Neuronet

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Efficiently Networking European Neurodegeneration Research

WP3 –Tools & Services

D3.11 Regulatory, HTA and payer strategies for neurodegenerative diseases

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Contents

Definitions and abbreviations

Partners of the NEURONET Consortium are referred to herein according to the following codes:

1. **SYNAPSE**: Synapse Research Management Partners SL
2. **NICE**: National Institute for Health and Care Excellence
3. **AE**: Alzheimer Europe
4. **JANSSEN**: Janssen Pharmaceutica NV
5. **LILLY**: Eli Lilly and Company Limited
6. **ROCHE**: F. Hoffman – La Roche AG
7. **TAKEDA**: Takeda Development Centre Europe LTD (*terminated partner*)
8. **SARD**: Sanofi-Aventis Recherche & Développement
9. **PUK**: Parkinson's Disease Society of the United Kingdom LBG
10. **TAKEDA AG**: Takeda Pharmaceuticals International AG

Grant Agreement: The agreement signed between the beneficiaries and the IMI JU for the undertaking of the NEURONET project.

Project: The sum of all activities carried out in the framework of the Grant Agreement.

Work plan: Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.

Consortium: The NEURONET Consortium, comprising the above-mentioned legal entities.

Consortium Agreement: Agreement concluded amongst NEURONET participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

IMI: Innovative Medicines Initiative

ND: Neurodegenerative Disorders

WP: Work Package

Abstract

Neuronet is a Coordination and Support Action (CSA) operating in the neurodegenerative disease space that aims to identify research gaps, communicate research findings and create links between Innovative Medicines Initiative (IMI) projects that form the IMI neurodegenerative disorders (ND) portfolio.

Neuronet included four Working Groups (WGs) for cross project discussions. One of these WGs was the HTA and Regulatory interactions WG that aimed to generate insight into regulatory and HTA challenges that are unique to neurodegenerative diseases. The WG activities included organising a workshop to discuss the projects activities around digital endpoints and the challenges faced in using them in regulatory and HTA submissions, and conducted/performed case studies to illustrate HTA and regulatory interactions for a number of IMI ND projects. This white paper summarises these activities as well as the key learnings, and is an output of Neuronet's Work Package 3 (WP3) which explored tools and services for ND products.

1 Introduction

Four working groups (WGs) were set up as part of Neuronet to create a space for cross-project discussions about common experiences, challenges and needs. Furthermore, they represent forums for discussions around lessons learned, priorities and opportunities for synergy and collaboration. The outputs from the WGs include producing tools, guidance and reducing duplication of effort across the portfolio through knowledge sharing. They also provide opportunities for networking across the portfolio.

The following are the four standing WGs in Neuronet:

1. Data sharing and re-use
2. Ethics and patient privacy
3. Sustainability
4. HTA/Regulatory interactions

The topics for the WGs were chosen at the initial stages of setting up Neuronet based on feedback from a subset of Neuronet projects about their key needs for support.

The HTA and Regulatory interactions WG has a specific aim to generate insights into the regulatory and HTA challenges and opportunities that are unique to neurodegenerative diseases (NDs) through:

- Developing tools to support effective engagement with regulators, HTA agencies and payers
- Identifying projects' needs and knowledge gaps in relation to specific procedures and processes where external expertise may be sought
- Providing a forum to share lessons learned from previous HTA and regulatory engagement
- Supporting the projects in the development of their regulatory, HTA and payer strategy, as applicable

The final deliverable from the HTA and Regulatory Interactions Working Group is a report on the challenges faced in engagement with HTA and regulatory agencies as informed by the

interaction with IMI ND projects and the lessons learned through the HTA and regulatory WG activities. The WG convened a workshop on digital endpoints with HTA experts to seek their guidance on interacting with HTA regarding their use. The WG also thought it would be valuable to use some of the IMI ND projects as case studies to describe specific interactions that they had with HTA and regulatory procedures. This document summarises these, along with the challenges and lessons learned from the HTA and regulatory WG activities.

