



Deliverable D7.1

Report on the selection of relevant brain diseases and engagement activities to establish collaboration



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Short description of the Deliverable:

This deliverable is linked to Task T7.1 which is to define the most important stakeholders to be included in the analysis of another BRAIN disease's (than multiple sclerosis) constellation of actors and to identify the most suitable engagement approaches to be considered for the metrics' assessment.

This task requires firstly to establish collaboration with a research consortium in another brain disease area than multiple sclerosis. This deliverable describes the selection process and engagement activities to establish the grounds for such collaboration.

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TABLE OF CONTENT

EXECUTIVE SUMMARY	5
1 INTRODUCTION	6
1.1 Purpose of this document	6
1.2 Structure of this document	6
1.3 Glossary.....	7
2 SELECTION OF RELEVANT CONSTELLATIONS OF ACTORS IN OTHER BRAIN DISEASES THAN MULTIPLE SCLEROSIS	8
2.1 Introduction to the EBRA Clusters	8
2.2 Engagement with EBRA clusters	9
3 TERMS OF COLLABORATION WITH EBRA CLUSTERS	10
4 CONCLUSIONS	11
APPENDIX 1 – TERMS OF REFERENCES ON THE COLLABORATION BETWEEN MULTI-ACT AND EBRA CLUSTERS.....	12

EXECUTIVE SUMMARY

The overall purpose of the MULTI-ACT project is to co-create a Collective Research Impact Framework (CRIF) that offers a more participatory and realistic evaluation of the health Research and Innovation (R&I) impact of multi-stakeholder initiatives.

Work Package 7 (WP7) aims to foster the application of the MULTI-ACT CRIF in Multistakeholder Research Initiatives (MRIs) focused on other brain disease areas in addition to Multiple Sclerosis MSRI carried out under WP4. The objective is to explore the applicability and utility of the MULTI-ACT framework on other brain disease areas including the elaboration of a tailored impact metrics' assessment

This first deliverable of WP7 reports on the identification and selection of another brain disease initiative and the establishment of the terms of the collaboration with the MULTI-ACT consortium.

Two brain research clusters established under the EU funded European Brain Research Area project (EBRA)¹ were identified and explored in terms of their suitability to complement the MULTI-ACT brain disease framework. These clusters were approached. One of them, the cluster in the field of epilepsy, the EPI-Cluster, turned out to be best suited and willing to collaborate with MULTI-ACT.

Terms of the collaboration were defined with respect to responsibilities and commitment of each party as well as the value of the collaboration.

¹ <https://www.ebra.eu/about/the-mission/>

1 INTRODUCTION

The EU-funded MULTI-ACT project, in full “A Collective Research Impact Framework and multi-variate model to foster the true engagement of actors and stakeholders in Health Research and Innovation”, aims to increase the impact of health research of Multi-stakeholder Research Initiatives and to better tie the research results to the mission of the initiatives.

To further develop and improve the MULTI-ACT framework, the MULTI-ACT Consortium already engaged in WP4 in a co-design effort with a potential user of the framework, a multi-stakeholder initiative in the disease area of Multiple Sclerosis (MS), i.e. the MS Care Unit Initiative.

In WP7, the aim is to explore the applicability and utility of the MULTI-ACT framework in the context of other brain disease multi-stakeholder initiatives, guide research promoters on how to use the MULTI-ACT CRIF and take the most benefit from it as well as collect feedback on the usability of the framework in the specific brain disease area.

For this purpose, the first step is to identify and engage with a research consortium in other relevant brain diseases in order to establish the grounds for the collaboration.

Therefore, the initial wording and scope of Deliverable 7.1 initially entitled ‘Report on the selection of relevant stakeholders in the agreed BRAIN disease and identification of suitable engagement approaches’ has been slightly amended to better reflect the outcome of the initial engagement activities with research consortia necessary to establish the collaboration with MULTI-ACT. The deliverable is now entitled ‘Report on the selection of relevant brain diseases and engagement activities to establish collaboration’.

