Neuronet

IMI2 821513 – NEURONET

Efficiently Networking European Neurodegeneration Research

WP5 CSA Management & Sustainability

D5.1 Initial Data & Knowledge Management Plan

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Document history

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V0.1	05/06/2019	First outline for initial discussion
V0.2	22/07/2019	First draft for internal review
V0.3	29/07/2019	Comments from Sandra Pla
V1.0	30/07/2019	Second draft for Consortium Review
V1.1	23/08/2019	Comments from Manuela Rinaldi
V1.2	29/08/2019	Final version for submission

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
8. **SARD**: Sanofi-Aventis Recherche & Développement
9. **PUK**: Parkinson's Disease Society of the United Kingdom LBG

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.

DKMP: Data and Knowledge Management Plan.

EU: European Union.

GDPR: General Data Protection Regulation.

IMI: Innovative Medicines Initiative.

MOU: Memoranda of Understanding.

ND: Neurodegenerative disorders.

SGG: Strategic Governing groups.

Publishable summary

This first deliverable of WP5 CSA Management & Sustainability (D5.1) constitutes the first version of the Data and Knowledge Management Plan (DKMP) for the NEURONET project, as required by the Innovative Medicines Initiative (IMI) JU guidelines. This DKMP represents a formal document describing in detail how data are handled for the entire duration of the NEURONET project (i.e complete data life cycle). It also outlines the strategies that NEURONET will implement to manage, analyse and preserve data and metadata. The types of primary data to be collected and used by NEURONET would include:

- Qualitative data, from semi-structured interviews.
- Quantitative data, e.g public data on project funding, web traffic analytics.

In accordance with IMI JU/H2020 requirements, NEURONET adheres to the FAIR data principles, whereby research data is made Findable, Accessible, Interoperable and Re-usable for the community, responsibly considering possible restrictions on public data sharing. With consideration of agreements between data providers and the consortium, and taking into account specific privacy regulations, data used within the consortium will as far as possible be made FAIR.

It is important to note that the plans outlined in this document are not static and they might be updated during the lifespan of the project.

1 Introduction

Deliverable 5.1 constitutes the first version of the Data and Knowledge Management Plan (DKMP) policy for the NEURONET project, as required by the IMI JU guidelines. This DKMP is a formal document describing in detail how data are handled for the entire duration of the NEURONET project (i.e complete data life cycle). It also outlines the strategies that NEURONET will implement to manage, analyse and preserve data and metadata. The types of primary data to be collected and used by NEURONET would include:

- Qualitative data, from semi-structured interviews.
- Quantitative data, e.g public data on project funding, web traffic analytics.

NEURONET WP1 *Projects & Impact analysis* will generate a metadata spreadsheet of information collected from IMI ND projects. This meta-data repository will be updated as the project progresses, and will be the master file for more detailed information on the data parameters collected, as described in the Data Summary below.

In accordance with IMI JU/H2020 requirements, NEURONET adheres to the FAIR data principles, whereby research data is made Findable, Accessible, Interoperable and Re-usable for the community, responsibly considering possible data restrictions on public sharing. With consideration of agreements between data providers and the consortium, and taking into account specific privacy regulations, data used within the consortium will as far as possible be made FAIR.

The format of the present DKMP follows the Horizon 2020/IMI JU template. It is important to note that the plans outlined in this document are not static, they might be adapted during the lifespan of the project. Updates on the DKPM will be reported in Deliverable 5.2 due in Month 15.

2 Data summary

2.1 Purpose of the data collection/generation and its relation to the objectives of the project

The primary aim of the IMI Coordination and Support Action NEURONET is to set up an efficient platform to boost synergy and collaboration across the IMI projects of the Neurodegenerative Disorders (ND) portfolio, assisting in identifying gaps, multiplying its impact, enhancing its visibility and facilitating dovetailing with related initiatives in Europe and worldwide.

NEURONET will sign Memoranda of Understanding (MoU; see annex) with the projects, to establish the overarching framework for collaboration and facilitate exchanges of information, whilst remaining in compliance with the terms of the respective projects' consortium agreements.

NEURONET will collect and analyse information from the IMI projects of the ND portfolio to:

- understand the intellectual and technological contributions of the projects.
- facilitate collaboration, communication and operational synergies among projects.
- support projects by organising tools, services, expert advice and guidelines/recommendations.
- identify gaps, bottlenecks and common issues across projects.

- assist in the building of future projects that will address any unmet needs detected.
- assess the impact of IMI ND research.

