

# Terms of Reference

Early Detection of Neurodegenerative Diseases Project

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This document outlines the Terms of Reference for the project-internal stakeholders of the Early Detection of Neurodegenerative diseases (EDoN) project, including their purpose, group membership, roles and responsibilities, meeting frequency and communication arrangements. Where voting or formal approval is necessary to make a decision, a quorum of over 50% of group members need to be in attendance (or provide a vote via email). For all groups, an annual review of membership will take place within the group and if there are any concerns about the continued membership of a particular person it will be decided by a majority vote of group members whether the person is to be removed from the group. None of the groups referenced in this document have the authority to vary the terms of the Consortium Agreement or enter into legally binding contractual commitments on behalf of the parties without their prior approval.

As an overview, the roles of the different groups are as follows:

- The Board **approves** the EDoN strategy, plans and budget
- The Steering Committee **defines** the EDoN strategy, plans and budget
- The Operational Group **supports the Steering Committee to define** the EDoN strategy, plans and budget
- The Hubs **implement** the EDoN strategy, plans and budget
- The Coordination group **monitors** the implementation of the EDoN strategy, plans and budget
- The Advisory Board **advises** on the EDoN strategy, plans and budget

## Board

### Purpose

The EDoN Board approves EDoN's overall strategy and plans, as well as the application of the budget that was agreed by the Alzheimer's Research UK (ARUK) Board of Trustees as part of ARUK's annual operational planning.

### Membership

The EDoN Board is led and chaired by the Rt Hon David Cameron. The maximum number of Board members should not exceed ten (to be reviewed on a regular basis). The normal term for Board members is two years, with a review after one year of membership. The initial EDoN Board was appointed by ARUK. Additional EDoN Board members are appointed by a majority vote of the current Board, following suggestions from the Coordination Group, Steering Committee, and current Board members.

### Roles and Responsibilities

The EDoN Board is responsible for reviewing, discussing and approving the annual plans, strategy and budget proposed by the Steering Committee. Any major deviations from the approved annual plans or budget need to be justified by the Steering Committee and reviewed and approved by the EDoN Board. The EDoN Board members, as part of the EDoN initiative, are formal representatives acting in the best interest of EDoN.

### Meetings and Communications

EDoN Board meetings are held in person or via video conference twice a year, with additional meetings scheduled in between if required. All meetings are chaired by the Rt Hon David Cameron (the Board chair and lead) and are attended by the Board members and additional representatives from the Coordination group or Steering Committee, as required. Decisions are made by a simple majority vote and all members of the EDoN Board are eligible to vote on all decisions.

ARUK's Senior Governance Manager leads the management of the EDoN Board. Agendas are set in advance with the chair and lead of the EDoN Board and the Coordination group, and materials for meetings are distributed at least one week in advance of the meetings. Minutes are shared after each meeting with the EDoN Board, as well as with the ARUK Board of Trustees, key funders and the EDoN Steering Committee. The Coordination Group is responsible for ensuring that the actions set by the EDoN Board are completed.

### Confidentiality and sharing of information

Board Meetings will be considered confidential. Members should normally preserve the confidentiality of what is discussed at their meetings. The approval of the chair should be sought prior to any disclosure.

## Conflict of Interest

All EDoN Board members will be asked to complete a register of interest form annually which will be kept on record by ARUK. Board members will be asked ahead of each Board meeting for any updates and any changes that will be recorded by ARUK on their register.

There will be a standing item on conflicts of interest at each meeting to allow Board Members to raise conflicts should they arise. If items are to be discussed where a conflict arises, members are expected to recuse themselves as necessary for that item.

Board Members should disclose in the Register any interest, financial or otherwise, which is likely or would, if publicly known, be perceived as being likely to influence the exercise of independent judgement on the Board. The Register does not cover all interests, but specifically those relevant or potentially relevant to an individual's role as a Board Member of the EDoN Board.

## Steering Committee

### Purpose

The Steering Committee decides on the priorities and the general course of the project, defining the EDON strategy, plans and budget.

