and will give you the tools to address the COVID-19 crisis:

1) Engagement: addressing the COVID-19 infodemic, which is something the countries are struggling with. To develop strategies to handle misinformation and disinformation (training, FAQ section, key messages), country visits to map the state of play on monitoring the wider effects of COVID-19, and stakeholder meetings every two months to inform countries about the activities. Those meetings will be similar to the ones held by the AoM.
2) HI portal: in this platform we will have the following materials available: catalogue of population health data sources in the different countries, catalogue of COVID-19 population health studies, catalogue on COVID-19 international guidelines, initiatives and projects; catalogue of COVID-19 training material and courses; practices on COVID-19 ethical and legal aspects and continuing our activities on the NN.
3) Methodologies to assess the impact of COVID-19: we will look at indicators and methodologies used to assess the wider impact of COVID-19, we will explore determinants of the severity of long-term health outcomes of SARS-COV-19 and we will assess the efficacy of digital tools for contact tracing and innovative tools for COVID-19 health monitoring.
4) Four use cases for measuring the impact of COVID-19: the use cases will demonstrate how a broad variety of secondary data (e.g. administrative and survey data) can be pooled and/or reused in a distributed way across Europe to produce actionable insights. The use cases are: 1) direct and indirect determinants of COVID-19 infection and outcomes in vulnerable population groups with reference to inequalities,2) COVID-19 related delayed care in breast cancer patients, 3) the impact of COVID-19 on perinatal health and perinatal health inequalities, and 4) COVID-19 related changes in population mental health. We will work closely with the ECDC and JRC to

test this use cases and later we will put them forward into the European Health Data Space.

5) Federated research infrastructure: PHIRI aims at showing the potential of the infrastructure for a rapid cycle analysis by being used as a demonstration pilot case. As a pilot, developing an advanced version of the federated research infrastructure, PHIRI will include: 1) the development of a common data model for a COVID-19 rapid response, 2) the design and deployment of the required data extraction, transformation and loading (ETL) processes, and 3) the implementation of the distributed analytical solutions, in particular the FAIR implementation of intermediate processes and final research outputs. This advanced version will mainly be built on WP6 use cases.
6) Rapid exchange forum: The aims of this component are: 1) to provide rapid response to research and policy questions that are raised by countries (the country representative submits the questions, we store them, we contact the experts and reply with the correct answers), 2) to promptly disseminate internationally agreed guidelines, standards, reports and initiatives, especially to support international organisations as well 3) to exchange (best) practices among countries regarding COVID-19, (best is within brackets because during this crisis a lot of practices are being published without a thorough assessment of the best of them) and finally 4) to provide a link with policy: the shifting landscape of evidence for policy making.
7) Foresight (Modelling and Scenario): the overall aim of this work package is to gain insights into possible future health impacts of the coronavirus outbreak, by developing scenarios for EU/EEA MSs and associated countries' national situation and draw lessons for the EU. The objectives are: to get an overview of how European countries have been using foresight, modeling and preparedness regarding COVID-19 (mainly indirect infects), to develop and provide foresight capacity (leveling the knowledge needed for performing foresight, reducing information inequalities, strengthening European data uniformity), and to support evidence-informed policy decisions, by exploring direct and indirect effects of COVID-19 on population health, on short and long-term, using scenarios and a broad conceptual model of health and care.
8) Capacity building: in terms of capacity building what is interesting is infodemic, burden of disease, methodologies to monitor the impact of COVID-19, capacity building and developers working group, in which we will support countries in IT implementation and building a capacity in foresight.

Before ending my presentation, I will answer the question on how PHIRI is related to DIPoH, PHIRI is a building block of DIPoH mirroring services and actions. First of all we will use the same scope (health status, determinants of health and healthcare systems). We are focusing on the same services: creating the HI portal, the one-stop shop, supporting innovative research, strengthening capacity and we are providing the tools that are needed for proper knowledge translation. The organizational structure is the same so we have the HI portal we are building with the different services and the NN and research infrastructures. Are any questions?

