multi-act

Deliverable D9.1

Project Quality and Stakeholder Engagement Plan

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Short description of the Deliverable (as in the DoA):

Report on analysis for risk management and intended management procedures, disclosure of QA, financial and administrative procedures. It includes the description of the project management processes and tools and a review of the risk assessment made in the proposal. Moreover it describes the stakeholder engagement strategy including selection criteria and roles of the external consultative bodies (EAB and PF) and a consensus based glossary of the key terms used across the project.

REVISION HISTORY			
REVISION	DATE	COMMENTS	AUTHOR (NAME AND ORGANISATION)

| V0.1 | 02/12/2018 | Sent all partners for review | Valentina Tageo (FISM) |
| V0.2 | 31/07/2019 | Second and final version including official project glossary, stakeholder WP individual plans and classification | Valentina Tageo (FISM) |

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STATEMENT OF ORIGINALITY:

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

TABLE OF CONTENT

EXECUTIVE SUMMARY

The document provides the MULTI-ACT Partners with a concise reference to the project management structure, tasks, responsibilities and procedures at all levels of the project (G.A. n° 787570) execution. Additionally, this document comprises documentation and communication standards in order to enable quick and efficient communication within the project consortium.

This deliverable describes the project management procedures foreseen for ensuring the proper implementation of the MULTI-ACT activities in the framework of the given resources and planned time schedule established by the Grant Agreement n. 787570. The purpose of this document is to provide to MULTI-ACT consortium with an overview of the most important project procedures (internal communication, project monitoring, reporting, financial management, etc.) in order to ensure efficient project execution, as well as high quality project results.

Furthermore, it gives partners guidance on how external stakeholders are going to be engaged in the project's activities, being stakeholder engagement one of the backbones of the whole project and essential part of its successful accomplishment.

1 Introduction

This document aims to be an easy-to-use handbook for project's execution prepared under the MULTI-ACT project (Grant Agreement (GA) no. 787570). The intended audience is each individual participant of the project consortium.

During proposal's preparation it was initially conceived as a traditional project quality manual. However, in the amended DoA the consortium has acknowledged the need of embedding the detailed stakeholder engagement approach in this document due to the centrality of stakeholder engagement processes for the overall execution of the project's activities.

Moreover, an internal consultative process has been put in place in order to come up to a shared MULTI-ACT glossary which sets the basis for the use of a common language and approach across WPs in a field (public engagement in R&I) whereas the proliferation of definitions and classifications in the field of stakeholder engagement and impact assessment in health research made this intent particularly challenging.

The purpose of this document is to provide MULTI-ACT consortium with an overview of the most important project procedures (internal communication, shared project's glossary, project monitoring, reporting, financial management, engagement of external stakeholders, etc.) in order to ensure efficient project execution, as well as high quality project results.

In order to fulfil its function as a quick reference to frequently asked questions and problems, this document will be updated according to the evolution of procedures and the progress during the second reporting period whereas needed.

It must be noted that the content does not express the opinion of European Commission and does not in any case replace the European Commission documentation.

1.1 Structure of the document

This deliverable is composed of an executive summary, ten main chapters and conclusions.

The structure of the core sections is the following:

1) Introduction
2) MULTI-ACT shared glossary
3) Project management structure and procedure
4) Quality management
5) Risk management
6) Document management
7) Stakeholder engagement strategy
8) Meetings
9) Issues management
10) Project financial reporting

1.2 Abbreviations

- CRIF: Collective Research Impact Framework

- CSA: Coordination and Reporting Action
- DoA: Desciption of Action
- EAB: External Advisory Board
- GA: Grant Agreement
- MSRI: Multi-Stakeholder Research Initiative
- PEG: Patient Engagement Group
- PF: Patient Forum
- R&I: Research and Innovation
- RFPO: Research Funding / Performing Organization

1.3 Purpose of the document

WP9 aims at ensuring administrative, financial and technical coordination and strategic management of the project, coherently with the indications described in the DoA. The main objectives are:

1) To direct and coordinate the collaborative work and communication among Consortium members;

2) To direct and coordinate the communication between Consortium and European Commission;

3) To manage and monitor project legal, financial and administrative procedures and issues;

4) To achieve timely submission of deliverables, technical and financial reports to European Commission;

5) To ensure effective coordination and monitoring of technical, scientific and engagement activities and alignment with project objectives, within the expected timeframe and budget, by developing and following a project risk management and quality assurance framework;

6) To ensure a quality framework by establishing advisory boards where external relevant competences are involved;

7) To set the general rules for stakeholder engagement across all WPs.

Within WP9, the Project Quality and Stakeholder Engagement Plan (D9.1) establishes the common and agreed rules for the appropriate coordination of the CSA. It also lists roles and responsibilities among partners and identifies the governance procedures for the different actions. This document provides information to project partners and the EC on the adopted coordination mechanisms and tools and represents a guideline for the management team to ensure an effective execution of the project.

The consortium partners internally agreed project management structure, roles, responsibilities and procedures during the elaboration of the CSA proposal.

Later, these have been further detailed and validated during the kick-off meeting (Genova, 14th and 15th May 2018) and the first semester of project's execution.

Project partners verified the effectiveness of the proposed methods of coordination and agreed on a common management approach, which is described in the present deliverable. However, any partner is prompted to suggest changes and improvements, if needed, throughout the whole project duration. Any change, whereas approved by the required majority, will be reported in the contractual reports.

2 MULTI-ACT shared glossary

The consortium has been working on a consensus-based glossary which has been built under the coordination of the beneficiary DiA. The glossary is reported hereafter with the aim to be used in all project's deliverables as a common basis for frequently used definitions and abbreviations.

Breaking down the boundaries see: Research & Innovation Path

Care providers see: stakeholders

Co-design see: engagement levels

Compliance Committee, **CC** see: governance bodies

Conduct & operate see: Research & Innovation Path

Consult see: engagement levels

CRIF Accountability Steps

Establishment of scope and mapping of stakeholders

No single stakeholder has the legitimacy to decide who is (or is not) a stakeholder. The following three sub-steps need to be applied, in a deliberative manner, in scoping and mapping stakeholders.

Establishing scope

Establishing objectives

Identifying and mapping stakeholders

Development of conceptual framework

The conceptual framework of the issues at stake has to be agreed upon. No single stakeholder has the right to prioritize his own goals.

Identifying inputs

Identifying outputs

Clarifying outcomes

Co-selection of indicators

Co-selected indicators must represent multi-stakeholder perspectives along the five dimensions of the CRIF.

Categorizing of indicators into input, output, outcome or impact

Co-developing and weighting key indicators

Searching or formulating metrics

Measurement of indicators

Systems for data collection, measurement and description of co-selected (quantitative and qualitative) inputs, outputs, outcomes and further impact indicators.

Data collection

Measurement (quantification/description) of indicators and analysis

Reporting, monitoring and assessment

Putting targets into action, visualization and use of the results, setting and executing an assessment plan.

Reporting to internal and external stakeholders

Field testing the developed solutions

Introducing monitoring and evaluation procedures

CRIF Dimension see: Collective Research Impact Framework

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. There are five **CRIF Dimensions**:

Efficacy refers to the capacity of a given initiative or programme to achieve its mission, whereas the term *mission* entails all the strategic priorities settled via the stakeholder engagement process.

Excellence concerns the quality of research data and findings in health research. Only excellent research will have a positive impact on people and society.

Social considers the evaluation of direct and indirect effects of health research to the whole society, beyond the mission related dimension that for health R&I would typically focus on patient needs.

Economic refers to the assessment of the long-term economic sustainability of health R&I.

Patient-reported concerns patients as key stakeholder, whose needs, information and perspectives must be understood and incorporated into the process of health research impact evaluation. Thus, it works as an overarching dimension in which the other four dimensions should be rooted.

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

Design & plan see: Research & Innovation Path

Design and planning see: Research & Innovation Path

Economic see: Collective Research Impact Framework

Efficacy see: Collective Research Impact Framework

Engagement levels

Co-design Stakeholders are engaged since the very beginning of the R&I processes with a decision making role, e.g. patients are asked to define a common/shared agenda and co-design research governance and sustainability.

Involve Stakeholders partnering in research design and development as co-researchers. Stakeholders are engaged in research project activities with active role by providing their perspective and data on a specific topic (e.g. gather patients perspective on functional domains the matter most to them, co-creation of PROMs for clinical trials development). However, the project is designed and initiated by the professionals and patients are not engaged in the co-design of the project as direct decision-makers.

Consult Stakeholders are asked to provide feedback for decision-makers on their analysis and/or decisions. Stakeholders participate by being asked for advice and opinion, by expressing their views and having discussions. It does not usually include any share in decision-making. For example

consulting activities, survey, interviews, establishing and maintaining relationship with stakeholders.

Inform Stakeholders are informed about research priorities, activities, outcomes and impact (e.g. . patients receive information by researcher in a passive way).

Evaluating research see: Research & Innovation Path

Excellence see: Collective Research Impact Framework

Executing research see: Research & Innovation Path

Experience a practical case study within a multi-stakeholder initiative, see: initiative

Experiential knowledge: "Experiential knowledge arise when [these] experiences are converted, consciously or unconsciously, into a personal insight that enables a patient to cope with individual illness and disability. When patients share experiential knowledge, the communal body of knowledge exceeds the boundaries of individual experiences." (Caron-Flinterman, Broerse, & Bunders, 2005) Thus, experiential knowledge is knowledge gained through experience, as opposed to a priori (before experience) knowledge.

Field testing see: CRIF Accountability Steps

Framework see: Multi-stakeholder framework

Governance bodies groups with specific roles within a multi-stakeholder initiative that are composed by individuals participating to the initiative itself. The following governance bodies are those suggested within the MULTI-ACT Governance Model

The **Leadership Board** (referred to as "LB") is composed by representatives from the categories of stakeholders that have a strategic importance for the initiative and represents the decision-making body.

The **Stakeholder Advisory Board** (referred to as "SAB") is composed by interested stakeholders and provides advices to the LB. Within the SAB, patients, their families and caregivers (one of the categories of stakeholders involved) might be asked by the LB to provide their specific contribution and advice for the most crucial decision-making processes according to the specific need of the initiative. This category of stakeholders can be defined as a sub-group within the SAB, called **Patient Advisory Board** (referred to as "PAB").

The **Committees and Working Groups** (referred to as "WG") can be appointed by the LB according to the specific needs of the program/project and the activities that will be carried out in order to achieve the desired change.

The **Engagement Coordination Team** (referred to as "ECT") is in charge of coordinating the involvement of stakeholders, including patients, relatives and caregivers, in all the operations.

The **Compliance Committee** (referred to as "CC") is in charge of maintaining a balance among stakeholders' stances and expectations and oversee the ethical issues that might arise during the implementation of the initiative.

Governance Initiative refers to the stages in a Multi-Stakeholder Initiative (including RFPOs) process concerned with the governance and management of a programme or a project (e.g. Horizon 2020 – Societal Challenges 1 Health Personalized Medicine Program or ICT Program; Research Program of ERANET NEURON, PMSA, etc.). See: Research & Innovation Path

Governance Program see: Research & Innovation Path

Governance Project see: Research & Innovation Path

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 optimisation of results and mobility of researchers in the Union" within the healthcare domain. (Eur-lex, n.d.)

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).

Industry see: stakeholders

Inform see: engagement levels

Initiative see: **Multi-stakeholder initiative**

Input the contributions made or required by each stakeholder/organization. It can include financial, human, technical and relational resources.

Involve see: engagement levels

Leadership Board, LB see: governance bodies

Mapping stakeholders see: CRIF Accountability Steps

Monitoring see: CRIF Accountability Steps

Multi-stakeholder framework a conceptual structure applicable by/to a variety of stakeholders. Framework examples include (but are not limited to) guidelines, standards, certifications, normative schemes, etc.

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.

Outcome the change arising in the lives of beneficiaries and others.

Output a way of describing the activity in relation to each stakeholder's inputs in quantitative terms. Alternatively, it can be defined as the tangible and intangible products resulting from brain research and innovation.

