Minutes of the Workshop on Digital Health

6 November 2018

Instituto de Salud Carlos III (ISCIII) – C/ Sinesio Delgado, 4. Madrid

Organized by:

Supported by:

Goal of the workshop

The aim of the workshop was to identify how the Innovative Medicines Initiative (IMI) programme could bring the most value in moving forward the digital health innovation agenda, taking into consideration the Spanish research and innovation community, showing the strengths of Spain in digital health field and opening a debate around the future.

A total of 55 participants attended the meeting (see annex).

Welcome and introduction

Raquel Yotti, director of ISCIII, opened the workshop. She outlined the collaboration between all the co-organizers of the workshop and the improvement of the participation of Spanish entities in H2020 calls and especially on IMI. She highlighted the importance of the personalized medicine to have better healthcare systems and the need to develop the digital health (Big Data, Artificial Intelligence, Internet of Things…) for its implementation. She also stressed the firm commitment of Spain to develop and implement a digital agenda strategy with all the stakeholders.

Innovative Medicines Initiative

Colm Carroll, IMI Scientific officer, explained the Innovative Medicines Initiative and the need to invest in innovation from a public-private partnership perspective. He outlined that IMI is a neutral platform where all actors involved in drug discovery and development can engage in open collaboration on shared challenges. He also remarked the need of share data

and knowledge to work more effectively. He highlighted the 10th Anniversary of the initiative and what IMI is delivering so far in terms of biological markers candidates, new tools, patent applications, clinical studies, spin-offs, jobs, SMEs involvement, etc. He gave some examples of IMI projects related to digital health, pointing out the benefits for different type of participants (industry, hospitals, SMEs, patients…) that take part in the projects.

He also explained the importance of the involvement of SMEs and patients on IMI projects, highlighting the opportunities and benefits for them.

Finally, he referred to the upcoming calls: Call 17 (submission deadline 25 April 2019) with three potential topics published on the website, and Call 18 (submission deadline September 2019). He also mentioned the opportunities that running project can pose, like the European Health Data & Evidence Network, that soon will open calls for health data harmonization activities (EUR 17 million budget available).

A digital Health Strategy for IMI

Philippe Bordes, from SANOFI and Operations Manager IMI Strategic Governing Group (SGG) on Digital Health & Patient Centric Evidence Generation, outlined that this SGG is new (kick off in April 2018) and its members are working in the development new ideas to lunch IMI topics.

First, he went through the rationale for a Public-Private Partnerships (PPP) in Healthcare: 1) Address R&D bottlenecks or societal challenges no company or institution can tackle alone, 2) Pool, standardize, combine and grant access to data, patients cohorts, samples, registries and knowledge, 3) Develop tools, methodologies, protocols which require full alignment of all stakeholders in the sector and 4) Share resources and risks in areas of high patient and societal needs. He stressed that IMI is the largest PPP in the global healthcare sector, with multiple partners working in the non-competitive space and that the public partner‘s selection is highly competitive.

He addressed the evolution from IMI 1, mainly focused in the preclinical area, to IMI2, that has gone beyond in the pharmaceutical value chain.

He also referred to the “Think Big” initiative in IMI, launched last year and sponsored by Pharma R&D Heads, with five areas of interest and being Digital Health one of them. He remarked that EFPIA has identified that there are important barriers for the industry to use digital tools in clinical development.

He presented de missions of the SGG that has to build a strategic and a comprehensive pipeline of Digital Health projects, and to tackle: synergies across projects, sustainability, communication of outcomes and synergies with other initiatives. He outlined the scientific priorities of the SGG which are divided in two pillars: the Health Pillar and the Clinical Trial Pillar.

To conclude, he highlighted the crucial pre-requisites for a successful PPP in Health in the future: long term strategy with full alignment of participants, appropriate governance, strong involvement of patients and stakeholders, fair and clear IP, project management and definition and monitoring of Key Performance Indicators upfront.

The perspectives of Spain

This session was focused on the Spanish standpoints.

Ferran Sanz, Director Research Programme on Biomedical Informatics (GRIB) (IMIM – UPF), outlined the strength of Spain in Bioioinformatics and the translational impact of the Spanish Institute of Bioinformatics (INB) by bringing together bioinformatics groups at Health Research Institutes certified by the ISCIIII. He also highlighted that INB is a very active node of the European Bioinformatics Infrastructure ELIXIR. He gave some examples of IMI projects in the Big Data domain led by Spanish entities and he presented the eTOX and eTRANSAFE IMI projects. Regarding the eTOX project, already finished, he outlined that represents an unprecedented information sharing among the pharmaceutical companies and with important exploitable results. About the new project eTRANSAFE, he remarked that it builds on eTOX results but with a broader and more ambitious scope, including not only pre-clinical data but also clinical data. To conclude, he referred to the OpenPHACTS project, a paradigmatic example of IMI project, with a significant Spanish contribution, that exploited the biomedical Big Data, delivering the most comprehensive catalogue of associations between genes and variants and human diseases (the DisGeNET platform).

