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Project Management Handbook

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D.9.1 – Project Management Handbook

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Topic:	SC1-BHC-36-2020: Micro- and nano-plastics in our environment: Understanding exposures and impacts on human health
Project Duration:	2021/04/01 – 2025/03/31
Coordinator:	Universitat Autònoma de Barcelona (UAB)
Associated Beneficiaries:	Tyoterveyslaitos Wageningen University & Research (WUR) Danmarks Tekniske Universitet (DTU) Commissariat à l'énergie atomique et aux énergies alternatives (CEA) Fundación para la Formación e Investigación Sanitarias de la Región de Murcia (FFIS) The University of Manchester AIMPLAS - Asociación de Investigación de Materiales Plásticos y Conexas Institut National de la Sante et de la Recherche Medicale (Inserm) Helmholtz-zentrum fur Umweltforschung GMBH (UFZ) Universitaet Leipzig

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PROJECT No. 965196

Innovative tools to study the impact and mode of action of micro and nanoplastics on human health: towards a knowledge base for risk assessment.

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1. Executive Summary

This Handbook is written in the framework of WP9 – Project Management (Task 9.1 Project management structure and procedures and Task 9.2 Project coordination and reporting activities) of the PlasticHeal project under Grant Agreement No. 965196.

This Project Management Handbook is intended to support partners in the effective and efficient administration, procedural and financial management of the project. It focuses on project implementation procedures, structures and coordination and sets out key responsibilities for EU engagement and interaction. It is intended to support the achievement of project objectives, the effective management of partner progress and the timely delivery of project results.

This Project Management Handbook sets out:

- The procedures and standards to be used in the PlasticHeal project;
- The key roles and responsibilities;
- How the project will be carried out, measured, monitored, accounted for and safeguarded during its implementation;

The initial version of this Handbook was delivered in June 2021 (M3) but will be updated, in case of changes, throughout the duration of the project.

The terms and provisions of the EU Grant Agreement (and its annexes) and the PlasticHeal Consortium Agreement will prevail in the event of any inconsistency with recommendation and guidelines defined in the present Project Handbook.

Note that this Handbook does not express the opinion of European Commission and does not, in any case, replace the European Commission documentation. This Handbook expresses only the authors' views.

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2. Acronyms and abbreviations

AB	• Advisory Board	**PDF**	• Portable Data Format
CMS	• Content management system	**PC**	• Project Coordinator or Project Manager (PM)
C	• Coordinator	**PR**	• Progress Report
CO	• Confidential	**PU**	• Public
D	• Deliverable	**QAP**	• Quality Assurance Procedures
DOI	• Digital Object Identifier	**RI**	• Risk
EB	• Executive Board	**RE**	• Restricted
EC	• European Commission	**RV**	• Review
FR	• Final Report	**SAL**	• Sub-action leader
GA	• Grant Agreement	**SC**	• Steering Committee
IAR	• Internal Activity Report	**TM**	• Task team member
MR	• Mid-term Report	**TL**	• Task Leader
MB	• Management Board	**WP**	• Work Package
MM	• Meeting Minutes	**WPL**	• Work Package Leader
P	• Presentation		

Table 1. ACRONYMS AND ABBREVIATIONS USED IN THIS PROJECT MANAGEMENT HANDBOOK.

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3. Introduction

3.1. Main objectives: how to use this document

This document describes the general project management plan and establishes the basis for the project supporting and control processes. It aims at providing PlasticHeal beneficiaries with practical information and guidelines about the management structures and reports. It describes the methodology to be followed, defines the roles and responsibilities of the beneficiaries involved in the deliverable production and refers to the relevant templates that will be used during the Project Management.

The PlasticHeal beneficiaries have a Grant Agreement that specifies how the project is organized and managed, and includes the contributions required by each beneficiary. UAB will manage the project and act as the interface of the PlasticHeal project to the European Commission, to finalize, sign and implement the Grant Agreement with the Commission. The management principle is to set-up agreed processes among the beneficiaries in order to monitor the activities and reach the objectives, by containing the risk and resolving any conflicts on a priority basis. The following figure shows the main objectives of the management in the PlasticHeal.

