Proceedings of the meeting "Collaboration in Alzheimer's disease & beyond: the present and future of the Innovative Medicines Initiative (IMI) initiatives in neurodegeneration"

The event "Collaboration in Alzheimer's disease & beyond: the present and future of the Innovative Medicines Initiative (IMI) initiatives in neurodegeneration" brought together the complete portfolio of active IMI neurodegeneration projects, and the IMI Strategic Governance Group Neurodegeneration, http://www.imi.europa.eu/content/strategic-governing-groups. The portfolio includes projects that were launched under the first phase of IMI in the FP7 framework programme, and many new initiatives that have been launched recently in IMI2 part of the H2020 framework. The three most advanced projects, AETIONOMY, EMIF and EPAD have developed a virtual collaboration framework as the IMI Alzheimer's Disease Research Platform, IMI AD Platform, http://www.imi.europa.eu/content/press-release-imi-ad-platform. The platform aims to facilitate collaboration between the three projects, helping them to deliver results faster. IMI has also signed a Memorandum of Understanding with the Global Alzheimer's Platform (GAP) to accelerate Alzheimer's drug development by building a global, standing, trial-ready platform for Alzheimer's drug development, http://www.ceoalzheimersinitiative.org/global-alzheimer%E2%80%99s-platform-and-innovative-medicines-initiative-sign-memorandum-understanding. The IMI AD Platform is also collaborating with the flagship Human Brain Project Medical Informatics Platform, https://www.humanbrainproject.eu/en/medicine/medical-informatics-platform/ to leverage learnings and tools.

This full day meeting was organised in order to take stock of what has been already implemented, what is in the pipeline and how to maximise impact by fostering collaboration and coordination. Most importantly representatives of key organisations and initiatives in the area, both within and beyond Europe were also invited with the goal of providing feedback on the IMI portfolio and strategy, and to foster opportunities for collaboration and coordination:

- Alzheimer's Association
- Alzheimer Europe
- Critical Path Institute
- Dementia Discovery Fund
- European Brain Council
- IMI State Representative Group
- IMI scientific Committee
- European Commission Directorate General for Communications Networks, Content and Technology
- European Commission Directorate General for Health and Food Safety, Unit B5 - Medicines: policy, authorisation and monitoring
- European Commission Directorate General for Research & Innovation, Neuroscience Sector
- European Medicines Agency
- European Research Council
- European Federation of Pharmaceutical Industries and Associations
- European Biopharmaceutical Enterprises
- Global CEO Initiative on Alzheimer's Disease, a network of UsAgainst Alzheimer's
- EU Joint Programme for Neurodegenerative Disease Research

- Human Brain Project – Medical Informatics Platform
- Medical Research Council
- National Institute for health and Care Excellence
- Parkinson's UK
- US Food & Drug Administration
- World Dementia Council

The morning session

IMI Executive Director Pierre Meulien welcomed the delegates to the meeting. In his welcome note he stressed how IMI is founded on the principle of open innovation, which means creating a dynamic, networked, multi-stakeholder, collaborative innovation ecosystem. IMI puts open innovation into practice by building ambitious projects that bring together academics, large pharmaceutical companies, small and medium-sized enterprises (SMEs), patient groups, and medicines regulators, among others, to join forces and share resources, ideas and expertise to tackle some of the biggest challenges in medical research and drug development.

In the area of neurodegeneration research this has led to the implementation of a significant portfolio of projects, each a public-private partnership. The open innovation approach enables IMI projects to achieve results and make a difference faster and at an unprecedented scale. Most importantly, the projects are now delivering results that could not have been achieved without the public-private partnership model.

IMI projects presentations.