1.1 Purpose of this document

Task T7.1 within WP7 aims to define the most important stakeholders to be included in the analysis of another BRAIN disease' constellation of actors and identify for them the most suitable engagement approach to be considered for the MULTI-ACT impact metrics' assessment.

This task requires first of all to establish collaboration with research initiatives in other brain disease areas than multiple sclerosis.

The purpose of this document is to describe the selection and engagement activities with other research initiatives and the establishment of the collaboration with MULTI-ACT Consortium.

1.2 Structure of this document

After the introduction, Section 2 describes the steps towards the selection of relevant research consortia in other brain disease areas than multiple sclerosis (MS).

Section 3 describes the terms of the collaboration of the MULTI-ACT Consortium with the EBRA clusters.

Section 4 provides the conclusions and introduces the next steps and deliverable under WP7.

1.3 Glossary

Criteria and sub-criteria: the set of guiding principles that constitute the MULTI-ACT Governance Model and are intended to be followed by the Model's user.

Co-accountability is the theoretical foundation of the overall MULTI-ACT framework. It refers to the approach of forming a broader and holistic expert knowledge and supports a plurality of perspectives in making decisions, not only in defining the performance indicators, but also in collecting data together and assessing the strategies in the long term. It represents a new form of democratic and participatory accountability, where a process of negotiation of interests and information is required. It promotes “multi-voiced” and tailored solutions that take into account the diversities of stakeholders’ value and interests. Co-accountability as a measurement framework promotes customized, qualitative and quantitative indicators that measure the accomplishments according to the multiple stakeholders’ priorities.

CRIF is a conceptual framework developed by MULTI-ACT enabling a new collective accountability approach for management and assessment of multi-stakeholder R&I initiatives in the field of brain diseases.

Multi-stakeholder initiative is a governance structure that seeks to bring different stakeholders together to participate in the dialogue, decision-making and implementation of solutions to the shared problems or goals.

Stakeholder refers to “any individual or group that is affected by, who can influence or may have an interest in the outcomes of an organization’s actions” (Freeman, 1984, *Strategic management : a stakeholder approach* (Latest edi). Boston, MA).

Stakeholder engagement refers to activities that can be done with stakeholders such as consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimizing their opposition or obstruction.

2 SELECTION OF RELEVANT CONSTELLATIONS OF ACTORS IN OTHER BRAIN DISEASES THAN MULTIPLE SCLEROSIS

2.1 Introduction to the EBRA Clusters

The European Brain Council (EBC) leader of WP7 raised the idea with the MULTI-ACT consortium to explore possibilities to collaborate with brain research consortia established under the EU funded European Brain Research Area project (EBRA)² named as 'EBRA clusters'.

The views of EBC, leader of WP7 were presented by the President of EBC, during the MULTI-ACT Consortium meeting held virtually on 3 March 2020. It included a brief description of the EBRA clusters and their potential relevance in relation to the MULTI-ACT WP7 activities.

The consortium's participants welcomed the idea which was further explored during two consecutive calls between the scientific coordinator of EBRA and President of EBC, and the coordinator of MULTI-ACT project, together with the relevant staff from each organisation. These calls were held on 2 April and 14 May 2020.

EBRA was created in 2018 as a catalysing initiative for brain research stakeholders (researchers, clinicians, patients, governments, funders and public institutions) to streamline and better co-ordinate brain research across Europe while fostering global initiatives.

EBRA Clusters are understood as "research communities that can be directed towards basic research, clinical research and/or methodological approaches under a common topic, and disease and/or thematic area".³

They aim to promote cooperation and exchange between brain research projects and to enable or enhance international collaboration in all areas of brain research.