2.2 Types and formats of data

NEURONET will collect the following qualitative and quantitative information and data from IMI ND projects, including:

- General information (e.g. title, call, funding, duration, research area....)
- Composition of project consortium (including third parties, etc)
- Work plan (e.g. list of WPs, deliverables, milestones)
- Communications data (e.g. google & twitter analytics for website traffic)
- Key outputs, assets and achievements (e.g. publications, datasets, cohorts, tools developed)
- Gaps and needs.

It is anticipated that data collected as outlined above will be stored in text, spreadsheet or database format (.doc, .csv,.mdb or .xls) or as voice recordings and/or video recordings in the case of semi-structured interviews with projects (e.g. .mp3, .mp4 formats).

No sensitive data (e.g. personal, biological or clinical data) from research participants taking part in any of the IMI ND projects will be collected, stored or used in any way by NEURONET. Moreover, data collected from IMI ND project team members during semi-structured interviews, focus groups or surveys will be de-identified and transcripts anonymised, unless explicit agreement has been previously obtained from the individuals in question (see 6. Ethical Aspects for further information).

2.3 Re-use of existing data

As stated in 2.2 above, NEURONET will collect and re-use existing data on some of the key project parameters, e.g general information, composition of project consortium, as well as work plan information that can be collected from the CORDIS and/or public project websites.
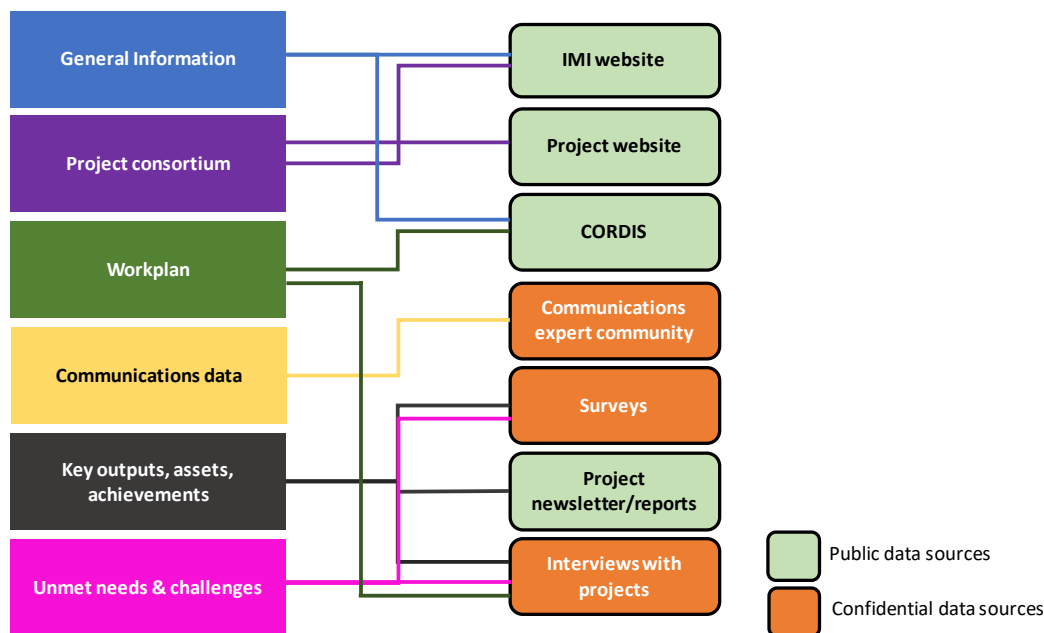
2.4 Origin of the data

NEURONET will collect and analyse general information and data from the following IMI projects of the neurodegenerative disorders portfolio:

1. ADAPTED
2. AETIONOMY
3. AMYPAD
4. EMIF
5. EPAD
6. EQIPD
7. IM2PACT
8. IMPRiND
9. MOPEAD
10. PD-MITOQUANT
11. PHAGO
12. PRISM
13. RADAR-AD
14. RADAR-CNS
15. ROADMAP

Figure 1 below shows the sources for the types of data and information listed in 2.2. As indicated in the figure, NEURONET will, wherever possible, collect and collate existing data that is publicly-available. Public data sources will include the project website, project entries in the CORDIS database, IMI website and project newsletters. Where necessary, NEURONET may also collect data from the projects using semi-structured interviews, focus groups or surveys. Data to be

collected in this way will include information on primary assets and outputs, and key gaps and challenges.