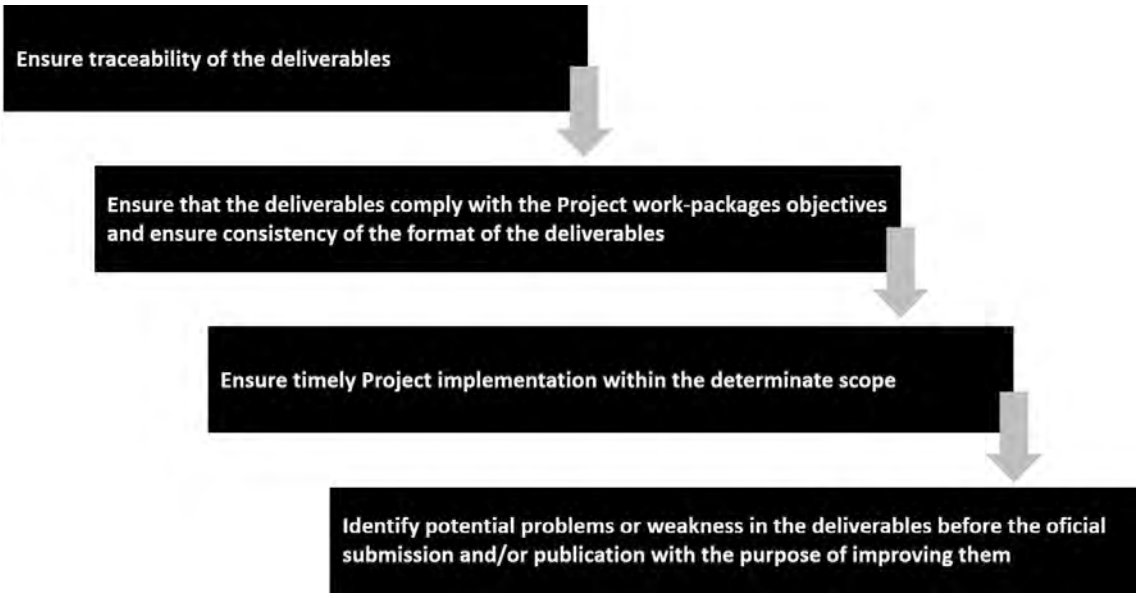

Figure 1. Main objectives of the PlasticHeal Management Handbook.

The project management is expected to be transparent as well as strict enough to keep the project progress in synchronization with the work plan. Quality aspects include the reporting of the project progress (both, financial and technical) and timely resolutions of technical and financial issues.

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The Management Handbook does not cover internal documents aimed at supporting Actions or Dissemination Documents. Dissemination documents such as presentations, publications or press releases are described in detail in the corresponding Deliverable “D8.1 Communication and Dissemination Plan”.

3.2. Project Reference Documents

Short name	Name
GA	Grant Agreement
DoA	Description of Action
Annex 1	Grant Agreement, Annex 1: “Description of the action”.
Annex 2	Estimated budget for the action
Annex 4	Grant Agreement Annex 4: “Model for the financial statements”.
Annex 5	Model for the certificate on the financial statements
CA	Consortium Agreement

Table 2. This table presents a list of the Reference Documents of the PlasticHeal project.

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4. Management structures: roles and responsibilities

The project organizational structure has been designed to offer maximum flexibility and operational capability towards objective achievement. Two considerations have helped define the structure setting process. These two considerations have influenced the proposed project management structure by considering the need for constant mutual understanding through the project implementation process by:

- Defining a fully functional structure, minimizing as much as possible the management expenditures (both in cost and time allocations) but assuring an implementation approach based on continuous feedback, monitoring and assessment of the outputs to be generated by the Consortium.
- Making sure that full involvement of all beneficiaries is achieved, offering an adequate platform for strategic planning and decision-making on project related issues.