Patient Advisory Board, PAB see: Governance bodies

Patient engagement see: Public and Patient Engagement in RRI

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)

Patient-reported see: Collective Research Impact Framework

Patients organizations see: stakeholders

Patients see: stakeholders

Payers and purchasers see: stakeholders

Policy makers see: stakeholders

Process "The research process includes all the activities that enable the research to happen (i.e. reviewing of evidence, data collection, analysis, reporting and so forth)." (Hinrichs-Krapels & Grant, 2016)

Project Development see: Research & Innovation Path

Public and Patient Engagement in RRI actions to engage patients in R&I processes for make them co-responsible (as sub-group of stakeholders). In line with RRI definition, patient engagement implies that patients work together with other stakeholders (researchers, citizens, policy makers, business, third sector organisations, etc.) in order to align both the process and its outcomes with their values, needs and expectations. The role of patient in research ranges from a passive one (patient is a data point), to an active one (patient is a researcher) and finally to a strategic one (patient has an active role in the governance and decision making of research process) – see: levels of engagement

Public engagement see Public and Patient Engagement in RRI

R&I Path see: Research & Innovation Path

R&I see: Health Research & Innovation

Reporting see: CRIF Accountability Steps

Research and education organizations see: stakeholders

Research & Innovation Path (R&I Path) sequence of processes and activities in the R&I where patients can be engaged in order to maximize the impact of R&I. Governance Program Level and Project Development Levels are distinguished (also see: Governance Initiative):

Governance Program stages in Multi-stakeholder initiative (including RFPOs) process concerned with the governance and management of research funding & performing programs:

Breaking down the boundaries conditions that should be set in RFPOs in order to facilitate patient engagement as standard practice.

Setting research priorities actions to establish justified interest in a specific research domain to a certain higher degree, importance, precedence, or rank over others.

Steering institutions actions performed to establish steering and advisory committees and bodies.

Design and planning the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the item's designated objective(s).

Executing research activities to actualize the research program or a specific research project for the purpose of achieving the item's designated objectives. Project Development Level takes places at this stage.

Evaluating research activities to determine the value created by a research program or project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact.

Translation to community activities to foster and facilitate the uptake of results of research programs or projects.

Project Development stages in Multi-stakeholder initiative (including RFPOs) process concerned with performing single research projects (e.g. single project for the development of an ICT Health monitoring device or clinical trials). In this case, patient is a scientist and co-researcher. Project Development pertains to Research Execution stage of the Governance Program Level.

Design & plan the design and planning of all the activities that lead to the realization of a concept or idea and which helps achieve the item's designated objective(s).

Conduct & operate project conduct & monitoring (e.g. ICT device development)

Evaluation activities to determine the value created by a research project, establishing their outputs and outcomes, the degree to which their pre-established goals were achieved, and their impact.

Translation to community activities to foster and facilitate the uptake of results of research projects.

Responsible Research and Innovation (RRI) implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society. (European Commission, n.d.)

Return on Engagement (RoE) the benefit, impact and value resulting to performing engagement in R&I. Evaluating whether engagement adds value for different stakeholder groups can be an effective tool to further support patient engagement and requires the development of metrics to measure the "return on engagement".

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

RRI see: Responsible Research and Innovation

Science of patient input occurs when data of people with a disease are used (active and passive contribution) to evaluate impact of R&I.

Science with patient input occurs when patients meaningfully and actively collaborate in the governance, priority setting, and conduction of research, as well as in summarizing, distributing, sharing, and applying the results.

Setting research priorities see: Research & Innovation Path

Social Return On Investment (SROI) a principles-based framework for measuring and accounting for extra-financial value (such as environmental or social value) material for the stakeholders.

Social return ratio total present value of the social impact divided by total investment.

Social see: Collective Research Impact Framework

Society see: stakeholders

Stakeholder "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)

Patients people with the diseases and affected by the diseases (i.e. relatives, caregivers).

Patients organizations patient associations, advocacy organizations, etc.

Society individual citizens, civil society organizations and networks.

Payers and purchasers public or private entities responsible for underwriting the costs of health care.

Care providers health and social care organizations and professionals (doctors, nurses, etc.).

Policy makers EU institutions; national, regional and local policy makers.

Industry companies developing and selling health products (drugs, devices, applications, etc.) and services.

Research and education organizations Research Organizations; Universities; Education Providers; Foundations; Other research projects

Stakeholder Advisory Board, SAB see: governance bodies

Steering institutions see: Research & Innovation Path

Sub-criteria see: criteria

Transformational mission Mission as transformational and transformative means 'changing forms'. The term became increasingly common within the science and health policy community in the 2000s for research that shifts or breaks existing scientific paradigms.

Translation to community see: Research & Innovation Path

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3 Project management structure and procedures

3.1 The MULTI-ACT consortium

3.1.1 Project coordinator

The MULTI-ACT Project coordinator is the Italian Multiple Sclerosis Foundation (FISM), leading not-for-profit research funding organisation in the field of multiple sclerosis (MS) in Italy and the third worldwide (after MS Societies in the USA and Canada). Their work revolves around improving the understanding of the causes of the disease and supporting people with MS in making decisions for their treatments and quality of life.

3.1.2 Project partners

The MULTI-ACT consortium brings together an interdisciplinary team of 11 partners[1] (referred as "beneficiaries" in the GA) with recognised, thoughtful and cross-sectorial expertise in brain diseases, sustainability and accountability domains. The competences of the partners ensure the appropriate execution of the project activities through their specific and complementary skills on research and innovation, advocacy, health management, enabling technologies and tools, stakeholder engagement and mobilization, project management, communication, dissemination and exploitation. The staff involved in the project have proven and relevant experience in the management of EU funded actions and bring competences on evaluation of the impact of health R&I process.

3.2 The project governance structure

The project governance structure (outlined in Figure 1), as well as the role and functions of each body within it, is explained in detailed in the Annex 1 to the GA (Description of Action, hereafter DoA).

The summary provided hereby is thought to be an easy-to-use guidance for partners so that they can have a clear and quick overview of "who is who" within the projects and address their communication to the appropriate recipient/s.
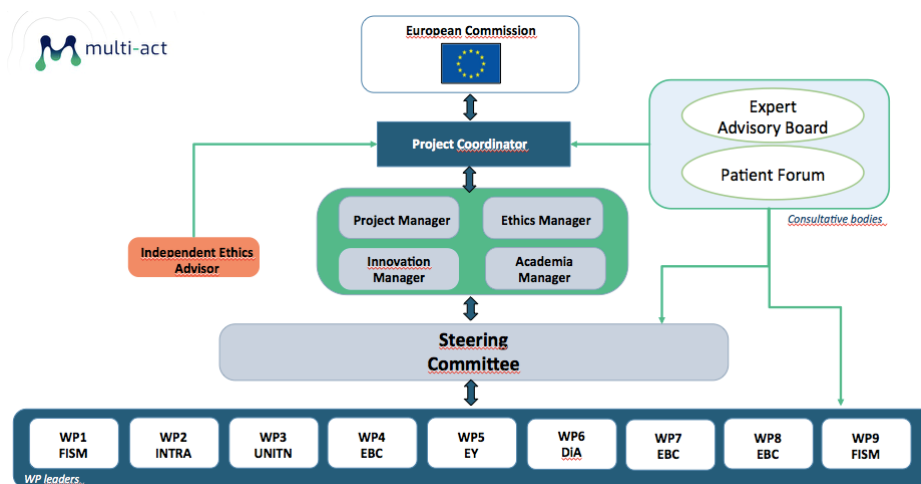

Figure 1. MULTI-ACT project governance structure

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[1] List of partners accessible here: http://www.multiact.eu/consortium.php.

Table 1. Project management: key roles and main responsibilities

Key roles	Acronym	Person/s in charge	Main tasks
Project Steering Committee	PSC	All partners chaired by the Coordinator	Composed of all consortium partners, it is responsible for the project as a whole, including any significant changes. PSC members and Deputies have been selected at the beginning of the project.
Project Coordinator	PC	Paola Zaratin	Responsible for overall coordination, management and liaison with the EC.
Project Manager	PM	Valentina Tageo	Supporting the PC in the technical coordination, responsible for the administrative and financial progress reporting as well as quality and risk management.
Academia Manager	AM	Michele Andreaus	Coordination of the academic team and its efforts within the consortium
Innovation Manager	IM	Giovanni Esposito	Securing the active involvement of external stakeholders, providing the link with the external consultative bodies in close coordination with the Project Coordinator and Project Manager and bringing their influence into the project with the aim to build the basis for capitalization and sustainability of project's results.
Ethics Manager	EM	Elisa Ferrara	Monitoring the project to ensure that the Ethical Issues are handled in the appropriate manner and activities are carried out complying with the new data protection regulation (GDPR).
Work Package Leader	WPL	See Table 2	Responsible for operative management and detailed implementation of respective work packages.
External Advisory Board	AB	External experts (see section 7.5.1)	Providing high level policy orientation, inputs during project's execution and validating the project results with the aim to have them applicable not only to MS but also to other brain disease.
Patient Forum	PF	External experts (see section 7.5.2)	Supporting the activities to be performed across the project, and specifically in WP1 and 3, with the aim to bring in the perspective of patients with MS and other brain diseases.

| Independent Ethics Advisor | IEA | Maria Bulgheroni | External expert appointed to comply with the ethics requirements included in the Ethics Summary Report (see deliverable D10.5). |

Table 2 summarises the list of Work Package leaders with the corresponding contact details.

Table 2. Work Package Leaders

WP	Contact	Organization	Email
WP1	Deborah Bertorello	FISM	deborah.bertorello@aism.it
WP2	Sofia Tsekeridou	INTRA	sofia.tsekeridou@intrasoft-intl.com
WP3	Michele Andreaus	UNITN	michele.andreaus@unitn.it
WP4	Giovanni Esposito	EBC	gies@braincouncil.eu
WP5	Costanza Monari	EY	costanza.monari@it.ey.com
WP6	Mateusz Lichon	DiA	mateusz.lichon@gmail.com
WP7	Giovanni Esposito	EBC	gies@braincouncil.eu
WP8	Giovanni Esposito	EBC	gies@braincouncil.eu
WP9	Valentina Tageo	FISM	tageo.multi-act@aism.it

The WPLs are responsible for the operational implementation of the activities foreseen in each WP ad the timely delivery of the corresponding project's outputs as well as their compliance with the quality standards set in section 4. To this purpose, they are requested to prepare and share in advance their Deliverable Development Plans (DDP) in order to provide a clear guidance to the contributing partners and facilitate monitoring from the Coordination Team.

For the sake of the efficient coordination of the work and in order to have a continuous and thorough control on the ongoing activities, **each WPL has to**:

- **Arrange internal WP monthly teleconferences** aimed at checking the status of the ongoing tasks, allocating activities among contributing partners[2] and identifying potential risks which might prevent the WP team from achieving the objectives stated in the DoA. In the latter case, the WPL must propose a feasible mitigation action and seek for an agreed solution with the contributing partners (for WP1 to 7; WP8 and 9, being transversal activities that will be

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[2] All partners that have Person Months allocated to a WP are considered "contributing partners" to that specific WPs.

ongoing throughout the whole project and engage ALL partners will use the monthly PSC telco for their updates).

- **Produce short minutes of each teleconference**, share them with the WP contributing partners.
- **Once approved, store the minutes in the dedicated folder of the project cloud space** (see section 3.3.1).
- In any case, the WPL is obliged to **inform the Coordinator and the Project Manager about any possible deviation** from the work plan.
- **Use Slack to communicate with the contributing partners** in either bilateral conversations or group chats.

Each WPL is also responsible for the design and implementation of the corresponding **WP-specific stakeholder engagement strategy** (see sections 7.4.1-7.4.7), thus including the identification of the most appropriate mean to reach and engage stakeholders in agreement with the Project Coordinator and the constitution, whereas required, of WP-specific working groups (such as the Patient Engagement Group in WP1).

3.3 Management and internal communication tools

The project coordination mechanisms rely on concrete and effective measures supported by tools aimed at securing the overall and day-by-day management and internal communication. The objectives of the project management activities can be listed as follows:

- To ensure high quality management of complex processes involving several different stakeholders within the project.
- To keep people motivated and focused on the project tasks.

The objectives of the internal communication activities include:

- To ensure a smooth and timely flow of information between the project consortium on all relevant matters.
- To secure a timely presentation of information and reports to the European Commission.
- To facilitate the integration of work in the various WPs and between the various actors in the project.