Figure 1. Data collection workflow. Shows the types of information/data to be collected (left) and the sources of this data (right). Green data source boxes indicate existing data that is publicly available, orange data source boxes indicate new data to be collected through interviews, focus groups or surveys.

2.5 Expected size of the data

NEURONET will initially collect information about the 15 IMI ND projects mentioned above (12 active, 3 terminated) but the list of projects will likely expand as NEURONET progresses and as new IMI ND projects begin. An estimation of data size for the project will be provided in the updated version of the DKMP (D5.2).

2.6 Data utility

Information and data collected by NEURONET will be used to:

1. Carry out the integrated analysis of the IMI ND portfolio (including a mapping, impact and gap analysis) as part of WP1 *Projects & Impact analysis.*
2. Establish synergies and collaborations between projects as part of WP2 *Programme integration.*
3. Develop specific guidance tailored to IMI ND projects in relation to data sharing, sustainability, ethics and interaction with HTAs and regulatory bodies and feed contents into the NEURONET Knowledge base as part of WP3 *Tools & Services.*
4. Compile communication strategies and support dissemination activities across the IMI ND portfolio as part of WP4 *Dissemination & Outreach.*

The stakeholders who are likely to benefit from the data collected are:

- IMI JU.
- IMI Neurodegeneration Strategic Governing Group (SGG).
- EFPIA and other industry representatives.

- NEURONET community (including NEURONET consortium partners and IMI ND projects).
- Policy makers at European Union (EU) and international level.
- Researchers, academics.
- Regulators, Payers and Health technology assessment (HTA) organizations.
- Related initiatives, e.g. European Brain Research Area (EBRA), Dementias Platform UK (DPUK) etc.
- Representatives of patient organisations/associations.
- Health and social care professionals.
- People living with neurodegenerative diseases and their carers.

3 FAIR data

3.1 Making data findable, including provisions for metadata

The focus of NEURONET is the analysis of existing information and data from IMI neurodegeneration projects to offer an integrated view of the IMI ND portfolio from a programme perspective.

Much of the information that will be collected by NEURONET will therefore be publicly available online, as outlined in section 2.4 above. Where public data is collected and used, NEURONET will ensure that the weblinks and Digital Object Identifiers (DOI) of the primary data sources are retained (e.g. on the NEURONET website and in the NEURONET Knowledge Base). In addition, a metadata spreadsheet of information collected from IMI ND projects will be maintained by WP1. This meta-data repository will be updated regularly and will act as a source file for information to be displayed on the NEURONET website and Knowledge Base (see 3.2.3 below).

3.2 Making data openly accessible

As indicated in 3.1 above, much of the source data that NEURONET will collect is already publicly available online. The knowledge generated as a result of NEURONET activities (e.g. recommendations, guidance documents, reports and white papers) will be made available to different audiences in various formats.

3.2.1 Project reports

Project reports comprising the progress of the NEURONET activities will be submitted to the IMI JU office once a year. Public deliverables will also be available for download from the NEURONET website.

3.2.2 Recommendations, guidance documents and white papers

Recommendations, guidance documents and white papers that are generated by NEURONET will be discoverable through the NEURONET Knowledge Base (see 3.2.3 below). A copy of such documents may also be shared with bona fide researchers who specifically request a copy by emailing info@imi-neuronet.org.

3.2.3 NEURONET Knowledge Base

WP3 *Tools & Services* will develop the NEURONET Knowledge Base, a free web-platform for the IMI ND community. The idea behind the NEURONET Knowledge Base is to provide an overview or summary of the IMI Neurodegeneration programme, in the format of a dashboard, where users can read and download information about the IMI ND projects (e.g. work plan, deliverables, results, tools developed, templates and documentation generated, etc.).

For security reasons, the registration of new users will be moderated by site admins. Access to the tool will require the use of an institutional email address in a verified registration process. The interface will be user-friendly and accessible using an internet browser such as Chrome. Identity of the users will be ascertained by means of an authentication process requiring username and password. The tool will be hosted in a virtual private server or server in an EU data center, and will only be accessed by pre-authorised users.

3.2.4   NEURONET publications

In compliance with Article 29 of the NEURONET Grant Agreement, publications directly arising from NEURONET's activities will use Open Access publishing. For publications arising as a result of collaborations with IMI ND project partners, the MoU established between NEURONET and collaborating projects states the following: '*Should the Parties like to publish and/or disseminate the results of collaborations, this will be done in accordance with the terms and conditions of their respective consortium agreements and the policies established by their consortia*'.