The project management structure is represented in figure 2 below. The figure shows the relationship between the different governance groups.

Tasks included in every action are not just a sub-division of the work, but they constitute key elements of the project with a significant degree of autonomy, jointly contributing to the goals of the Action (A).

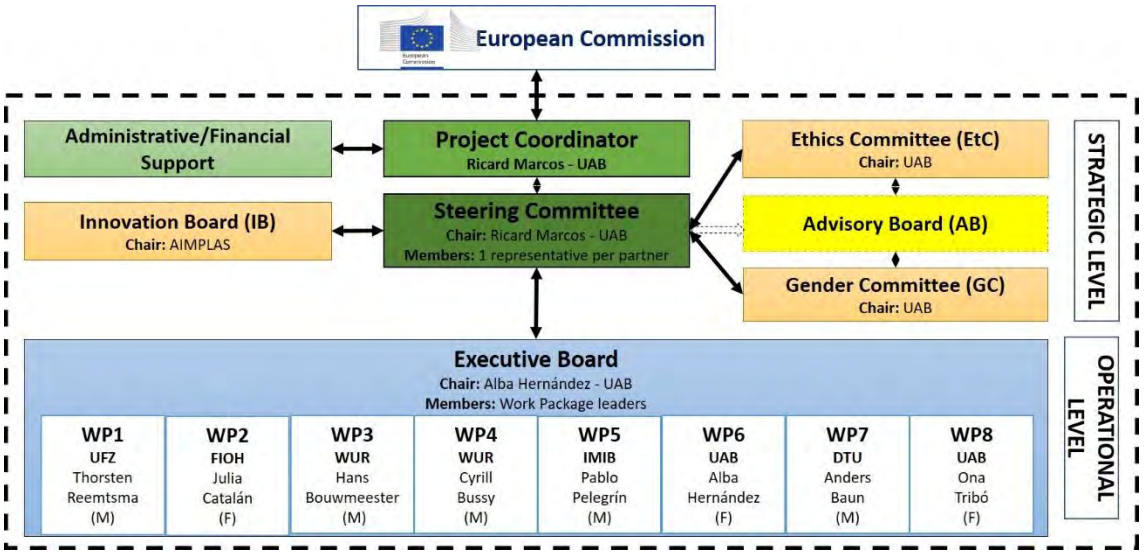

Figure 2. Management structure of PlasticHeal.

The Management structure of PlasticHeal and its procedures are key to ensuring the successful implementation of the project and achieving its goals.

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The structure distinguishes two different levels of management, ensuring a simple hierarchy but at the same time an effective management, the steering and the execution level. Two main committees with two complementary management figures have been developed in order to ensure a proper monitoring process in both steering and execution levels:

- The Steering Committee led by the Project Coordinator and one representative per partner.
- The Executive Board led by the Technical Manager and consisting of one representative of each Work Package (Work Package Leaders) and the Project Coordinator.

4.1. Steering Committee

The Steering Committee (SC) is the project's core group led by the Project Coordinator (PC) and consists of one representative of each beneficiary. The SC oversees the high-level monitoring of project progress, used resources and costs incurred. The SC will ensure that the strategic direction of the work remains within the interest of the beneficiaries and according to the objectives agreed with the SC as well as to manage the relationship between the Consortium and the EC. The SC has the overall responsibility to ensure timeliness and quality of all project deliverables as well as the proper execution and implementation of the taken decisions regarding the strategic direction of PlasticHeal project. The SC will ensure sufficiently wide and quality dissemination through the most appropriate means (website, reports, brochures, etc.) and prepare the content and timing of joint publications by the Consortium or proposed by the EC. Finally, SC will be responsible for undertaking all administrative arrangements regarding the successful completion of the project objectives and associated deliverables.

The SC will assess the strategy of the project and could be consulted on any technical issues and make introductions to other stakeholders. The SC will assist the access to relevant national and international stakeholders that influence the funding bodies and development of research priorities.