The management and internal communication tools listed below will help the implementation of the MULTI-ACT project.

3.3.1 Dropbox

The main project archive is Dropbox that allow saving and making documents available for all the consortium members.

The Dropbox space is called MULTI-ACT_General and contains two main folders:

MULTI-ACT_Official: this folder is for download only, thus partners are not allowed to move, modify or delete any document. It is structured as follows:

- **00_Contractual documents**: this folder is the place where we will store all our official contractual documents (e.g. Grant Agreement, Consortium Agreement, Amendments).

- **01_Execution**: this folder will contain the final version of the deliverables, which will be submitted to the EU. The Coordinator is in charge of uploading them here once finalized and uploaded onto the EC portal too.
- **02_Reporting**: here Partners are going to find the Reporting Excel Tool personalized per each tool and a guide to use them (a dedicated email with guidance has been sent to provide specific instructions about that).
- **03_Meetings**: this folder will contain the final versions of the relevant documents of the face-to-face meetings: agenda, minutes, presentations and list of attendees as well as the minutes of the Project Steering Committee (PSC) teleconferences.
- **04_Templates**: here you can find the relevant templates to be used for the execution of the project activities (e.g. minutes, deliverables, presentations).
- **05_Official communication materials**: these materials are those produced in the framework of WP8 and approved by the overall Consortium to be used for external communication and dissemination purposes.
- **06_Project Reviews**: here we will store the Review Reports provided by the European Commission in correspondence with the formal Project Reviews and any other relevant document to this purpose.

MULTI-ACT_Working Area: this folder is intended to be used by all partners as a free collaborative space under the guidance of the WP leaders.

- It is structured in **9 WPs** as it is our work plan.
- **The respective WPL has the responsibility to arrange its internal structure** as it is more convenient to the purpose of the WP itself.
- **Important!** For WP1 to WP7 only one **mandatory folder** is included in each of them and this is the one where the WPLs have to store the approved **minutes of the internal WP team telco**. WPLs can find the template in the folder MULTI-ACT_Official/04_Templates and are asked to use the naming used for the template so minutes will be ordered by date.
- As said above, WP8 and WP9, since they are horizontal and engage all partner, will have their team telco together with the monthly PSC telco.

3.3.2 Email

Email remains the primary form of communication within the MULTI-ACT project for official announcements and communications related to the consortium contractual obligations (e.g. reporting, amendments, etc.).
For ease of identifying MULTI-ACT relevant emails, all email subjects should begin with "[MULTI-ACT]".

3.3.3 Slack

In support to the emails, the MULTI-ACT consortium is using an online working space tool based on the **Slack** application, which will allow all the partners to communicate, exchange information and documents.
Slack is a cloud-based set of proprietary team collaboration tools and services including persistent chat rooms (channels) organized by topic, private groups and direct messaging. All content inside Slack is searchable, including files, conversations, and people.
Specifically, in the MULTI-ACT Slack workspace we have set up a **#general** channel, which is the online space to be used for general communications to the whole consortium since all partners have access

to it. Moreover, a specific channel has been set up per each of the WPs (e.g **#WP1**). WPs Leaders are kindly requested to use these spaces for internal communication in alternative to the emails.

Additionally, all the Slack users have been added to another channel named **#calendar** with the aim to support project Google Calendar (see below section 3.3.4). Anytime a new event will be created at the project Google calendar it will be automatically posted also there. Moreover, all partners invited to a specific channel will receive personal Slack notifications when there is a new message on the corresponding channel[3].

The WP Leaders are the ones responsible for setting up the internal WP teleconferences and take minutes of them that have to be uploaded in the corresponding Dropbox.
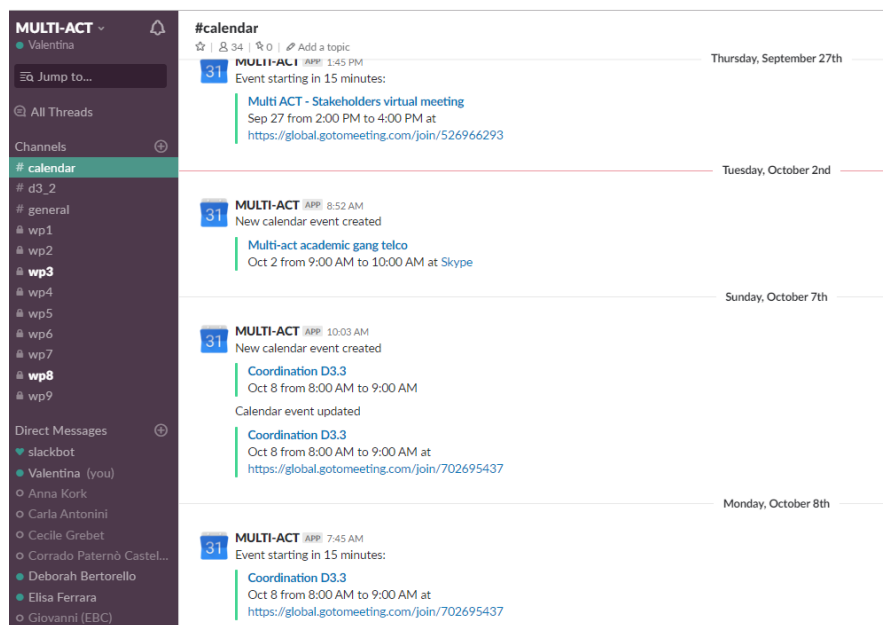

Figure 2. Screenshot of the MULTI-ACT Slack workspace

In addition, the **Dropbox space is integrated with the Slack workspace**. This integration allows to import Dropbox files into Slack so partners can share their work, get feedback and collaborate. To do that, when one person is participating in a conversation within one of the channels he/she is invited to, he/she has to click on the "+" (Add files) button besides the message typing box and select the file he/she wishes to share.

3.3.4 Calendar

The **Google shared MULTI-ACT Calendar** is thought to make the scheduling of project online meetings easier.

The MULTI-ACT Calendar is a project dedicated Google Calendar that any partner may add into his/her own agenda in order to see all the meetings scheduled during the project course. The aim is to have a quick overview of the timeslots every person/partner commits to the project and also, importantly, to avoid overlaps in the use of the shared Gotomeeting license that FISM provided for the project's purposes.

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[3] Check here how to enable and personalize Slack notifications: https://get.slack.help/hc/en-us/articles/201355156-Guide-to-Slack-notifications-.

An invitation to the shared Google Calendar has been sent to all partners by the Project Manager.

Here below the instructions on how to make the integration of the MULTI-ACT Calendar in your own calendar app:

- If a person is using a Google account he/she will directly see it in his/her own Calendar in the menu "*Other calendars*" after accepting the invitation.
- If a person did not receive the invitation or is using a different provider, the URL below allows to integrate it in the personal agenda (e.g. Outlook or others):
https://calendar.google.com/calendar/ical/ehelfdpe37tdr4p7dnnoabn4sc%40group.calendar.google.com/private-98072c93c07c8ace3998123338757a17/basic.ics

If one person prefers not to integrate the MULTI-ACT Calendar with his/her own agenda, of course this is possible. In that case, anytime the partner wishes to create an event in the MULTI-ACT Calendar, he/she has to:

- Access it through Chrome (preferable, see section 3.3.5 below) or other browser
- Create the event
- Include himself/herself in the list of invited guests so to receive an invitation directed to his/her own calendar management app (e.g. Outlook invitation)
- Accept the invitation (without sending the answer to the organizer) and the event will automatically appear in his/her personal agenda.
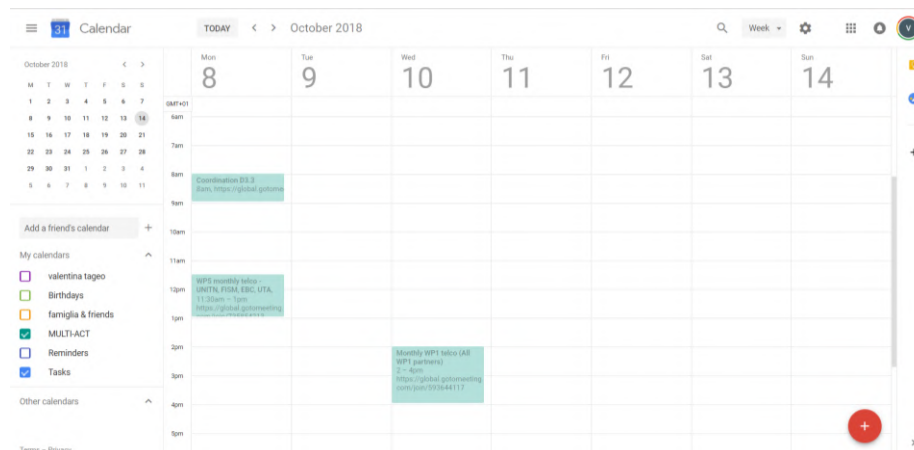

Figure 3. MULTI-ACT shared google calendar

Regarding the type of meetings, the ones included in the Calendar and for which the use of the shared Gotomeeting license is allowed (see section below) are:

- **monthly PSC teleconferences** (recurring meeting from June 2018 – ALL partners expected to join)
- **monthly WP leaders' teleconferences** (recurring meeting from January 2019 – ALL WP LEADERS expected to join)
- **monthly WP internal teleconferences** (recurring meeting for those WPs that are active – responsibility to set them up is of the WP Leaders and all contributing partners are expected to participate)
- **internal or cross-WP meetings** provided that:
    1. they are not bilateral conversations (in that case using skype or phone is recommended) and

2. they do not overlap with any of the previous ones.

Any partner who is going to create a meeting in the Calendar and book the corresponding Gotomeeting slot is required to name the meeting as follows:

- If only a subset of partners must be involved: *WPn / Dx.y / Meeting title – Acronyms of the organizations involved* → Example: WP3 monthly telco – UNITN, FISM, EBC, etc.
- If all partners are to get involved: *WPn / Dx.y / Meeting title – ALL*

This way everybody can have a clearer view about which are the teleconferences he/she is expected to join or not.

3.3.5 Gotomeeting

FISM has made its conference call facility Gotomeeting (www.gotomeeting.com) available for all remote project meetings via a dedicated account (multiact@aism.it). FISM already provided all the partners with the access details to the online tool Gotomeeting to allow WPLs to arrange the project's teleconferences by their own.

There are different ways to access Gotomeeting and schedule teleconferences. Here below the instructions:
1) All the partners have to check whether the time slot they wish to book is free in the Google Calendar;
2) After that partners can proceed to book the desired slot as follows:
   a. **Option A** (highly recommended). If the Partner is a Chrome user, he can directly download the **Gotomeeting extension for Google Calendar**. It is an easy self-installing extension to their browser that allows them to book a meeting and at the same time the slot in Gotomeeting. If you enable it, you will see that anytime you book a meeting you will have the option to click on the Gotomeeting "Add" button above the event description. It will book the slot automatically, generate the link and include it in the text of the invitation.
   b. **Option B** (Not Chrome user). In this case the Partner has to do this in two steps: first book the slot in the Calendar and then secure it in Gotomeeting too.

Lastly, if a Partner is chatting in a Slack channel and wants to setup a Gotomeeting conversation that was unplanned he can do the following:
- Check if there is any overlapping event in the Google Calendar;
- Book the slot needed;
- Type */G2M* in the Slack chat and the teleconference will be immediately created.

The use of Gotomeeting for bilateral conversations or conversations related to issues that are not related to the project is not allowed.

3.3.6 Skype

All the consortium members can have bilateral chats via Skype, this tool can also be used to exchange instant messages and set-up VoIP calls whenever it is needed. All partners have been invited to share their Skype nick names which are collected in the project contact list available on Smartsheet (see next section).