### Membership

The Steering Committee consists of at least one representative with relevant expertise from each of the founding members of the EDoN consortium (for the duration of their engagement in EDoN) and is initially led by the ARUK representative. Throughout the project, a different lead may be appointed if this is decided by the Steering Committee. In that case, the ARUK representative will, nevertheless, retain the position of Steering Committee chair (i.e. the roles of lead and chair will be held by different people). Additional members will be appointed if any further organisations join the EDoN consortium by signing a Deed of Adherence. In addition, individuals not representing one of the consortium partners may join the Steering Committee if the current Steering Committee members decide that those individuals add value to the group and should thus be invited to join.

Should any member of the Steering Committee wish to step down from their position, they are asked to notify the Coordination Group lead, at least 15 working days before the last Steering Committee meeting which they are planning to attend, so that a suitable replacement may be found.

### Roles and Responsibilities

The Steering Committee makes decisions (by a simple majority vote) relating to procedures, outputs, and stakeholders that have an impact on a project-wide scale. This includes leading the EDoN scientific strategy, defining the initiative's priorities, approving project-wide

policies (e.g. on data and software management), addressing high-level issues that affect the operation of the initiative, and selecting new project partners.

Steering Committee meetings provide a platform for deliberating 'big picture' aspects of the project, which affect the majority of the Hubs, including funding, high-level plans, and engagement with project-external partners. More detailed discussions of specific inter-group dependencies should ideally take place in separate meetings between the leads of the relevant Hubs.

## Meetings and Communications

Steering Committee meetings are held for about 1.5 hours via video conference or in person at the Alan Turing Institute (London) on the first Monday of the month (or at any other time at the request of the members). Meetings are chaired by the ARUK representative (the Steering Committee chair) and are attended by Steering Committee members, as well as by members of the EDoN Project Management subgroup who create the agenda, take minutes, and share with the Steering Committee relevant updates and materials before the meetings. Decisions are made by a simple majority vote of those Steering Committee members who are present at the meeting (or via email). In case of a tie, the Steering Committee chair makes the final decision.

Occasionally, Steering Committee members are asked to take action or make decisions via email outside the regular meetings. Responses should be provided within 5 working days of the request (unless there is a need for substantial discussion).

## Operational Group

### Purpose

The Operational Group supports the Steering Committee, making proposals with specific suggestions to help the Steering Committee to reach agreements. This group will cover operational and scientific topics, that require the input from the 3 hubs and the coordination group, and require some work before the SC can make a decision. Some examples of these topics are: Data access within the EDoN initiative or the Prospective data application budget. These topics can be proposed by the Hubs, the SC or the Coordination group.

### Membership

The Operational Group consists of the leads of the Operational Groups (Digital Hub, Clinical Hub, Analytics Hub, Coordination Group and the Steering Committee). This group will be chaired by the Coordination Group lead. Throughout the project, a different lead may be appointed if this is decided by the Steering Committee.

## Roles and Responsibilities

The Operational Group raises cross-Hub issues and suggests a range of solutions to the Steering Committee which makes the final decision about these topics. This includes gathering operational and scientific issues across the three Hubs, suggesting strategy to address these topics and present the discussed solutions to the Steering Committee.

Topics include project-wide policies on data sharing and software management, publication strategy, cross-Hub budget, or any other high-level issue that affects the three Hubs. More detailed discussions of specific inter-group dependencies should ideally take place in separate meetings between the leads of the relevant Hubs.

## Meetings and Communications

Operational Group meetings are held for 1 - 2 hours via video conference or in person at the institution of one of the Hub leads or members on the third Monday of the month (or at any other time between two Steering Committee meetings at the request of the members). Meetings are chaired by the ARUK representative and are attended by the three Hubs leads (or by Hubs delegates designated by the Hubs leads), as well as by interested members of the Hubs and members of the Project Management subgroup. The agenda and attendees will be defined by the Steering Committee depending on the priority issues to be discussed.

A Project Management subgroup representative is assigned to create the agenda, take minutes and share relevant materials to the Group before each meeting. The agenda and minutes should contain a discussion of issues, concerns and questions and the suggested solutions to be presented to the following Steering Committee meeting (or a definition of the next steps (actions) if needed).

## Coordination Group

### Purpose

The Coordination Group coordinates, project-manages, monitors and supports the implementation of the project strategy, plans and budget.