2 Case studies- IMI ND projects interacting with HTA and regulatory agencies

The HTA and Regulatory Working Group felt it would be valuable to collate case studies illustrating interactions that specific projects have had with HTA and regulatory procedures to share the learning from these interactions with other ND projects.

The case studies below include the following procedures and interactions:

1. EMA Innovation Task Force (ITF). This is a multi-disciplinary group that includes scientific, regulatory and legal competences. It was set up to ensure coordination across the EMA and provide a forum for early dialogue with applicants on innovative aspects in medicines development.
2. EMA qualification of novel methodologies. Advice is given by EMA's Committee for Medicinal Products for Human Use (CHMP) based on recommendation by the Scientific Advice Working Party (SAWP). This is to support the qualification of innovative development methods for a specific intended use in the context of research and development into pharmaceuticals.
3. EMA scientific advice. This can be accessed at any stage of a medicine development and the EMA can provide advice on the most appropriate way to generate robust evidence on a medicine's benefits and risks.
4. Parallel scientific advice: EMA-HTA. This is an offering by the EMA in parallel with the European Network for Health Technology Assessment (EUnetHTA) 21 consortium. This allows for advice from regulators and HTA bodies in EU member states on evidence generation plans.

2.1 Case study 1- EMA innovation task force

This case study focuses on a research project whose goal is to develop clinically meaningful digital endpoints for functional decline in early Alzheimer's disease. The project was in the early stages of planning the design of their study and wanted to engage early with health authorities to ensure the study design met regulatory expectations. The EMA's Innovation Task Force (ITF) was chosen as the most appropriate mechanism for engagement as it would allow the project to explore more high level, conceptual questions about exploratory, novel techniques without the need to share data which would be required for other procedures (e.g. qualification of novel methodologies).

Preparation for the meeting was relatively straightforward and light touch, and involved the preparation of a presentation about the project. However, planning the presentation required consortium discussions and agreement on how to present the project, the key issues they wanted to highlight, and the questions that they wanted to ask. The project also had to consider who would represent them at the meeting, balancing the practicalities of availability of representatives (taking into account the different time zones of partners) with ensuring they

had a good mix of people with a good working knowledge of the project as well as more senior, strategic representatives.

The ITF meeting itself provided the opportunity to engage with an expert panel in an informal, two-way dialogue. As a result of the meeting, the project changed its strategy for regulatory engagement. It had originally planned to seek a qualification opinion but following ITF feedback determined that this was too ambitious within the project timelines. The project is now planning to seek qualification advice from the EMA and, in parallel, HTA advice, at the end of the project. The intention is to use the qualification advice to inform the development of a longitudinal study which could potentially result in a qualification opinion. The team is also planning to engage with HTA bodies in parallel. They may also seek interactions with the FDA, following recommendations resulting from the IMI mid-term review. This is a meeting with IMI representatives at the midpoint of the project to assess its progress.

Overall, the project felt that the ITF offered a useful means of engaging with a diverse panel of experts, enabling them to get some fresh ideas and options that they had not considered as a consortium. For more detailed feedback the team is planning for a qualification advice.

Before undertaking this, or any other procedure, the project recommends agreeing as a consortium what the project's ultimate aim is and what outputs the consortium would like to see as a result of the procedure. It is also important to embed regulatory engagement into the project structures and strategy and to provide regular feedback to consortium members, ensuring that they understand why it is relevant to their work in the project.

2.2 Case study 2- EMA Qualification of Novel Methodologies

For researchers developing innovative methods or drug development tools, scientific advice is available through the EMA's qualification procedure. This case study focuses on a research project with an objective to establish validated and accepted digital mobility outcomes, derived from wearable sensors, that can be used as appropriate biomarkers for clinical benefit in clinical trials of new pharmaceutical products. To achieve their objective, the project chose to seek qualification advice from the EMA using a staged approach. So far, the project has sought two rounds of qualification advice and received two letters of support which publicly endorse the project's approach.