3.3.7 Smartsheet

Smartsheet is an online collaboration software for project management and team task management needs. It combines the ease of use of spreadsheets with automated workflow capabilities, collaborative file sharing and discussions, and visual timeline management.
Any partner has been invited to indicate the name of the team member will have the role of **Smartsheet contact person**.
Up to now, the following shared Smartsheets have been created and shared by the Project Manager:

- **MULTI-ACT Gantt – DoA**: an interactive timeline representing the work plan including WPs, tasks, leading partner and durations as they are stated in the MULTI-ACT DoA
- **MULTI-ACT Gantt – AMENDED**: all the changes which have been made within the Amendment requested submitted in December 2018 are displayed in this sheet. All Smartsheet contact persons can have an overview of who is in charge for each task and deliverable, as well as the specific new deadlines which will be in official once the Amendment formalization will be concluded.
- **Deliverables**: this sheet includes all deliverables (number, name and description), responsible partners, appointed quality reviewers, internal deadline for submission to the quality reviewers, formal deadline as per the original DoA, formal deadline as per the amended DoA.
- **Contact List - General**: this is the general mailing list of the project. All contact persons that each partner has provided are included. The Smartsheet contact persons are responsible to manage and update it as well as tick the relevant boxes per each person. Applying the **filter "Slack access"** to the list, the sheet displays the list of people currently involved in the execution of tasks and delivery of outputs in the projects.
- **Contact List – Governance**: this is the contact list including all those (internal and external) people who have a role in the project's governance.
- **Effort allocation**: this sheet contains a detailed allocation of the effort assigned to each partner (i.e. the person months) per task and it is aimed to ease monitoring of resources' consumption.
- **Specific attendees' lists** to facilitate the handling of logistics anytime a meeting is arranged.

Additionally, temporary sheets may be created upon request or answering specific needs by the Project Manager and shared with the Smartsheet contact persons.
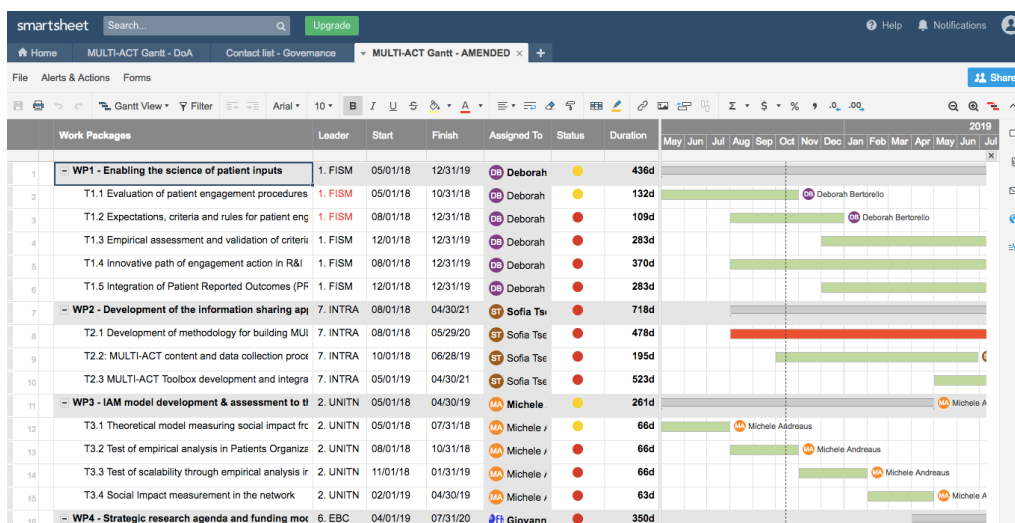

Figure 4. Example of Smartsheet spreadsheet

4 Quality Management

The core outcomes of the project are represented by its deliverables which, thus, must be released with the highest quality standards and in a format and language which is accessible, useful and usable for the targeted final beneficiaries.

They consist of a combination of documents such as written reports as well as non-document deliverables. However, the EC requires that all non-document deliverables be documented appropriately as a written report as well – thus a brief written summary shall be produced to accompany this kind of deliverable.

The intention of the deliverable generation and review process is to ensure the highest quality of MULTI-ACT results.

Partners responsible of the preparation and release of the Deliverables are indicated in EC-GA Annex I (DoA) as their "Lead beneficiary". In order to produce the planned deliverables, they will gather contributions from both Task Leaders and all partners participating to the relevant Task and they will be supported by the corresponding WPL.

For each written deliverables, the following roles are defined and indicated in the cover page of the deliverable:

- **Authors**: members of the organization that is responsible for the completion of the deliverable;
- **Reviewers**: members of the organization/s who eventually provide inputs to the entity responsible and actively reviewed the document besides the Project Coordinator.

The project partners have proven complementary skills, which guarantee the quality of work to be performed. However, a number of measures are put in place to avoid any possible delay and ensure that high quality products are delivered in each WP.

Firstly, each deliverable has a responsible partner who has to prepare a **Deliverable Development Plan (DDP)** at the beginning of the WP.

The DDP has to be communicated to the involved partners either during a WP telco or uploaded in the corresponding #WP Slack channel and serves to communicate in a concise way to the contributing partners the following key information:

- The **work phases** towards the completion of the deliverables
- **Who does what**, i.e. a clear allocation of tasks and duties among the contributing partners
- The **timeline** for the expected contribution
- (If applicable) how and when the **contribution from external stakeholders** is envisaged and how the responsible partner (in agreement with the WP leader and the Coordination team) has planned to manage it (e.g. intervention from the EAB or the PF, interviews, focus groups, surveys, etc.)
- The **proposed table of contents**.

Anytime during the preparation of a deliverable, if an unforeseen risk occurs, the responsible partner and the WPL must inform the Coordinator and the Project Manager. Extraordinary meetings are then arranged with the aim to promptly identify the most suitable and effective mitigation action.

Secondly, in order to guarantee the compliance with the highest quality standards, the following **three-step review procedure** is established:

1) *3 weeks before the final deadline for submission*: Once the final draft is produced (i.e. a stable and mature draft where all contributions and inputs have been taken into account and incorporated by the responsible partner to the greatest extent possible), the partner responsible for the deliverable sends it to the two quality reviewers previously appointed (and indicated in the "Deliverable" Smartsheet) for them to review the quality of the deliverable.
2) *2 weeks before the final deadline for submission*: The quality reviewers send the document back to the responsible partners and the WP leader (if it is not the same organization). Changes and suggested improvements must be clearly highlighted using track changes mode or different colours.
3) *1 week before the final deadline for submission*: The responsible partner submits the deliverable improved based on the reviewers' feedback to the Project Coordinator and Project Manager.

If no major changes are required, the Project Manager finalizes the editing and formatting and submits it. On the contrary, in case additional comments are raised, the responsible partner has the obligation to address them the earliest possible in order to comply with the final submission deadline scheduled in the DoA.

The Project Coordinator (with the support of Project Manager) has the responsibility for the final approval and submission through the EC Portal.

If the reviewers detect a need for a deep English linguistic revision, they must inform immediately the Coordinator and the Project Manager to check whether it can be done by some native consortium members internally or must be externalized.

In order to both guide the partners who are responsible of deliverables' preparation in their job and make easier the reviewers' tasks, a **quality checklist** is provided in Table 3.

Table 3. Deliverable quality checklist

Quality Checklist	
Category	**Lead questions**
Overall Credibility	• Could your report be defended against someone who sought to discredit it? • Is it based upon solid evidence, not just assertions made by interviewees? • Is it biased in favour of the viewpoint of any interest group? • Does the deliverable provide recommendations which are practical, cost effective and necessary?
Executive Summary	• Are the points raised in the Executive Summary section really the most important? • Are all statements within the Executive Summary actually explained in the core document?
Right for its target audience	• Is the wording suitable for the intended audience? • Is there any ambiguity about meanings, definitions or the consequences of the findings? • Have definitions and working assumptions been defined correctly?

Facts not opinions	• Are the statements based on fact or opinion? • Is there always data supporting the key findings? • Have you referenced the quotations correctly? (Source, Author, date)
Clarity and detail	• Is your wording clear, and have you given enough details? • Have you stated the essentials of the issue or risk and not included any inessential background information?
Findings impact and recommendations	• Are your findings, impact assessments, and recommendations consistent and concise? • Are the key facts stated in as few words as possible without missing the essential evidence? • Are the documents referenced properly and pointing to the right appendices?
Proposed distribution	• Is the 'draft' status of the document properly documented? • Has the limitation of onward distribution been made clear?
Spelling, Grammar and Formatting	• Have you checked that the document has the correct spelling etc.? • Is the layout consistent throughout the document: font, bullet points, numbering, etc.?

5 Risk management

In the DoA, the consortium ensures an internal quality control of the project outputs through an assessed risk management methodology. The aim is to prevent operational bottlenecks for delivery of quality outputs. The methodology proposed, is based on three stages:

1. Risk Identification
2. Risk Assessment
3. Mitigation Plan

First all risks are identified and evaluated on a qualitative scale. After that, all risks are plotted into a risk analysis matrix (see Figure 5). This points out not only the probability of the risk but also the impact on the project, thus allows the Coordination Team to define risk prioritization. The Critical risks matrix provides a sound basis to highlight the most significant potential risks and lead to the development of corrective mitigation action planning.

The risk mitigation planning process guarantees those corrective actions are chosen after a meticulous analysis of alternative options.
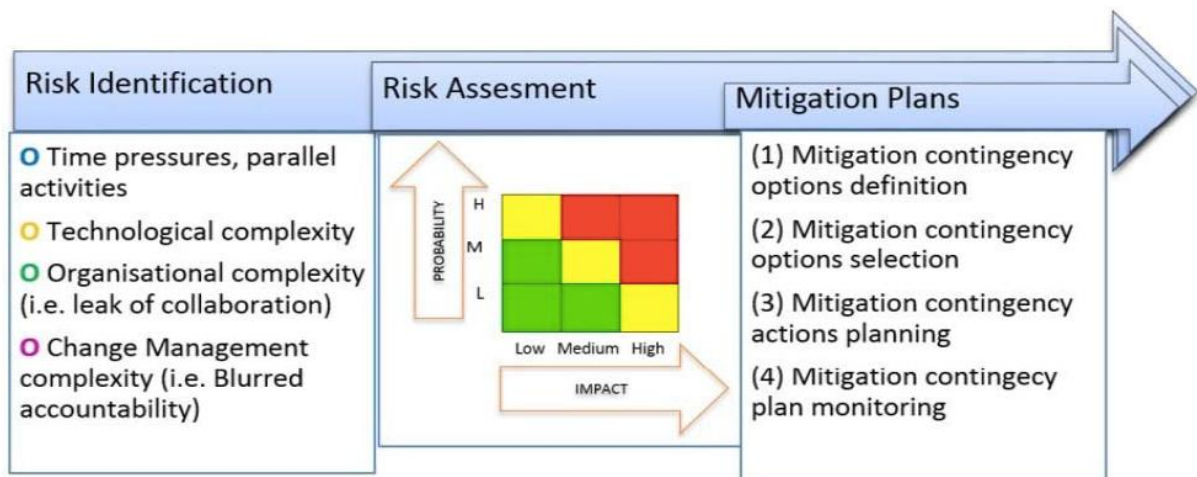

Figure 5. Risk analysis matrix

After project's start, the consortium constantly monitors critical risks and identifies new ones, which eventually arise adding them into Table 4.

Whereas a risk occurs, the adoption of the corresponding risk mitigation action/s is promptly undertaken by the Coordination Team and communicated to the European Commission.

Table 4. Updated risk table at the end of the first reporting period

Description of risk	WPs	Proposed risk-mitigation measures
Likelihood: Medium Delay in meeting the deliverable deadlines, and	WP9	The project partners have proven complementary skills and vested interests in the project to guarantee the quality of work. The project has its own review agenda to monitor the progress to predict possible delays and act accordingly. Each deliverable will be quality assured by the qualified senior researchers from other partner organizations. Several of the partner organizations are also experienced research partners and coordinators, also with good track records in different lines of EU

poor quality of deliverables		research programs. Moreover the risk assessment methodology includes appropriate mechanism to ensure an high quality deliverable and to avoid any possible delay. **Each deliverable has a responsible partner who has to prepare a Deliverable Development Plan (DDP) at the beginning of the WP.**

Status after the first 15 months of the project:

Due to the high number of deliverables expected to be ready in the first months of the project and the tight and ambitious schedule of the original work plan included in the DoA, the following measures have been undertaken:

- An amendment request including an updated timeline and a thorough explanation of the delays has been submitted. Such amendment request doesn't affect the delivery of the core outcomes foreseen at the end of what is referred as Phase 1 of the project i.e. the MULTI-ACT CRIF first version composed by the governance model (WP5) and the Master Scorecard (WP3) along with the first release of the patient engagement guidelines (WP1), all of them needed to run the case study in WP4. Moreover, an adjustment in the timing of WP2 (toolbox development) is included in the amendment request in order to avoid that the rescheduling of WP1-3-5 activities does not have a negative impact on the delivery of the two releases of the toolbox.
- The Coordination Team will perform a closer control on each DDP securing that each partner who is responsible for one or more deliverables is making adequate and realistic plans from the very beginning of the corresponding task and allocating duties and effort to each contributing partner in an orchestrated and balanced way proportionally to the budget and the expected involvement of each of them.

