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D6.6 – Interim patient expert group report on EPND platform and principles for health data and sample sharing

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Abstract

Deliverable 6.6 is the Interim Patient Expert Group report on the EPND platform and principles for health data and sample sharing/re-use. It reports on feedback provided by the Patient Expert Group (in the context of the Public Involvement work in EPND) on the topic of principles of health data and bio-sample sharing/re-use, and on the development of a lay glossary, which currently contains over 200 terms. This feedback and a revised version of the lay glossary will be incorporated later into the final PI deliverable (D6.10 on Patient Expert Group report on patient and participant trust in data sharing). Whilst people with neurodegenerative diseases and their carers/supporters are not users of the EPND platform or technical hub that is being developed, it is important that they continue to provide their data to researchers as research participants and to feel comfortable about how such data and bio-samples are managed and further shared or re-used. For this reason, it is important to hear their perspectives, views and possible concerns about the process of data and sample sharing/re-use and to maximise their potential to understand information they may come across on this topic (e.g. on the Internet) and, in particular, any information provided in participant-facing documentation such as informed consent forms and participant information sheets. The work outlined in this deliverable will be revisited and the lay glossary further elaborated in the course of the EPND project.

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Repository of primary data ..... **Fel! Bokmärket är inte definierat.**

Introduction

This document (D6.6) is the Interim patient expert group report on the EPND platform and principles for health data and sample sharing/re-use and is structured as follows.

- Methodology
- Public Involvement feedback:
  - Part 1: Attitudes towards health data and sample sharing/re-use
  - Part 2: Glossary of lay terms of relevance to information about health data and sample sharing/re-use
- Next steps
- Conclusions

In addition to the principles of health data and sample sharing/re-use, and the lay glossary, it was planned to seek feedback on the system or process to access data and samples available on the EPND platform. Unfortunately, work on this issue was not sufficiently advanced to enable a concrete proposal or even a series of possible approaches to be shared as a starting point for discussion. Whilst it is ideal to involve the members of the PEG early on, this has to be balanced by at least some details of what is possible and feasible, and to have technical input from the project partners involved in the development of the system and procedure. It was agreed that this was not currently possible. This issue will therefore be addressed at a later date, together with the issue of ongoing participation of lay people (especially those who have neurodegenerative disorders) in the future governance of the final platform/hub. This will then be incorporated into the final PI deliverable (D6.10 on Patient expert group report on patient and participant trust in data sharing).

Methodology

The information in this deliverable was obtained via a series of face-to-face and zoom consultations in parallel with three different groups, namely people with dementia (e.g. with Alzheimer's dementia, Dementia with Lewy bodies, Frontotemporal dementia etc.), people with Parkinson's disease and parkinsonism, and carers and supporters of people with dementia in June, November and December 2023 and in January and February 2024. The people involved in these consultations were the members of the European Working Group of People with Dementia (please see: https://www.alzheimer-europe.org/about-us/european-working-group-people-dementia) and their supporters and the members of the Parkinson's Advisory Group (GAP), known collectively as the Patient Expert Group (PEG). There are currently 15 members of the EWGPWD who have contributed to the EPND PI work so far from 11 different countries. There are 17 members of the GAP from 10 different counties within Spain and they do not usually all participate in each consultation. The men and women who were members of the PEG (i.e. both groups combined) were aged between 50 and 82. There were people from rural as well as urban areas, people living in their own homes or in semi-residential care settings, and single people as well as people living with partners.

The consultations were moderated by Alzheimer Europe and the Federación Española de Párkinson respectively. Audio recordings were taken so as to enable the moderators to focus on the discussion and ensure that everyone was involved. Background information was sent one to two weeks before the consultation and this included five extracts on the topic of health data and sample sharing/re-use from real informed consent forms, obtained from EPND project partners. Feedback was summarised and organised into a coherent structure. In some cases, general agreement was noted with regard to a certain

issue and also cases where one or two people had a totally different perspective or opinion. However, this should not be considered as "analysis" of "data" and the feedback provided should not be considered as being generalisable. By means of a bottom-up approach, the people involved in this Public Involvement activity shared their unique insight, priorities, concerns and recommendations with the goal of improving the EPND research process, including the development of the platform/hub.

The focus of these consultations was on:

1. principles for health data and sample sharing/re-use:
   a. by researchers who initially collected the data or samples for a specific research use, and would now like to use it for new research activities;
   b. by researchers not involved in the collection of the data or samples, who would like to use the data or samples for new research activities
2. the development of a lay glossary (i.e. a list of terms with accompanying definitions targeted at members of the general public who are not specialists in any or all of the domains covered).

Part 1: Public Involvement feedback on principles for health data and bio-sample sharing/re-use

A principle is a basic idea or rule that explains or controls how something happens or works. It may serve as a foundation for a system or to guide behaviour (e.g. in the case of ethical principles). Principles may be documented and formally adopted by groups or organisations (such as the White Paper currently being developed by WP2 which the Patient Expert Group (PEG) will also contribute to). The feedback about principles related to health data and bio-sample sharing reported in D6.6 was carried out in the framework of the Public Involvement work. The aim of such work is to ensure that researchers benefit from the unique insight that people with neurodegenerative diseases and their carers have, thereby giving the latter a voice in research about their condition and also improving the research process.

Scope and terminology surrounding the sharing/re-use of health data and bio-samples

The consultations focused on issues related to sharing/re-use of health data and bio-samples collected in the context of clinical research. They did not cover real-world data, which relates to patient health status and/or the delivery of health care that is routinely collected from various sources, or specifically focus on the concept of big data. For this reason, we did not use the term "secondary data" or "secondary use of data", which would have had a broader coverage. An important part of the consultations was to ensure that everyone was discussing the same thing. It was therefore necessary to check people's understanding of the terms being used. This was also useful information for the development of the lay glossary. The following sub-sections each reflect an issue or concern that was raised with regard to the specific terms.

Health data and bio-sample sharing/re-use

The terms "health data and bio-sample sharing" and the "re-use" of health data were sometimes confused with the initial provision of data or samples within a particular study. This is because people also use the term "sharing" to describe the initial *provision* of data and samples to researchers in terms of "sharing" information about themselves, their perspectives and various samples. It was often necessary for the PI team (AE and FEP) to clarify whether a particular point being made was in relation to the initial provision of data (which was not the aim of the consultation) or to the sharing/re-use of that data for further research.

It was suggested that the distinction between sharing health data and re-using health data is not always necessary and that it is not possible to distinguish between the two in some languages (e.g. in German and Finnish). The term “re-use” had different connotations for different people, ranging from being interchangeable (with “sharing”) to it representing a more active use of health data than is the care for sharing (i.e. data is not only shared with other researchers but there is an implication that they actively “use” it for further research).

To summarise, the terms “sharing and re-use” of health data and bio-samples were not always understood and the term “sharing” was sometimes confused with the initial provision of health data and bio-samples for research projects.

Health data

The consultation covered the sharing/re-use of “health” data and “biological” samples. The distinction between the two was quite well understood. However, the term “data” alone was considered by many as being too broad a term. This was reflected in the following definitions they provided when asked what data means:

- literally anything (e.g. bank details, age, height, gender, having a particular condition or blood type)
- written down information about biological samples
- all the information and samples collected by the research team
- just sociodemographic or contact data.

Both groups concluded that research teams should always clearly specify (e.g. in information available to the public about their study or in informed consent forms) what data they are referring to (namely, health data or more specifically genetic data, brain scan data etc.) in order to avoid generating doubts and creating misunderstandings.

It was suggested that even when the term “health data” is used, examples of what it covers should be provided. Some people preferred the term “clinical data” or “anonymised clinical data”. They felt that it was more obvious what it meant but that examples should still be provided. It was not clear to several people that either of the two terms (i.e. clinical or health data) excluded personal data.

To summarise, the terms “health data” and “clinical data” were considered clear and acceptable.

Biological samples

Samples were understood as being small quantities of biological material (described by some people as “physical body parts” or “things that have been taken from the body of a human being”) such as urine, stool, saliva and blood. It was agreed that researchers should use the terms “bio-sample” or “biological sample” rather than just “sample”. For this reason, we are using the term bio-sample throughout this report.

Bio-samples are available in limited and diminishing quantities, determined by the quantity initially collected, the amount already used and how long they can be stored. Whatever is left of the bio-sample can, in principle, be used in a further study as opposed to destroying it. One person stated that she was not sure whether in research projects the sharing/re-use of samples was always on the basis of “left-overs” or whether researchers might take some samples (that they do not intend to use in their current study) solely for future sharing/re-use.

The reference to CSF (cerebrospinal fluid) samples in Example 4 (see Appendix 2) was not understood by everyone. It was suggested that it should be written in full and for the sake of clarity "taken from a lumbar puncture" should be added, even if this was already explained in the Participant Information Sheet. The reference to a specific type of bio-sample was considered good practice as people then know exactly what the researchers are interested in potentially sharing beyond the initial study. However, some people would prefer to have the opportunity to give overall consent to the further use of all their health data and bio-samples. To summarise, the terms "biological sample" or "bio-sample" were considered clear and acceptable, and thus preferred.

Key reasons for interest in sharing/re-use of health data and bio-samples

Everyone was keen on the principle of health data and bio-sample sharing/re-use. This was accompanied by some concerns or wishes related to how this was achieved, which are discussed later in this report.

Interest in the advancement of science and drug development

People involved in research into neurodegenerative disorders often describe being hopeful about scientific progress, especially in the area of drug development. This tends to be accompanied by an understanding that drug development is a lengthy process and may come too late for many people. Members of the group expressed an interest in the sharing/re-use of data and samples to help with the development of drug treatments for neurodegenerative disorders, not only for themselves but also for other people (future generations). This included accepting possible risks related to privacy if it meant that this might contribute towards helping find a cure for dementia and other neurodegenerative disorders. Some people felt a sense of pride and satisfaction in being able to help others and to continue to contribute towards society or their community in an important way. Some people with less common forms of neurodegenerative diseases were particularly keen for researchers to share and re-use their health data and bio-samples for research in under-represented conditions.

Altruism

The motivation to share health data and bio-samples was also linked to the concepts of altruism and reciprocity. Altruism is about people putting other people's interests ahead of their own. It reflects a desire to help or benefit other people without being under any obligation or pressure to do so. It is a selfless act, involving a desire to help or benefit other people, even at the risk of people jeopardising themselves or their own interests. Such jeopardy could involve issues related to data protection and to the possible impact of mis-use of data. Altruistic goals were reflected in statements about wanting to benefit future generations and other people in general. One person described taking part in research, sharing data and PI as a form of philanthropy.

> *"I am proud to share my data because it helps people in the future. All these things we give to the researchers. They can use it." (Jack)*

> *"I would like to share data if it will contribute to helping others." (Maria)*

Altruistic goals were not solely limited to benefiting people with a similar condition. The need for a broader focus for research into brain diseases was suggested as a possible way to discover links between different conditions and there was general agreement that the sharing/re-use of data should not be limited to neurodegenerative disorders.

> *"I would be happy for my data to be shared with anybody who would find it useful, regardless of whether it pertains to dementia or any other condition." (Pierre)*

Reciprocity

Reciprocity is a social norm whereby people typically wish to give something back for what they have received. In the context of data sharing/re-use, people described a desire to contribute towards society through research. This wish was linked to the initial provision of data and samples, as well as to data sharing/re-use. The contribution to society included helping others (as mentioned above) but also helping ensure that researchers have the necessary data and samples to conduct worthwhile research (which in turn will benefit society). The reciprocal nature of data sharing/re-use was also linked to appreciation of the sacrifices, effort and risks that others had made in the past (i.e. in the context of research), which they were currently benefiting from either in the form of effective drugs or through support and care.

> *I feel that I have received so much support and assistance as a result of previous research, so it is very important to me to contribute back to the community." (Nelly)*

Reciprocity can also be understood as researchers giving something back to the people who initially provided and/or allowed for their data and samples to be shared or re-used. One suggestion was for researchers to contact people who had shared their health data or bio-samples, even 10 years later, to explain how that data (in the sense of datasets rather than individual data) had been used insofar as it is possible to do so. However, it was agreed that even just knowing that health data or bio-samples from a certain number of people in a particular study or cohort were used in another study some years after they were initially provided would be good. People would know that it was possible that their data or samples were used for that additional research. It was agreed that general information could be sent back to the participants of the original study explaining how the health data and bio-samples were used for the further research and thanking the participants of the initial study. There may, however, be some restrictions linked to contacting people who did not agree to be re-contacted, some people may have since been placed under guardianship with the result that such information might actually be shared with other people (i.e. a breach of confidentiality) and many people will no longer be reachable at the address initially provided.

Contributing towards research in under-researched conditions

Some members of the group have forms of dementia which are somewhat under-researched. They were keen on health data and bio-sample sharing/re-use as a means to maximise available data and samples so as to enable more research into these conditions. This could also apply to data and samples provided by people from minority ethnic groups.

Data protection

Levels of confidence in the protection of shared/re-used data and samples

Many people share personal information about themselves, their family and friends, their health, hobbies and their views on a daily basis (e.g. through social media such as Facebook, at the checkout in supermarkets and whilst surfing the Internet). This is a personal choice but people also often tick boxes on forms or on the Internet authorising the sharing of information without paying great attention or even reading the details of what they are agreeing to. In other cases, they may simply be unaware or insufficiently informed about information they are sharing and the consequences of this. The sharing/re-use of health data and bio-samples was considered normal and just part of the overall trend towards data sharing in everyday life. An important difference between the numerous examples of data sharing in daily life and the sharing or re-use of health data in the context of research is that for the latter, people have already consented to their data being used and the issue is about whether they agree to it being used for additional research

A few examples of breaches of data security, faulty data systems and the mis-use of people's data in different countries were mentioned, in each case having resulted in catastrophic consequences for hundreds and thousands of people. There was, however, evidence of trust in the research community. In an earlier research project on the use of AI-based prediction tools, this was described as a "desire to trust", meaning that people wanted to feel able and justified in placing their trust in researchers.