NC: At this point I can speak about the usefulness of the forum that InfAct has created during these months because I think it was the single most important forum where you can actually pose questions in a safe environment, not representing necessarily the political opinion of the EU/EEA MSS. In the forum you get quick technical answers to your questions, and I do not think any other international organizations replicated this. Despite for example the EC having groups to address the challenges of the pandemic, there was always this barrier of

technical issues at that level, InfAct filled the gap and definitely worked. Moreover, I think that PHIRI is a step forward

PB: Our next steps for DIPoH are to further support the implementation on the national roadmaps, something that is very important. Also we were thinking of having another AoM by the end of April. InfAct will keep on going until the end of May but we do not want to overburden you, so we would like to know if you want to continue this. As the results of the Mentimeter I noted that you consider that the AoM is a good platform to interact. For PHIRI we will invite MoH and MoR to participate in the 2-months stakeholders meetings and then for TEHDAS there will be also political forums, which is foreseen the participation of MoH and MoR. Another thing that I would like to bring forward that might be important to you is that the EC is working in the Horizon 2020 Work Program, which also includes the recovery plan for the COVID-19 crisis and you can see there €15.5 million to set up a population HI research infrastructure to collect and make available data to support research and policy decisions. For all of this, and thinking on sustainability, I believe that we are in very good place.

Round table Members

PB: Now, I would like to do a round table to know each ones´ opinion about the following questions:

1. How would you like to be involved in the future?
2. What would you like to see addressed in the next meeting?

NC: I could ask the hosts, Spain, first, given their involvement in the AoM and the Sustainability Plan

GA: In the short term, another AoM in April would be good for us to follow up and to facilitate Spanish position towards this initiative. More information would facilitate to have a position looking also to what happen with the rest of elements. This is linked to the second question, what is happening with the rest of different initiatives? We have to see how, not only the Horizon 2020 program is launched, also how is launched the EUPHA Health program, how it is closed, which activities are foreseen to be conducted; so it is more than convenient to be involved in the future with an additional AoM and I think that to see how this initiative fits with the new programs would be a key element to be addressed in the next meeting.

NC: Lithuania has anything to add to these questions? if not, Portugal

CC: For now I have nothing to add or any comment, just looking forward to the next AoM in April

Isabelle Zablit (IZ) (France): Apologies as I have to leave now. We are highly interested in exchanges and best practices regarding the coming COVID-19 vaccination campaign.

NC: Next on my list is Dimitrios, Greece, any feedback?

Anne Marie Yazbeck (CHAFEA): I cannot say too much about the EU program for next year, what I can say it is a real pleasure to see how things are developing in your project and how you are leveraging and looking into the future. I would like to see how you can keep up with this kind of Consortium and tight network you have developed. All I can say is keep leveraging and is almost sure that you will attained the goals that you have envisioned.

NC: Thanks Anne Marie for your encouraging. I definitely see a lot of ground for HI, right now with COVID-19 there will be a higher demand for HI that is for sure. If Greece has no comments next will be Austria.

Claudia Habl (Austria): Nothing to add from Austria

NC: Iceland

Gudrun Gudfinnsdottir: I do not have comments at this time, I am just interested to follow the work. It is nice to see how it is progressing so I look forward to the next steps

NC: Czech Republic

Hanna Marie Broulikova: I see a really great progress so I would like to be involved for sure and to connect your work to the Czech Republic more, because it seems to me that this COVID-19 situation really has shown how important is to have initiatives like InfAct. Please keep us informed on the progress and I look forward to hear more about the outcomes. For the next meeting it might be great to go through one or two case studies, how the initiative for COVID-19 helps to address the questions and how the countries implemented the results.

Hrvoje Belani (Croatia): I would like to thank you for all the efforts you put through this project. From the MoH we would like to be informed and involved in supporting and co-steering this work and how it fits in the next programming and funding period so we will actually make sure that all our efforts are well coordinated both at EU level and at the national level

Luigi Palmieri (Italy): I suggest that the question should be addressed to the Italian representatives of the MoH and MoR, I do not know if any of them are attending the meeting, otherwise you could ask them via mail

NC: Thanks Luigi, is a good suggestion.