Likelihood: Low Withdrawal of a partner	WP9	The Project Coordinator will identify and preliminarily contact a substitute partner with similar expertise and propose a solution to the PSC which will urgently meet and find an agreement within 2 month from partner withdrawal.
Likelihood: Medium Problem of coordination	WP9	Roles for each partner have been clearly identified. Also, the consortium has been assembled on the basis of its complementary of skills and fields of actions. This element is a key factor to prevent this risk.
Likelihood: Low No agreement on IPR management of the project	WP9	A Consortium Agreement will be signed by all partners before the beginning of the project, establishing the basic rules for the management of the IPR, identifying the expected results of the project (foreground) as well as the owner.
Likelihood: Medium Unpredictable costs	WP9	The financial aspects of the project will also be assessed at regular intervals and unexpected costs will be identified early. Furthermore, investment decision points will be planned, where requirements will be revised.
Likelihood: Medium/High Difficulties in developing the framework due to the constraints of different actors	WP3	The interaction and follow up with actors will be assessed and planned at the beginning of the study to minimize constraints. Furthermore, if needed stakeholders could nominate their own professional consultants as representatives of their interests or propose independent verification of the measurement method adopted.
Likelihood: Medium	WP1, 3 and any other	Questionnaires and interviews will be designed to reduce the length and complexity of the questions, have a good visual design, make responding

Failing in the engagement strategy: low engagement rate, not all relevant actors are involved	where stakeholder engagement is foreseen	convenient, minimize request to sensitive information and clarify the importance of the participation for the co-creation of an accountability framework.
Likelihood: Medium Low interest in joining the focus groups	WP3 and 7	Focus Groups will be carefully planned, designed and advertised to ensure that the content is relevant to the target participants. Participants will be involved early in the preparation of the focus group in order to increase the level of engagement.
Likelihood: Medium Delayed content collection task	WP2	The content collection task is core for the calculation of any indicators and any type of impact assessment and statistics evaluation. Thus, if content is poor, or very scarce then the results will be sub-optimal, maybe meaningless. Additionally, if initial content is not given/uploaded on time, then the development and testing of MULTI-ACT toolbox functionalities will be delayed. The two releases of the toolbox have been better conceived and described in the amendment request in a way that clearly states that the release 1.0 will contain the Master Scorecard in the format of a catalogue of indicators (thus not allowing for calculations). In the release 2.0 (thus having more time to gather data and content to "train" the calculation functionalities of the toolbox, the possibility to calculate quantitative indicators will be included.

6 Document Management

6.1 Documents repository

Documents can be stored and exchanged on the shared Dropbox folder, which is organized as detailed in section 3.3.1.

In the MULTI-ACT_Working Area folder specific folders may also be created by partners for storing temporary files where, for example, these are too large to circulate by e-mail.

6.2 Version Control and File Naming

To avoid working with obsolete versions of documents is essential that every document circulated to other partners in the consortium includes a version number and date. In order to help all partners in quickly recognizing the documents, the guidelines below should be followed as much as possible.

The file name should (as appropriate):

- Start always with the correctly written project acronym MULTI-ACT;
- Be descriptive of the contents of the document/file;
- Indicate the date (yyyymmdd) of issue or of reference of the document/file;
- Include version numbering vX.Y and substitute it with "final" when the document is ready to be submitted to the EC and stored in PDF formal in the corresponding folder;
- Include the short name of the partner that has the ownership of the document/file.

Table 5. Examples of document naming

deliverables	MULTI-ACT_DX.Y_PartnerAcroym_yyyymmdd_vX.Y
minutes	MULTI-ACT_Meetingtitle/type_city(if applicable)_yyyymmdd_vX.X
presentations	MULTI-ACT_presentationtitle_yyyymmdd_vX.X MULTI-ACT_Meetingtitle/type_city(if applicable)_Day no. or date_presentationtitle

7 Stakeholder Engagement strategy

7.1 Background

A stakeholder's engagement strategy is a strategy designed to shape and conduct the active involvement and participation of stakeholders in the implementation of a project, initiative or campaign.

In this regard and depending on project's characteristics and aims and on the stakeholder's type different levels of stakeholder engagement can be identified, ranging from the provision of information to a genuine collaboration and proactive involvement in outcome delivery and decision-making processes.

MULTI-ACT stems from the acknowledgement that **stakeholder engagement** in health research and innovation is being increasingly promoted by health research funding organisations, and indeed by many performing organisations themselves, as an important pathway to achieving impact[4] through the establishment of Multi-Stakeholder Research Initiatives (MSRIs). Considering this, the project aims at giving a step further in promoting research co-accountability towards its stakeholders through the design, test and validation of a Collective Research Impact Framework (CRIF).

Thus, the whole project work plan is built in a way that prompts and stimulates interactions with external actors and cross-fertilizations with other initiatives, thus posing the need for a rigorous stakeholder engagement strategy, planning and evaluation.

7.2 Key definitions

As stated in the glossary in section 2, a **stakeholder** is "*any individual or group that is affected by, who can influence or may have an interest in the outcomes of an organization's actions*".

The project glossary also includes a generic definition of **engagement**: *'Engagement' signifies all the activities that can be done with stakeholders: consult, listen, understand, communicate, influence, negotiate, etc., with the broader objectives of satisfying their needs, gaining approval and support, or at least minimising their opposition or obstruction*[5].

However, being MULTI-ACT's focus on MSRIs and their mechanisms of engagement and c-accountability in research and innovation processes, it is worth to mention that other more specific definitions apply.

In this regard, Dverka et al.[6] for instance define engagement as "*an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interest in a particular issue, for the dual purposes of creating a shared understanding and making relevant, transparent and effective decisions*".

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[4] Kok M, Gyapong J, Wolffers I, Ofori-Adjei D, Ruitenberg J. Which health research gets used and why? An empirical analysis of 30 cases. Health Res Policy Syst. 2016;14:36. https://doi.org/10.1186/s12961-016-0107-2.

[5] RICS Professional Guidance, Stakeholder engagement 1st Edition, 2014 (https://www.apm.org.uk/sites/default/files/rics%20stakeholder%20engagement-final-proof-pw%20protected_0.pdf).

[6] Deverka PA, Lavallee DC, Desai PJ, Esmail LC, Ramsey SD, Veenstra DL, et al. Stakeholder participation in comparative effectiveness research: defining a framework for effective engagement. J Comp Eff Res. 2012;1(2):181–94.

When it comes to **stakeholder classification**, in the context of MULTI-ACT, the following general categories apply (Figure 6):

- **Internal stakeholders** are considered the groups and/ or individuals that are already part of the project (Project Coordinator and Partners).

- **Key stakeholders** represent a subset of all the external stakeholders that are either highly impacted by the project or specifically interested in the accomplishment of its objectives and for this reason decide to actively support it. In MULTI-ACT, they are namely the members of the External Advisory Board, the Patient Forum, the Patient Engagement Group, the MSRI to be selected as case study in WP4 and any other key actor identified in the course of the project.

- **External stakeholders** are those individuals or groups that are outside the project's environment, have some interest in the project's aims and might influence to different extent its execution and the accomplishment of its expected results.
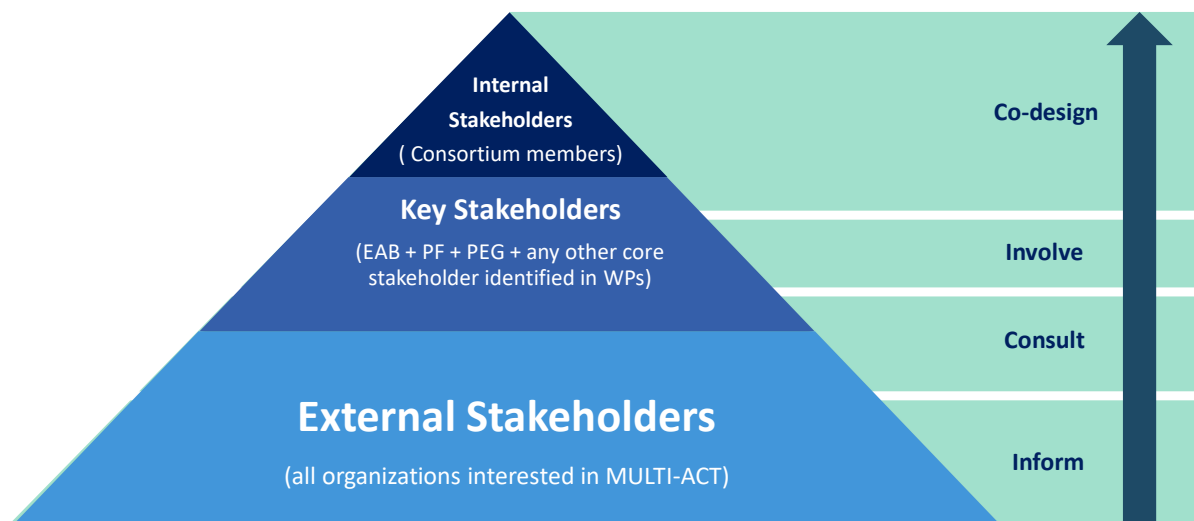

Figure 6. Stakeholder classification and level of engagement

7.3 The MULTI-ACT strategy

The project stakeholder engagement strategy may be illustrated as a four-step process (Figure 7), which entails the following activities:

1. Data collection and stakeholder analysis
2. Stakeholders mapping and draft of the engagement plan
3. Design and implementation of the engagement plan (including WP specific actions)
4. Reporting and follow up

Figure 7. The MULTI-ACT four step stakeholder engagement strategy

7.3.1 Stakeholder analysis

A preliminary **analysis** of the actors composing the health R&I ecosystem has been provided in WP3 (deliverable D3.3 whereas the first stakeholder meeting has been arranged and reported). Such preliminary analysis was based on the "7Ps" Stakeholder Classification elaborated by Concannon et al. (2014)[7] For the sake of harmonization and consistency, we provide hereby a thorough explanation, based on the MULTI-ACT approach, of what groups of persons and organizations each "P" category includes (Table 6). Such classification is going to be used across all project's activities including the design of the MULTI-ACT toolbox and its interface to profile MSRIs that will decide to start using the CRIF. An additional layer of information is provided indicating whether the analysed stakeholder in a Research Funding and/or Performing Organization (RFPO) or not.

Table 6. Stakeholder classification adopted by MULTI-ACT

7P classification in WP3	Proposed classification	Definition
Patients and the public	Patients	People with the diseases and affected by the diseases (i.e. relatives, caregivers)
	Patient organizations (RF/PO)	Patient associations, advocacy organizations, etc.
	Society	Individual citizens, civil society organizations and networks
Payers	Payers and purchasers	Public or private entities responsible for underwriting the costs of health care
Purchasers		
Providers	Care providers (RF/PO)	Health and social care organizations and professionals (doctors, nurses, etc.)
Policy makers	Policy makers (RF/PO)	EU institutions; national, regional and local policy makers
Product makers	Industry (RF/PO)	Companies developing and selling health products (drugs, devices, applications, etc.) and services
Principal investigators	Research and education organizations (RF/PO)	Research Organizations; Universities; Education Providers; Foundations; Other research projects

7.3.2 Stakeholder mapping and draft engagement plan

As a second step, stakeholder groups have been mapped according to their **level of interest** into the project and **capacity to influence** the project itself and its results. Such classification makes use of an adapted version of the Mendelow's "power-interest grid"[8], which considers stakeholder power and expectations (and therefore their likely interest) to determine the potential influence of stakeholder groups (Figure 8).