There was some degree of suspicion regarding data protection and security issues during the transfer of health data and bio-samples. Although it was understood that the data are coded to render people unidentifiable, and despite being convinced of the importance of sharing/re-using data and samples, feelings of insecurity and lack of control over their contribution to the research were mentioned. The fear was that possible security breaches might result in shared personal data being unprotected. It was suggested that people should be informed and their permission sought each time their data is shared, prior to such sharing and even when people have consented "broadly" to such sharing/re-re-use in the informed consent form.

A few members of the group expressed concern about the security of databases, adding that "no database in the world is entirely secure" and highlighting some of the inherent risks associated with sharing data and samples. This was more of an observation than a reason not to consent to the sharing/re-use of their data and samples.

Anonymity

In their comprehensive "Guidance on Anonymisation and Pseudonymisation" (2019), the Data Protection Commission describe the effective use of anonymisation and pseudonymisation as helping protect the privacy rights of individual data subjects (i.e. people who provide and/or further share their data), whilst allowing organisations to balance this right against their legitimate goals. Anonymisation means irreversibly preventing the identification of the person to whom it relates and involves securely deleting the information identifying individuals such that data cannot be linked in any way to the people who provided it. For some forms of data (e.g. genetic data), this is practically impossible and there is a risk that it might be possible to identify the person to whom it relates at some point in the future. Pseudonymisation involves the removal, replacement or transformation of information that identifies individuals (e.g. names, addresses or details of physical characteristics) and keeping that information separate, to preserve privacy and confidentiality. The distinction between the two processes and types of data is important because data which has been irreversibly anonymised (which it is generally considered impossible to claim with 100% certainty) is no longer considered as personal data and does not fall under the protective measures of the General Data Protection Regulation.

In the context of the PI work, privacy of health data was not a major concern for everyone and was often balanced against the desire to contribute towards scientific progress, particularly in relation to drug development. A couple of people stated that they would not mind if their names were disclosed and that if personal data constituted additional information that was important for the purpose of research, then sharing that data should take priority over anonymity. Another felt that anonymity was more important in relation to attitudes and opinions than for bio-samples as the former are more personal.

> *"I'm happy to share everything. I have no concerns, even using my name. Also, where I live… it might be useful for researchers to understand my location. I even want to go further than what might be covered in a consent form. Share everything!" (Stefan)*

Overall willingness and interest in the sharing and re-use of health data and bio-samples was, for most people, dependent on measures having been taken to ensure that it could not be traced back to them. Some described this as rendering them untraceable, others as having an anonymous identifier. There were individual differences regarding the perceived importance of anonymity depending on what would be shared or reused (e.g. attitudes and opinions, biological samples or details of personal medical history).

Given the reported importance of anonymity in relation to health data sharing/re-use, we asked for feedback on related terms typically used in informed consent forms. People with dementia and their supporters were shown several extracts from consent forms that had been collected from different project partners (please see Appendix 2), and were asked how clear/understandable they were.

- The terms “anonymous” and “anonymised” were not considered problematic and were by far the most popular of the terms used when referring to different aspects of or approaches to ensuring that health data and bio-samples cannot be easily or in any way traced back to the people having provided them. A few people, were aware that health data can never be 100% non-retraceable. The definitions provided in the pre-reading materials for the consultation were considered as being understandable and helpful. However, during the consultation some people used the terms “anonymised” and “pseudonymised” as if they were interchangeable, often saying “anonymised” when describing “pseudonymised” data or processes. Therefore, whilst people were generally comfortable with the “anonymity” terminology, some had not fully grasped the meaning of the term in the context of data sharing within research.
- The term “pseudonymised” was considered neutral by some people and scientific jargon by others. A few people did not understand what it meant and pointed out that dictionary definitions of “pseudo” typically refer to something that is “not genuine”, “spurious or a “sham”. It was also suggested that “pseudonymised” implies that something is not real and therefore the term has negative connotations.
- Terms such as “coded” and “de-identified” were more problematic. The term “coded”, for example, was considered neutral by some people and incomprehensible or too technical by others. Some people did not understand it as being linked to anonymity (or pseudonymity). Others commented that it suggested a lower level of security (in terms of traceability and reidentification).
- Some people felt that the term “de-identified” suggested taking people’s identity away (in a personal/negative sense) and that anonymous was therefore better. The phrase “only de-identified data, which does not include anything that might directly identify you” was considered confusing, technical and difficult (especially for non-native English speakers).

Shared health data and bio-samples should always be anonymous even if the initial data was pseudonymised but this can be quite difficult to achieve or fully guarantee from a legal/data protection perspective. Researchers therefore often prefer to talk about pseudonymisation even when all attempts have been made to anonymise health data or bio-samples in the strict sense of the term. Whilst this may be in the interests of research participants (i.e. not to claim to have fully anonymised data when in fact this cannot be guaranteed with 100% certainty), it may result in some confusion, lack of clarity and even to distrust of researchers.

To summarise, the preference for “anonymised” related terminology seems to be linked to the fact that it is easy to understand and straightforward, rather than to people preferring the actual anonymisation of health data in accordance with the GDPR definition. Discussions seem to indicate that what people really

wanted was “to share everything” and for their health data not to be easily traceable back to them (which is achieved through pseudonymisation, the less popular and less well-understood term). So, whilst people had preferences for specific words, the bigger problem is that some misunderstood the meaning of certain key words, which also emphasises the importance of the lay glossary that is currently being developed (see Part 2 of this report).

Confidentiality

Confidentiality is about keeping things secret or private. This means not sharing personal information without the consent of the person concerned and ensuring that any such information is protected from improper access, disclosure or loss. When data goes beyond primary research, it must be anonymous, and confidentiality should no longer be an issue (i.e. as the researchers acquiring the data and samples do not possess the personal details of the people who initially provided it). However, feedback from the group suggested that this was not sufficiently clear to everyone. Some people had concerns about their personal details being shared with third parties not connected to the initial research team to whom they had provided it. This included concerns not only about other researchers receiving identifiable information but also relatives, colleagues, employers, friends and insurance companies.

> *“Prior to diagnosis, I would not have wanted people to know about my high blood pressure.” (Kevin)*
>
> *“I would have concerns about my data being disclosed to people in my workplace." (Lilo)*

Conditions and restrictions on sharing/re-use of data and samples

Transparency and respect for autonomy

The importance of transparency regarding the sharing or re-use of health data and bio-samples was of paramount importance to most people. For some people, the main issue is transparency and trust, in that they want to know exactly how their health data and bio-samples might be used in the future, by whom, where and for what purpose. This then allows them to consider whether or not to agree to such sharing or re-use, thereby exercising their autonomy. This occurs via the informed consent procedure and is dependent on how clearly explained the sharing and re-use of data is, as without clarity consent cannot be considered as informed and autonomy cannot be considered as having been respected.

It is also important to ensure that people realise that in most cases they will not be asked again about sharing the health data or bio-samples that they are providing in the initial study if they consent to health data and bio-sample sharing/re-use. For some people, this did not correspond to their concept of autonomy with regard to maintaining control over the possible future use of their data and samples. Whilst expressing a keen interest in research teams making the maximum use of their data and samples to advance knowledge about neurodegenerative diseases, they still felt that they should have the following rights:

- to be informed whenever their data or samples are shared, even after signing the informed consent form.
- to be informed which research team, entity or institution those data and samples are going to be shared with before the exchange takes place.
- to have the power to give or withhold permission for their data and samples to be shared (e.g. depending on who would receive them and for what purpose they would be used), even if they have signed an informed consent form.

Clearly this may not be possible and if so, this would need to be clear to participants so that they can make an informed decision on that basis.

Sharing/re-use of data and samples with/by external or commercial companies

The term "commercial" companies or organisations was understood differently by different people and it was generally agreed that it suggested that when used, it should be defined. Concerns about the sharing/re-use of data and samples was largely dependent on the type of company or organisation that people understood the term to be referring to (e.g. an insurance company, a technology firm developing a monitoring device or a pharmaceutical company). It was also considered important to specify whether an "external" organisation is commercial or not and for what purpose the organisation would use the data or samples.

There were fairly mixed views amongst members of the EWGPWD compared to the members of the GAP who had more doubts and expressed greater distrust. Their main fear was of data and samples being used for commercial rather than research purposes (i.e. to companies making a profit from their data and samples). Some people stated that they would feel reassured if the data custodians were patient organisations, as this would give them greater confidence in the preservation of data security.

There were some concerns about data and samples being used solely in the interests of profit and not for the purpose of conducting or contributing towards worthwhile research. Another concern was the data and samples might be sold to companies for marketing, sales or insurance purposes. This was described by some as being ethically questionable.

Despite the above-mentioned concerns and criticisms, there was some degree of recognition that commercial organisations should not be considered as being "all bad". Some people emphasised that research can be both profitable and worthwhile and suggested that companies have huge role to play in developing much needed drugs. The crucial role that some commercial organisations play in research in developing drugs and improving diagnostics was recognised, including the provision of much needed financial resources to academic institutions.

> *"I would be happy for my data to be shared with pharmaceutical companies because they are involved in developing new medicines. So even if they are driven by profit, if they can cure me, that would be OK". (Inge)*

With regard to the involvement of commercial companies in research, it was deemed important for researchers to be transparent about any possible sharing of health data and bio-samples with them (e.g. in informed consent forms). Example 1 (see Appendix 2) was described as easy to understand and simple but it was suggested that people would not necessarily realise that this could include sharing health data with commercial organisations. For example 2, on the other hand, it was felt that as it contained important details and examples, it would help people make an informed decision about the possible future use of their data and samples.

Example 3 was particularly appreciated for the amount of detail about the purpose of the sharing/re-use, the area of research, who might receive the data and samples and the issue of research ethics etc. It was felt that the amount of detail made people feel more secure and would lead to a more considered response.

Ethically-approved research

Some of the informed consent forms referred to ethically-approved research. Some people felt that it was not necessary to state this as all research has to be ethically approved. However, others pointed out that although this is or should be the case, it is good to have the safeguard of this being a condition for sharing/re-use and to reassure people who might not be familiar with research practice and requirements. Also, it is possible that requests are made for data from non-academic researchers who do not have access to research ethics committees or are not dependent on having such approval.

A distinction was made between possible references to ethical research and ethically approved research. Some people thought it was sufficient to state that the researchers receiving the data or samples had the appropriate ethics approval for their research. Others, however, felt that it was important to know that they were contributing towards research that was broadly consistent with their ethical values and principles. The value of research ethics approval in certain countries was questioned as a guarantee of ethical research (see sub-section below).

Geographical boundaries to data sharing/re-use

In some informed consent forms, there are details of geographical boundaries to the sharing of data linked to levels of data protection and/or ethical standards or an acknowledgement that ethics approval and data protection standards may be lower in the country receiving the data or samples (see Example 5 in Appendix 2). Some people had concerns about sharing and re-use of health data and bio-samples in counties which might have different ethical values and standards. Most were comfortable with data and sample sharing/re-use within "Europe" (which seemed to reflect countries in the European Economic Area as well as the UK), and less so for more distant locations (e.g. in China).

> *"I might want an option about location because of concerns about ethical reuse beyond Europe." (Agata)*

> *"I would feel safer if it was regulated by my country or area (Europe)." (David)*

The reason for such caution was the belief that controls may be less rigorous outside of "Europe", and might not meet ethical standards comparable to those in the country where the data or samples were obtained. Another concern was that there is no guarantee that research ethics committees in Europe reflect the ethical values and principles of the people who agree to the sharing of their health data or bio-samples. The likelihood of divergence from personal beliefs was considered greater in countries perceived as having very different cultures, traditions and regulations than in the country where the data and samples were initially collected.

> *"It's got to be officially regulated by the country or a university. And that's why I am not racist but would stick to Europe because I know that some countries have regulations that are very below standard." (Saoirse)*

> *"Yes, and their stamp of approval is not quite the standard of a European one." (Manuel).*

Concerns about data protection standards being possibly lower outside of Europe, this was balanced by the belief that only anonymised health data and samples would be shared.

> *"But If data is anonymised, once it is anonymised, it is just a number that can never be traced back to me. If there is not the same amount of data protection, what harm can that do if data is shared in another country?" (Paula).*

This was, however, not reinforced by one of the Informed Consent Forms which requested consent for "pseudonymised data" to be "transferred to countries outside the European Union that may not provide the same level of data protection as provided within the European Union, within the terms explained in the Subject Information Sheet". One of the groups reflected on the importance of transparency versus ambiguity, and how this might impact on readiness to consent. The issue of trust was also considered in that it was suggested that very brief statements (like in Example 1) might suggest that people are not being told everything.

> *"That final paragraph in Example 5 just gives me fear and makes me not want to share. But even though it doesn't say anything about that in Example 1, I am not scared about sharing. But it's exactly the same thing" (Hanna).*

The question about whether research is conducted in an ethical manner in some countries (particularly those outside Europe) was not everyone's main concern. Some people were entirely open to their data and samples being shared/re-used in any country.

> *"I don't mind where my data or samples are shared, or for what purpose." (Oskar)*

> *"In general, if it can be used to find out things… it's sometimes a genetic problem of a small group of people… and if I can help by donating a sample, and later it goes to China… I don't care. If it helps a person, that's what matters." (Einar)*

Benefit to others

In some informed consent forms, it is stipulated that health data and bio-sample sharing/re-use would only be for research for the future benefit of patients with Parkinson's and related conditions or with neurodegenerative diseases. In others, it is stipulated that such data and samples would be used for future academic or biomedical research. In addition to the interest that most people had in their health data and bio-samples not being restricted to research into specific conditions, the term "benefit" was problematic. Some of the comments made reflected an awareness that research is about testing hypotheses and by definition it is not possible to know in advance whether a particular study is going to be beneficial for any group of people. Others felt that the reference to benefit could put psychological pressure on people to share their health data and bio-samples.