Fátima Al-Shahour (CNIO), Javier Quiles, (SERGAS), Juan Cruz Cigudosa (NIMGenetics) and Salvador Capella (INB, BSC) contributed to explain the perspectives of Spain in this area.

Fátima Al-Shahour explained the role of personalized medicine in the prevention, diagnosis, and treatment of cancer. She pointed out that it is important to identify and understand the molecular landscape for each patient to stratify the patients for the treatments. She remarked that, although the number of patients eligible for genome-driven treatment has increased over time, more biomarkers are needed. She addressed the precision medicine workflow, which requires computational infrastructures to efficiently store and process data on patient genotypes and phenotypes and the interpretation of such data to support clinical decision-making. She highlighted that personalized medicine requires coordination across multiple stakeholders in the infrastructure, clinical and human resources areas, stressing the need of bioinformatics teams in the hospitals with multidisciplinary experts and the mutual training for clinicians and bioinformaticians to enhance the information exchange.

Javier Quiles presented the IANUS electronic health record (EHR) system that has helped the Galician Public Health Service to introduce enormous efficiencies in the delivery of patient care. He pointed out that one of the main objectives is to give tools to empower the patients. He explained also the Galician experience using the European Regional Development Funds (ERDF) for e-health and the use of public procurement of innovation. He also addressed how they are working on EHR secondary use of data for the patient stratification, which can deliver many benefits to the healthcare system. He concluded underling the success factors and challenges of regional initiatives, insisting on the importance of the alignment among the different initiatives at regional, national and European level.

Juan Cruz Cigudosa addressed the key role that genomics plays in personalized precision medicine (PPM) and its benefits for the healthcare system. He gave a view of the genomic medicine landscape in the Spanish National Health System, pointing out that although the use of NGS tests has increased considerably **(**13 more times from 2013 to 2016) there are big differences among regions and hospitals and with different performing strategies as well (NGS panels in-house/outsourcing), that generate inequity and inefficiency in the national system. He concluded analysing the main needs in this area: training, storage, computational capacity and a National Plan for PPM.

Salvador Capella presented the Barcelona Supercomputing Center (BSC) pointing out its storage and computational capacity (22th in the world, 6th in Europe) and presenting the structure of the Life Sciences Department with six areas connected with personalized medicine: machine learning, computational genomics, bio-infrastructure, protein and drug modelling, text mining and evaluation of social impact. He explained the ELIXIR platform and the role of the Spanish node represented by the INB, highlighting the leadership of Spain in the Human Data use case. He also referred to the Translational Bioinformatics Network (TransBioNet), established and led also by the INB to increase the translational impact of the INB in the Spanish National Health System. He concluded remarking the main Spanish strengths: computational infrastructure, *know-how* for integrating, analysing and/or interpreting omics data and strong connection with hospitals that offers a unique opportunity to drive end-to-end projects including the acquisition and analysis of Real World Data.

The perspectives of the European Commission

Carmen Laplaza, Deputy Head of Unit Innovative and Personalised Medicine, DG Research and Innovation, represented the European Commission in this workshop.

She remarked the necessary transformation of the healthcare systems to be sustainable and the key role of technologies in this process. She highlighted three main points to achieve this transformation: data-driven innovation, trust and user-driven innovation.

She briefly explained the Digital Single Market Strategy and how digital health is a core part of it. She presented the three pillars of the Communication on the Digital Transformation of Health and Care: 1) Citizens' secure access to and sharing of health data, 2) Better data to promote research, prevention and personalized health and care and 3) Digital tools for citizen empowerment and for person-centred care. She pointed out the different topics of Horizon 2020 calls set to address the actions proposed in each pillar of the Communication.

She remarked the importance of Member States working together to reach the objectives proposed in this Communication, putting as an example the Declaration for delivering cross-border access to genomic database, signed on 10 April 2018 by several European countries, included Spain.

Concluding remarks

The Workshop convened a significant number of front-line scientists, stakeholders and delegates from the most relevant Spanish institutions involved in digital health.

A debate was driven by means of presenting different points of view emphasizing the national strengths and capacity with regards to digital health research priorities.

The representatives of the Innovative Medicine Initiative (IMI), the European Commission and the Strategic working group on digital health expressed their willingness to continue the dialogue and receive inputs from the Spanish community.