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[7] Concannon, T. W., Fuster, M., Saunders, T., Patel, K., Wong, J. B., Leslie, L. K., & Lau, J. (2014). A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. Journal of general internal medicine, 29(12), 1692–1701. doi:10.1007/s11606-014-2878-x.
[8] Mendelow, A. (1991) 'Stakeholder Mapping', Proceedings of the 2nd International Conference on Information Systems, Cambridge, MA (Cited in Scholes, 1998).
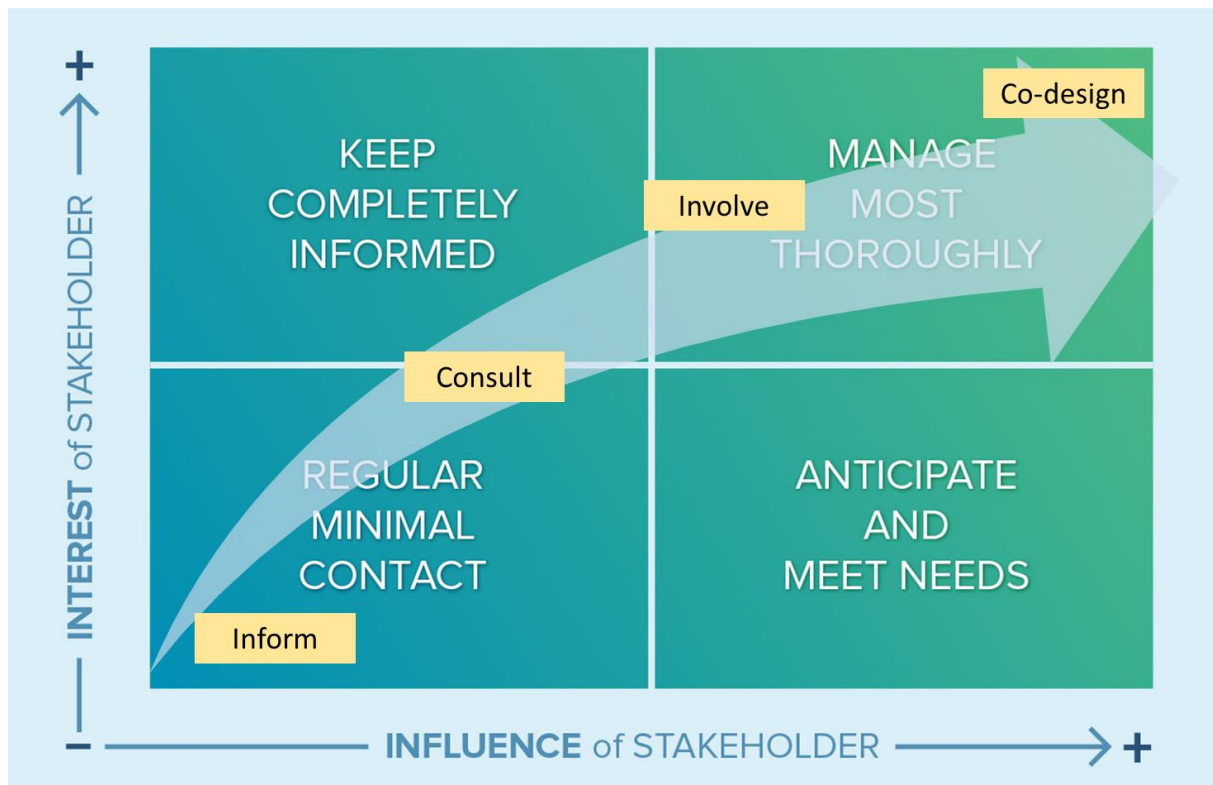
Figure 8. Stakeholder mapping across level of interest and influence

This results in a stakeholder map which is going to be included in the updates of the Communication and Dissemination Plan (D8.6 and D8.7) as it is a key element to guide the project communication strategy of the project.

1. **Type of organization (RFO, RPO, RFPO, policy makers, etc.)**
2. **Geographical coverage (local/regional, national, international)**
3. **Level of interest (low/moderate, medium/high)**
4. **Level of (potential) influence (low/moderate, medium/high)**
5. **Level of foreseen engagement (inform, consult, involve, co-design)**
6. **Specific dissemination, communication and engagement actions planned.**

Influence indicates a stakeholder's relative power over and within a project. A stakeholder with high influence would control key decisions within the project and have strong ability to facilitate implementation of project tasks and cause others to take action. Usually such influence is derived from the hierarchical, economic, social, or political position. Other indicators[9] may include: expert knowledge, negotiation and consensus building skills, holder of strategic resources, etc.

Importance indicates the degree to which the project cannot be considered successful if needs, expectations, and issues raised by a certain stakeholder or stakeholder category are not addressed. This measure is often derived based on the relation of the stakeholder need to the project's goals and

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[9] Overseas Development Administration. (1995, July). Guidance note on how to do stakeholder analysis of aid projects and programmes. Social Development Department.

purposes. For instance, the users of the project's product or service typically are considered of high importance.

Currently the uncategorized list included in the first version of the Communication and Dissemination Plan (D8.1) contains more than 200 individuals and/or organizations. It has to be highlighted that the list is a living document: names are added when new relevant ones are found or when different knowledge/stakeholder group is detected as relevant for project activities.

Also, entries are being deleted, when individuals explicitly mention they don't want to be involved in communication related to the project, as well as added when new subscribers to the project's newsletter join. It also needs to be stressed that personal data of individuals (name, e-mail address, organisation, country) are collected according to framework defined in the project Data Management Plan and in full compliance with the data protection regulation (GDPR) and the relevant ethics guidelines.

In addition to identifying and start analysing and mapping its stakeholders, the consortium designed the following engagement plan which comprises:

- Goals
- Guiding principles
- Tools
- Detailed outline of engagement activities in each WP.

The **goals** of MULTI-ACT stakeholder engagement strategy are the following (Figure 9):

1. **To ensure effective communication:** the communication must take into account the audience as well as the objectives for the communication and therefore investigate the stakeholder's preferred method communication.
2. **To anticipate and understand needs and challenges by setting up early, authentic and regular consultations:** engagement should not be an ad hoc action but must be deeply rooted in all project's activities. Early engagement with stakeholders is fundamental to success, providing a fair framework allowing to ask questions, to collect, to answer and to address concerns. The effectiveness of engagement is strong if it occurs at a moment when it can help to produce the final outcome of the project's activities.
3. **To plan in advance and select appropriate and targeted means and tools for stakeholder engagement:** MULTI-ACT considers that carefully planning and time investing in stakeholder engagement activities bring compelling payoffs. In this regard engagement is recognized to be a targeted process, providing a powerful use of the entire range of concerns, interests, knowledge and expertise of its diverse stakeholders. This approach allows stakeholders to target their interests and concern on those activities where they can add and extract value from cooperating with MULTI-ACT.
4. **To build durable relationships which may pave the way for MULTI-ACT endorsement and/or adoption:** building strong and clear positive working relationships with the stakeholders represents the key that leads to successful and sustainable project outcomes. The relevance of establishing and preserving good relationships is vital for reaching the stakeholders' support for project's activities, as well as for designing and delivering the suitable solutions.
5. **To assess carefully all risks connected to stakeholder engagement:** using stakeholder analysis tools is a means of evaluating risks and opportunities stakeholders might inflict on the project's success.
6. **To monitor thoroughly engagement progress:** the MULTI-ACT consortium will regularly measure the stakeholders' engagement progress to evaluate its success and use the findings

for conceiving and developing forthcoming engagement. Progresses will be reported in the Periodic and Final Reports.
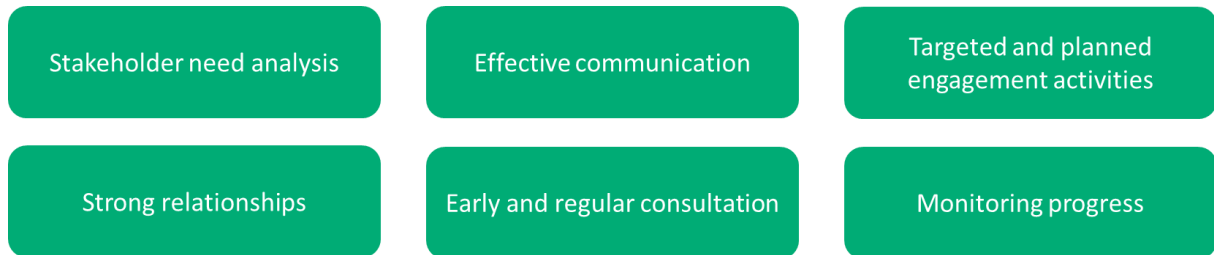
Stakeholder need analysis	Effective communication	Targeted and planned engagement activities
Strong relationships	Early and regular consultation	Monitoring progress

Figure 9. MULTI-ACT stakeholder engagement goals

To accomplish such goals the design of an effective stakeholder engagement strategy must be informed by a set of **guiding principles**[10] that all WPLs are called to keep in mind when planning the specific WP-related engagement activities. Such principles are categorised into three groups, namely organisational, values and practices.

The principles of engagement outlined in this strategy are universal. However, the level of engagement, governance and process, and how MULTI-ACT will engage with stakeholders will vary. Stakeholder engagement is an evolving process and should be planned for longer period based on an approach that will continue to mature as MULTI-ACT learns and builds on its progressive achievements.

The engagement guiding principles are intended to shape MULTI-ACT's approach to stakeholder engagement strategy.

Organisational

1) Clarify the objectives of stakeholder engagement

The objectives might be one or more of accessing knowledge and skills; supporting interpretation of the results and drafting recommendations; supporting future influence and impact on policy and practice; increasing recruitment/enabling research; supporting transferability. The objectives need to be shared then among all parties.

2) Embed stakeholder engagement in a framework or model of research use

There are a number of models and frameworks designed to show how stakeholders might be engaged in a way that helps increase the chances of research being used in policy and practice, for example, the linkage and exchange model[11].

3) Identify the necessary resources for stakeholder engagement

Resources to consider are budget, time, skills and competences to manage engagement.

4) Put in place plans for organisational learning and rewarding of effective stakeholder engagement, for example, through appropriate evaluation of stakeholder engagement.

5) Recognise that some stakeholders have the potential to play a key role

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[10] Boaz, Annette & Hanney, Stephen & Borst, Robert & O'Shea, Alison & Kok, Maarten (2018). How to engage stakeholders in research: Design principles to support improvement. Health Research Policy and Systems. 60. 10.1186/s12961-018-0337-6.

[11] Lomas J. (2000), Using 'linkage and exchange' to move research into policy at a Canadian foundation. Health Aff. 2000;19(3):236–40. https://doi.org/10.1377/hlthaff.19.3.236.

We need to identify those stakeholders who are particularly interested in being engaged and those who are likely to be influential. Depending on the objective of stakeholder engagement, they may provide the most useful input, and are most likely to play a key role in using the results; their engagement should be especially encouraged. This is the case of those stakeholders who are forming part of the EAB, the PF and the WP-specific working groups.

Values

6) Foster shared commitment to the values and objectives of stakeholder engagement in the project team

Ideally, it is important to make sure the commitment is there from the outset. For this reason, for instance, at the very beginning of the project a virtual stakeholder meeting has been planned and arranged within WP3.

7) Share understanding that stakeholder engagement is often about more than individuals

Consideration needs to be given to stakeholders' roles where they act as representatives – their power and influence within organisations and networks they represent and how these change over time

8) Encourage individual stakeholders and their organisations to value engagement

MULTI-ACT has to seek to support and build capacity for stakeholders and their organisations to engage. This specifically refers to provide assistance to umbrella organizations which are gathering relevant national or disease-specific organisations in order to enable the creation of a multiplier cascade effect.

9) Recognise potential tension between productivity and inclusion

Engagement may lead to greater relevance and impact, but may have implications for productivity in meeting project objectives (for example, in a timely fashion). Engaging stakeholders, taking into account their needs and inputs and adjusting elements of the project based on their feedback takes time and can slow down the research process. This is a risk that has been added into the risk assessment plan of MULTI-ACT because it is specifically relevant for the nature of the project itself. WPLs, under the supervision of the Coordinator, are responsible for managing this trade off in the most balanced possible manner.

10) Generate a shared commitment to sustained and continuous stakeholder engagement

Project teams and stakeholders see the value of links between research producers and research users to build ongoing collaborations in order to meet the objectives

Practices

11) Plan stakeholder engagement activity as part of the research programme of work

The present document responds to such principle by embedding stakeholder engagement in the key plans and procedures of the project. Below, the specific stakeholder engagement plans per each WP are illustrated in a nutshell.