> *"We don't know if it is going to be of benefit until they've done the research and even research that has no results [in the sense of the hypothesis not being supported] can lead to research that has results." (Hanna)*

> *"It's detective work. I'm into sharing data whether it is of benefit of not. I just want to see things going forward." (Minna)*

> *Referring to benefit to other people with similar conditions might make people feel bad or guilty about not consenting to it, so it is like a subtle form of pressure. (Saoirse).*

The group agreed that it was a very personal matter and that people should have the choice about whether or not to share their health data and bio-samples with researchers in different countries. The group was pleased to hear about the practice of some researchers who set a condition that any future sharing of their health data and bio-samples would need to be authorised by the ethics committee in their country.

Recommendations

The following recommendations draw on the feedback provided in the context of the PI work and are targeted at researchers, from within and beyond the EPND consortium, when preparing general information for lay people about research involving the sharing and re-use of health data and bio-samples and documentation linked to the informed consent process.

The recommendations are particularly relevant to individuals and organisations collecting initial data and making it available for re-use/sharing, but also to EPND partners who are responsible for managing the sharing/re-use of that data through the platform/hub and are in a position to encourage the adoption of the recommendations.

These will, however, hopefully be discussed further by lay people, researchers and EPND project partners, and further refined towards the end of the project, perhaps resulting in a short stand-alone document on the EPND website.

- inform people about the possibility of health data and bio-sample sharing/re-use,
- provide clear explanations about what is meant by the sharing or re-use of health data and bio-samples,
- provide a clear definition and explanation in Participant Information Sheets, Informed Consent Forms and any other participant or public-facing information about the difference between anonymity and pseudonymity in relation to the sharing/re-use of health data and bio-samples in research,
- ensure that terms are being used accurately and consistently, and either correct or ask for clarification from co-researchers when this is not the case,

- target information not only at people with particular neurodegenerative conditions but at members of the general public (who might now or later also take part in research and consider sharing their health data and bio-samples),
- reach out specifically to individuals who may not know how to find out about contributing to research through health data and bio-sample sharing/re-use,

- provide brief information about where health data and bio-samples could be used,
- provide details and examples of how health data and bio-samples could be shared/re-used
- provide details and examples of the kinds of organisations that would be eligible to receive health data and bio-samples,
- provide a list of counties with which health data may be shared and explain why this might be important to consider (in relation to data protection and ethical concerns),
- give people an option to restrict data and sample sharing/re-use to specific geographical areas,
- give people separate options (i.e. to opt-in or opt-out) for the sharing/re-use of health data and bio-samples in general and in relation to specific conditions (e.g. geographical areas or commercial companies),

- provide general information and training on database management so that people have a better understanding both of the opportunities to contribute towards research and the potential risks involved,

- ensure that information, training, participant information sheets and informed consent documents are not culturally biased and “speak” equally to different societal groups and people with specific needs,
- use clear and simple language so as to ensure that information is accessible to everyone,
- ask for feedback from lay people (i.e. within the framework of Public Involvement) when developing Participant Information Sheets and Informed Consent Forms to help ensure that various terms linked to the topic of health data and bio-sample sharing/re-use are understandable to lay people,

- ensure that it is clear in relevant clauses in Informed Consent Forms that only anonymised (non-identifiable) health data and bio-samples might be shared,
- specify as clearly as possible in the informed consent form which data and/or samples might be shared/re-used,
- indicate in the Informed Consent Form not only whether health data and bio-samples might be shared (subject to the person’s consent), but also whether specific consent will be sought before any such sharing/re-use takes place (i.e. every time),
- avoid using generic terms such as "external commercial organisations" (clearly specify what type of organisation it is/could be),
- include a clause which states that people understand that if they consent to health data and bio-sample sharing/re-use, they will not be asked for their consent each time such data or samples are shared (unless this is not the case).

Part 2: Lay glossary of research-related terms for the general public

Introduction

A key goal linked to the sharing and re-use of data is that participants in research studies are properly informed, understand what is involved and can make a fully informed decision whether or not to do so. Biomedical research is complex and has its own vocabulary, which many lay people are not familiar with. The data and samples of people with neurodegenerative diseases are valuable to researchers but people with such conditions tend to have additional challenges related to reading and comprehending complex and specialised texts. It is therefore essential for all concerned to ensure that texts are as accessible as possible to lay people. This glossary was developed by the Patient Expert Group (i.e. by members of the EWGPWD and the GAP) together with Alzheimer Europe (AE) and the Federación Española de Párkinson (FEP) through a series of consultations and written feedback. The background information for the consultation in January 2024 can be found in Appendix 4.

Methodology

A selection of terms was first proposed by AE, building on glossaries that had been developed over the years mainly in the context of its ethics working groups which included people with dementia and carers/supporters, some of whom were also from marginalised groups, as well as philosophers, clinicians, healthcare professionals and experts in each relevant domain. These terms were organised into different categories to facilitate discussion and enable members of the Patient Expert Group (PEG), consisting of the EWGPWD and the GAP, to spot gaps and reflect on topics that were more or less important or useful to them. A separate list of acronyms was developed.

The terms and acronyms, accompanied by a first draft of definitions, were circulated to the members of the EWGPWD prior to an online consultation and then discussed during a virtual meeting. Following feedback and the elaboration of a new draft of the glossary, each revised term and definition was checked by at least one person with dementia and amended accordingly. Some of the acronyms were included both in the list of terms and in the list of acronyms. This is because the full terms are seldom, if ever, used and for some (e.g. DNA), few people know what the full term is.

The list was then discussed by the members of the GAP who provided further feedback and suggestions for additional terms. FEP also shared a few lay glossaries on Parkinson's disease and parkinsonism in English from international organisations and merged these terms into a section on Parkinson's disease and parkinsonism. For practical reasons and issues related to resources, this was considered preferable to translating terms from Spanish into English, back-translating for verification of accuracy, checking glossary items with native Spanish-speaking lay and academic experts and making any necessary linguistic and cultural adaptations. This will need to be acknowledged when the glossary is eventually made public. Members of the EWGPWD and the GAP provided feedback on the possible layout, structure, functionality and dissemination of the future lay glossary separately in a series of online consultations.

On the basis of this feedback, the lay glossary was further elaborated and in addition, two additional sources were checked for any terms that were not already in the glossary that might be helpful to lay people, namely:

- the filters of the EPND catalogue (https://discover.epnd.org/catalogue/studies)
- the data dictionary (linked to the EPND catalogue) currently being developed by the cohort interaction work package.

The additional terms, from the two above-mentioned sources, which will be further developed, can be found at the end of Appendix 3, after the list of abbreviations and acronyms. The terms and definitions which currently make up the lay glossary can be found in Appendix 3. As explained in the section "Next steps", the lay glossary is "work in progress" and will be updated and further elaborated during and beyond the project.

Feedback within the context of the Public Involvement work

The key issues discussed and feedback provided by the PEG so far are as follows:

Structure and layout

As stated above, the terms in the glossary had been organised into categories for the purpose of helping members of the two groups to think about any useful terms that could be added. Glossaries are, almost by definition, structured in alphabetical order. However, rather than assuming that this would be the default structure of the lay glossary, we asked to comment on what people preferred. Everyone agreed that the glossary should be presented in alphabetical order.

A few people liked the different categories. They felt that it would be interesting to find out more about different terms linked to a particular theme. This would be more in the context of familiarising themselves with different specialised terminology as opposed to using the glossary to find a specific term that is not understandable when reading a text. The conclusion was that the glossary should ideally be in the standard form but if it were possible to also have a version structured around different themes, that would

be a bonus, even though there would most likely be some overlap between the terms in the different sections.

Regarding layout, the examples we found on the Internet were broadly similar, consisting of a term followed by a definition (either below or to the right of the term). Several examples were shown to the group which were considered equally acceptable.

Search method

There was general agreement that the best way to find a word would be to click on a letter of the alphabet and then to look for the required term by scrolling down the list and then to click on the term if it is included in the glossary. A few people felt that this method was good but that it should also be possible for users to search the glossary by typing the word they are looking for in a text box.

Accessibility and user-friendliness

It was suggested that all types of disability should be considered and therefore that it should be possible for users to adapt the size of the font, the colour and background of the glossary.

A few people suggested adding examples to the definitions. This may help people who have difficulty understanding abstract concepts and would benefit from something more concrete that they might be better able to relate to.

Another suggestion was for users to be able to change the language. This had not been envisaged in the project proposal. Whilst three of the five people supporting the PI work are native Spanish speakers, we nevertheless decided to focus on an English version alone rather because we did not have the available resources for professional translation and for the additional work that would be needed to ensure that any non-English versions would be adapted to a lay audience. This is also the reason why the Federación Española de Párkinson provided existing glossaries in English, as well as providing feedback on the English terms and definitions being developed.

Lay people across Europe, who might be interested in and willing to consent to their data and samples being shared/re-used, do not all necessarily have sufficient knowledge of English to understand complex texts in English even with the help of a glossary. Moreover, they would probably have signed consent forms and received information in their mother tongue. Additional language versions would therefore be beneficial to a wider range of people but would need to be developed with input from lay people, including those with neurodegenerative diseases and their supporters.

Navigability

Although the alphabetical structure of the proposed lay glossary was considered straightforward, it was suggested that there should be a system to help users find their way back to the start of the list or to where people can select a letter or type in a new term. A simple but clear and sufficiently large “Go to the top” button was suggested.

A different button might be appropriate in the case of cross referencing (see below) so that people can go back to the initial term that they were looking at rather than back to the start of the glossary. This was not discussed.

Cross referencing

A system of cross referencing was described whereby terms that are used in one definition might be explained in more detail elsewhere in the glossary. This was considered very helpful and it was suggested

that such terms could perhaps be highlighted in a different colour (but not green or red) or put in bold, italics or underlined. The precise method for highlighting the cross references would need to be clearly explained and visible from any place in the glossary. As mentioned above, this would need to be accompanied by a clear and obvious way to return to the original term or to the start of the glossary.

Specialised terminology

As mentioned in the introduction, the purpose of the lay glossary is to help people who are not specialists in the domains of research, data sharing and healthcare to understand terms they are not familiar with that they may encounter in documents related to their participation in research and decisions about the sharing/reuse of their data and samples. Through the Public Involvement work, it was possible to agree on an initial list of terms to include in the EPND lay glossary. This included terms related to the conduct of research, including some linked to the analysis of data. However, lay people frequently encounter references to specific statistical tests and results which they do not understand at all. An initial attempt to include some of those terms led to the realisation that such definitions would have to be fairly long and include several cross references, which could lead to confusion and not help people to fully understand the test or procedure.

There were mixed opinions in the group. Some people thought that it would be good to include them for anyone who might be interested, adding that people are free to decide whether or not they want to read them. Others suggested that explanations about statistics do not have their place in a glossary and that people would not expect to find them there or be interested in knowing the difference between one test and another. No one expressed the view that it would be important to include terms for specific statistical tests in the glossary.

The group considered it important to keep the terms related to minority or marginalised groups in the lay glossary. These had been developed by various ethics working groups, comprised of academic and lay experts, including people with dementia and their supporters, people from minority ethnic groups and people with different gender and sexual identities. The group felt that the inclusion of such terms was important as a means to promote awareness about diversity and inclusion in the context of research, even if the relevance of some of the terms might not be immediately obvious.

Next steps

Wider consultation within the EPND consortium

The next step will be to obtain feedback from a couple of members of the consortium with relevant expertise for different sections of the glossary. This will need to involve close collaboration with AE and FEP in order to ensure that the definitions and examples are not transformed into others which are no longer user-friendly or understandable, as this would result in a glossary that is not useful to the targeted lay population. Some feedback from members of the EPND consortium has been incorporated into the lay glossary prior to submission of this report as an interim deliverable. However, as every term and definition must be discussed and verified with people with neurodegenerative diseases (i.e. from the PEG), the lay glossary will be further elaborated in the context of the ongoing PI work throughout the duration of the EPND project and beyond (please see next sub-section). A revised version will be presented in the final deliverable on the PI work (D6.10).

Management of the glossary and ongoing involvement of lay people

The PEG felt that it was important to encourage users of the lay glossary to suggest additional terms to be added to the glossary and if necessary to amend certain definitions to make them more

understandable. No specific method was agreed (e.g. whether this should be done online or by email) but it was considered important to have a clear procedure so as to ensure that new definitions are not only accurate but also developed together with lay people, including those with neurodegenerative diseases and their carers/supporters. As this should be possible during and beyond the end of the project, a reliable system will be developed involving people and organisations who are able and willing to take on this task, and a procedure developed to manage the technical aspects linked to updating the glossary. AE and FEP will develop such a system/procedure together with relevant members of the EPND consortium and of the PEG.

Awareness raising and promotion of the lay glossary

Whilst the lay glossary has been developed for the purpose of the EPND project, there were concerns that people who might benefit from it would not necessarily find it. Many lay people participating in research who might be faced with decisions about data and sample sharing/re-use will not know that there is information and a glossary on the EPND website or indeed what EPND is. For this reason, the group stressed the importance of raising awareness of the lay glossary through associations, other research projects and on social media. Examples of the kinds of organisations in the UK that could be contacted and asked to provide links to the EPND glossary were provided, such as “Join Dementia Research”, “Brain Health Scotland” and “Neuroprogressive and Dementia Network”

Some people felt that the glossary could have a broader utility (e.g. in schools and colleges) and also for people with neurodegenerative disorders, their family, carers and supporters not necessarily involved in research but interested in understanding the results of relevant research. It was suggested that the glossary could also help people with neurodegenerative disorders and their carers/supporters to better understand their condition (e.g. to look up specific terms related to their condition such as symptoms, prognosis and relevant tests or bio-markers).