Two established clusters from EBRA were presented as potentially relevant to explore the applicability and utility of the MULTI-ACT framework:

- 1) Epilepsy - Epi-Cluster⁴
- 2) Prevention of Severe Mental Disorders (PSMD-cluster)⁵

The selection criteria for the identified clusters above were mainly their:

- Strategic priorities including to increase stakeholder engagement, foster collaboration and harmonise impact assessment (see Table 1. Objectives of EBRA clusters);

² <https://www.ebra.eu/about/the-mission/>

³ <https://www.ebra.eu/call4clusters/>

⁴ <https://www.ebra.eu/epi-cluster/>

⁵ <https://www.ebra.eu/psmd/>

- Multi-stakeholder composition and multidisciplinary collaborations: Researchers, Clinicians, Quality Assurance and ethics, Industry, Patient representative, Professional association, research infrastructures;
- Suitability for complementing MULTI-ACT CRIF brain disease end users

Table 1. Objectives of EBRA clusters

EPI-Cluster strategic priorities	PSMD-cluster strategic priorities
<ul style="list-style-type: none"> • Advance the existing collaboration • Expand the network • Advance research on core topics • Enhance resource-sharing • Develop a preclinical trial network and enhance clinical trial structures • Develop researcher exchange mechanisms • Increase engagement of persons with epilepsy and their representatives • Develop a global funding initiative onepilepsy research across agencies 	<ul style="list-style-type: none"> • Cross-fertilise leading European research organisations • Harmonise assessment, outcome measures and interventions • Implement digital health, big data and precision medicine into healthcare • Promote clinical research partnerships • Produce clinical guidelines • Apply for European grant funding • Disseminate preventive culture in psychiatry • Engage policy makers, healthcare systems, patients and their families

2.2 Engagement with EBRA clusters

The mission, strategic intent and tools offered by MULTI-ACT CRIF were briefly presented by EBC to the EPI-Cluster during their internal virtual consortium meeting on 17 June 2020. Interest was expressed in exploring the use of MULTI-ACT tools and guidelines in particular to support the EPI-Cluster building its community, identify and engage with relevant stakeholders. Patient engagement guidelines were seen as particularly valuable to the community as well as the governance criteria to define the stakeholders and possibly better define the cluster’s priorities and agenda. Several informal opportunities were used to brief the chair of the cluster on the possibilities offered by a collaboration with MULTI-ACT Consortium.

Interactions with the Prevention of Severe Mental Disorders (PSMD) cluster, revealed that in its current stage of development, the MULTI-ACT CRIF was not suitable in addressing their current needs and could be reconsidered at a later stage. Therefore, WP7 will focus on the collaboration between the MULTI-ACT consortium and the EpiCluster.

3 TERMS OF COLLABORATION WITH EBRA CLUSTERS

The consortium agreed that Terms of Reference would be necessary to outline the terms of the collaboration between EBRA clusters and MULTI-ACT in the context of Work Package 7 (WP7) of which the scope is “transferability and test of the methodology beyond Multiple Sclerosis (MS)”.

The terms of reference define the responsibilities and commitment of each party -the clusters and MULTI-ACT - as well as the value and expected outcome of the collaboration.

The Terms of Reference template is included in Appendix 1.

4 CONCLUSIONS

The identification and selection of relevant brain diseases with the view to explore the applicability and utility of the MULTI-ACT framework on other brain disease areas than multiple sclerosis required a step-wise approach. MULTI-ACT tools had to be explained for the clusters to grasp the potential value of the collaboration. The time and resources required to incentivize research consortia to collaborate and use the MULTI-ACT tools should not be underestimated and reiterates the need for user-friendly material.

It appeared that a collaboration with the EBRA EPI-Cluster presents a timely opportunity. EBRA epilepsy research community is looking to expand and engage with relevant stakeholders including patient groups.

With the help of the MULTI-ACT Governance Model criteria⁶, the next step will be to define the most important stakeholders to be included in the analysis of the EPI-cluster' constellation of actors and define the best engagement approaches with these actors and their needs.