3.3   Making data interoperable

NEURONET will use common terminology wherever possible. For example, in semi-structured interviews and focus groups, NEURONET will generate a predetermined list of questions, using a glossary of standard terms. All information to be gathered from projects will be structured and collected in a standard way that enables the analysis of the data.

3.4   Increase data re-use

Due to the nature of the NEURONET project and the reasons exposed in previous sections of this document NEURONET will not make specific provisions for increasing data re-use.

Traction, buy-in and uptake of NEURONET's tools and services will be critical factors that will inform any future discussions about models for the exploitation of results or tools, such as the NEURONET Knowledge Base.

4   Allocation of resources

Data collection is amongst the project activities of WP1 *Projects and impact analysis* and development and management of the Knowledge Base falls within the tasks of WP3 *Tools and services.* All costs derived from these activities are covered by NEURONET budget.

The resources for long-term preservation and sustainability of the NEURONET Knowledge Base will be explored at a later stage, as part of task 5.3 CSA Sustainability.

5   Data security

An internal SharePoint repository managed by partner SYNAPSE is used for storage of NEURONET documents and information. Microsoft SharePoint has been chosen after an evaluation of similar systems as the best option in terms of security, General Data Protection Regulation (GDPR) compliance and ease of use. All NEURONET data will be backed up regularly, with up-to-date versions stored on NEURONET SharePoint. Metadata will include clear labelling of versions and dates. Although NEURONET does not involve processing of personal sensitive data, the project will establish a system for protecting data while it is being processed, including use of passwords and safe back-up hardware.

With regards to data compiled in the NEURONET Knowledge Base, partner SYNAPSE will take on the responsibility of developing the tool and its contents in compliance with GDPR. In order to have greater control over data access and prevent data leaks we will implement a verified registration process for new users of the NEURONET Knowledge Base, which will need to be manually moderated by site admins. When personal data is provided by users, they will be duly informed about the purpose for storage and processing of their data according to the principles of the GDPR.

6 Ethical aspects

NEURONET may carry out interviews, surveys and focus group exercises as part of the integrated programme analysis (task 1.3) and mapping, impact and gap analysis exercise (task 1.4) in WP1. A letter explaining the purpose, approach and dissemination strategy (including plans to share data) for NEURONET, and an accompanying consent form (including consent to share data) will be prepared for interviewees and focus group participants. Commitments to ensure confidentiality will be maintained by ensuring recordings are not shared beyond the NEURONET project consortium; that transcripts are anonymised and details that can be used to identify participants are removed from transcripts or concealed in write-ups. As the highly focused nature of the research means that many participants may be easily identifiable despite efforts to ensure anonymity or confidentiality, where there is such a risk, participants will be shown sections of transcript and/or report text to ensure they are satisfied that no unnecessary risks are being taken with their interview data. Interviews with leaders of IMI ND projects will also follow any request from the interviewees for sections they wish not to be recorded or made public, recording will be paused or sections of text will be expunged from shared transcripts, and an indication made that this is the case.

In the context of WP2 *Programme integration*, NEURONET will aim to facilitate the implementation of collaborations and synergies across IMI ND projects. To do this, NEURONET may create task forces, hold meetings or organise thematic workshops. In case of materialization of collaborations, these will be enacted between the projects directly, and therefore the ethical policies, rules and regulations being followed by the participating projects will apply.

7 Annexes

7.1 Memorandum of Understanding

MEMORANDUM OF UNDERSTANDING

BY AND BETWEEN

8 THE NEURONET CONSORTIUM

AND

THE XXX CONSORTIUM

This Memorandum of Understanding ("MOU") between the IMI2 Consortium *Efficiently Networking European Neurodegeneration Research* (*NEURONET*) and the Consortium ==Full name of the project (ACRONYM)== (both Consortia hereafter collectively referred to as "the Parties" or individually as a "Party"), expresses the willingness of the two Consortia to collaborate by establishing an overarching framework to facilitate interactions and exchanges of information between the Parties in accordance with the terms of the respective Consortium Agreements. This MOU is not a legally binding document. The Parties as designated are not considered as a legal entity. Separate appropriate formal written collaboration agreements shall be executed as required for any specific activities that result from this collaboration and need formalisation.