Conclusions

The Public Involvement work described in this report represents valuable feedback on perceptions of and attitudes towards the sharing/re-use of health data and bio-samples in the context of research. The two groups involved, namely the European Working Group of People with Dementia and the Parkinson’s Advisory Group, were enthusiastic about platforms like EPND, which seek to make such sharing and re-use of health data and bio-samples possible. They expressed some concerns but were keen to emphasise the need to balance a certain degree of possible personal risk (mainly linked to privacy and ethical issues) with the desire to promote much-needed research, especially in the realm of drug development for various forms of neurodegenerative diseases and prodromal conditions.

In keeping with the desire to play a role in the advancement of scientific progress, the PEG felt that the lay glossary would be an important tool to help ensure that lay people are fully informed about what they are signing up to when considering health data and bio-sample sharing/re-use in the context of research. The feedback that they provided and their work on the development of the lay glossary, which is planned to continue, should hopefully help ensure that platforms like EPND bear in mind the hopes, concerns and needs of lay people and that lay people are fully informed and hopefully continue to be motivated to consent to their data and samples being further shared and re-used for much-needed scientific research.

Repository of primary data

It should be noted that the Public Involvement work for this deliverable did not include the collection of any primary data. This will also be the case for the upcoming deliverable D6.10. Public Involvement draws on feedback and insight provided by people with neurodegenerative diseases and their carers/supporters in an advisory capacity. It does not involve the collection or analysis of any data and the people providing such feedback or sharing their insight are not research participants.

Appendix 1: Background reading for the November 2023 consultations

Informed consent in the context of biomedical research

Informed consent is essential for research. Informed consent is a process. It entails providing information to potential research participants about the key elements of a research study and what their participation will involve.

It usually includes:

A written document or form which contains the required information and details. This typically includes information about the research project's objectives, procedures, potential risks and benefits, confidentiality, the participant's rights, and how their data will be used.

- The presentation of that information by the researchers to the potential participants
- In most cases, researchers are expected to obtain a signature of the participant in the consent form.

By signing the informed consent form, research participants confirm that they understand the study and willingly agree to take part, ensuring that their involvement is voluntary, a fundamental ethical principle in research. This process helps protect the rights and well-being of research participants.

Data and samples from a research study on a specific topic can also be shared and re-used much later, for other types of research.

QUESTIONS

- How do you feel about your data and sample being shared in these two different ways? Would you have any concerns?
- How much detail would you want in the consent statement for data and sample sharing? (e.g. with whom, disease area, where etc.).
- What difference would it make if you were consenting to a research study which may in the future share your data, vs a biobank or data sharing platform which aims to share your data immediately?

Terminology used and your opinions about the re-use/further sharing of data and samples

In this part of the consultation, we will be referring to some examples of consent forms used in studies that are part of the EPND project, a research project focused on increasing access to data for researchers working on neurodegenerative diseases such as dementia or Parkinson's.

We will ask you about your opinion and perspectives about different issues linked to the use of your information/data in a study and how this is phrased and made understandable in consent forms.

Type of data/ samples collected and potentially further shared

The data/ samples collected for research and referred to in consent forms may include the following types of research data and materials:

- Memory test results
- Genetic information/results
- Blood, urine and stool samples (this is sometimes referred to as 'biological material' in consent forms)

QUESTIONS

- When you think about "data sharing", is this what you understood by the term "data"? If not, how did you understand the term?
- How do you feel about sharing these different types of data and samples?
- Is there any specific information that you think is important to highlight in the consent form, with regard to these different types of data and samples?

Sharing data beyond the initial study/ research

In some studies, the data a participant provides for that study might also be used for other future studies and/or by other researchers. This depends on the research project but should always be specified in the consent form. The following are some examples of how this has been referred to in some consent forms:

- 'Your data can be reused for medical research purposes'

- 'Your data will be used for future ethically approved research'

QUESTIONS

- How understandable and clear is this for you?
- Can you give any examples of what this kind of reuse might include?

In some cases, a participant's data might be shared with external commercial organisations for future research. In other cases, it might only be shared with non-commercial organisations. Big biomedical research projects usually have some pharmaceutical companies involved and this is encouraged by research funders (like the European Commission and national funding agencies) because of the nature of the study. They are then research partners (i.e. part of the actual research team as opposed to operating individually for their sole commercial benefit).

QUESTIONS

- How would you feel about researchers further sharing your data with external commercial organisations?
- Do you think it is important for it to be specified in a consent form, whether an external organisation is commercial or not?
- Should this always be specified, and if so, in what way?

Please see examples below of how this may be phrased in a consent form:

→ 'The data will be used for new academic research but no samples will be shared with or given to commercial organisations'

→ 'I consent for my anonymised clinical data to be shared with researchers in other academic centres and commercial companies (e.g. in the development of new treatments) for the future benefit of patients with Parkinson's and related conditions. I understand I will not receive any financial compensation for doing so'

QUESTIONS

- How clear and understandable do you think the above extracts are?
- How do you feel about pharmaceutical companies being research partners in biomedical studies? (please note that this situation is not the same as sharing data directly with commercial companies)
- Please see a possible explanation of "coded form" below (mentioned in one of the consent forms). What do you think of the explanation below, and would you add/change anything to make it clearer?

'All information and samples will be processed without name and birth number or other directly recognisable information. A code links to your information. Only authorised personnel associated with the project have access to the list of names and can find you again.'

Appendix 2: Extracts from informed consent forms

Example 1:

I agree to the use of my data/samples to be used to test for new biomarkers without further/separate consent being requested from me.

Example 2:

I consent for my anonymised clinical data to be shared with researchers in other academic centres and commercial companies (e.g. in the development of new treatments) for the future benefit of patients with Parkinson's and related conditions. I understand that I will not receive any direct commercial benefit in doing so.

Example 3:

I agree that my anonymised samples can be retained and used for future ethically approved research by the research team into Parkinson's and related conditions.

I consent for my anonymised samples to be shared with researchers in other academic centres and commercial companies (e.g. in the development of new treatments) for ethically approved research for the future benefit of patients with Parkinson's and related conditions. I understand that I will not receive any direct commercial benefit in doing so.

Example 4:

I understand my coded CSF sample will be kept and used for future academic research. The sample may be given to academic collaborators to support new research and will not be shared or given to commercial organisations.

I understand my coded biological samples will be kept and used for future academic research. Samples may be given to academic collaborators to support new research and no samples will be shared or given to commercial organisations.

Example 5:

I give my consent:

To donate my biosample material to the XXX to be used for biomedical research in the domain of neurodegenerative diseases.

To donate my biosample material to the XXX to be used for future biomedical research in other health related research domains.

To allow transfer of my collected pseudonymised data to countries outside the European Union that may not provide the same level of data protection as provided within the European Union, within the terms explained in the Subject Information Sheet.

Example 6:

By signing this consent, you are authorising the use of your data for large-scale, multi-center studies that will combine data from similar populations. These multi-center studies are being conducted by the XXX, a neuroscience consortium of universities and research institutions. Your data will be stored with

a coded research identifier to protect your identity. Only de-identified data, which does not include anything that might directly identify you, will be shared with XXX members and the general scientific community for research purposes. This data will be entered into study databases to be used from this date and going forward.

Appendix 3: Terms included in the lay glossary

Glossary of research-related terms for a lay audience

The lay glossary below is structured around different categories of terms. The current layout is provisional and starts with the terms for Parkinson's disease because the methodology for this part of the glossary is, as explained below, different to that of the rest of the lay glossary. The final layout of the glossary in the online version will be further discussed with the members of the three groups contributing to the PI work, together with the technical partners, and should be different from the other glossaries that have been developed in EPND because the target audience is very different.

Parkinson's disease

The following terms in this sub-section of the glossary on Parkinson's disease have been extracted from: Peñas, E., et al., El Libro Blanco del Párkinson en España. Aproximación, análisis y propuesta de futuro. Madrid, Real Patronato sobre Discapacidad, Federación Española de Párkinson, 2015, pp. 197-201 and a few terms from the International Parkinson and Movement Disorder Society (marked by an Asterisk in the list below). We have only made a few minor adjustments (e.g. replacing the term "patients" with "people"). The full glossary from Peñas and colleagues and the list of terms from the International Parkinson and Movement Disorder Society can be freely downloaded at:

- https://www.esparkinson.es/wp-content/uploads/2017/10/libro_blanco.pdf
- https://www.movementdisorders.org/For-Patients.htm

Acetylcholine: Neurotransmitter involved in motor processes (striatum), memory (hippocampus) and sleep regulation (brainstem).

Akinesia: Absence of movement, loss of the ability or speed to move. There is no actual paralysis or muscle weakness. When the alteration of movement is not complete (more common) it is more correctly called hypokinesia (little or slow movement).

Agonists: Depending on how it is used, it can have two meanings: drugs that stimulate dopamine receptors or any other neurotransmitter in the brain. Muscles that actively contract to perform a movement.

Amantadine: A substance that may be used early in Parkinson's disease or in more advanced stages as a treatment for dyskinesias (involuntary movements).

Amimia: Complete lack of facial mimicry, with marked reduction in expression and gestures.

Antagonist: A substance which, by blocking a receptor, prevents it from being stimulated or, alternatively, a muscle which has an opposite action to another. Anticholinergics. Drugs used in Parkinson's disease primarily to reduce tremor.

Ataxia: The word Ataxia comes from the Greek and means "without order." Ataxia refers to disorganised, clumsy movements and difficulties with balance. Coordination of movement requires multiple parts of the

nervous system to work together and if one area is damaged ataxia may occur. The doctor will examine someone to see if it can be determined if ataxia is caused by dysfunction of the brain, spinal cord, or nerves. The most common area of the brain responsible for ataxia is the cerebellum. (*)

Basal ganglia: Nuclei located deep in the brain made up of interconnected nerve cells that coordinate movements.

Bradykinesia: Slowness of movement.

Bradyphrenia: Slowed thinking, reduced mental reflexes. The brain takes longer to process information and has difficulty switching from one motor programme to another in response to a demand for movement. Slowing of certain mental processes.

Blood-brain barrier: A device that acts as a filter between the blood and the brain, preventing the passage of some substances (such as dopamine) and allowing the passage of others. Levodopa is therefore administered to people with Parkinson's disease (which does cross the blood-brain barrier) so that the patient's own neurons produce dopamine.

Botulinum NeuroToxin (BoNT): is a naturally occurring protein made by the bacterium called clostridium botulinum. In the past, people only knew BoNT as a dangerous and feared poison. When BoNT contaminates food, it can cause botulism: a severe and potentially deadly illness. In the last 40 years, however, researchers have transformed this poison into an effective and safe drug to treat many medical conditions (e.g. dystonia) when used at the correct dosages. (*)

Bromocriptine: Dopaminergic agonist

Carbidopa: A substance used in association with Levodopa to prevent its destruction or degradation outside the central nervous system and thus allow more Levodopa to reach the brain.

Contralateral: Opposite side, a word widely used in neurology as the pathways leading to motor actions and sensory perception (heat, pain, etc.) are crossed.

Corticobasal degeneration (CBD): A rare, progressive neurodegenerative disease. It was first identified in 1968. The disease typically starts between ages 60 and 70. CBD is a complex disease with a wide variety of symptoms and signs. (*)

Dopamine agonists. Drugs that act directly on dopamine receptors.

Dysarthria: Speech articulation disorder. Can be caused by a number of neurological problems, including Parkinson's disease. Speech is weakly articulated, uncoordinated or poorly vocalised.

Dyskinesia: From the Greek, dis (altered) and kinetos (movement). In neurology it is applied to designate excessive or altered movements of one or more parts of the body. Most of them are caused by the use of Levodopa for years, but they can also occur after the use of drugs that block dopaminergic receptors (neuroleptics, some antiemetics, etc.).

Dysphagia: Swallowing disorder. Swallowing is considered safe when no liquid, food or saliva is diverted into the airway and is completed within a few seconds. Parkinson's disease can affect both of these features of swallowing: the conduction of food or liquid through the appropriate anatomical pathway and the speed of swallowing.

Dystonia: Neurologically caused sustained contractions of muscles in one or more parts of the body. This often results in twisting or writhing of the affected parts.

Dopamine: A chemical used by some neurons to connect with each other. Neurons in the substantia nigra emit long extensions (axons) to connect and communicate with the striatal nuclei using dopamine. In people with Parkinson's the main deficit is dopamine, due to the death of the neurons that produce it, but other neurotransmitters such as serotonin, noradrenaline and acetylcholine are also missing.

Dopaminergic receptor: A small portion (molecule) of the neuron that is sensitive to stimulation by dopamine or other neurotransmitters sent by another neuron to transmit information.

End-of-dose impairment: Loss of effect of Levodopa.

Hallucination: False visual, auditory, tactile, gustatory, olfactory or any other type of perception of something that does not exist at that precise moment.

Hereditary ataxias (HA): Include a wide variety of inherited diseases where the main symptom is ataxia. Ataxia refers to uncoordinated, clumsy movements and walking problems with loss of balance. Changes in certain genes cause HA. In most cases, the disease affects more than one family member. However, sometimes there is no family history at all. In HA, ataxia is usually not the only symptom. (*)

Huntington's disease: A chronic, neurodegenerative brain disease. That means the nerve cells in a person's brain break down over time. The disease typically starts between ages 30 and 50, but it can begin when people are younger. (*)

Hypomimia: From the Greek hypo (little) and mimia (facial expression, mimicry). It means lack of mimicry or expression in the face and gestures.

Hypophonia: Phonation disorder. The problem lies in the amount of air that passes through the vocal cords causing a low pitch of the voice.

Hypotonia: Reduced muscle tone, which is maintained by a balanced contraction of agonist and antagonist muscles. Occurs in diseases of the cerebellum.