12) Build flexibility within the research process to accommodate engagement and the outcomes of engagement

It will also be important to build in mechanisms to allow researchers to have the independence to articulate what is out of scope.

13) Consider how input from stakeholders can be gathered systematically to meet objectives

The importance of some face-to-face contact and interactions should be considered. To this purpose, face-to-face meetings are planned with the EAB members.

14) Consider how input from stakeholders can be collated, analysed and used

This important aspect of stakeholder engagement needs to be considered earlier than often happens.

15) Recognising identification and involvement of stakeholders is an iterative and ongoing process

Ongoing interaction will be fostered by taking the time and creating the structures to build trustful relationships.

As said above, the deliverables where specific plans for communication, dissemination and engagement towards each stakeholder category and the corresponding **tools** that best fit the purpose to reach and involve them are going to be detailed are D8.6 and D8.7.

Nevertheless, in the following section a summary of the **WP-specific actions** that are going to be put in place in each WP to secure successful engagement is provided.

7.4 WP specific stakeholder engagement strategies

Figure 10 summarizes the key activities and tasks where some kind of stakeholder engagement action is envisaged to be instrumental to reach WP-specific objectives.

In the following sub-sections the WPLs have detailed their draft plans for engagement with specifc emphasis on answering the following key questions:

- Who is going to engaged?
- How are you planning to engage the relevant stakeholders?
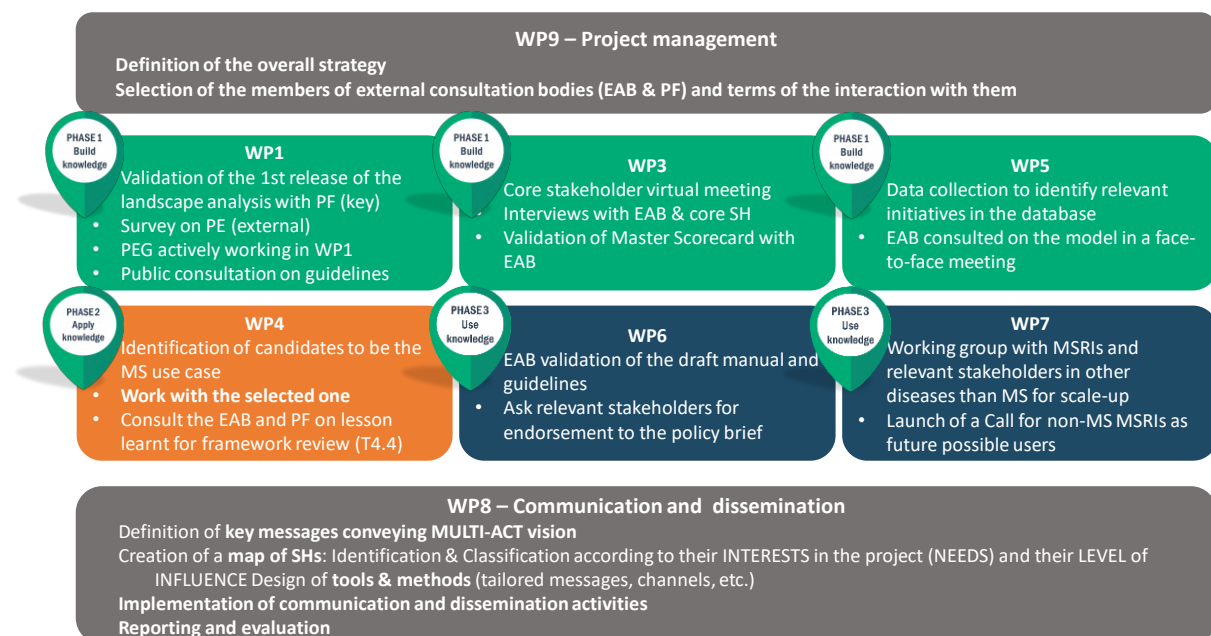- When do you foresee the planned stakeholder engagement activities to take place?

Figure 10. WP-specific stakeholder engagement key actions

7.4.1 WP1 stakeholder engagement plan

Stakeholder engagement is the core backbone of WP1. Since its very beginning the WP1 team has constituted a Patient Engagement Forum (composed by both internal and external experts) to support the activities of data collection, study and review of existing patient engagement initiatives, methods and tools with the aim to identify gaps and barrier and develop innovative guidelines to make patient engagement more effective and impactful.

Other stakeholder engagement activities foreseen in the frame of WP1 are:

- Validation of the 1st release of the landscape analysis with the members of the PF in a virtual meeting;
- A survey on PE initiatives, methods and tools aimed to collect inputs from external stakeholders such as the Multiple Sclerosis International Federation, European Multiple Sclerosis Platform, among others;
- A public consultation to be launched to validate the final version of the Patient Engagement Guidelines.

7.4.2 WP2 stakeholder engagement plan

WP2 has the following major aims and consequently outputs:

- To design the MULTI-ACT toolbox, an information sharing and decision support tool for research impact assessment for health-related R&I initiatives. The design process includes effectively addressing user requirements and envisioned usage scenarios into functional capabilities and user interface elements of the MULTI-ACT toolbox.
- To aggregate, in synergy with relevant health domain stakeholders, the content needed for analyzing impact from different dimensions and evaluating respective indicators and statistics
- To develop and to publicly release the Multi-act toolbox in the form of a web portal with the envisioned backend services, to be accessed and experienced by the targeted stakeholders.

For each of the above mentioned aims and relevant activities, WP2 plans to engage and actively involve stakeholders in the following ways:

- **MULTI-ACT Toolbox design**: a **design-oriented questionnaire** will be formulated with questions aimed to retrieve feedback from **internal stakeholders** on desirable MULTI-ACT toolbox features and functions from an end-user perspective along with MULTI-ACT toolbox UI mockups, which will be provided to EAB members to collect feedback, to be taken into consideration in the design specification of the Multi-act toolbox.
- **MULTI-ACT content collection**: To ensure that relevant and of adequate size content is collected to enable the execution in their entirety of all MULTI-ACT toolbox functionalities, a **content collection awareness campaign** will be initiated, starting from consortium stakeholders, towards EAB and PF members and through social media and other open dissemination channels to external third party stakeholders.
- **MULTI-ACT toolbox release**: Upon the release of each version of the MULTI-ACT toolbox (initial and final), EAB members will be invited to access and navigate through the MULTI-ACT portal and its functionalities, and subsequently provide their feedback by answering a adequately formulated **user experience and usability questionnaire**.

7.4.3 WP3 stakeholder engagement plan

The major goal of WP3 is the development of a Master Scorecard including a set of indicators to measure health R&I impact according to five dimensions.

After having conducted an extensive literature review, systematized and classified the indicators in a database, the WP3 engagement has put in place two core engagement activities:

- A virtual stakeholder meeting aimed to establish a community of interests around the objectives of the project and the WP3
- A series of interviews to the EAB members aimed to gather inputs about priorities and core aspects of the health R&I impact that they would deem as central to be measured

Those indicators selected to be part of the Master Scorecard have gone through a refinement and validation process.

The EAB members have been involved in such process as well. During the first EAB meeting the overall approach and selection criteria have been presented and shared. During the second EAB meeting the final list of indicators composing the Master Scorecard and the rationale behind its selection has been discussed with the EAB experts as well.

The inputs and suggestions provided by the EAB members on the indicators are going to be taken into account in shaping the refine Scorecard which will be made available via the Toolbox.

7.4.4 WP4 stakeholder engagement plan

The WP4 overall stakeholder engagement approach to implement the MULTI-ACT framework in the MSRI selected as case study initiative relies on collaborative tools such as workshops, surveys and consultations. This enables the engagement of both the consortium partners (internal stakeholders) and the promoters of the selected MSRI (key stakeholders) as well as of other relevant stakeholders and experts. Through the implementation of the MULTI-ACT model, the consortium will provide the case study initiative with recommendations on how to link future investments more closely with research impact and how to secure multi-stakeholder engagement for sustainability of the initiatives.

Key steps of the engagement approach might include:

1) Establishment of a MULTI-ACT Task Force in charge of steering the implementation process. The task force includes beside the WP4 leader also members of WP1, WP2, WP3, WP5 that will develop the MULTI-ACT model components and the MULTI-ACT Toolbox.
2) Internal consultation among Consortium members to select and prioritise potential test case initiatives;
3) Selection procedure entailing virtual meetings with potential candidates;
4) WP4 workshop involving the selected initiative in order to set up an implementation plan and distribute tasks and responsibilities;
5) Implementation process;
6) Consultation to validate the results and to evaluate the implementation process.

7.4.5 WP5 stakeholder engagement plan

The stakeholder engagement plan related to WP5 namely refers to the involvement of the EAB in the refinement of the governance model and its 5 criteria which have been presented and discussed during the face-to-face meeting in Milan (9th April 2019).

7.4.6 WP7 stakeholder engagement plan

Similarly to WP4, the WP7 overall stakeholder engagement approach to scale-up the MULTI-ACT CRIF to MSRIs in **other brain disease areas than MS** relies on collaborative tools such as workshops, surveys and consultations. This enables the engagement of **external stakeholders**, specifically those belonging

to MSRIs in health research which can benefit of using the MULTI-ACT CRIF. Through the implementation of the MULTI-ACT framework, the consortium will provide MSRIs with recommendations on how to adapt and adopt the MULTI-ACT framework.

Key steps of the engagement approach might include:

1) Establishment of a MULTI-ACT Task Force in charge of steering the implementation process. The task force includes beside the WP7 leader also key actors involved in WP1, WP2, WP3, WP4, WP5 as well as WP6 that will develop the MULTI-ACT framework guidelines and toolbox manual.
2) Set-up of working groups dedicated to translating MULTI-ACT result to other brain disease.
3) Consultation to tailor the Multi-ACT model to other disease areas.
4) Consultation to explore opportunities for the implementation of the MULTI-ACT model beyond the lifetime of the project.

7.4.7 WP8 stakeholder engagement plan

The plan for communication and dissemination to be put in place by WP8 is detailed in D8.1 which is going to updated on month 18 (D8.6) and month 30 (D8.7).

7.5 Consultative bodies

7.5.1 External Advisory Board

An international External Advisory Board (EAB) has been established within the first 3 project months to engage a larger set of stakeholders in the fields of brain domain, health research management, accountability, impact measurement, governance development and policy making to ensure the diffusion and uptake of project results.

The EAB performs a key role since providing high-level policy orientation and validating the project results with the aim to have them applicable not only to MS but also to other brain disease. For this reason, it includes and engages future potential users of the model in order to carry out a critical review of it and increase uptake and exploitation opportunities. To this aim the EAB provides inputs and views on key draft outputs, especially referring to:

- The indicators included in the MULTI-ACT Master Scorecard and identified to capture the impact of health (and specifically brain) R&I on their own stakeholder categories and, in general, on the society
- The CRIF and its five governance criteria, related sub-criteria and practical guidelines to secure compliance
- The plans for sustainability and exportability of the CRIF to other brain diseases than MS and potentially other health domains.