The Project Coordinator (PC), who has the main responsibility of overseeing the PlasticHeal project, leads the Steering Committee which will consist of one representative from each partner. The PC's main tasks will include interaction with the EU Commission Desk Officer, supervision of the Administrative and Financial (A&F) management and the chairing of the Steering Committee (SC) which will be the decision-making body of the Project. The PC will ensure the successful implementation of the project, as well as the technical, administrative and financial reporting in compliance with the Grant Agreement and the Consortium Agreement.

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The SC will be composed of one representative from each partner body of the project and represents the highest level of decision-making of the project and responsibility for the overall project strategy. Their mission includes:

- The evaluation of the technical progress and the impact of the project based on the reports given by the Executive Board and decisions made about strategy and the scheduling of the project. This will include consideration of proposed changes or new procedures.
- To intermediate and solve conflicts that may impact the project, its objectives, resources and strategies.
- To decide about changes that may affect the initial contract, e.g. change or exchange of WP and tasks, reviewing or amending of the GA, entering of new contractors, financial allocation, etc. The decisions will be taken by confidential vote.

The SC will ordinarily meet five times: at the beginning of the project (Kick-off meeting in Barcelona), at month 12 (in Helsinki), at month 24 (in Wageningen), at month 36 (in Leipzig), and at the end of the project (Final meeting in Brussels). However, extraordinary meetings may be organised if any critical issue needs to be discussed and a decision made in accordance.

STEERING COMMITTEE MEMBERS	
PARTNER	**NAME**
UAB	Ricard MARCOS Alba HERNÁNDEZ
FIOH	Julia CATALÁN
WU	Hans BOUWMEESTER
DTU	Steffen Foss HANSEN
CEA	Thierry RABILLOUD
IMIB	Pablo PELEGRIN
UNIMAN	Cyrill BUSSY
AIMPLAS	Raquel LLORENS
INSERM	Veronique MAGUER SATTA
UFZ	Thorsten REEMTSMA
ULEI	Irina ESTRELA-LOPIS

TABLE 3. STEERING COMMITTEE MEMBERS

4.2. Project Coordinator

The Project Coordinator (PC) represents the project and the consortium as a whole by managing and monitoring the overall project performance, ensuring the successful implementation of technical and business objectives,

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promoting project visibility and collecting the consolidated periodic reports presented to the SC. The PC is responsible for resolving issues arising from the detailed project work program and ensuring that effective solutions to any implementation problems or technical limitations are devised. They are also the chair of the SC meetings and the primary contact point for all formal communication between the project and the Commission as well as external stakeholders.

PROJECT COORDINATOR	
PARTNER	**NAME**
UAB	Ricard MARCOS

TABLE 4. PROJECT COORDINATOR

4.3. Project Manager & Administrative and Financial Manager

The Project Management will be coordinated by the PC. The Project Manager (PM) will oversee the communications between the consortium and will organize the consortium meetings: kick-off, 12M, 24M, 36M, and final meeting. PM will be in communication constantly with the Technical Manager to ensure the proper development of the technical work and that possible deviations are properly detected and managed in due time. The PM will bring to the SC any critical issue that needs to be discussed and requires a major decision for the development of the project.

Furthermore, the PM will ensure that the deliverables are prepared and sent on time. To do so, the PM will have direct contact with each WP leader who will be responsible for the revision of the technical and formal quality of each deliverable before the PM performs a final revision of each document before submitting it to the EC. Moreover, the PM will also assist in the GA and CA preparation, will create and manage the project intranet for the partners and ensure that the middle and final reports are done by the WP leaders by the end of the corresponding reporting periods.

PROJECT MANAGER		
PARTNER	**NAME**	**EMAIL**
UAB	Mª Belén Gómez	PlasticHeal@uab.cat

Table 5. PROJECT MANAGER

The Administrative and Financial (A&F) Manager will be in charge of the Financial Management of the project. The financial tasks include: (i) the overall budgetary management and coordination; (ii) the management of the payments received by the EC; (iii) the delivery of administrative and financial

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documents between the contractors and the EC; (iv) gathering of partners' Financial Statements for Financial Reporting to the EC.