In preparation for the procedure, the project was required to develop a briefing book which was submitted to the EMA and provided the basis for discussions. Having pharmaceutical companies with vast experience of regulatory procedures on the consortia was an advantage as it helped them to navigate the formal processes. However, building a compelling and robust argument was particularly challenging. The consortium created a Qualification Task Force (QTF), which included all partners who were willing to actively contribute to the preparation of the briefing book, and a Qualification Interest Group, which included all those in the consortium who wanted to be kept informed about this work. Once the QTF was established, the first request for qualification advice was submitted after six months. The process included an informal face to face preparatory meeting with an EMA officer, and a formal meeting with the Scientific Advisory Working Party of EMA.

The procedure resulted in a change to plans to undertake qualitative research to support the need for monitoring real world mobility which had originally been discounted as an idea. The project is now preparing a submission to the FDA Drug Development Tool (DDT) Qualification Program, including plans for qualitative research following advice from the EMA. It is also

hoped that the project will have sufficient data to pursue a qualification opinion before the end of the project.

The key learning from undergoing this process was the need to communicate a clear logical reasoning on the constructs and the hypotheses, and how they were going to test them. In dealing with complex problems, such as these, it takes time and a lot of work to do this effectively.

2.3 Case study 3- EMA Scientific Advice

This case study focuses on a research project that sought scientific advice before starting critical aspects of the project. They undertook two scientific advice procedures, as well as a consultation with the EMA's Clinical Trials Facilitation Group. The purpose of these interactions included advice on the development of a master protocol, the approach being taken to establish a proof-of-concept (PoC) platform for use in drug development, the use of the PoC trial as a pivotal study for regulatory purposes, and plans for the statistical analysis of data from a longitudinal study.

In preparation for these interactions, the project team spent considerable time and effort developing a briefing document and writing specific questions. For the scientific advice procedures the project team received clear and detailed written answers to the scientific advice questions, and written minutes from the meeting with the Clinical Trials Facilitation Group.

Overall, the project received useful advice from both scientific advice and the Clinical Trials Facilitation Group. This included clear advice from the Clinical Trials Facilitation Group on what to do if submitting to the EMA, and scientific advice on exploratory endpoints and analysis. However, whilst useful, the advice received did not result in any changes to the master protocol or to the clinical or scientific outputs. One reflection was that it isn't always clear which procedure to follow. The project also felt that it would've been useful to have engaged with HTA bodies on how they would value exploratory endpoints in their assessments, even if it was just for educational/awareness raising about the work they were leading.

A key learning from the procedures was that, as a consortium, it is helpful to identify one partner that will take responsibility and ownership for driving the process forward. In addition, whilst completing the briefing books was straightforward, it can take considerable time. This particular project found that not all partners had the same level of understanding of the purpose of the procedures and the questions that were appropriate to ask. It therefore took time to ensure that all partners were aligned on the purpose of the procedure and to develop clear questions that would be asked, taking into account the different needs and expectations of project partners.

The project found that their informal interactions with the EMA were extremely useful in guiding their thinking and tried to enlist the EMA as a consortium member, although were unsuccessful. As a compound agnostic project, they felt that taking an informal partnership approach would've been better than the formal scientific advice route they ultimately followed. One way to facilitate this would be to require all future projects to include a regulatory representative on the consortium in an advisory capacity.

2.4 Case study 4- Parallel Scientific Advice: EMA-HTA

One way to ensure that the design of research studies meets the needs of both regulatory and HTA bodies is to seek parallel scientific advice. This case study focuses on the advice provided to a project from the EMA and one HTA body on the design of a diagnostic study and the choice of efficacy measures and health outcomes to effectively evaluate impact.

For the scientific advice procedure, the project was required to develop a briefing document, including the specific scientific questions relating to the design of the study and their proposed responses. The document took around 3 months to prepare. After submission, a face-to-face meeting was held with the EMA and NICE to discuss the questions and then both agencies provided separate written responses to the questions.

Overall, the advice received from both agencies helped to shape the development of the study protocol. For example, the EMA provided valuable guidance on study designs and endpoints which resulted in a change to the primary endpoint of the study. Additionally, secondary endpoints relating to resource utilisation were added as a result of the HTA advice.