⁶ Deliverable D5.4: “MULTI-ACT Governance Model for collaborative initiatives”, Jun 2019, <https://www.multiact.eu/project-deliverables/>

APPENDIX 1 – TERMS OF REFERENCES ON THE COLLABORATION BETWEEN MULTI-ACT AND EBRA CLUSTERS

Collaboration between MULTI-ACT and third parties in the context of Work Package 7:
“Transferability and test of the methodology beyond MS”

Terms of Reference (ToR)

I. Introduction (purpose and background)

These Terms of Reference (ToR) are intended to describe the roles and responsibilities of the MULTI-ACT consortium and third parties in the context of Work Package 7 (WP7) of which the scope is “transferability and test of the methodology beyond Multiple Sclerosis (MS)”.

The EU-funded MULTI-ACT⁷ project, in full ‘A Collective Research Impact Framework and multi-variate model to foster the true engagement of actors and stakeholders in Health Research and Innovation’, aims to increase the impact of health research of Multi-stakeholder Research Initiatives.

To further develop and improve the MULTI-ACT framework, the MULTI-ACT Consortium already engaged in a co-design effort with a potential user of the model, a multi-stakeholder initiative in the disease area of Multiple Sclerosis (MS), i.e. MS Care Unit Initiative.

After the MULTI-ACT framework co-design is concluded, in WP7, the aim is to explore the applicability and utility of the MULTI-ACT framework in the context of other brain disease multi-stakeholder initiatives, guide their promoter on how to use the model and take the most benefit from it as well as collect their feedback on the usability of the framework specific to the brain disease area.

For this purpose, the MULTI-ACT Consortium explored possibilities of collaboration with clusters established under the EU funded European Brain Research Area project (EBRA)⁸. EBRA was created in 2018 as a catalysing initiative for brain research stakeholders (researchers, clinicians, patients, governments, funders and public institutions) to streamline and better co-ordinate brain research across Europe while fostering global initiatives. Clusters are understood as associations of research projects that can be directed towards basic research, clinical research and/or methodological approaches under a common topic, and disease and/or thematic area.

⁷ The project started on the 1st of May 2018 and will continue for three years. It has received funding from the European Union’s Horizon 2020 Research and Innovation Programme under the Grant Agreement No. 787570.

⁸ <https://www.ebra.eu/about/the-mission/>

II. [MULTI-ACT Consortium] responsibilities under these ToR

[The MULTI-ACT Consortium] shall undertake the following activities:

- 1) Present the MULTI-ACT framework model and its key aspects.
- 2) Provide guidance on how to implement the MULTI-ACT framework.
- 3) Gather the Cluster's perspective on the usability and applicability of the MULTI-ACT framework in its brain disease area.
- 4) Use the information collected and feedback provided by the Cluster to draft sustainability plan for the MULTI-ACT framework.

III. [Cluster] responsibilities under these ToR

The [Cluster] shall undertake the following activities:

- 1) Selection of one or more of the key aspects from the MULTI-ACT framework that are relevant to its specific Cluster:
 - Governance model
 - Patient engagement strategy and guidelines
 - Co-accountability impact assessment model

A working group will be created to work closely with the MULTI-ACT consortium

- 2) Assess utility and applicability and identify potential uses of the MULTI-ACT framework within and for the benefit of the [Cluster]'s activities.

The time that the working group of the [Cluster] will spend on this project will be limited to 2-3 virtual meetings of max 2 hours each and may include supporting material to read and complete (e. short surveys)

IV. VALUE OF COLLABORATION REGULATED BY THE PRESENT ToR

For the [Cluster]:

- Competitive advantage of early access to the newly developed MULTI-ACT framework namely composed by:
 - A new governance model made of a set of criteria allowing effective cooperation of all relevant stakeholders in multi-stakeholder research initiatives and transformative governance;

- Innovative guidelines for effective patient engagement across the health research and innovation path (science *with* patients input);
- A new tool (Master Scorecard) for the assessment of the research impact across different dimensions including excellence, efficacy, social, economic and patient reported dimension (science *of* patients input) and to better tie the research results to the objectives of the initiative.
- Access to MULTI-ACT digital toolbox and involvement in the definition of a strategy for its sustainability beyond the project.