Professor **Martin Hofmann-Apitius** presented the project **AETIONOMY** https://www.aetionomy.eu/en/vision.html, which key objective is the generation of a mechanism-based taxonomy of disease with a focus on neurodegenerative diseases: Alzheimer's and Parkinson's diseases (AD & PD). The project has developed the AETIONOMY knowledge base: the most comprehensive knowledge base on AD and PD worldwide, which is publicly available (http://aetionomy.scai.fhg.de/). It has also implemented a mechanism enrichment server NeuroMMSigDB and generated a comprehensive mechanism inventory currently including 126 disease mechanisms for AD (of which currently only four are object of ongoing clinical trials) and 76 disease mechanisms for PD. A very innovative development is the ongoing work on a "virtual dementia cohort". AETIONOMY has ongoing collaborations with other IMI projects (EPAD) for patient recruitment, with universities outside of the consortium (university of Oxford) for validation of mechanisms in real world data, and with the Human Brain Project (HBP) on data curation and modelling of brain pharmacology.

The project **EMIF-AD**, the Alzheimer's research pillar of the **EMIF** project, http://www.emif.eu/ , was presented jointly by the four leads of the partnership, two from the public side (**Pieter Jelle Visser** and **Simon Lovestone**) and two from the industry side (**Johannes Streffer** and **Bart van Nieuwenhuyse**). In the context of the overall EMIF aim of developing a framework for evaluating, enhancing and providing access to human health data across Europe, EMIF AD re-uses existing data, builds an infrastructure for data access and data-sharing and uses extreme phenotypes as outcome to research AD pathophysiology, and to discover diagnostic and prognostic markers of AD to improve treatment opportunities for pre-dementia AD. The project has developed several infrastructures for re-use of data for research, including a cohort finder with metadata of 40 cohorts representing 60.000 subjects (publicly available: http://www.emif.eu/about/emif-platform/emif-catalogue); a tranSMART data platform with subject level data of 3400 subjects from 14 cohorts and for access to Electronic Health Record (EHR) data sets. The tools are well used and have allowed both the creation of novel datasets built on on-going studies and the pooled analysis of existing data at much faster pace and more efficiently than it would have been otherwise possible. Their utility has been already demonstrated beyond the project by being leveraged by other initiative such as EPAD and the DPUK.

The **EPAD** project, http://ep-ad.org/ was presented by the coordinating public-private duo **Craig Ritchie** and **Serge Van der Geyten**. The project objective is simple and powerful: to develop a platform to test treatments for the secondary prevention of AD dementia. To this end EPAD will establish a European-wide register of approximately 24,000 people at risk of developing Alzheimer's dementia drawing from existing population-based and clinical cohorts. From this group, 6000 research participants will be asked to join a pan-European EPAD Cohort for consistent, longitudinal follow-up, of which approximately 1500 will be invited to the EPAD Proof of Concept Trial (PoC), a unique, standing, adaptive clinical trial engine. At the time of the meeting the first version of the EPAD register included 17000 non-demented research participants over 50 years old and the EPAD Longitudinal Cohort Study (LCS) was up and running aiming to >1000 enrolled by end 2017. The project had obtained EMA Scientific Advice on LCS and the PoC, which framework is established, ready to accept interventions by June 2017. The EPAD project is highly collaborative with other IMI projects, other national and European initiatives and globally to share learnings relevant to target identification and development, trial ready cohorts and data and clinical trials.

The **AMYPAD** project, http://amypad.eu/ , has started only in October 2016 and was presented by industry project leader **Gill Farrar** and the coordinator **Frederik Barkhof**. The project aims to improve the understanding of the value in imaging β-amyloid deposition using positron emission tomography (PET). Understanding the role of β-amyloid imaging enables the achievement of three goals: to improve the diagnostic work-up of people suspected to have Alzheimer's disease and their management; to understand the natural history of the disease in a pre-symptomatic stage and to select people for treatment trials aiming at preventing Alzheimer's disease. The project works closely with the EPAD project and collaborates with other IMI and international initiatives. The AMYPAD diagnostic study is a randomised, open-label study that will evaluate the impact of amyloid imaging on diagnostic thinking and patient management in 900 subjects. The AMYPAD prognostic study D will quantitatively analyse up to 6000 ß-amyloid PET scans from a large population in the early stages of AD.