Impulse Control Disorders (ICDs): are a group of excessive and/or harmful urges and behaviours that may occur in people with Parkinson's disease (PD). They are characterised by persistent thoughts or uncontrollable urges to do things. They often are a side effect of certain medications. The people themselves sometimes do not know that it is a problem. Approximately 10-20% of people with PD may develop ICDs at some point. (*)

Infusion therapies: are treatments either through a small needle inserted under the skin or through a tube (catheter) inserted into a person's small intestine. This provides a continuous flow of drugs throughout the day. Levodopa and apomorphine are two common infusion therapy drugs that address the lack of dopamine in the brain. (*)

Levodopa: A substance that is converted into dopamine once it reaches the brain.

Lewy bodies: Damaged neurons occurring in Parkinson's disease that stain with antibodies and act against α-synuclein.

Monotherapy: Treatment with a single substance.

Motor fluctuations or on-off periods: Periods during the day when the person with Parkinson's will be more mobile due to the effect of the medication (on-periods) or, in the case of off-periods, times when the medication has generally stopped working and symptoms worsen.

Multiple System Atrophy (MSA): A rare disorder that affects the functioning of multiple systems in the brain. Some of these are involved in the control of movement, balance and coordination, while others ensure blood pressure, bladder, bowel and sexual function. (*)

Postural instability: When balance and coordination are affected and often cause people with Parkinson's to lean forward or backward and fall easily.

Prolonged-release formulations: Drug preparations (e.g. Levodopa) that are absorbed slowly in the digestive tract after each dose.

Parkinson's Plus: It applies to some neurological diseases which, like Parkinson's disease, are degenerative and of unknown cause but in which, in addition to damage to the substantia nigra, there are lesions in other nerve centres and pathways, such as various brainstem nuclei, the cerebral cortex, the cerebellum or the pyramidal pathway.

Parkinsonisms (or parkinsonian syndromes): These are pathological processes in which the symptoms resemble those of Parkinson's disease. It is used as a very general term but is often used to refer to degenerative diseases other than idiopathic Parkinson's disease which, although they have similar symptoms, do not have such a marked response to treatment.

Progressive Supranuclear Palsy (PSP): The most common type of Atypical Parkinsonism, but it is only about one tenth as common as Parkinson's disease. Atypical parkinsonism, also called Parkinson-plus syndrome, is when the patient has parkinsonism plus other features including early balance problems/falling, poor reaction to the drug levodopa, early cognitive problems, and impaired control of blood pressure/bowel/bladder. (*)

Restless legs syndrome (RLS): A condition of the nervous system that causes an irresistible urge to move the legs. People with RLS may describe a sensation of stinging, burning, creeping and/or painful tension deep within their legs. RLS symptoms worsen in the evening and at night time, which may lead to sleep problems. Symptoms can also occur during the day, especially after sitting for a long time. RLS symptoms are often on one side, but may shift from side to side or affect both sides at the same time. Between five and 10% of the population is affected. RLS is even more common in older people. (*)

Stiffness: A symptom of Parkinson's disease in which the muscles appear stiff and show resistance to

movement, even when another person tries to move the affected part of the body, such as an arm.

Substance Nigra: A small area located in the midbrain (upper part of the brain stem) that is so called because of its dark colour.

Tremor: Shaking, often of one hand, which in Parkinson's disease is usually most apparent when the affected part is at rest.

Ethics (ethical principles, concepts and values)

The following sub-sections of the lay glossary have been developed with members of the PEG. Some of the terms were initially developed in the context of Alzheimer Europe's earlier ethics multi-disciplinary working groups, which included people with dementia and carers. All the terms have been further reviewed by people with neurodegenerative disorders and carers/supporters and adapted where necessary.

Autonomy: Traditionally described as the condition or quality of being independent and the ability to make decisions for yourself about what you do or what is done to/for you. However, it is increasingly recognised that people exist in the context of relationships, engage in give and take, and are interdependent. Relations, institutional conditions, legislation and dementia therefore affect the exercise of individual autonomy.

Beneficence: Doing things for the benefit of others (whilst balancing possible benefits against risks and costs).

Compassion: Deep awareness of the suffering of others coupled with the wish to relieve the suffering. Compassion is also closely related to caring about other people/ others

Conscience: Our personal, "inner judge" or moral sense of what is right and wrong.

Confidentiality: Keeping information that has been obtained in confidence secure and private; not sharing it with other people without permission.

Discernment: Being able to judge well and make sound judgements without being influenced by personal attachments and external factors.

Ethics: Well-based standards of right and wrong that prescribe what humans ought to do, moral principles that people live by usually in terms of rights of others, obligations, benefits to society, fairness in day-to-day life, or specific virtues. Not necessarily about big societal issues or life and death situations (like the death sentence, corporal punishment and abortion) but about everything that affects our daily lives.

Familism: Putting family first i.e. putting family relationships, values and demands before personal interests.

Integrity: Strict adherence to a set of consistent moral values and principles; acting in accordance with one's core beliefs.

Humility: Not feeling that you have any special importance that makes you better than anyone else.

Justice/equity: the moral obligation to act on the basis of fair adjudication between competing claims. Involves treating people equally and fairly through a fair distribution of benefits, risks and costs. Ensuring that they have the same opportunities and access to goods and services. This is not the same thing as equality because treating everyone equally regardless of their needs may mean that they do not have the same opportunities and access.

Non-maleficence: Not doing what might be harmful or hurt somebody.

Personhood: What makes a person (i.e. a member of the human species) unique and determines who they are and their individual interests.

Privacy: Freedom from unauthorised intrusion or observation.

Relationality: The importance of trusting relationships. The way we experience ourselves in relation to others.

Truthfulness/fidelity: Telling the truth/being true.

Trustworthiness: The state of deserving confidence/trust.

Virtue: An inner disposition which enables a person to live well or flourish as a human being.

Vulnerability: Being in need of special care and protection especially in situations where one's rights and needs might not be respected. Should not be applied to people with dementia in a blanket fashion. Some people with dementia might often experience fear or distress – while these may not always be due to a real external threat, they can also contribute to feelings of 'vulnerability'.

Medical terminology

Biomarker: a biomarker is a biological substance (e.g. a protein that may or may not be detected in a body fluid) or a structure (such as some changes in size in specific parts of the brain) that is considered as a "mark" indicative of a disease. Biomarkers can change, appear or disappear during the development of a particular pathology. They can be detected through tests and technologies such as neuroimaging (brain scans) and through the analysis of cerebrospinal fluid (CSF - a body fluid found around the brain and spine) and blood.

CNS: central nervous system (the brain and the spinal cord).

Cerebrospinal fluid: a body fluid found around the brain and the spine.

Clinical-biological entity: something that has clinical and biological characteristics.**Clinical diagnosis:** the act or process of discovering or identifying a disease or medical condition by means of a medical examination to detect signs and symptoms or of laboratory tests etc. which can then be communicated to patients by doctors in the form of a diagnostic label and an explanation of what that means.

Clinical onset: When symptoms manifest (tremor, rigidity, reduced mobility etc.).

Continuum: a range or series of things that are slightly different from each other and that exist between two different possibilities/extremes (e.g. between being underweight and overweight, between hypotension and hypertension.

Delirium: Perceptual disorder of a systematic nature in which the patient interprets the information that reaches him/her in an erroneous manner.

Disease markers: A term used by physicians to refer to signs or data that characterise a disease, whether anatomical, clinical, biochemical, radiological or other.

DNA: This stands for deoxyribonucleic acid. DNA contains our hereditary material and our genes. It is like a set of instructions for the development, functioning, growth and reproduction of all known organisms. There are different letters in some other languages. In German, for example, it is DNS and in French, it is ADN.

DSM-V: the fifth edition of the *Diagnostic and Statistical Manual of Mental Diseases which is the* standard classification of mental diseases used mainly by mental health professionals in the United States of America.

Faeces: This is the solid or semisolid remains of food that could not be digested or absorbed in the small intestine of humans. It is broken down by bacteria in the large intestine and eliminated from the body (sometimes called stool or “poo”).

ICD-10: the tenth edition of the International Classification of Diseases developed by the World Health Organizations**Incidence:** the number of new cases of people with a specified disease during a specified period in a specified population (e.g. the number of new cases of AD in Poland in 2022).

Idiopathic: Used in medicine to designate a pathological process or a disease for which we do not know the cause. disease for which we do not know the cause.

MRI: this stands for magnetic resonance imaging which is a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in your body.

Neuroimaging: Methods by which images of the nervous system can be obtained. The most commonly used are CT (computerised axial tomography) and MRI (magnetic resonance imaging).

Neurotransmitter: A chemical messenger between neurons, a substance that one neuron sends to another to transmit a message.

Neurodegenerative disease: a disease which primarily affects neurons (it involves a degeneration of nerve cells)

Neurons: also called neurones or nerve cells. They produce one or more substances called neurotransmitters which serve to communicate with other neurons in the nervous system. Neurons are fundamental units of the brain and nervous system. These cells are responsible for receiving sensory input, sending motor commands to our muscles, and transmitting the electrical signals needed to make this happen.

Neuroscientific: related to various scientific disciplines dealing with the structure, development, function, chemistry, pharmacology and pathology of the nervous system.

Pathogenesis: Mechanisms by which a disease develops.

Pathology: deviations from what is considered as normal in relation to diseases or biological processes.

Pathophysiological: the effects of disease on physiological processes (i.e. on the functioning of organisms).

PET-Amyloid: This stands for amyloid positron emission tomography (PET) imaging. It is an imaging procedure (also known as a scan) that enables the detection of amyloid deposition (one of the hallmarks of Alzheimer’s disease) in people’s brains. This is just one of a number of different imaging procedures available for investigating different types of dementias.

Physiopathology: relating to biological and physical manifestations of disease related to underlying abnormalities and physiological disturbances. About processes within the body that result in the signs and symptoms of a disease.

Plasma: the largest single component of blood, making up about 55% of total blood volume. It is a clear, straw-coloured liquid, which carries platelets, red and white blood cells around the body.

Post mortem: Latin for “after death”

Premorbid: anything that occurs before a disease manifests itself.

Prevalence: The number of patients with a given disease that exist at a given time in a given area.

Prevalence: The number of cases of a disease that are present in a particular population at a given time (e.g. in 2022, over 800,00 people had dementia in the UK, old and new cases combined).

Saliva: saliva (sometimes called “spit”) is a fluid substance produced and secreted by salivary glands in the mouth. It is around 99% water.

Serum: an amber-coloured, protein-rich liquid which separates out when blood coagulates (transforms into a semi-solid or solid state)

Stool: solid or semisolid remains of food that could not be digested or absorbed in the small intestine of humans. It is broken down by bacteria in the large intestine and eliminated from the body (sometimes called faeces or “poo”).

Syndrome: a disease that involves a particular group of signs and symptoms OR a group of symptoms that together are characteristic of a specific disease.

Urine: (sometimes called “pee”) a liquid produced by the kidneys to remove waste products from the bloodstream. It is stored in the bladder.

Alzheimer’s disease, dementia and related conditions

Alzheimer’s disease: A few decades ago, the terms Alzheimer’s disease and Alzheimer’s dementia tended to be used interchangeably. Nowadays, the term Alzheimer’s disease is used to refer to a continuum extending from pre-clinical Alzheimer’s disease (in which there are abnormal changes in the brain) to Alzheimer’s dementia (marked in addition by changes in cognition and functioning which interfere with daily life).

AD: AD is a common acronym used to refer to Alzheimer’s disease but it is also sometimes used to refer to Alzheimer’s dementia, which can lead to confusion. In this deliverable and in this glossary, the abbreviation is used to refer to Alzheimer’s disease.

Amyloid plaques: abnormal clusters of “sticky” proteins called beta-amyloid that build up between nerve cells and interfere with signalling in the brain e.g. triggering inflammation and destroying cells. One of the hallmarks of AD pathology

Asymptomatic/at risk for AD: in the context of the new AD definitions, a sub-group of preclinical AD consisting of pathological changes in people’s brains which are specific to AD but with no clinical signs/symptoms of AD. Not everyone in this sub-group will develop AD dementia which is why the term “at risk” is often preferred.

Dementia: a syndrome (i.e. a set of symptoms which typically occur together) including, for example, loss of memory, mood changes, and problems with communication and reasoning. Dementia is not a normal part of the ageing process. There are many causes of dementia, the most common being

Alzheimer's disease and vascular dementia. Dementia is usually a progressive condition. This means that symptoms become more severe over time and that people with dementia typically need support and eventually care as their dementia advances. Not all difficulties that people face are directly linked to the disease (please see section on disability).

Hippocampal lesion: damage in the region of the brain known as the hippocampus, which is one of the first regions to suffer damage in the case of AD pathology and is known to be important for the recollection of new information.

IWG: International Working Group (one of the main groups responsible for developing the new model and definitions of AD). The IWG is the European group. The NINCDS-ADRDA, which is an American group, also developed terms that are slightly different but refer to the same concepts.

MCI: this stands for Mild Cognitive Impairment. Mild Cognitive Impairment is often considered as the stage between the expected cognitive decline of normal ageing and the more significant decline of dementia. It may increase a person's risk of later developing dementia but some people with mild cognitive impairment don't deteriorate further and some eventually get better. MCI denotes the severity of impairment, and differs from the possible cause of the impairment, that can be AD, or another neurodegenerative disease.

MCI due to AD: Mild cognitive impairment (MCI) due to Alzheimer's disease is a specific type of MCI. It is considered to be the earliest symptomatic stage of Alzheimer's disease and is sometimes referred to as prodromal AD. People with MCI due to Alzheimer's disease often experience very mild changes in their cognitive abilities, such as difficulties with memory, keeping track of conversations, orientation, planning and decision making. These changes may cause concern but do not significantly impact on people's daily lives.

Neurobrillary tangles: twisted fibres of a protein called tau present inside the neurons. The twisted strands of tau interfere with the transportation of nutrients and other essential supplies in the brain and cause cells to die. One of the hallmarks of AD pathology.

NIA-AA: National Institute on Aging and the Alzheimer's Association (one of the main groups responsible for developing the new model and definitions of AD).