I. Background

NEURONET and ==XXX== projects are both funded by the Innovative Medicines Initiative, a pan-European public and private sector collaboration between large and small biopharmaceutical and healthcare companies, regulators, academia and patients. In the spirit of collaborative working across relevant IMI-funded projects, the *NEURONET* and ==XXX== consortia have proposed to establish a relationship to cooperate in a range of areas identified in Annex I.

The goal of NEURONET is to set up an efficient platform to boost synergy and collaboration across the IMI projects that address Neurodegenerative Disorders (ND), assisting in identifying gaps, multiplying their impact, enhancing their visibility and facilitating dovetailing with related initiatives in Europe and worldwide.

The goal of ==[project 2]== is to ==xxx==.

II. Purpose

The purpose of this MOU is:

- to establish the overarching framework for collaboration between the Parties, and
- to facilitate and develop existing synergies between the Parties and with other IMI ND projects in relevant activities, in accordance with policies and procedures for each Party and of the relevant projects.

III. Substance of Agreement

The areas on which the Parties agree to collaborate could include but are not limited to the following:

1. To maintain effective communication between the Parties to identify areas of

mutual research interest;

2. To foster exploratory discussions amongst scientists in the Parties and other projects in order to identify areas of shared scientific interest and potential collaboration;

3. To explore the sharing of information, knowledge and data that advance the mutual interest of the parties in accordance with policies and procedures for each Party;

4. To publish and disseminate the results of collaborations in accordance with the policies of each Party and their respective consortia.

5.   To participate at the NEURONET Scientific Coordination Board (SCB), formed by the leaders of the different IMI Neurodegeneration projects and to collaborate and identify synergies with the other projects represented at the SCB.

6. **To participate at the NEURONET Working Groups (WGs), formed by** representatives from projects who are experts in key priority areas.

IV. Operation of the collaboration

Each Party will appoint a contact person (see clause VII) to lead the interactions described in this MOU. Additionally, *[project 2]* will appoint representatives to actively participate at the SCB and WG meetings, engaging in discussions, bringing relevant topics to the table and providing their expert opinion as needed. NEURONET has elaborated Terms of Reference for participation in the SCB and WGs, which are part of this MOU as Annex 1. Project xxx agrees to convey and take all reasonable measures to ensure that the appointed representatives commit to the terms and conditions of this MOU.

For the avoidance of doubt, no disclosures of Confidential Information in the framework of the NEURONET activities and particularly during any meeting of the aforementioned SCB/WGs, are expected, in the spirit of open science and collaboration. In the event that disclosure of Confidential Information is desirable according to mutual interest, such disclosure shall be subject to confidentiality obligations acquired by the relevant NEURONET and/or SCB/WGs participants prior to their first receipt of Confidential Information via the corresponding Non-Disclosure Agreements (NDA).

V. Dissemination and publications

Should the Parties like to publish and/or disseminate the results of collaborations, this will be done in accordance with the terms and conditions of their respective consortium agreements

and the policies established by their consortia. The Parties are responsible of obtaining the corresponding approval of their respective relevant governance bodies, as required in accordance with the Consortium Agreements or established policies, prior to any communication or dissemination.

Authorship credit for any publication shall be guided by the usual practices of academic scientific publications (i.e. ICMJE recommendations), provided that all publication authors shall have made substantial contributions to the conception and design of the results described in the publication, the acquisition of the applicable data, and/or the analysis and interpretation of the applicable data.

VI. **Resource Obligations**

This MOU describes in general terms the basis upon which the Parties intend to collaborate. It does not create binding, enforceable obligations against any Party. All activities that may be derived from the collaboration framework established in this MOU are subject to the appropriate approvals and resourcing of the involved consortia, being each Party responsible of getting such approvals and providing any required resources. Separate agreements shall be implemented as needed to formalise any specific collaborations and before exchanging any confidential information.

This MOU does not affect the ability of the Parties to enter into other agreements or arrangements.

VII. **Appointed contact persons**

Communications and Liaisons related to this MoU
9   For NEURONET:
Name:
Address:
Tel:
Email:

For [project 2]:
Name:
Address:
Tel:
Email:

VIII. **Period of Agreement**

This MOU becomes effective upon the date of the last Party to sign ("effective date") and will continue until the termination date of the xxx project, which is set at *xxx*. This MOU may be modified by mutual written consent or terminated by either Party upon a 30-day advanced written notice to the other Party.

SIGNATURES OF PARTIES:

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR NEURONET

_____   Date _____
Name
Function

APPROVED AND ACCEPTED FOR *[project 2]*

_____   Date _____
Name
Position