Martin Thissen (Germany): From my side there is nothing to add. I appreciate a lot your work and how everyone is involved actively. I think the points are really well addressed to the targeting groups so go on with this wonderful work.

NC: UK, anything to add?

Ronan Lyons (UK): From our perspective we are delighted of what InfAct has achieved. Very keenly are involved in PHIRI. One thing that obviously is the elephant in the room is that we are still trying to work out the relationship between the UK and the EU, which is currently on negotiations. We hope that it will work out positively so we could still be involved.

NC: Belgium has anything to say from the national perspective?

HVO: I can speak a little from my side as Director of Epidemiology and Public Health, but I have huge conflict of interest. We are running this project from quite some time, but thanks to all collaborators inside and outside Belgium. The main element I have been putting forward is that, with all the questions that have been formulated and with all the research infrastructures Petronille has shown, she has proved that we are in some point ahead of them. Another point we can learn from the experience and also from other European elements is the context that you are working on. The health of European populations really comes forward as being the added value to what people of life sciences or people working on a patient-based approach have been doing. This notion of real world data, most of the time is just moving from laboratory to patients but now we are moving to population health. With the questions and discussions we have with DG Research to work on this PHIRI, the question is what is the real added value? People is wondering what do we add to what ECDC is doing, we are also putting forward a few cases that show how the impact of these infectious disease goes beyond the pure infectious diseases outcomes, in which we will see the interaction between ECDC and InfAct to complement each other. It is also important to get new EU/EEA MSs on board so whatever needs you have please contact the coordination team to help you get on board this initiative. It does not matter if you are actually working in PHIRI; is not sufficient because PHIRI is actually a case example. The same way we have connections with other projects that we take under the umbrella of DIPoH like the COST action on burden of disease. We really want to build on this platform open to other research initiatives within Europe.

NC: If I am allowed to take my chair's hat off for a minute, I am aware that there is no one representing Malta right now. Unfortunately the gentleman that used to join us in the AoM (Richard Blundell) was definitely very useful for the discussions. He has moved to the private sector so we do not have him with us anymore. My concern is one, especially from the perspective of a small state. Because of the importance of the pandemic, everybody is clamoring for preparedness and information networks and platforms. Now, unless we definitely build links within these initiatives we will be sidelined, that is how the world works. If people need something and they do not know there is a repository for that, they will just create a new one and I am afraid this is going to happen if we do not make sure that connectivity within DIPoH is there at every opportunity. Coming from a small state I ended up with pretty much working on all the things and that has been my main role in the COVID-19 response team locally: attending tourism meetings, home affairs meetings at European level, health meetings, etc. And trust me, on the decisions that we have seen taken at European level, HI was visibly absent. It took me 3 months of insisting to actually get the ECDC to start reporting testing data regularly for MS. We need to make sure that policy-makers not just in health know that DIPoH is there at the European level and come to us for advice. That is my whole point.

Back to my chair's hat. At this point unless anyone has anything to add maybe I guess we can start wrapping up and I would like to invite Isabel to make some closing comments.

6. Closing remarks, Isabel Noguer, ENS-ISCIII, Spain

Isabel Noguer (IN): Thank you very much Neville. We are very happy with this AoM. At the beginning of InfAct we foresee only two meeting, but we have managed to organize 4 so far. They have given us a lot of insights, recommendations and all WPs has followed the recommendations not only from the representatives of MoH and MoR in the AoM but also from the National Experts in the Technical Dialogues with wide participation of the EU/EEA MSs. I would like to highlight that was really useful for us and all WP leaders from InfAct to incorporate in the outcomes all the points that were highlighted in these AoM. As you have been discussing before, we will have a new AoM by May 2021 and as for this meeting we will distribute the minutes as soon as possible and we will include any suggestions, comments and insights from you as EU/EEA MSs representatives. I would like to thanks all the participants, the coordination team and Neville for chairing this meeting

HVO: I am very pleased that in cooperation with Spain we organized not only two but more AoM. Moreover, we have also had a very good participation, in spite that nowadays is difficult for people to free themselves given this COVID-19 pandemic. I think it is very important that we can have an additional AoM and I very much enjoyed this meeting with all the different questions and also on how people reacted to this Mentimeter surveys.