### Membership

There are seven Coordination subgroups which consist of individuals with relevant expertise: Project Management, Policy and Ethics, Communications, Capacity Building, Fundraising, Governance and Legislation. Coordination subgroup leads are selected by the Coordination Group lead, who is appointed by ARUK. Members of the subgroups are selected by the subgroup leads.

## Roles and Responsibilities

### Project Management

The role of the Project Management subgroup is to ensure the timely delivery of the project, within budget and scope, and to facilitate project-internal communication supporting the Hubs and the Steering Committee. This is achieved by providing project management tools, monitoring progress, organising and supporting regular meetings, and disseminating information internally. In addition, the Project Management subgroup handles project-related open calls as required.

### Policy and Ethics

The role of the Policy and Ethics subgroup is to ensure that the public perception of EDoN is taken into account throughout the project. For this purpose, the subgroup creates policy statements for circulation to the Hubs and works closely with the Communications subgroup to ensure that project messaging is sensitive to potential ethical and practical concerns. Additionally, the Policy and Ethics subgroup supports the regulatory approval process and the integration of the EDoN digital toolkit into the NHS.

### Communications

The role of the Communications subgroup is to manage messaging around the project to effectively promote EDoN to both researchers and the public. To this end, a communication strategy is developed, and a social media account, a project-dedicated website, and regular newsletters are created and maintained. Where externally released materials refer to the partner institutions, the communications teams of the relevant organisations will be consulted prior to publication of the content.

### Capacity Building

The role of the Capacity Building subgroup is to engage with external stakeholders that may be able to contribute to, or benefit from, the EDoN project. In addition, the subgroup ensures that the training needs of project members are met. This is accomplished by establishing strategic partnerships, and by organising talks, workshops, networking activities and training events.

### Fundraising

The role of the Fundraising subgroup is to secure funding for the project by engaging with major donors and corporate partners. This involves creating a fundraising strategy, writing cases for support, identifying and contacting potential donors, and organising fundraising events.

### Governance

The role of the Governance subgroup is to define the governance structure of EDoN and to support the meetings of the Board and Advisory Board. This includes ensuring that the

structure/ Terms of References are suitable for the project requirements, as well as organising Board and Advisory Board meetings, agendas and preparatory materials.

## Legislation

The role of the Legislation subgroup is to provide legal advice as required. This includes ensuring that contracts, products and services generated by the project are in line with laws and regulations, and defining legal responsibilities of the project partners in the consortium agreement and funding contracts.

## Meetings and Communications

Meetings of the Coordination group, including the subgroups, take place once a month and are chaired by the Coordination Group lead, who will also be preparing the agenda and assign the responsibility for taking minutes to one of the group members. By default, the meetings are held at the ARUK offices, with an option to join remotely by video conference or phone. Where possible, decisions are made by consensus, i.e. in a way that all meeting attendees are satisfied with the decision, even if it is not their first choice. If this is not possible, the Coordination Group lead makes the final decision.

In addition, meetings of the Project Management subgroup are held in person at the ARUK offices or via video conference once a week for a total of two hours and are chaired by the lead of the Project Management subgroup. The meeting frequency may be adjusted throughout the project based on requirements. The Project Management subgroup lead is responsible for setting the agenda and taking minutes, with contributions from the other group members. Where possible, decisions are made by consensus, i.e. in a way that all meeting attendees are satisfied with the decision, even if it is not their first choice. If this is not possible, the Coordination Group lead makes the final decision.

Additional meetings of the other Coordination subgroups may take place ad hoc as required and when requested by the Project Management subgroup.

## Hubs

### Purpose

The Hubs are responsible for implementing the EDoN strategy, plans and budget and delivering the outputs of the project.

### Membership

There are three Hubs consisting of experts in the relevant fields: digital (technology), clinical (research and practice), and analytics. The Hubs incorporate several subgroups, the structure of which may change during the course of the project. Presently, the Clinical Hub incorporates the Cohorts & Biomarkers and Clinical Support subgroups, the Digital Hub consists of the Digital Tools, Digital Platform and Digital Support subgroups, and the Analytics Hub is synonymous with the Fingerprint Analytics group.