Preclinical Alzheimer's disease: In the preclinical stage of Alzheimer's disease, amyloid plaques and tau tangles start accumulating in the brain. However, there are no outward signs of disease and these changes can only be detected using brain imaging scans or biomarker tests, which are not yet routinely used in clinical practice. The preclinical stage of Alzheimer's disease can last many years, or even decades.

Pre-symptomatic AD: This is a sub-group of preclinical AD which includes people who carry a dominant genetic variant of AD which makes it almost certain that they will develop AD dementia. Most people with preclinical Alzheimer's disease, however, fall into the asymptomatic/at risk group and there is no certainty that they will develop Alzheimer's dementia.

Prodromal AD: In the context of the new AD definitions, this corresponds to the early symptomatic, pre-dementia phase of AD during which clinical symptoms are present but not severe enough to affect activities of daily life and are associated with specific biomarker changes. This term was coined by the IWG. This is equivalent to "MCI due to AD" in the model of Alzheimer's disease developed by the American working group.

Subjective cognitive decline: self-perceived cognitive decline (e.g. confusion or memory problems) among people with "normal" cognition that does not show up on tests and has been happening more often or getting worse in the last 12 months.

Research terminology

Adverse event/effect: an unintended effect that is harmful or otherwise unwanted, that is believed to be related to or caused by a drug, treatment or intervention.

Arm (of a clinical study): this is a subsection of people in a clinical study (e.g. in a drug trial) who have a particular intervention. They may, for example, receive the "usual treatment" for a particular condition whereas people in another "arm" might receive the experimental drug.

Cohort: a group of people who have something in common (e.g. having dementia or being a certain age). Researchers often follow cohorts over time (e.g. in longitudinal studies).

Control Group: a group of participants in an experimental study that receives either no treatment or a different treatment from another group (known as the experimental group). Their results can then be compared to those of the other group.

Cross-sectional: A cross-sectional study is a type of study that analyses data collected from a group of people at a specific point in time, rather than over a period of time. Cross-sectional studies are often used to estimate the prevalence of a health condition, or to examine the link between two different variables/things (e.g. the relationship between socio-economic status and cardiovascular health) at a specific point in time.

Dependent and independent variables: Variables can be quantitative (expressed in numbers e.g. age or height) or qualitative (expressed using words, e.g. eye colour). In research studies looking at causes and effects, variables can be classified as independent or dependent. For example, in a study looking at the effect of a medicine on blood pressure, the "cause" variable (blood pressure medicine) would be known as an independent variable, and the "effect variable (blood pressure) would be known as a dependent variable. Researchers could manipulate the independent variable (e.g. varying amounts of blood pressure medicine) and measure its effect on the dependent variable (blood pressure).

Dichotomous: divided into two distinct parts or states (e.g. heads or tails, rich or poor, healthy or sick)

Double-blind: double-blind in the context of clinical trials means that neither the participants nor the researchers know who is receiving a particular treatment/drug.

et al. : stands for "and others". Often used when referencing authors of research articles in the main text of published articles (e.g. Jones et al. instead of Jones, Patel, Kurz and Finkel)

Eligibility criteria: rules/criteria, usually in the form of a list, used by researchers to decide which people to include or exclude from a study.

Epidemiology: Epidemiology is the branch of medical science that investigates all the factors that determine the presence or absence of diseases and disorders. Epidemiological research helps us to understand how many people have a disease or disorder, if those numbers are changing, and how the disorder affects our society and our economy (source: https://www.nidcd.nih.gov/health/statistics/what-epidemiology)

Ethics approval: researchers are obliged to obtain ethics approval from universities and/or external research ethics committees for all research involving human participants. The aim of this approval is to protect both the researchers and the participants from potential harm and to ensure that their dignity, rights, safety, and welfare respected. To obtain ethics approval, researchers have to present a plan of their research in advance to an ethics committee which decides whether or not they can conduct such research. Sometimes, the committee insists on certain changes being made.

External Validity: the extent to which the results of a study are generalisable or transferable.

False positive: a research or medical finding which suggests that a person has something that they don't have. An example of a false positive would be the claim that people have dementia when in fact they don't.

False negative: a research or medical finding which suggests that a person doesn't have something that they do have. An example of a false negative would be the claim that people don't have dementia when in fact they do.

Generalisability: the extent to which research findings and conclusions from participants or situations of one study can be applied to the population at large (based on statistical calculations).

Homogenous: consisting of parts or people that are similar to each other or are of the same type (e.g. all women, all from the same social class or in the same age group).

Hypothesis: an assumption/educated prediction about what researchers expect to happen or find in their study. This is usually expressed in the form of a statement which is then tested in the research project.

Independent variable: the characteristic that the researchers manipulate or change in their study or experiment.

Informed consent: This is a process, generally accompanied by the signing of a form, that potential research participants go through sign before they commit to participating in a particular study. Prior to signing an Informed Consent Form, potential participants receive a Participant Information Sheet and have the opportunity to discuss any questions they may have with the researchers. A signed informed consent form does not release researchers from their duty to continuously monitor participants' wellbeing and participants can withdraw from a study at any time (i.e. the form does not constitute a legal obligation to participate).

Internal Validity: reflects the extent to which the research design was effective in ensuring that it measured what was intended to be measured.

Longitudinal studies: research studies that are conducted over an extended period of time. Researchers note and collect data (including samples sometimes) from the same subjects over several or many years to observe changes in participants, behaviours, or attitudes.

Meta-analysis: the statistical analysis of the results of multiple scientific studies that all answered similar research questions.

Participant information sheet: document that is given to potential research participants to explain to them what the study is about, why they are being asked to participate, what potential risks and benefits there are and what would be expected of them if they decided to participate. It should be written in a way that is easy for people who are not researchers to understand.

Public Engagement (PE): raising awareness or providing information about ongoing or completed research or about a particular research topic (e.g. about artificial intelligence or risk prediction).

Public Involvement (PI): involving lay people in research not as research participants but as advisors (carrying out research and developing policies with or by members of the public rather than on or for them. PI is not the same as public engagement or as being a research participant. Rather, it is about creating a partnership between researchers and the public/patients, whereby all contribute collaboratively in varying degrees towards the research process or the research output.

Placebo: a substance or tablet that has no therapeutic effect, which is used as a control in clinical trials for new drugs. Having a group of people who take a placebo enables researchers to determine whether there is any benefit to taking the new drug. Sometimes, instead of a placebo, researchers compare the experimental treatment with an existing treatment .

Principal or Primary Investigator (PI): the person who is responsible for the preparation, conduct, and administration of a research grant for a research project.

Prospective study: a study in which the health or other characteristic of people (the research participants) are recorded as they happen and monitored over a set period of time.

Protocol (or research protocol): a detailed plan describing how the research will be done (e.g. what question will be asked, how information will be collected, from whom and how it will be analysed.

Pseudonym: a number or name with no meaning that is used by some authors and in the context of research (instead of information relating to a particular person such as their name or email address) so that it is impossible to see who the information relates to.

Qualitative research: this research focuses on non-numerical (descriptive) data. Qualitative studies concentrate mainly on words and meanings and aim to capture the richness and complexity of human experience and to understand complex phenomena by means of focus group discussions, interviews and observation. Researchers try, for example, to gain insight into people's attitudes, beliefs, motivations and underlying reasons for behaviour. They try to capture people's social reality and what is meaningful to them.

Quantitative research: this type of research involves recording information obtained from participants in numerical form so as to enable statistical analysis of the findings and the generalisation of those findings to the wider population. Various procedures are used to measure or convert what people think, feel or do into numbers so as to make the statistical analysis possible. Researchers typically look for patterns and averages, make predictions and test causal relationships.

Randomised-controlled trial (RCT): a controlled experiment/study in which people are allocated (by chance alone) to receive one of several clinical interventions, one of which is the placebo (sometimes called the sugar pill), standard practice or simply no intervention. Differences between the results from the different groups are statistically analysed

Research: a general term that covers all kinds of studies designed to find responses to worthwhile questions by means of a systematic and scientific approach.

Research participant (or research subject): a person who voluntarily participates in a research project (after having given informed consent) by providing researchers with data or samples.

Research question: a research hypothesis expressed in the form of a question.

Statistical significance: the probability that the observed effect or result was caused by something other than mere chance. This is not the same thing as "importance" because statistical significance does not tell you anything about how important or meaningful the results are.

Treatment arm/group: the participants in a study that receive whatever is being investigated (e.g. an experimental drug) as opposed to the participants that do not.

Variable: Variables are the measurable attributes of what is being studied in a scientific experiment. There are several different types. Experiments are usually designed to find out what effect one variable has on another. For example, to find out what effect daylight has on plant growth, researchers could manipulate the independent variable (different levels of exposure to daylight) and then measure the dependent variable (how much the plant has grown or even withered) to find out what this effect might be.

Inclusion and recognising diversity

Discourse: how we think and communicate about people, things and the social organisation of society, as well as the relationships between these. Discourse refers to a conversation or exchange of ideas between two or more people. Discourse affects language, thought and various structures that shape our lives and relationships in society.

Intersectionality: the interconnected nature of social categorisations such as race, class, and gender whereby these categorisations interact to produce overlapping and interdependent systems of discrimination, disadvantage or privilege. A Black disabled woman, for example, may experience not only more but also a different kind of discrimination than a White disabled woman or a Black man who is not disabled.

Public discourse: anything written, spoken, televised or heard via some media. A way to achieve mutual understanding through a rational exchange of arguments within the public sphere/domain.

Socially salient: a particular attribute (e.g. having AD, having ginger hair or being blond, being unemployed etc.) that is considered by some people as being socially meaningful (i.e. it matters socially and may therefore affect how people with that attribute are considered and treated by others).

Stigmatisation: when a person or group is devalued and discriminated against on the basis of a shared characteristic or attribute (e.g. being divorced, having dementia or having a criminal record) that is considered in some societies as socially salient (see above). The process of stigmatization also involves labelling, negative stereotyping, thinking about people with the shared attribute as being a group apart (i.e. "other" in the sense of "them" not "us") and feeling pity, anger or fear in relation to them. These different components of stigma are inter-related and occur within a context of unequal power relations.

CRPD: abbreviation for the United Nation's Convention on the Rights of Persons with Disabilities, which came into force in 2006. The provisions of the CRPD also apply to people with dementia.

Disability: Dementia is the leading cause of disability and dependency in older adults, affecting almost 8 million people in the European Union. According to the CRPD, disability "results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others" (Source: CRPD 2006, Preamble e).There are different models of disability. The medical model of disability, which has been widely criticised, views

disability as a problem residing in the person, something that is directly caused by disease, trauma, or other health condition which therefore requires sustained medical care provided in the form of individual treatment by professionals (i.e. to fix the disabled person). The social model of disability sees disability predominantly as a socially created problem (i.e. not an attribute of an individual, but rather a complex collection of conditions, many of which are created by the social environment). Hence, the management of the problem requires social action and is the collective responsibility of society at large to make the environmental modifications necessary for the full participation of people with disabilities in all areas of social life (see the CRPD for more information).

Disabled person: It is sometimes assumed that it is more respectful to refer to someone as a person with disability but many people (with disabilities) prefer the term "disabled person" because it emphasises that they do not "possess" a disability but are disabled by society (including people, structures, environments and attitudes). Both terms are acceptable but it is important to respect people's preferences if known.

Impairment: any loss or limitation, albeit physical (e.g. loss of limbs), physiological (e.g. kidney disease), cognitive (e.g. Alzheimer's disease), sensory (e.g. loss of hearing or vision), psychological (e.g. behavioural problems), or mental (e.g. psychosis) in nature, that may contribute to disability.

Interdependency: the way in which people are never fully independent and always rely in some ways on others.

Paradigm: a philosophical and theoretical framework or school of thought with underlying theories, laws, assumptions and generalisations which influence the way we make sense of a particular issue e.g. in the field of dementia, disability, research or psychotherapy. If we think of the phrase "thinking inside the box", the paradigm might be the box.

Pathological: caused by or related to a disease.

Marginalised groups

Minority ethnic groups

Ancestry informative markers (AIMs): a set of genetic variations for a particular DNA sequence that appear in different frequencies in populations from different regions of the world. Genetic ancestry describes genetic relatedness more accurately than race or ethnicity, but the interaction of biological and social factors in relation to health must still be considered.

BAME/BME: BAME stands for Black, Asian and Minority Ethnic and BME for Black and Minority Ethnic. However, terms such as 'Black' and 'Asian' are applied to very different groups of people, with quite different cultures. This may sometimes result in assumptions being made that people have things in common when this is not the case and overlooking significant differences such as different languages, religious beliefs, shared histories and traditions. Also, the term Asian is often used by US and European researchers differently (i.e. excluding or including people identifying with the Indian community).

Black: the term "Black" has gone from being considered offensive, and thus replaced by "coloured", back to being considered a respectful way to refer to Black people, with "coloured" now generally being considered offensive. There is still some disagreement as to whether the word should be capitalised or not, although there is currently a movement in favour of capitalization. Lay people, clinicians and researchers are not always aware of the developments in language which, as just explained, take place gradually over many years and sometimes fluctuate in terms of what is considered appropriate and

respectful. There may also be differences in the use and acceptability of direct translations of terms in different languages and in different countries.

Cultural awareness: knowledge about different cultures (e.g. different religions, traditions, common beliefs and preferences, history and shared values).

Cultural sensitivity: acknowledging cultural differences and similarities between people without assigning them a value (e.g. of good or bad, right or wrong).

Cultural competence: knowledge combined with appropriate attitudes and skills (e.g. openness, respect, awareness of one's own background, readiness to question one's own assumptions, ability to communicate with people from different cultures and readiness to use external help when needed).

Ethnicity: a shared culture, often incorporating a common language, geographic locale or place of origin, religion, sense of history, traditions, values, beliefs and food habits.

Interculturalism: the acceptance and promotion of cultural diversity, reflected in the way that people interact, understand and relate to each other, and through policies and practice which help ensure equal opportunities, respect and fair treatment of people from all ethnic groups.