The project benefitted from the parallel procedure and recognised the value in seeking early advice in helping to shape the design of the study. However, there were also some challenges and lessons learned. Firstly, the preparation for the procedure was very time consuming. As a consortium, time was needed to gain agreement from all partners on what the questions would be and the position that they want to take on them. Sufficient time therefore needs to be factored into any project planning.

As a parallel procedure, all HTA bodies in Europe were invited to participate but only one body accepted and participated in the procedure, and a further one HTA body observed the meeting. From a HTA perspective it would have been better if they could have received advice from multiple HTA bodies at the same time. In addition, whilst some of the advice provided by the EMA and HTA body was similar, there was also some contrary advice relating to the design of the study. For example, EMA advice for a study demonstrating the impact of initial diagnosis compared to HTA advice for a complete pathway of care study. These differences reflected the different requirements of the agencies. The project had to determine which advice was most relevant and achievable to implement within the project timelines and resources.

Following the initial scientific advice procedure, the project sought further scientific advice from the EMA later in the project on more conceptual questions relating to biomarkers. As well as gaining feedback it also gave them the opportunity to introduce new concepts to the EMA.

3 Key challenges with procedures to interact with regulatory /HTA agencies

3.1 Consideration of HTA/Regulatory aspects in clinical studies

HTA/Regulatory aspects are typically considered at later stages of clinical studies, it would be more appropriate for there to be HTA/regulatory input from the outset of studies to allow adequate planning and ensure that study design align with requirements of HTA and regulatory agencies.

3.2 Knowledge of procedural aspects of engagement

There are different procedures and routes for engagement with HTA and regulatory agencies at different stages of research. It is not always clear which procedure should be followed unless there are partners within the consortium with extensive experience of dealing with these agencies.

3.3 Time and resource for HTA and regulatory interactions

It is important to have regulatory interactions as part of IMI projects. However, resource to allow these interactions is not always included in project budget allocations. Getting consensus among consortium members on what to ask, especially given the variable knowledge of HTA and regulatory requirements can be very time consuming in addition to the preparation and internal sign-off documents prior to submission and can therefore be very resource intensive.

3.4 Alignment between HTA and regulatory agencies

When undergoing parallel scientific advice procedures with HTA and regulatory agencies there may be instances when the advice received may be different or contradictory reflecting the requirements of the bodies. This can create challenges in terms of choosing the final approach to follow.

4 Key learnings from the case studies and WG activities

4.1 Key learnings from project interactions with HTA and regulatory agencies

4.1.1 Learnings for regulators and HTA

- The landscape is evolving, and procedures, processes and work programmes in regulatory and HTA organisations are constantly changing. There is a need for clearer guidance for stakeholders and industry on which paths to take for different technologies.
- It would be useful to have a single point of access to regulators and HTA organisations for synthesised advice and clear pathways.
- Clearer pathways are especially important for technologies that straddle the traditionally siloed categories such as digital endpoints and some medical devices. There are more organisations involved in regulatory and access strategies for these types of products and it can be particularly confusing to understand where to get advice.
- Earlier engagement with developers, preferably using collaborative approaches, is important in order to ensure methods development adequately responds to the challenges posed by innovative technologies.

4.1.2 Learnings for industry

- It is important to consider HTA and regulatory aspects of clinical studies at design stage to ensure the appropriateness and acceptability of the approach taken.
- It is important to have guidance on the appropriate procedures to follow for engaging with regulatory and HTA agencies at each stage of research/ product to development.