NC: Thank you everyone, thanks for your time, and to the ISCIII from Spain, our organizer, for this wonderful meeting. Hope to see you physically again not too far into the future, stay safe, thank you

V. Implications and limitations

At the beginning of the project EU/EEA MSs needed clarity on what kind of infrastructure and outcomes were going to be provided and how they will be funded since for being useful in terms of EU-HIS most countries should be involved and provide national data in a standardized way.

In the Second AoM the business plan was presented and country representatives pose the following concerns in setting up the infrastructure: 1) to have alternatives for funding and for the design of the research infrastructure, apart from the business plan for ESFRI roadmap and the ERIC/DIPoH 2) to have a more precise definition of expenses that should be covered by EU/EEA MSs and the location of the central office, 3) to advocate about the added value and potential benefits at the national level of funding the infrastructure, as financing DIPoH would depend on political commitment across EU-EEA MSs so countries should see the return of investment, 4) to clarify the role of the European Commission in supporting the research infrastructure, and 5) to give more emphasis about the definition the National Nodes and the Research Networks.

These issues were appropriately addressed during the time of the Third AoM but representatives mentioned some country-specific barriers to provide political support to the infrastructure as: 1) some countries needed also to guarantee financial support before signing the letter of political support, 2) in others, the responsibility of funding belongs to

the Ministries of Science, 3) in some of them the internal process of application at national level was over so they should wait for the next year call and 4) the remaining countries would support an enlargement of scope of ECDC rather than the research infrastructure. In the last AoM the European Commission was satisfied with the work that has been done in building the infrastructure and stressed the importance of InfAct contributions in the future initiatives for strengthening HI across Europe. Country representatives raised some concerns on the individual financial contribution for each country; EU/EEA MSs also wanted to know how DIPoH and PHIRI were connected, the interactions with existing research infrastructures, which role will play in the European Health Data Space initiative and how data sharing and privacy will be managed within DIPoH.

VI. Conclusions and recommendations

- ✓ The terms of reference for the AoM were approved unanimously.
- ✓ All countries agreed on the interest of setting up a unique infrastructure gathering research, best evidence to inform policies and HI systems for health management.
- ✓ Country representatives highlighted the work on setting up DIPoH, the importance of building the national nodes and considered that the proposal was well articulated at national and European level.
- ✓ 14 countries have already given their political support or sign the Memorandum of Understanding to the DIPoH infrastructure.
- ✓ DIPoH proposal was submitted to the ESFRI roadmap.
- ✓ Country representatives welcomed setting up PHIRI as a practical use case of DIPoH, because it fills a gap of rapid data exchange between countries and recommended the linkage with other initiatives on HI at national and European level.
- ✓ InfAct is closely cooperating with international organisations (Eurostat, ECDC, European Commission, WHO Europe, OECD), research infrastructures through the Healthy Cloud (Elixir, EATRIS, ECRIN, BBMRI-ERIC, Euro Bioimaging), EGI-ACE (EOSC Pilot, EOSC Life, EGI) and the European Health data Space.
- ✓ All countries would like information to be involved in future initiatives as PHIRI and DIPoH and consider that the AoM is the most suitable way to inform the EU/EEA MSs of the advances in the development of DIPoH.
- ✓ All countries agreed with the Sustainability Plan proposal for InfAct and DIPoH.

Evaluations

References and appendices

For additional documentation on the Assembly of Members please visit InfAct website in the following link https://www.inf-act.eu/assembly-members

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