The **ROADMAP** project (http://roadmap-alzheimer.org/) was presented by the industry project representative **Catherine Reed**. ROADMAP aims to deliver a series of data integration methods and tools for patient outcomes, developed and tested through pilot projects, which are scalable and transferable, and which will provide the foundation for a future Europe-wide RWE platform on AD. In parallel, ROADMAP is developing tools for stakeholder engagement, understanding the ELSI (ethical, legal social implications) context and health economics impact of a RWE approach in AD. The project has several data collaborations and is leveraging and maximising synergy with existing initiatives/projects with which partners have direct links to leverage methods, tools, constituency, policies, etc.

The **MOPEAD** project, http://www.mopead.eu/ started in December 2016 and was presented by the coordinator **Mercè Boada** and by the industry project leader **Laura Campo**. MOPEAD will test and evaluate four Patient Engagement Models to help identify patients at risk of AD in a five-country, multi-centre setting. The aim of the project is to determine key tools, mechanisms and processes for patient engagement in order to contribute to better identification of undiagnosed individuals with prodromal AD/MCI. In doing so, MOPEAD will shift the paradigm from late diagnosis to early identification of a hidden prodromal AD population, increasing significantly the knowledge about this important population. It will improve the robustness of diagnosis and promptly communicate the onset of signs and symptoms to subject and family, providing opportunities for patients to participate in clinical trials. The project is eager to link to other projects and this was discussed later in the meeting.

The **PRISM** project, https://prism-project.eu/en/prism-study/ was presented by the deputy industry project leader, **Bernd Sommer**. The project objective is to demonstrate that quantitative biological parameters of shared symptom domains across neuropsychiatric disorders including schizophrenia (SZ), Alzheimer's disease (AD), and major depressive disorder (MD) can be used to create biologically meaningful clusters blind to the starting diagnosis. These will provide new assessment tools across disorders, and predictive, preclinical animal systems for subsequent neurobiological and pharmacological testing. The homologous PRISM preclinical and clinical deep phenotyping protocols for assessing social withdrawal, attention, working memory, and sensory processing are established and the deep phenotyping study in AD and SZ patients and healthy controls is scheduled to start end of April, 2017.

The **ADAPTED** project, https://www.imi-adapted.eu/ was presented by the coordinator **Agustin Ruiz** and the industry project leader **Margot Bakker**. ADAPTED started in October 2016 and aims to increase the

understanding of the function of the APOE gene in AD. APOE is well known as a risk factor for developing the disease and a widely used stratification factor, but precisely how this gene contributes to the risk of developing AD is not known. ADAPTED will address the following goals: clarification of the role of APOE as a risk factor; target identification; generation and validation of high value APOE-related model systems and patient stratification.

The **PHAGO** project, www.phago.eu was presented by the coordinator **Harald Neumann** and the industry project leader **Andreas Ebneth**. PHAGO objective is to identify druggable points of interaction in TREM2 and CD33 signalling to modulate phagocytes for treatment of AD. The ambition of the project is to improve patient outcomes through a better understanding of the biology of TREM2 and CD33 and their biological networks and pathways, and pave the way for future development of therapies aimed at phagocyte dysfunction in AD. PHAGO will generate knowledge on the role of TREM2 and CD33 in neuroinflammation and will develop validated assays and identify tools and/or tool antibodies targeted to TREM2/CD33 and related target functions.

The **IMPRIND** project, https://www.imprind.org/ was presented by the coordinator **George Tofaris** and the industry project leader **Kenneth Thirstrup**. The project had just started at the time of the meeting. IMPRIND will map and target critical processes in the propagation and proteostatic response against misfolded α-synuclein and tau to help arrest the progression of PD and AD. This will allow identifying disease-relevant misfolded assemblies and imprint their biological properties, develop assays to monitor propagation and clearance that are suitable for screening, perform genetic screens based on disease-relevant gene/protein networks and assess druggability of identified targets. IMPRIND will deliver robust validation using complex cellular systems with greater functional resemblance to the brain and improve existing animal models to accelerate the assessment of therapeutic interventions.