Minority ethnic group: a group of people who share a common cultural identity which differs in some way to that of the majority ethnic group in a particular country.

Majority ethnic group: the group of people sharing the most common ethnicity in a particular country, often believed to be a homogenous group and often considered as being one unified nation consisting of a single ethnic group. Sometimes referred to as 'native' or 'White' even though these terms are somewhat problematic.

Migrant and immigrant: unclear concepts with varying definitions. Sometimes defined by foreign birth, foreign citizenship or movement into a new country to stay temporarily or to settle for the long-term. Often associated with ethnic or religious minorities and with asylum seekers and refugees.

Race: a contested concept reflecting the categorisation of groups of people into sub-groups on the basis of alleged biological differences (including visible physical traits or characteristics as well as behaviours), which it is claimed have been passed down from generation to generation through people's genes. The term is still commonly used in the United States of America.

Racial discrimination: discrimination on the basis of the belief that there are different races and that some are inferior compared to others. The term would also extend to discrimination against different ethnic groups, regardless of whether the perpetrators believe that the members of those groups are biologically or genetically different to people from other ethnic groups (i.e. the group might be defined on the basis of shared linguistic or other cultural characteristics).

LGBTQ+ people

Cisgender: refers to a person whose sense of personal identity and gender corresponds with the sex attributed to them at birth.

Gender: the social and cultural differences between men and women. Including gender roles, behaviour, expectations and what is considered appropriate by society. These things change over time.

Gender Identity: an individual's personal understanding of their gender and how they feel inside. This may match the gender given at birth (as in cisgender), but can also differ (e.g. in the case of non-binary or transgender people).

Heterosexuality: a romantic or sexual attraction, or sexual behaviour towards/between people of the opposite sex or gender. Sometimes, heterosexual people are referred to as being "straight".

Heteronormativity: the taken-for-granted assumptions that people are heterosexual, cisgender, married or in a stable relationship with one person and have or will have children. It rests on biased, narrow-minded and discriminatory beliefs and attitudes towards LGBTQ+ people and on the belief that these heteronormative characteristics are the default, preferred or normal mode of sexual orientation and gender identity.

Homosexuality: being attracted to people of the same sex or gender (see also under "sexual orientation"). The term "homosexual" is sometimes considered offensive as it has a history of being used to pathologize gay and lesbian people.

Intersex: refers to people who are born with hormones, chromosomes, anatomy or other characteristics that are neither exclusively male nor female. Intersex people may identify as male, female, intersex or with a non-binary identity.

LGBTQ+: abbreviation of "lesbian, gay, bisexual, transgender and other minority sexual orientation and gender groups (apart from heterosexual and cis gender groups)", typically used as a self-designation and typically covering anyone who does not consider themselves to be heterosexual or whose gender identity does not match the sex that they were assigned at birth. The Q stands for questioning (when a person is exploring their sexuality, gender identity and gender expression) or alternatively for queer (see below). The plus (+) refers to people who are genderqueer, gender fluid, genderless, agender, non-gender, third gender, bi-gender or non-binary.

Non-binary: refers to people whose gender identity does not exclusively fall into the binary gender classification of either "man" or "woman". They may identify with either masculinity or femininity in some way, both or neither (i.e. having a neutral androgynous appearance). It is a gender identity on its own but is sometimes used as an umbrella term for many gender identities.

Queer: a broad term, which is used to described gender identities and sexual orientations that do not fall within the heteronormative assumptions of being heterosexual and cisgender (please see these terms in the glossary). It can be used to describe nonbinary gender identities, homosexuality or bisexuality and the whole LGBQT+ community. The term is quite controversial because it was often used in the past as a slur against gay men. To some extent, the term has been reclaimed in much the same way as "Black" has been (i.e. having initially been considered offensive and replaced by "coloured", back to being considered respectful, with "coloured" now generally being considered offensive or a euphemism). Due

to the confidential nature of the term “queer”, it is perhaps best to avoid it, unless someone uses it to describe themselves.

Sex: This term is used to describe the biological characteristics that define humans as female or male. These characteristics include hormones, chromosomes and internal and external sexual organs. Sex is also used as an abbreviation for sexual intercourse.

Sexuality: a central aspect of being human throughout life and encompasses sex, gender identities and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction.

Sexual orientation: romantic or sexual attraction (or lack thereof) towards others. This can include heterosexuality (being attracted to the opposite sex), bisexuality (being attracted to both males, females and/or other genders), homosexuality or gay/lesbian (being attracted to people of the same sex), asexuality (the lack of or low sexual desire) and pansexuality (being attracted to people regardless of their gender), as well as other sexual orientations.

Transgender/trans: refers to people whose gender identity is different from the sex they were given at birth. People who have transitioned (see below) do not necessarily identify their gender as trans. They may see their gender identity as a man or woman or have a non-binary gender identity.

Data sharing

Data: Measurements or observations that convey information, and that can be computed, analysed and shared. There are many different types of data, for example: temperatures, blood pressure measurements, names, and brain scan images. Data may be **qualitative**, meaning that it is descriptive and conveyed in words and paragraphs. Data can also be **quantitative**, meaning that it is based on numbers, which can be counted, measured and calculated.

Data Cleaning: a process which involves removing unqualified, biased or incomplete responses from a survey so as to improve the quality of the data and protect against bias.

Data discovery: The act of browsing and locating available data related to a specific purpose, such as answering a particular research question.

Data repository: A place where data is collected and stored in a computerised, digital format. Data repositories are sometimes called data libraries, or data archives. Data repositories are often used by researchers to deposit data so they can preserve, publish or share them.

Data set: A data set consists of a collection of linked but independent data that can be called up and processed either individually or together. Each set is organised in a specific data structure (e.g. in a table in columns). A standard data set can contain, among other things, information about a patient or research participant.

Data sharing: The process of making existing data accessible and available to others.

Data Transfer Agreement: A legal agreement or contract that governs the transfer of data from one person or organisation, to another or multiple persons or organisations. Data Transfer Agreements (sometimes abbreviated to DTA) explain the terms and conditions, rights and obligations for the signatories.

Electronic Health Record: An Electronic Health Record (sometimes abbreviated to EHR) is a computerised, digital version of a person's health record. It gathers together health information and data about an individual, such as age, gender, health history, medicines, electronic medical schedules, doctors' letters and reports and other medical details. It may be consulted, managed and shared by the different healthcare providers that are involved in caring for a particular person in question who can also access their own patient file (e.g. via a QR code or a defined website combined with their own username and personal password).

FAIR acronym: The FAIR acronym stands for "Findable, Accessible, Interoperable, Reuseable". FAIR data are data that are easy to find, access and re-use, and are interoperable. Interoperable means that data can be exchanged, used and combined across different digital systems or databases. Data should therefore be prepared in such a way that people and machines can find, retrieve, link and reuse it.

Federated database: Federated databases allow multiple data sources to be connected and accessed in parallel. In these systems, data remain in their original source location (e.g. a hospital database) but can be viewed and accessed via a single interface.

Harmonisation: Harmonisation refers to the process of aligning the formats, dimensions and layouts of different data sources so they can be compared and analysed together. For example, researchers may use different rating scales, where 2 = good for one researcher, but 2 = average for another researcher. The process of harmonisation ensures data sources are aligned and comparable.

Interoperable: This means that data can be exchanged, used and combined across different digital systems or databases.

Metadata: Metadata are data that provide information about other data, without revealing the data itself. For example, a digital file containing data may have metadata on the source, type and ownership of the data within.

Real-world data: Real-world data (sometimes abbreviated to RWD) are data relating to health status of an individual, collected during the delivery of routine health care by a variety of healthcare practitioners and organisations.

Secondary use of data: The use of data for a different purpose from that for which it was originally collected.

Traceability: Refers to the ability to track the origin, movement and uses of data across digital systems.

Data protection and privacy (terms relating to the GDPR

Anonymisation: Rendering personal data anonymous. That is, transforming the data such that it is no longer possible to associate the data with an identified or identifiable person. Anonymous data is not subject to the GDPR.

Consent (under the GDPR): The definition of consent under the GDPR is: "Any freely given, specific, informed and unambiguous indication of the data subject's wishes by which they, by a statement or by a clear affirmative action, signify agreement to the processing of personal data relating to them".

Data controller: A person, authority, organisation or entity that solely or jointly determines how data will be processed.

Data processor: A person, authority, organisation or entity that processes data on behalf of a data controller.

Data processing: Any operations that are performed on personal data or on sets of personal data, for example collection, organisation, storage, alteration, consultation, use or destruction.

Data protection: Data protection is the process of safeguarding data from corruption, mis-use or loss.

Data protection authorities: In the EU, data protection authorities are national supervisory authorities charged with assessing GDPR compliance of various entities under their jurisdiction and, in the event of infringements, issuing fines.

Data subject: An individual who can be identified, directly or indirectly, through reference to personal data about them.

Data subject rights: Under the GDPR, data subjects may have a number of legal rights designed to give them more control over their personal data. These include rights: 1) the right to be informed, 2) the right of access; 3) the right to rectification; and 4) the right to be forgotten.

GDPR: The General Data Protection Regulation is an EU law that came into force in May 2018, and regulates processing of personal data across all Member States, and for all EU residents and citizens.

Legal basis: Under the GDPR, the legal basis means the legal justification for the processing of personal data. Examples of GDPR legal bases include consent (e.g. for research) and vital interests (e.g. for delivering healthcare services).

Personal data: Any information that relates to a living, identified or identifiable person. Examples include names, phone numbers, physical characteristics or location data.

Pseudonymisation: The processing of personal data in such a manner that the personal data can no longer be attributed to a specific individual, without the use of additional information. Frequently used in clinical research, for example by using a coding system to attribute a numbered identifier to an individual and their data.

Sensitive personal data: Under the GDPR, data that reveals a person's ethnic origin, political opinions, religious beliefs, trade union membership, sexual orientation or health status. Sensitive personal data requires additional security and processing measures to safeguard against corruption, mis-use or loss.

The right to be forgotten': a term used in the GDPR which means the right for individuals to have their personal data erased. For more information, please see: https://gdpr-info.eu/art-17-gdpr/

AD: Alzheimer's disease or Alzheimer's dementia (should be specified which of the two when used)

ADL: activities of daily living

ALS: Amyotrophic lateral sclerosis

BoNT: Botulinum NeuroToxin

CAA: Cerebral amyloid angiopathy

CBD: Corticobasal degeneration

CNS: central nervous system (the brain and the spinal cord).

CRPD: United Nations Convention on the Rights of Persons with Disabilities (sometimes referred to as UN CRPD)

CSF: cerebrospinal fluid (a body fluid found around the brain and the spine).

DALY: Disability-adjusted life year. The disability-adjusted life year is a societal measure of the disease or disability burden in populations. One DALY represents one lost year of healthy life.

DLB: Dementia with Lewy bodies

DNA: This stands for deoxyribonucleic acid. DNA contains our hereditary material and our genes. It is like a set of instructions for the development, functioning, growth and reproduction of all known organisms.

DOI: Digital Object Identifier (a unique and permanent identifier consisting of a string of numbers, letters and symbols, assigned to online works). This can often be found at the end of references to articles in scientific journals. It can be copied and pasted as a search term on the Internet instead of typing in the title of an article.

DSM-V: the fifth edition of the *Diagnostic and Statistical Manual of Mental Diseases* which is the standard classification of mental diseases used mainly by mental health professionals in the United States of America.

FTD: Frontotemporal dementia

GDPR: General Data Protection Regulation

HD: Huntington's disease

IiRBD: Isolated REM sleep behaviour disorder

HD: Huntington's disease

ICD-10: the tenth edition of the International Classification of Diseases developed by the World Health Organization

iRBD: Isolated REM sleep behaviour disorder

IWG: International Working Group (one of the main groups responsible for developing the new model and definitions of Alzheimer's disease).

LGBTQ+: Stands for lesbian, gay, bisexual, transgender, queer (or sometimes questioning) and others. The "plus" represents a wide range of additional identities that are not accounted for in this and similar acronyms.

MCI: this stands for Mild Cognitive Impairment. Mild Cognitive Impairment is often considered as the stage between the expected cognitive decline of normal ageing and the more significant decline of dementia. It may increase a person's risk of later developing dementia but some people with mild cognitive impairment don't deteriorate further and some eventually get better.

MMSE: Mini-Mental State Exam. The MMSE (sometimes called the Folstein Test) can be used to screen for suspected dementia and can also be used to determine the stage and severity of dementia for someone who has it. It can show changes over time if taken every year or so.

MSA: Multiple system atrophy

NIA-AA: National Institute on Aging and the Alzheimer's Association (one of the main groups responsible for developing the new model and definitions of AD).

PI: Public Involvement

PI: Principal or Primary Investigator

PSP: Progressive supranuclear palsy

RLS: Restless legs syndrome

SCD: Subjective cognitive decline

Additional terms for which definitions will be developed

Amyotrophic lateral sclerosis

Atypical or plus parkinsonism

Bio-sample

Cerebral amyloid angiopathy

Cerebellum

Cognitive data

Cross-sectional cognitive data

DaT scan

Data manager

Dementia with Lewy bodies

Diagnostic marker:

Electrophysiology:

Frontotemporal dementia: (frontaltemporal in EPND catalogue)

Idiopathic Parkinson's disease

Isolated REM sleep behaviour disorder

Maximum age

Minimum age

Neuropathology:

Neuropsychiatric assessment:

Parkinson’s disease

Participant

PET-Tau

Subject

Tau

Appendix 4: Background materials for lay glossary consultation

In the online meeting of the EWGPWD on 31 January, we would like to discuss a glossary that we have developed in collaboration with some members of the EWGPWD.

A glossary is an alphabetical list of the words or phrases in a text that people are likely to find difficult to understand, accompanied by their meaning. Glossaries are usually designed for people who are not trained, qualified or experienced in a particular subject or activity.