- It is important to time the advice from regulatory and HTA well. It is not useful to go with too few results, but it needs to be early enough so that any advice can be incorporated.
- Seeking scientific advice is a useful means of engaging with a diverse panel of experts, enabling projects to gain new perspectives and to consider additional options that would not have been considered otherwise. This is useful to guide subsequent formal steps.
- It is important to have resources and time allocated within projects to allow HTA and regulatory interactions and to embed regulatory engagement into the project structures and strategy. Regular feedback should be provided to consortium members, ensuring that they understand why it is relevant to their work in the project. This helps get everyone on board, particularly academics who may not normally be focussed on market access. This is especially important in the context of limited resources that consortiums have which can sometimes be a barrier to seeking regulatory and HTA advice.
- The sustainability and operationalising of outputs from projects is important e.g. the priority outcome work developed through ROADMAP could be used to inform the development of a core outcome set.
- It is useful to have partners within the consortium who have extensive experience with HTA and regulatory interactions. It is important to make use of combined expertise in the consortium and WG members felt it was particularly valuable to have regulatory experts from the pharmaceutical industry.
- It is important to assemble a dedicated team or task force responsible for HTA and regulatory engagement activities and to identify a partner within the consortium that will take ownership of driving the process forward.
- There should be agreement within the consortium on what the project's ultimate aim is from engaging with a regulatory or HTA agency and what outputs they would like to see as a result of a scientific advice procedure.
- There is a need to communicate clear logical reasoning on constructs and hypothesis being tested by projects and how they are going to be tested when undergoing scientific advice processes to make the most of the opportunity.
- If provided with different or contradictory advice when seeking parallel advice from different agencies, a decision needs to be made on the most appropriate way forward based on what is relevant and feasible within project timelines.

4.2 Key learnings from HTA and regulatory WG activities

- Having a working group as part of Neuronet dedicated to understanding and addressing the needs of projects in the portfolio from an HTA and regulatory perspective provided a space for the following:
    - Sharing knowledge and learnings from HTA/Regulatory experiences helps to reduce duplication across projects.
    - Development of tools and collating resources to support projects in HTA and regulatory interactions (e.g., Decision tool).
- Including HTA agencies as partners in consortia is useful because of guidance they can give in terms of processes and providing access to external experts and key opinion leaders that can provide additional input (e.g., workshop on digital endpoints) when needed.

5 HTA and regulatory interaction regarding digital endpoints

A workshop was convened with external HTA experts for IMI ND project representatives to ask about engaging with HTA agencies regarding digital endpoints. This is a summary of the key issues and recommendations that they provided for the development of digital endpoints. Also relevant to the digital endpoint discussion is case study 1 which details an IMI research project whose goal is to develop clinically meaningful digital endpoints for functional decline in early Alzheimer's disease, and their interaction with the EMA via the EMA's Innovation Task Force procedure.

5.1 Key issues

5.1.1 Limited experience of HTA agencies of digital endpoints and measures

While there is a need for better and more accurate tools to demonstrate the value of newly developed treatments, HTA agencies have limited experience of the use of digital endpoints and data. In the few instances when they have been used, they were assessed as secondary or exploratory endpoints, and not as pivotal evidence.

5.1.2 Limitations of real-world data

HTA agencies have variable experience of using real world data (RWD) for decision making and there is no broad agreement among them on the use of RWD. Digital data is simply RWD that is being collected and presented to HTA agencies in a different format, using technology to support its collection. RWD has many challenges, including that it is more prone to bias and confounding factors. A number of methods have been developed in the HTA field to enable researchers to adjust for these issues. However, even these methods cannot overcome issues related to data quality.

5.1.3 Limited scope for formal engagement with HTA and regulatory agencies

While it is important to engage with HTA and regulatory agencies early on in the development process, given that projects developing digital endpoints are not product-specific it may not be possible to undertake formal engagement with them.

5.1.4 Validity and generalisability of digital endpoints

It is important that developers focus on getting the methodology of the clinical studies right, to limit potential bias (e.g., selection bias) and ensure the validity and reliability of the digital data derived from both the target and the treated population. The generalisability of digital measures is also important so they need to have face validity and capture data that can be applied to a real-world situation, such as when patients are in a clinic or living their normal lives.

5.1.5 Lack of clear work programmes and governing bodies

Digital endpoints are generally captured using digital health technologies, which challenge the existing silos we have in terms of work programmes and processes for the actual product to achieve regulatory and reimbursement status. For example, some of these technologies may qualify as medical devices, but technical validation is not in the remit of regulators such as EMA. Sometimes there is a not a clear path for navigating regulatory and HTA processes for this product and a general lack of guidance.