The last presentation of the morning was by the industry representative **Thomas Steckler** on the at the time upcoming IMI project on "Data quality in preclinical research and development". The project, that started in October 2017 with the acronym EQIPD, http://eqipd.org/ , aims to tackle the serious issue that the robustness, rigor and validity of preclinical research are limited and problematic. The project will define the variables in study design and data analysis that influence outcome in preclinical neuroscience (focus on Alzheimer's disease) and safety studies (focus on CNS safety). On these bases, it will define the components that will make up a fit-for purpose Quality Management System (QMS) for non-regulated R&D and validate the feasibility of the QMS in prospective studies, including in animal models of Alzheimer's disease. Importantly it will deliver an online educational platform providing education and training in the principles and application of quality and rigour.

The lunch Alzheimer's Lecture.

Craig Ritchie and **Jean Georges** gave a very inspiring Alzheimer's Lecture that is available to watch on the IMI Youtube channel (https://www.youtube.com/watch?v=VNPOaV2uHj0; https://www.youtube.com/watch?v=Q6aHlz3KjbM). Jean Georges (Alzheimer Europe) provided the patient view. Alzheimer's disease is a well-known disease by the general European population and the second most feared. There are 8.7 million people with dementia in the European Union, with numbers expected to at least double by 2050.Key messages are: the need for the development of a European dementia strategy/action plan and appointment of EU dementia coordinator; the improved coordination of European research initiatives and programmes in the field of dementia; the full involvement of people with dementia, carers and Alzheimer's associations in these initiatives; Europe must engage and lead at global level. Overall there is the need for a holistic approach to dementia research, "Cure tomorrow, care today.

Craig Ritchie followed and discussed the approaches that we have to win AD: We can go earlier in the disease, we can use interventions well and effectively, we can find the people who will benefit most. There are several challenges that have to be overcome: scientific challenges, numerous but well defined (but accept innovations and discovery will raise new ones); engagement challenges with patients and the public and the global partners; efficiency challenges, how to best use resources and achieve coordination and leadership. A potential help may be provided by coordinating all IMI projects in the "IMI-AD (almost complete) platform in the European (Translational) Union".

The Afternoon session

IMI rules of play

The afternoon session opened with an introduction to the IMI funding model by **Elisabetta Vaudano** and to the IMI Intellectual Property (IP) rules by **Magali Poinot**. Key to IMI achievements is the way its budget is structured. Public funding (from the European Commission) is reserved for eligible beneficiaries (selected via open competitive Calls). The public funding can only be liberated once IMI private EFPIA partners (and in some projects associated partners), which receive no public funding, have aligned around a challenge and create a precompetitive consortium to release the kind co-investment. This mechanism allows IMI to work as neutral platform where all involved in health research and innovation can engage in open collaboration on shared challenges. An enabler for the IMI platform is the flexible IP policy that based on the principle of "One size does not fit all" can be adapted considering the specific needs of each IMI project.

The vision of the Strategic Governance Group Neurodegeneration

Luc Truyen on behalf of the **Strategic Governance Group Neurodegeneration** (SGG ND) presented the vision of the IMI EFPIA partners on this strategic area and the future areas of priority. The strategy is comprehensive, from a detailed investigation of the course of the disease with the aim of identifying and validating new drug targets and molecules acting on them, to development and validation of biomarkers for patient stratification and treatment effect assessment. The SGG will also drive the development of new trial methodologies with novel endpoints as well as supporting infrastructure requirements to speed up clinical development, including the early generation of more patient and payer-relevant data so that access to effective therapies is facilitated. Ultimately, preventative, curative and/or symptomatic therapies should emerge from research programs supported by the SGG ND. The portfolio already generated is large and complex and there is an emerging tension between continuous new ideation, management of the ongoing portfolio and maintaining or realizing synergies between projects. Public Private Partnerships in dementia in IMI and beyond have today created a continuum of collaboration, but the challenge is how to support it to achieve the expected impact for patients, and return of the significant investment.