Annex: List of participants

Nombre	Apellido	Cargo	Entidad
Sara	Alfonso	Técnico	CDTI
Fátima	Al-Shahrour	Translational Bioinformatics	CNIO
Gonzalo	Arévalo	Director OPE	ISCIII
Elena	Arredondo	Gestor de Innovación	Fundación para la Investigación Biomédica - Hospital Clínico San Carlos
Juan Manuel	Báez	Técnico Coordinación de Proyectos	PHARMAMAR
Philippe	Bordes	Global Alliance Manager /Operations Manager	SANOFI/SGG Digital Health
Salvador	Capella	Group leader	INB / BSC
Colm	Caroll	Scientific Officer	IMI
Carolina	Carrasco	NCP H2020 SC1	CDTI
Andrés	Castillo	Director de Innovación Pediátrica	FIB Hospital Niño Jesús
Ángel	Cebolla	CEO	BIOMEDAL
Juan C.	Cigudosa	Director Científico	NIMGenetics
Marta	de Diego	Técnico/Experta IMI	CDTI
Maite	de los Frailes	Director of Drug Discovery Programs	Fundación KERTOR
David	de Mena	Responsable de proyectos de innovación en TIC	Sistema Sanitario Público de Andalucía (FPS)
Helios	De Rosario	Investigador (Área de I+D)	IBV
Carlos Manuel	Díaz	CEO	SYNAPSE Research Management Partners, S.L
Carmen	Eibe	Directora Coordinadora de Proyectos	PHARMAMAR
Laila	El Qadi	Head of Communication & Data Translation	Aplicaciones en Informática Avanzada S.L / Grupo AIA
Gorka	Epelde	Investigador Senior. Responsable de la línea de Big Data y Medicina Personalizada.	VICOMTECH
Pilar	Gangas	European Project Manager	FIIBAP
Rubén	García	Técnico de Innovación	OSI EE CRUCES
Mireia	Giménez		LEITAT Centro Tecnológico

Marta	Gómez	Representante Salud e IMI - H2020	CDTI
Jonathan	Gómez	Coordinador Científico	FUNDESALUD - Junta de Extremadura
Magdalena	Guilera	Real World Evidence Specialist	Novartis Farmacéutica
Mª Elena	Hernando	Catedrática	Universidad Politécnica de Madrid
Carmen	Laplaza	Deputy Head of Unit Innovative and Personalised Medicine	DG Research & Innovation, CE
Antonio	López	Director de Gestión Programa de Inv. Clínica	CNIO
Beatriz	Maroto	Gerente I+D+i	NIM Genetics
Amelia	Martín	Responsable Plataforma Medicamentos Innovadores	FARMAINDUSTRIA
Fátima	Montes	Apoyo plataforma medicamentos innovadores	FARMAINDUSTRIA
Santiago	Moralejo	Project Manager – IMI HARMONY	Instituto de Investigación Biomédica de Salamanca (IBSAL)
Adolfo	Muñoz	Jefe de Unidad	ISCIII-Unidad en Telemedicina y eSalud
Cedric	Notredame	Senior PI – Comparative Bioinformatics Group	Centre for Genomic Regulation (CRG)
Francisco José	Núñez	Investigador Senior	Instituto de Biomedicina de Sevilla
Elena	Oliva	Facultativo Especialista de Área	H.U. de Gran Canaria Dr. Negrín. Servicio Canario de Salud
Nicolás	Palomo	Responsable Proyectos de Investigación Clínica	Roche Farma, S.A
Beatriz	Palomo		ASEBIO
Marta	París	Legal Counsel	JANSSEN
Galo	Peralta	Director de Gestión	IDIVAL
Lilisbeth	Perestelo-Pérez	Investigadora	SESCS - Servicio Canario de Salud
Ricardo	Poyato	Gerente de Área Centro	Abbott Medical
Javier	Quiles	Jefe de Servicio de Proyectos de Sistemas de Información	SERGAS
Josep	Redon		INCLIVA
Juan E.	Riese	Asesor Científico Técnico OPE	ISCIII
Cristina	Rodríguez	Coordinadora	CIBER
Luis	Rodríguez	Investigador Miguel Servet Tipo 2	Hospital Clínico San Carlos
María	Saarela	Project Manager	IMIBIC
Ferran	Sanz	Director	GRIB, IMIM / UPF
Pablo	Serrano	Director de Planificación	Hospital Universitario 12 de Octubre
Bernardo	Valdivieso	Director del Área de Planificación	Hospital La Fe de Valencia
Adriana	Varela	Técnico Proyectos Internacionales	Hospital Universitario La Paz - IdiPAZ
Carles	Vericat	Business Development Director	Aplicaciones en Informática Avanzada S.L / Grupo AIA
Raquel	Yotti	Director	ISCIII