5.2 Recommendations from experts consulted

The following were the key recommendations from the experts that joined the workshop:

5.2.1 Engagement with HTA agencies

- Developers are advised to approach individual HTA agencies, e.g. through their scientific advice procedures, to determine what their perspectives and recommendations are in terms of digital endpoints.
- Informal engagement through channels such as the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), HTAi and DIA are also a good mechanism for discussions with HTA agencies. There are numerous publications and outputs from other Horizon 2020 and IMI projects which provide further information about the different methodological approaches that European HTA agencies use in relation to these types of questions.

5.2.2 Demonstrating the value of digital endpoints for decision-making

- Developers need to provide a rationale as to why digital endpoints should be assessed instead of the more traditional final outcomes on which HTA agencies would usually base their decisions, and to consider whether the use of these endpoints will help bridge the uncertainty gap and enable HTA agencies to make better-informed decisions.
- Decision-makers need to be able to understand the properties of the new measure, how to interpret the data it provides and why it is an improvement on the old measure.
- Developers need to follow a stepwise, iterative process to show that proposed measures have greater precision than traditional measures and highlight how they will reduce uncertainty and are more relevant to patients to be considered by decision-makers.
- It is important to highlight the value of digital data as additional evidence at different stages including in the post-launch evidence generation stage to inform conditional access agreements.
- Developers need to demonstrate that new digital measures are generalisable to the wider population in which treatments and therapies would be delivered and are of relevance and value to patients.
- New digital endpoints should have the capacity to be mapped to validated quality of life measures that can be used to populate economic models.

6 Overall Key Recommendations

6.1 For regulators and HTA

6.1.1 Establish a single point of contact

Establish a single point of contact for projects to be able to access appropriate regulatory and HTA advice. There are different procedures and routes for engagement with HTA and regulatory agencies at different stages of research and it is not always clear which procedure should be followed.

6.1.2 Issue clearer advice for technologies that straddle traditional boundaries

Synthesised and clearer advice is particularly needed for technologies that straddle the traditionally siloed categories. Especially concerning digital endpoints and medical technologies where the regulatory processes are less centralised.

6.2 For industry

6.2.1 Include RWD and patient engagement

Keep in mind that there will be a future expectation from regulatory and HTA organisations to include RWD and patient engagement.

6.2.2 Use Neuronet generated tools

Utilise tools that have been produced through Neuronet. WP3 has produced resources such as the Decision Tool to aid understanding of and interaction with regulatory and HTA organisations. There is also the priority outcome work developed through ROADMAP that could be used to inform the development of a core outcome set.

6.2.3 Consider the timing of advice

Seek guidance on which procedures to follow at each stage of research and product development. For example engage with regulatory and HTA at design of clinical studies to ensure acceptability of approaches. Some procedures will need to be more carefully timed so there are enough generated data to allow for usefulness, but also sufficient time to incorporate advice. Access to a diverse panel of experts is useful for guiding subsequent formal steps.

6.2.4 Consider the consortium make up

Make use of combined expertise in the consortium. WG members felt it was particularly valuable to have regulatory experts from the pharmaceutical industry.

6.2.5 Engage consortium members and consider the desired output from the advice

The consortium should agree on the project's ultimate aim and the outputs they would like to see as part of the advice procedure. This is also useful to ensure that everyone in the consortium is on board with getting advice and understands why it is relevant to their work in the project. This can be challenging as resources are limited and not everyone is coming from a market access perspective.

6.2.6 Have sufficient time and resources

Ensure time and resources are allocated within projects to allow HTA and regulatory interactions. Some advice procedures can have time intensive preparation. Assembling a dedicated team responsible for activities can drive the process forward.

6.2.7 Be prepared for conflicting advice

Regulatory and HTA organisations may give contradictory advice due to their different roles and requirements. In this case, a decision should be made on the most appropriate way forward based on what is relevant and feasible within project timelines.

6.3 For IHI

6.3.1 Establish a platform for sharing regulatory and HTA feedback

Establish a platform that project members can use to share feedback on interactions with regulatory and HTA bodies. There are valuable learnings that WG members felt could be better used to aid collective understanding across projects. IHI could help support and facilitate this.

6.3.2 Aid consortium knowledge sharing

Keep in mind the consortium's publication plans and facilitate the sharing of these across the ND projects.