For [MULTI-ACT Consortium]:

- Enlargement of the MULTI-ACT stakeholder base and community of potential users.
- Joint publications and presentations in relevant dissemination events (if any).
- Acknowledgement of the support received by MULTI-ACT and the use of any MULTI-ACT outcome and tool in the publicly available documents and resources.
- MULTI-ACT Framework endorsed by the [Cluster] for potential implementation in other Multi-stakeholder Initiatives in the case study brain disease area.

V. PRIVACY AND CONFIDENTIALITY

The [Cluster] and [MULTI-ACT Consortium] recognise that in a collaborative arrangement the protection of private information (personal, sensitive and confidential) relies upon all collaborative parties protecting privacy with regard not only to their individual agency obligations but also having regard to the whole system.

The [Cluster] and [MULTI-ACT Consortium] undertake to maintain the privacy of data provided to them by another party according to the requirements of the party providing the information and according to the General Data Protection Regulation (GDPR), which came into effect on 25 May 2018.

VI. DURATION AND BREADTH

It is mutually understood and agreed by and between the Parties that:

1. Modification

If needed, the responsibilities under this ToR can be either updated or broadened upon approval of the Parties involved via written communication.

2. Termination

This ToR will terminate at the end of the MULTI-ACT project (April 2021).

VII. FUNDING

The representatives of the [Cluster] involved in the activities regulated by the present ToR will be compensated for the participation (time commitment) in virtual meetings upon receipt of invoices.

VIII. DISCLOSURE AND DISSEMINATION

Any dissemination or communication mean used must display the sentence “This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 787570” as per the Article 38 of the Grant Agreement which is regulating the visibility of the EU funding.

IX. EFFECTIVE DATE

This ToR shall be effective from XXXX to the end of the project.

A dedicated annex is accompanied describing the specific activities foreseen as part of the collaboration between the [Cluster] and the MULTI-ACT consortium under these ToR.

X. GLOSSARY

The list below is a compilation of key terms and definitions extracted from the consensus based glossary elaborated by the [MULTI-ACT Consortium] that are specifically relevant to the purposes of the present ToR.

Collective Research Impact Framework (CRIF): Conceptual framework that MULTI-ACT is developing to enable a new collective accountability approach to multi-stakeholder R&I initiatives in the field of brain diseases.

Health Research & Innovation (Health R&I): “activities of research, technological development, demonstration and innovation, including the promotion of cooperation with non-EU countries and international organisations, the dissemination and optimization of results and mobility of researchers in the Union” within the healthcare domain (Eur-lex, n.d.⁹).

Impact: reflection of outcomes as measurements, adjusted for the effects achieved by others (alternative attribution), for effects that would have happened anyway (deadweight), for negative consequences (displacement), and for effects declining over time (drop-off). (GECES Sub-group on Impact Measurement, 2014; Jeremy Nicholls et al., 2012).

⁹ https://eur-lex.europa.eu/summary/glossary/research_and_development.html.

Indicator: "quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention, or to help assess the performance of a development actor" (OECD, 2010).

Multi-Stakeholder Initiative: a governance structure that seeks to bring stakeholders together to participate in the dialogue, decision-making, and implementation of solutions to problems or goals.

Patient Reported Outcomes (PROs): FDA defines PRO as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (FDA, 2009), while EMA describes it as "any outcome evaluated directly by the patient him/herself and based on patient's perception of a disease and its treatment(s)" (European Medicines Agency, 2014).

Return on Investment (ROI): a measure of the efficiency of an investment as a percentage of return relative to the investment's cost.

XI. Further information

Guidance for these ToR is provided by the project management team of WP7. Please contact the Project Management Team at: E-mail: multiact@braincouncil.eu Phone: +32 25132757.

XII. ANNEX 1

Collaboration between MULTI-ACT and [Cluster] in the context of Work Package 7: "Transferability and test of the methodology beyond MS"