This glossary has been developed in the context of the EPND project.

The EPND project is a European-wide research project focused on increasing access to data for researchers working on neurodegenerative diseases such as dementia. Members of the EWGPWD have already provided feedback on some aspects of this project (e.g. the topic of data sharing and consent). Some members of the EWGPWD also reviewed some definitions of terms included in the glossary, making sure they were understandable and clearly explained.

Currently, the EPND lay glossary includes around 200 terms in relation to the topics of dementia and medical terminology, research, data sharing and privacy, ethics, diversity and marginalised groups

In the EWGPWD meeting, we would like to discuss the following three topics:

- The layout of the glossary
- The content of the glossary
- How to ensure that people can find and use the glossary

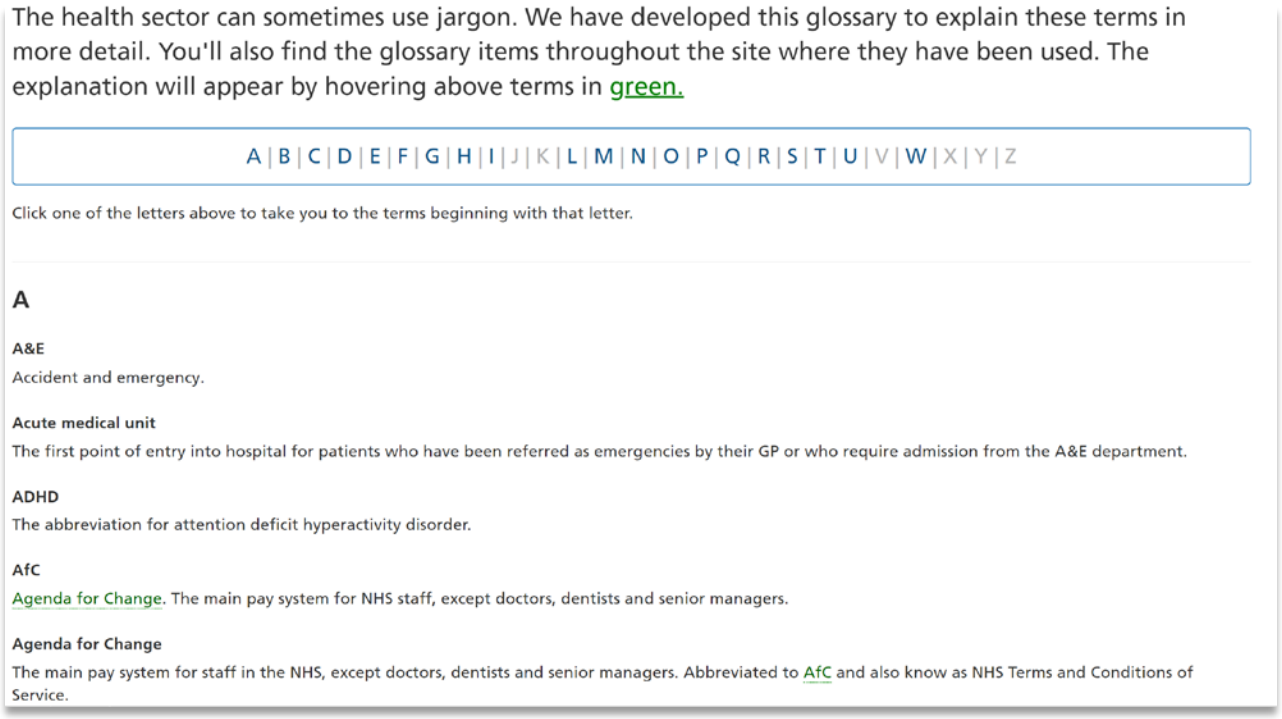
Please see below for each topic some examples of other existing glossaries that we have found, an explanation of how these glossaries work and the questions that we will discuss at the meeting.

In the annex document also attached in this email, you can see the full list of terms currently included in the glossary.

TOPIC 1: The layout and functioning of the glossary

Please see below 3 possible examples with slightly different layouts

Example 1 – National Health Service Glossary



The health sector can sometimes use jargon. We have developed this glossary to explain these terms in more detail. You'll also find the glossary items throughout the site where they have been used. The explanation will appear by hovering above terms in green.

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V | W | X | Y | Z

Click one of the letters above to take you to the terms beginning with that letter.

A

A&E
Accident and emergency.

Acute medical unit
The first point of entry into hospital for patients who have been referred as emergencies by their GP or who require admission from the A&E department.

ADHD
The abbreviation for attention deficit hyperactivity disorder.

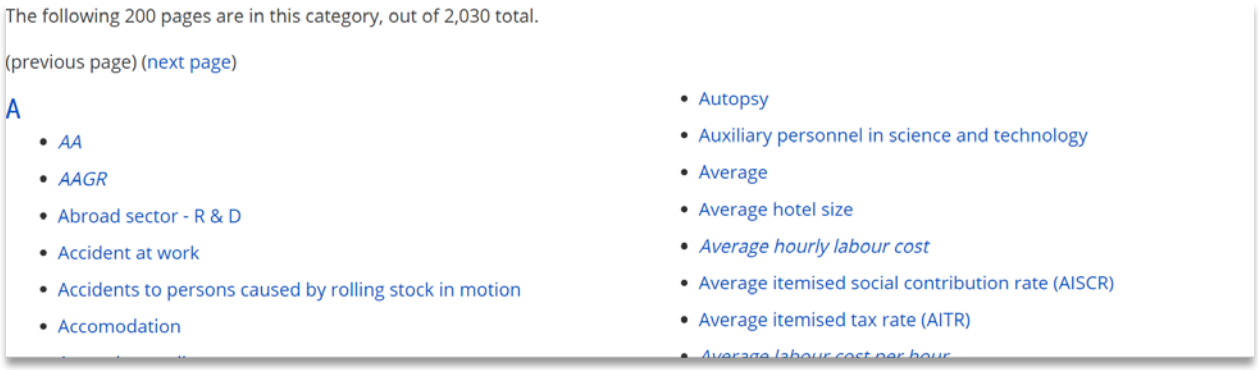
AfC
Agenda for Change. The main pay system for NHS staff, except doctors, dentists and senior managers.

Agenda for Change
The main pay system for staff in the NHS, except doctors, dentists and senior managers. Abbreviated to AfC and also know as NHS Terms and Conditions of Service.

Explanation for members of the EWGPWD

- The glossary is organised in alphabetical order (from A to Z). Users can either scroll down the entire list or click on a letter at the top in the box to go straight to a particular letter of the alphabet.
- If a term is highlighted in green (e.g. Agenda for Change), clicking on that term will take users to where it is explained in the glossary. In this example, it is right below. This is a form of cross referencing.
- A similar system is used by the National Institute for Health and Care Research, by the National Institute for Health and Care Excellence (NICE), the European Medicines Agency and by the Patients Voices Network.

Example 2 – Eurostat statistics glossary



The following 200 pages are in this category, out of 2,030 total.

(previous page) (next page)

A

- *AA*
- *AAGR*
- Abroad sector - R & D
- Accident at work
- Accidents to persons caused by rolling stock in motion
- Accomodation
- Autopsy
- Auxiliary personnel in science and technology
- Average
- Average hotel size
- *Average hourly labour cost*
- Average itemised social contribution rate (AISCR)
- Average itemised tax rate (AITR)

Explanation for members of the EWGPWD:

This glossary is also organised in alphabetical order but showing the terms in the glossary, not the definitions. If users hover over a particular term, the first 20 or so words of the definition can be seen. If they click on the term fully, they are taken to another page showing the full definition as well as the source. At the bottom on each page, it is possible to move to the next page but there does not seem to be a way to jump to terms starting with another letter later on in the alphabet (i.e. to jump from letter A to letter P).

Example 3 - (a) Glossary from Health Government in Australia and (b) from US National Council

a)

Glossary of Lay Terminology

MEDICAL TERM	LAY TERMINOLOGY
abdomen	belly
ablation	remove
Absorb	Take up fluids, take in
abstain	avoid
acuity	Clearness
acute	short-term; sudden onset
adenopathy	swollen glands
adjuvant	Helpful, assisting, added

b)

GLOSSARY OF TERMS
RELATED TO INTERPRETING IN HEALTH CARE

"A" language	a language in which the interpreter has native proficiency in speaking and listening [ASTM]. See **"B" language**.
accreditation	a term usually referring to the recognition of educational institutions or training programs as meeting and maintaining standards that then qualify its graduates for professional practice. See **certified interpreter**.
ad hoc interpreter	an untrained person who is called upon to interpret, such as a family member interpreting for her parents, a bilingual staff member pulled away from other duties to interpret, or a self-declared bilingual in a hospital waiting-room who volunteers to interpret. Also called a *chance interpreter* or *lay interpreter*. See **certified interpreter, qualified interpreter.**
advocacy	any action taken (by an interpreter) on behalf of an individual that goes beyond facilitating communication, with the intention of supporting good health outcomes. In general, advocacy means that a third party (in this case, the interpreter) speaks for or pleads the cause of another party, thereby departing from an impartial role. See **transparency**.

Explanation for members of the EWGPWD:

These glossaries are arranged in table form. In example a), the definitions provided are fairly short and, in some cases, merely an alternative plain English term. In some places, the definitions do not seem to be sufficiently comprehensive to explain what the medical term really means. The terms in this glossary can only be seen by scrolling through the complete list.

In example b) it is the same system for slightly more detailed definitions.

Questions for the EWGPWD meeting in relation to Topic 1:

Considering these 3 examples about different possible layouts ...

1. What do you like and dislike about one long continuous list of terms (like in example 1)?

2. What do you like and dislike about presenting the terms in columns (like in example 2)?

3. Is it important to be able to click on a letter of the alphabet and to be taken to the terms starting with that letter (like in example 1) or is it fine to just scroll through all the entries (like in example 2)?

4. What do you like and dislike about glossaries that present terms in table form (with the term on the left and the definition on the right) like in example 3?

5. A cross reference is where a term that is used in a definition is explained somewhere else in the glossary. Is cross-referencing helpful and if so, what is the best way to do this?
   (In the first example, the term to be cross referenced was highlighted in green. Some glossaries put the term in *italics* and others use a hyperlink which takes users straight to it).

TOPIC 2: The content of the glossary

The terms included in the glossary for EPND have been taken from earlier work conducted by Alzheimer Europe as well as from the Spanish Parkinson's Disease Association. They were circulated amongst all the members of the European Working Group of People with Dementia for feedback and amended based on the suggestions made. The ones linked to Parkinson's disease were taken from published glossaries and this will need to be acknowledged.

We put the terms in different categories to help us all see if any important terms are missing. By definition, glossaries should be organised in alphabetical order. Some of the terms, particularly those linked to diversity and marginalisation might seem unnecessary but large-scale studies are paying increasing attention to such issues so some might be worth holding on to.

We have not included in the glossary a multitude of terms specifically related to statistical analysis. Please see Example 4 below. This is because many of them, which people will nevertheless see in articles and information about research, are highly specialised terms. We would need to provide lengthy explanations to avoid using a lot of terms in the explanation which themselves need explaining or cross-referencing.

Example 4: Sage Publications commonly used statistical terms

Chi-square (χ^2): A nonparametric test of statistical significance appropriate when the data are in the form of frequency counts; it compares frequencies actually observed in a study with expected frequencies to see if they are significantly different. *NPT

Cochran's *Q*: Used to evaluate the relation between two variables that are measured on a nominal scale. One of the variables may even be dichotomous or consisting of only two possible values. *NPT

Coefficient of determination (r^2): The square of the correlation coefficient (r), it indicates the degree of relationship strength by potentially explained variance between two variables.

Explanation for members of the EWGPWD: The above glossary was not designed for lay people but for researchers. There are dozens of terms like these that lay people may come across on the Internet or in scientific articles in connection with data sharing/re-use. Any definition would need to be fairly long in order to make it truly understandable without using other terms that also need explaining or having a lot of cross references.

In addition, for the terms included, in some glossaries there is an invitation to users in the introduction to let them know if certain useful terms are missing. See two examples below from existing glossaries

Example 5:

> *"If you come across terminology or methods that aren't in our glossary and you think they would be helpful to other patient partners, please let us know!"*
>
> *"If you cannot find the term you are looking for, please email us so that we can consider adding it to the glossary."*

Questions for the EWGPWD meeting in relation to Topic 2:

In relation to the contents of the glossary:

6. Should we attempt to include statistical analysis terms or should we exclude them from our glossary?

7. Should we invite people who eventually use the glossary to request additional terms (of any type)?

8. If so, how should we do that (e.g. ask them to email us, have the possibility for them to do that from the glossary itself or in another way)?

9. Are there any terms in the glossary that you think are missing?

TOPIC 3: How to ensure that people can find and use the glossary

Once we have a good glossary, we need to ensure that people can find it and use it. The plan is to put the glossary on the EPND website, where there are other specialised glossaries for experts in different domains which will be merged together. Ideally, the lay glossary will be available on the website but separately in a format that is more accessible to lay people in terms of its layout and ease of access. There may be some technical constraints but your feedback would help us to try to ensure that the best solution is found.

Once the glossary is on the EPND website, people will only use and benefit from it if they know that it is there. However, the website is mainly for researchers interested in obtaining data for their planned research (i.e. based on EPND's goal to facilitate data sharing/re-use). This is, therefore, quite a challenge.

Questions for the EWGPWD meeting in relation to Topic 3:

10. How should the glossary be presented on the EPND website (e.g. have an icon to click on, create a section of the website dedicated to lay people in which the principles of data sharing/re-use are explained and the glossary included, some other way)?

11. How can we make sure that people who do not know about the EPND project or website find out about the glossary and can easily access it (e.g. through links on other websites and if so which and how to organise that, via frequent targeted tweets on X/Twitter, some other way)?

12. In which other contexts could this glossary be valuable (i.e. beyond the EPND project)?