The Final discussion and feedback

The last part of the event was a lively discussion between the IMI projects, the SGG ND representatives, IMI staff and the organizations represented at the meeting. In addition some feedback was also received in writing by the IMI Office in the days following the meeting and this input has been integrated in the proceedings.

An important positive feedback was that the atmosphere fostered at the meeting was one of inclusivity and collaboration.

The IMI projects portfolio

All delegates agreed that the scale, scope and innovation of the projects generated under the Strategic Governing Group for Neurodegeneration (SGG ND) is impressive and in the words of one delegate, "nearly overwhelming". The projects scope links nicely with topics discussed among regulators and in their external activities. The concept of creating highly interactive networks is also very important since we simply do not know as much as we need to if we are going to develop effective treatments for neurodegenerative diseases.

Early intervention clearly was the motor of all initiatives showcased, including simulations/modelling initiatives. The projects represent a very diverse group of goals, some very broad (creating discovery or development platforms that are agnostic as to target or approach) and some highly focused (especially ADAPTED, PHAGO and IMPRiND). It will be important to demonstrate how the more focused projects would contribute to the overall goals of IMI, and corroborate the choice of the particular areas, but this may be a valid approach if the projects can create clear precedence for moving into new, under-resourced approaches to neurodegeneration

discovery. A hope was that some of the discoveries from these projects might lead to projects and companies that other organizations, like the Dementia Discovery Fund (DDF http://theddfund.com/team/) can support.

It will also be important to support the projects in their efficient interaction with regulators and Health technology assessment bodies to ensure results have an impact on regulatory science and on timely access of patients to innovative treatments.

The need to communicate on what has been achieved so far and to demonstrate value and impact

It is important to show case the IMI portfolio, ideally in a high impact publication, to reflect the expansion of the IMI AD platform with an outlook also beyond Europe.

A key objective of IMI is to impact and improve the current drug development process. Thus IMI will have to demonstrate that the outcomes of the research programmes are having a real and valuable impact on the activities of the industry partners.

Communication and justification of results has to also target the public and patient groups: IMI has to reflect how it could successfully report if it had to do so to the annual meetings of the largest Parkinson's and Alzheimer's patient groups: "We have taken 450M EUR from you and your neighbours through taxes, and distributed it as grants to universities across Europe, and here is exactly how, and when, all this is going to help you".

The gaps

A gap was flagged in incorporating input from, and collaboration with, SMEs. There really is a lot happening in this sector, and they are often more willing than large pharmaceutical companies to publicise the novel discovery they are doing. Some of the academics will be aware of this work and some of the EFPIA representatives will as well, but if there is a way IMI could consider for a more systematic inclusion, it would bring real benefit.

It was also remarked that there is currently a very limited involvement of EU12 countries and it would be valuable to reflect how to ameliorate this situation by foreseeing activities in the projects inclusive for teams in the new Members States.

Projects as ROADMAP have dedicated work packages to ensure stakeholder engagement is sufficiently embedded in the project. However, ensuring wide stakeholder engagement in project remains a challenge and might be especially important to the SGG ND to reflect on how best achieve this in future initiatives. The National Institute for Health and Care Excellence (NICE, https://www.nice.org.uk/about) has been already collaborating with IMI in such activities in the projects ADAPT-SMART (http://adaptsmart.eu/) and GetReal (http://www.imi-getreal.eu/) and it would be important to consider these experiences.

Future activities

Several ideas and suggestions for future initiatives came from the project teams (see the presentations for full details), and from other delegates. It was proposed to go beyond the amyloid hypothesis and look more holistically the biology of AD/neurodegeneration; to develop a platform for innovation from SMEs/biotech to be moved forward; to carry out interventional studies not pharmacological to understand how life style factors modify the base line for pharmacological interventions; to use learnings from other areas (e.g. immunology) to develop new/less invasive biomarkers. Alzheimer Europe (representing the patient voice at the meeting) stressed the value to get a true understanding of what the experiences of research participants have been when it comes to their involvement in research and to identify what obstacles and barriers they encountered, how they experienced the whole research process and what lessons they would have for future research projects to improve their experience.

