

## 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-ACT<sup>1</sup> 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)<sup>2</sup>. 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.

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<sup>1</sup> The project started on the 1<sup>st</sup> 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.

<sup>2</sup> <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 1 July 2020 to the end of 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.<sup>3</sup>).

**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).

**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

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<sup>3</sup> [https://eur-lex.europa.eu/summary/glossary/research\\_and\\_development.html](https://eur-lex.europa.eu/summary/glossary/research_and_development.html).

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](mailto: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"