The Hub and subgroup leads were selected by ARUK based on their expertise. To accelerate the preparation and planning of the project, members of the Steering Committee were selected to lead the Hubs and subgroups. Should any Hub leads need to be added or replaced, the new Hub leads will be suggested and approved by the Steering Committee. Should any subgroup leads need to be added or replaced, the new subgroup leads will be suggested and approved by the Hub members. Additional group members are hired/selected by the subgroup leads, as well as through open calls, depending on project requirements.

## Roles and Responsibilities

These Hubs are responsible for the implementation of EDoN activities and facilitate each others' work by providing relevant resources and expertise. Hub leads are responsible for proposing Hub plans and ensuring these plans are implemented. The Hub plans, which include deliverables, timelines and budgets, need to be approved by the Steering Committee and the Board.

### Clinical Hub

The Clinical Hub plays a key role in identifying the cohorts and digital biomarkers relevant to the project. Additionally, this Hub is responsible for engaging with existing research cohorts to drive the application and validation of the EDoN digital tool(s) through prospective data collection.

Moreover, the members of the Clinical Hub support the other Hubs by providing advice on areas such as cognition, neuroimaging, fluid-based biomarkers and health records.

### Digital Hub

The Digital Hub is responsible for building the data infrastructure that supports the capture, storage, analysis and visualisation of the data generated by the project. In addition, the Hub supports the development of the integrated EDoN tool, which consists of wearable devices and smartphone applications that were tested for their early detection utility throughout the project.

Moreover, the Digital Hub members support the other Hubs by providing guidance on best practices in health informatics, as well as by giving advice on choosing the most appropriate technologies for capturing, linking and aggregating data, and developing robust, safe, accurate and intuitive digital tools.

### Analytics Hub

The Analytics Hub is responsible for developing, validating and refining machine learning ('fingerprint') models that can detect specific dementia-causing diseases years before dementia symptoms become apparent.

## Meetings and Communications

Each Hub meets once a month for 1 - 2 hours via video conference or in person at the institution of one of the Hub leads or members. Meetings are chaired by the Hub leads and are attended by all Hub members, as well as by interested members of the other Hubs and members of the Project Management subgroup. The Hub leads assign someone to create the agenda and take minutes. The agenda and minutes should contain a progress update, a discussion of issues, concerns and questions and a definition of the next steps (actions). Where possible, decisions are made by consensus, i.e. in a way that all Hub members are satisfied with the decision, even if it is not their first choice. If this is not possible, the relevant Hub lead makes the final decision.

In addition, face-to-face meetings with all Hub and subgroup leads (and occasionally all Hub members) and relevant Coordination subgroups are organised by the Project Management subgroup as required.

## Advisory Board

### Purpose

The Advisory Board provides technical and scientific advice on the strategy, budget and implementation plans of the project.

### Membership

Advisory Board members are individuals with expertise in one of the subject areas relevant to the Hubs (i.e. clinical research, data analytics, data service provision, or digital technology) or in broader areas relevant to the project (e.g. healthcare, the pharmaceutical industry, or the technology industry).

Advisory Board members are suggested by the Hub leads and the Coordination Group and are approved by the Steering Committee chair. The latter also appoints the Advisory Board lead.

### Roles and Responsibilities

The Advisory Board reviews and provides feedback on the annual reports and project plans of the Hubs. Moreover, Advisory Board members are available to give ad hoc advice to the individual Hubs and the Board, as required. In addition, the Advisory Board provides guidance on the strategy to achieve the overall aim of the project.

## Meetings and Communications

The Advisory Board meets in person or via video conference once per year with the Steering Committee and the Project Management subgroup between 2 to 4 weeks after the Hubs have submitted their annual plans. Additional meetings might be proposed by the Coordination Group to provide an update to the Advisory Board. The Advisory Board lead will be appointed by the Coordination group lead and will chair the meetings and create the

agenda in collaboration with the Project Management subgroup, with someone from the latter group taking minutes. The Advisory Board members provide advice for the decision-making process of the Hubs and the Board, as required, but are not themselves involved in the decision. In addition to attending the annual meetings, Advisory Board members provide ad hoc advice to the Hubs as required. This may take place via email or video conference calls.