Another area relevant from patient perspective is to find ways of developing registries of people interested in participating in dementia research which would not be limited to clinical trials only: All too often people would like to volunteer only to find out that they don't fit the inclusion or exclusion criteria for the one study they

volunteered for and then quickly lose interest in volunteering for other studies, Initiatives like "Join Dementia Research" (https://www.joindementiaresearch.nihr.ac.uk/) in the UK or the TrialMatch of the US Alzheimer's Association (https://trialmatch.alz.org/find-clinical-trials#createaccount) would be fantastic initiatives to develop across Europe to match willing research participants (including people with dementia, but also people concerned about developing dementia, family members, and also carers) with researchers.

Collaboration and coordination

It was insightful that several projects representatives stated that a big value of the meeting was for them to become aware of other projects activities and challenges, which often are the same, or highly related. Indeed a recurrent comment was that there seen to be a certain degree of overlapping. These could clearly be complementary but there may be some duplication also. The meeting was a first step to help identifying those areas and highlighted the need for new collaborations and to build connectivity and cross pollination across IMI projects.

There was strong consensus from the IMI projects, and other organizations on the willingness and value of collaboration and coordination, and indeed the vice chair of World Dementia Council, https://worlddementiacouncil.org/ , stated that it would be unacceptable to not to do so. Alzheimer Europe indicates its will to push the need for not only the IMI projects but also the wider dementia research community of JPND and H2020 programmes to develop a closer collaboration. This should also include the flagship Human Brain Project (https://www.humanbrainproject.eu/en/), building on already started fruitful interactions.

One of the main take home points was the need for greater alignment between major initiatives. The work done in the Joint Programming Neurodegenerative Diseases Research (JPND, http://www.neurodegenerationresearch.eu/) and IMI2 is extremely complementary and creating bridges among the two EU initiatives would provide both of new strength and be of benefits for the ultimate stakeholders that are patient suffering of neurodegenerative diseases. Several JPND projects now reached the level of maturity sufficient to generate data to be considered for more applied non-competitive studies. It would be very helpful to organize a meeting in which the scientists working in areas of interest for Industry present and discuss the results so far obtained or even develop a more structural platform for information exchange. Such initiative would have several potentially beneficial out comes, for industry, for scientists and for funders. Another suggestion would be the creation of an interactive platform for the presentation and discussion of the experimental models available for the study of Neurodegeneration. The effort made in the case of Alzheimer's shows how relevant is for the scientific community to have experts helping in underlying the pros and cons of the zillions of models of disease available. JPND is working on the platform for the models of Parkinson, but the work is humbling. Maybe a dedicated joint IMI2-JPND call could be a solution. It should also be reflected how best collaborate and coordinate with the rest of the H2020 programme including ERC.

The European Brain Council (EBC, http://www.braincouncil.eu/) has just concluded a study on the value of treatment for brain disorders, aiming to assess the treatment gap and the cost of non- (or inadequate) treatment, and promote a holistic healthcare approach. This study demonstrates health gains and socio-economic impacts of best practice health care interventions. It would be important to find ways for future collaboration to leverage these learnings.

An important activity of the Medical Research Council (MRC, https://www.mrc.ac.uk/) is the establishment of the Dementia Research Institute (DRI, https://www.mrc.ac.uk/about/institutes-units-centres/uk-dementia-research-institute/). It will be critical for the DRI to be well connected to industry/biopharma and IMI would be an ideal channel for future interactions in this respect.

Parkinson's UK (https://www.parkinsons.org.uk/) was very pleased to see that the SGG ND is including an increasing focus on Parkinson's disease in its future priorities and would be very interested to be involved, support or influence, IMI – SGG Neurodegeneration programme.