The EAB involves persons representing both the health domain (e.g. manager and representative of patients organizations, health research consortia, clinicians, health professionals, etc.), the final users sector (e.g. RFPO directors and committees, research and educational ministries, health and social systems, policy makers, research initiatives and consortia, PPPs initiatives, etc.) and other stakeholders (e.g. industry, hospitals, payers, purchasers, health insurers, etc.) that will provide their professional experience to guide the project development, assuring a comprehensive and relevant stakeholder representatives involvement.
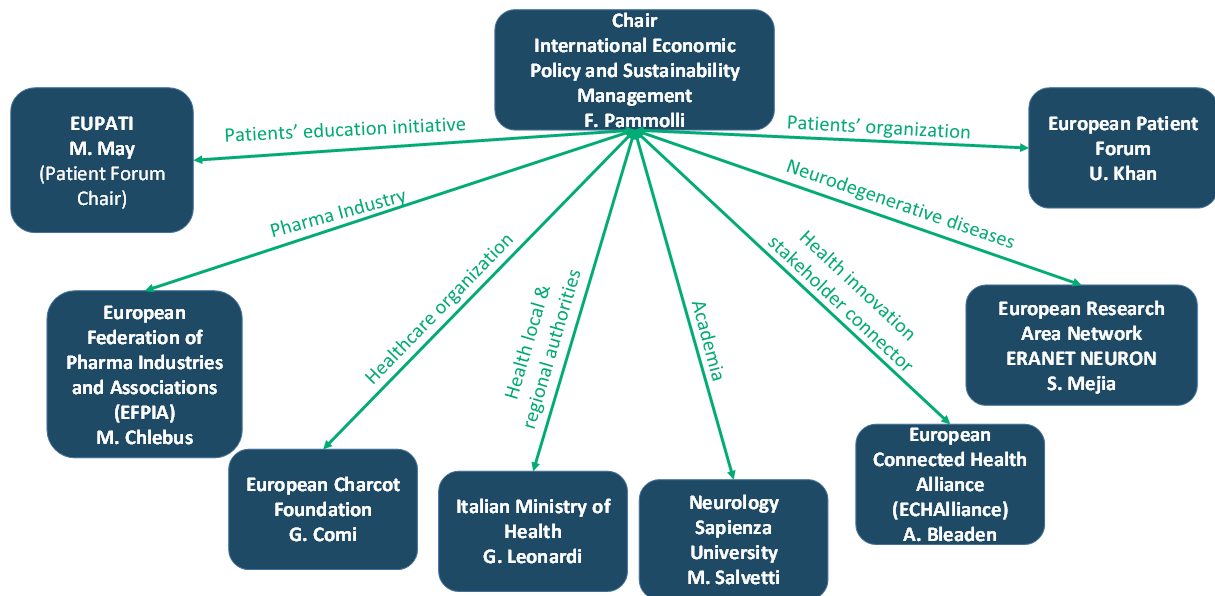
Figure 11. EAB composition

The EAB is asked to: 1) meet at least once a year (remotely) to monitor project's implementation and progress and consequently to formulate research questions on project outcomes; 2) join at least two face-to-face EAB meetings; and 3) providing inputs and suggestions on specific core deliverables that will be carefully taken into consideration by the PSC.

The EAB members have been fully informed on the project to decide autonomously and spontaneously whether to participate or not and have signed a nondisclosure agreement attached to the appointment letter. The EAB will be formed by maximum 8 members (including the Patients Forum Chair). Costs for their travel and accommodation expenses and daily fees are included in the "other direct costs" claimed by FISM and EBC.

The EAB composition is represented in Figure 11.

To date, **two face-to-face meetings** have been arranged with the aim to involve all EAB members in a constructive discussion about the project's intermediate results (namely the governance model and the scorecard):

- The first meeting took place in Milan at the beneficiary EY's premises on the 9th April 2019. Four EAB members participated (M. May, A. Bleaden, S. Meija, M. Salvetti).
- The second meeting has been held in Rome in the occasion of the Annual FISM Congress and 3rd MULTI-ACT Consortium meeting (28th May 2019). G. Comi, M. Chlebus, F. Pammolli, G. Leonardi, M. Salvetti and U. Khan (online) participated.

7.5.2 Patient Forum

During the first 3 project months, a Patients' Forum (PF) has been established to support the activities to be performed, specifically, in WP1 and 3. The PF activity is coordinated by FISM and a person with MS with low EDSS (or a caregiver) who has been asked to be the referent for the PF in order to do not stress highly impaired people with organizational issues.

PF members (Figure 12) have been selected among those more interested in scientific research, with a cultural background that allows a full understanding of project design, activities and scientific terminology.

All patient-related tasks within the project will be quality assured by the PF, which is directly involved for the identification of patients' needs and priorities while considering the impact of research.

PF has been asked to work closely with the EAB to contribute to project development, formulating research questions on project findings, defining relevant outcomes from a beneficiary perspective, monitoring research conduct and progress. They also collaborate in the implementation process, identifying the steps of health research process where patients input is essential and identify communication channels for patients community and selecting specific applications for information and social awareness.

The PF has been asked to meet twice a year to monitor research conduct and progress and consequently to formulate research questions on project outcomes. These meetings will be held remotely so no costs are foreseen to cover them. Nevertheless, the PF Chair will seat in the EAB and report the insights gathered during the PF meetings in order to have them incorporated in the "project progress assessment report" to be released yearly by the EAB. So, costs for travel, accommodation and participation fees for the PF Chair have been budgeted along with the other EAB components.
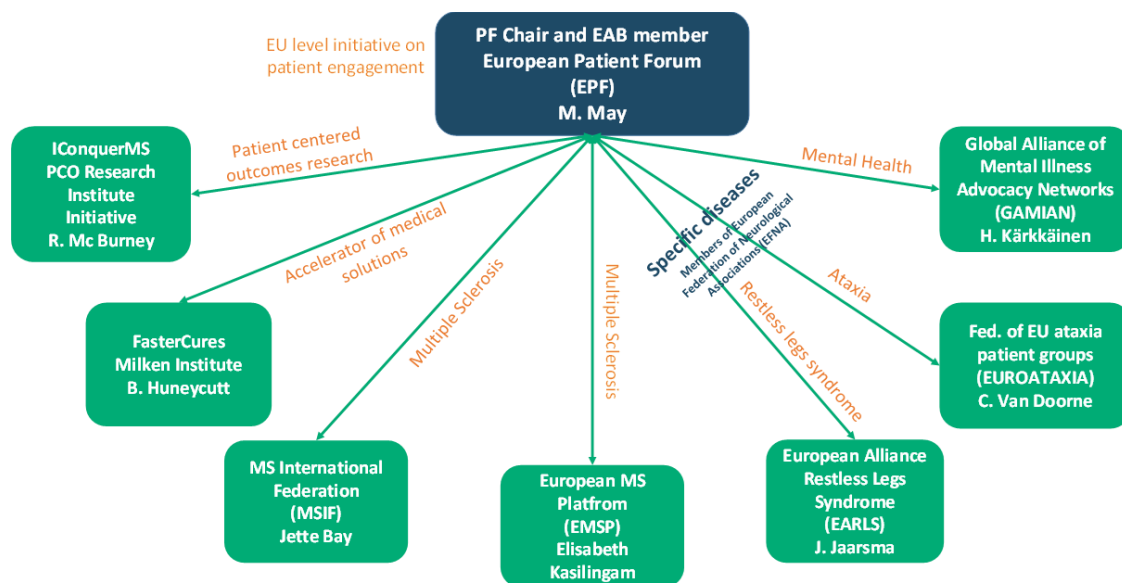

Figure 12. PF composition

The PF has gathered virtually on the 25th March 2019. After introducing the core mission and objectives of the project, the PF members have proactively participated in a discussion with the consortium partners aimed to 1) consolidate the governance criteria; 2) validate the engagement criteria for patients identified in WP1; validate the impact indicators selected in WP3 and prioritise them.

8 Meetings

Consortium meetings (CM) are an important forum for discussion and review of ideas and plans, and will occur every 6 months.

Moreover, monthly remote meetings of the PSC are scheduled to ensure alignment and make all partners aware of progresses, potential pitfalls and plans for next steps.

For the interim monthly meetings the consortium will make use GoToMeeting that will allow regular web interface integrated teleconference facilities with the possibility to also share presentations and other files.

The EAB and PF members will meet remotely or face to face as well, chaired by FISM, once a year, 1-2 months before the annual meeting, in order to be updated on project progresses, jointly discuss and provide shared feedbacks to the PSC before the corresponding consortium meeting.

They will also be invited to join a dedicated session of the annual consortium meeting, physically or via GoToMeeting, to provide advice for quality management and problem solving and contribute to assure project adherence to stakeholders' (and particularly, patients') needs and rights.

Extraordinary meetings may be requested and convened at any time upon written request.

The procedures described in this section apply to all MULTI-ACT meetings. Some important aspects referring to the CA are reminded and some operative indications are given.

8.1 Participation

Any member of the Consortium contributing to a WP or Task:

a) Should be present or represented at any meeting of the related Committee, WP or Task.

b) May appoint a substitute (representative) to attend and vote at any meeting.

c) Shall participate in a cooperative manner in the meetings.

Whereas an extraordinary PSC meeting is convened to take important decisions that affect the GA and/or the CA implementation (e.g. exclusion of a partner) the appointed PSC representative or its Deputy must join as vote.

The names of appointed representatives and deputies have been communicated by the partners at the beginning of the project and are indicated in the corresponding Smartsheet "*Contact list – Governance*".

8.2 Consortium meeting (CM) agenda

For each face-to-face Consortium Meeting (CM) a Preliminary Agenda will be set up by the Project Manager. The meeting agendas will be prepared using the dedicated format, available in Dropbox. The agenda shall be posted in the calendar as attachment to the meeting invitation when sending invitations to the meeting participants, and in any case communicated by the necessary notice time. If any change arises in the agenda previously shared, the participants of the meeting shall be promptly notified to go check the new version uploaded in Dropbox and the #general Slack channel.

The table below summarizes the Consortium Meetings to be held during the first year of the project. The same six-monthly schedule will be maintained also for the rest of the project unless specific needs arise (e.g, the possibility to couple a CM with a relevant dissemination event and save travel costs).

Moreover, the day prior the two reviews which are planned in the DoA the consortium will meet to have a full day dedicated to the preparation of the review in Brussels.

Month	Meeting	Date	Location
M1	Kick-off Meeting	13-14 May 2018	Genoa (Italy)
M7	Consortium meeting (CM2)	12-13 November 2018	Brussels (Belgium)
M13	Consortium Meeting (CM3)	27-28 May 2019	Rome (Italy)

Table 4: Project Consortium Meetings held during the first reporting period

8.3 Minutes

Keeping minutes for all project meetings is extremely important as they are a record of the decisions taken and the actions required by the partners in the project. Meeting minutes have to be concise and clear and will be prepared using the dedicated format, available on Dropbox. It is the responsibility of the Project Manager to take the minutes in collaboration with the chair of the meeting.

The Project Manager shall produce written minutes of each CM, which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 15 calendar days after the meeting. In addition, if no comments are received within 7 calendar days, the minutes are automatically approved. If the minutes need to be updated, the updated and final file will be again sent by e-mail and upload by the author to the dedicated folder on Dropbox.

9 Issues Management

The timely and effective management of any issue (technical, administrative or of relation between partners) that may arise will contribute to ensure the progress of the project.

Special attention is thus paid to this matter, and indications are given for each main type of issue.

9.1 Technical Issues management

If any issue arises in the frame of a WP, the issue should be notified by the partner to the related Task and WP Leader. The issue will be thus addressed first at WP Level, keeping the PC informed, considering:

- Possibility of a solution or work-around
- Possibility of another partner (or third party) assistance
- Impact on the WP schedule

If it is deemed that the issue will generate any shift in the WP schedule, the PC and Technical Committee should be promptly alerted, in order to take the necessary actions (including amendment of the EC-GA Annex I (DoA), if necessary).

In case of difficulties or impossibility in addressing the issue at WP level, the PC should be immediately alerted and the Technical Committee summoned to collectively address the issue.

9.2 Administrative Issues management

If any issue arises in the frame administrative/legal issues, the PM should be promptly notified. The PM will then verify the possible solutions, and eventually request the advice of the EC Administrative/Legal Officer.

10 Project financial reporting

10.1 Reporting Tool File Excel

All Partners have been provided with a ***Reporting Tool File Excel including an easy-to-use guideline in the first sheet.***

All the Partners are required to fill in the relevant part of the file for each "*Interim Period*" in order to report all the personnel, direct and indirect costs incurred.

In particular, partners are expected to deliver the *Reporting Tool File Excel* duly filled in not later than 15 days after the end of each Interim Period (every 6 months).

This allows the Project Coordinator to have a thorough overview of the expenses and use of resources and detect any potential deviation which might occur.

Conclusions

This Project Quality and Stakeholder Engagement Plan is the main deliverable issued under the umbrella of WP9. It has been prepared by FISM with the contribution of all partners. The deliverable details the rules and procedures governing the project, the coordination structures, partner roles and responsibilities, reporting mechanisms and timing for delivery; stakeholder engagement plans, principles and main tools. The Plan originates from the provisions established in the Grant Agreement n. 7787570 and in the Consortium Agreement signed by the partners.

Any changes to the management issues described in this document will be reported through the progress reports scheduled in the GA.

List of Figures

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