The C-Path Institute (https://c-path.org/) focuses on regulatory strategy and qualification of novel methodologies with the EMA, FDA and PMDA. Additional core competencies revolve around data standards, database generation and curation, modelling and simulation. There are number of areas for potential

collaboration between C-Path and IMI and the clear opportunity to leverage C-Path's focused set of core competencies to advance the IMI calls towards deliverables which are regulatory in nature. This is facilitated by the already existing memorandum of understanding between the two organizations.

IMI and the Global CEO Initiative on Alzheimer's Disease should continue and extend their collaboration in particular looking at use of Real World Evidence and use of Big Data which are central to the research agendas of both organizations.

It would be also important to find opportunities to create synergies and share learning and insights with the Alzheimer's Association. For example, considering the common focus on preclinical Alzheimer's disease, the Association has already developed principles to guide data and sample sharing in preclinical Alzheimer's disease trials (http://www.nature.com/nrneurol/journal/v12/n1/abs/nrneurol.2015.177.html).

Indeed in the last ten years there has been a flourishing of initiatives in neurodegeneration and dementia research. Now a major effort will be necessary for the harmonization of all the platforms already generated and to be generated in the future. Efficient and effective data use/reuse and data sharing is of paramount importance for final impact. An extra effort should be made to make the data collected in these platforms available to all relevant stakeholders, beyond the single initiatives, as much as possible.

In parallel to the expression of interest for more collaboration and coordination, everybody also agreed that the good will is not sufficient, some "glue" mechanism, some "oil" has to be provided.

All are so busy to work on their projects that it is difficult to find the time for the extra-work necessary to create collaborations. A support instrument would put together the brains and expertise necessary to create strong ties among the initiatives.

A potential mechanism would be via the establishment of a Coordination and Support Action (CSA) that might be better suited to work across projects than having the individual projects work on this, as they will primarily be concerned with delivering the work in their projects.

To successfully implement a CSA it is important first to clearly identify the deliverables that such collaboration coordination should achieve, and to identify the facilitating instruments to be provided via the CSA. Some suggestions were:

To facilitate and foster interaction via workshops in specific areas (modelling and simulation was the first area identified);

to provide a platform for sharing of data and samples and learnings on how to do so;

to provide a tool for gathering patient' feedback on their involvement in clinical studies, beyond clinical trials;

to provide support to foster interactions with regulators and HTAs.

Final remarks

The event "Collaboration in Alzheimer's disease & beyond: the present and future of the Innovative Medicines Initiative (IMI) initiatives in neurodegeneration" has been a success and IMI is grateful to all the projects for their enthusiasm and commitment to achieve their objectives and to do so as collaboratively as possible. We like to extend our gratitude to all organizations and institutions that joined IMI in this initiative and their valuable inputs and to the chairs and members of the SGG ND.

Most particularly it was important to have Alzheimer Europe and Parkinson's UK to represent the Patient voice.

Now it will be important for us at IMI to continue our work together with the SGG ND to progress neurodegeneration research.

While more funding may be an enabler to ensure that more scientists with more diverse ideas will be able to do the science that tests their hypotheses, this can no longer come in the absence of clear thinking about how the investment will lead to better answers to the questions we have been asking for years. One reason that oncology and cardiovascular disease get more money than neurodegeneration is because they have shown they can create medicines that make a difference in the world, and without those medicines there is an extra burden of proof on researchers in this field. Thus it will be important to reflect which new initiatives should be launched that can move the needle significantly.

A big challenge and at the same time enabler is that of Data in all its aspects. Inclusion in future topics of provisions to facilitate the sharing of data and results would be important. But it would be valuable also a more strategic reflection on how to do this better between sectors, between projects, between organizations in Europe and globally.

It was stated by different voices that (micro)-SMEs should be involved more. The rather long and slow projects that are mostly funded under IMI do not match well with the demand for speed and the tight focus of the most interesting SMEs (<50 employees), and in addition they probably cannot spare much resource for even in-kind contributions. It will have to be considered how within the IMI legal framework, to create opportunities and incentives for more SMEs involvement.