ADMINISTRATIVE AND FINANCIAL MANAGER		
PARTNER	**NAME**	**EMAIL**
UAB	Mª Belén Gómez	PlasticHeal@uab.cat
UAB	International Project Justifications Office	

TABLE 6. ADMINISTRATIVE AND FINANCIAL MANAGER

4.4. Innovation Management

The Innovation Management is a group led by Aimplas and this is composed by all the following partners; UAB, FIOH, WU, DTU. Aimplas has been appointed as leader, due to its technical expertise, but also because of its wide experience in EU projects. Innovation Management team will evaluate the future exploitation of the implementation of PlasticHeal integrated solution.

INNOVATION MANAGEMENT	
PARTNER	**NAME**
AIMPLAS	Raquel LLORENS (IB Chair)
UAB	Martin Buffa
UAB	Montserrat López
FIOH	Julia CATALAN
WU	Hans BOUWMEESTER
DTU	Steffen Foss HANSEN
UNIMAN	Sandra VRANIC
INSERM	Boris GUYOT
ULEI	Irina Estrela-Lopis

TABLE 7. INNOVATION MANAGEMENT

4.5. Executive Board

The Executive Board (EB) is a group led by the Technical Manager and consists of one representative of each Work Package (Work Package Leaders) and the project coordinator. The aim of this group is to supervise the project's actions, i.e. to measure and document the effectiveness and benefit of the Project Actions as compared to the initial objectives and expected results. The Executive Board monitors the project by updating and assessing the Gantt chart and the monitoring indicators. The main objective of this Board is to ensure the correct progress of the project with the technical quality it requires, that the KPI's are being met and all reports and documents are delivered with the expected quality.

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The EB will monitor and control the project's technical strategy, which includes, for example, verification of achieved objectives, control of deviations, the application of contingency measures and the establishment of corrective actions. For that, the main tasks of the EB are listed below:

- Control and monitor the technical work of the project.
- Take decisions about the technical schedule of the project.
- Assure the technical planning and the coherence of the results. If necessary, assist on the revision of certain deliverables and be consulted for any issue in the strategy of technical tasks of the project.
- Reporting to the SC any potential technical risk and the planning of mitigation measures as required.

EXECUTIVE BOARD		
WORK PACKAGE	**PARTNER**	**NAME**
WP1	UFZ	Thorsten Reemtsma
WP2	FIOH	Julia Catalan
WP3	WU	Hans Bouwmeester
WP4	UNIMAN	Cyrill Bussy
WP5	IMIB	Pablo Pelegrin
WP6	UAB	Alba Hernández Bonilla
WP7	DTU	Steffen Foss Hansen
WP8	PRUAB	Ona Tribó
WP9	UAB	Alba Hernández Bonilla
WP10	UAB	Alba Hernández Bonilla

TABLE 8. EXECUTIVE BOARD MEMBERS

4.6. Technical Manager

The Technical Manager (TM) will continuously monitor the technical progress of the project. The TM will review technical reports and deliverables before they are uploaded in the project's intranet and EC portal. Any progress or alteration of the scheduling will be reported to the PM through continuous and fluid communications. The Scientific Committee will also evaluate the Project's scientific development and the eventual correcting measures. The TM will manage fluid communications with work package leaders by phone, e-mail, video-conference or physical meetings.

TECHNICAL MANAGER	
PARTNER	**NAME**
UAB	Alba Hernández Bonilla

TABLE 9. TECHNICAL MANAGER

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4.7. Ethics Committee

The Ethics Committee (EtC) is composed by partner representatives who have enough experience and expertise in ethics, data protection, data management in research and science. The EtC was constituted during the Kick-off meeting and will ensure that the project complies with the relevant ethical and data management regulations of the EU, member states, and participating institutions, as well as the code of conduct, guidelines, and best practices of the relevant professional associations.

The EtC will interact with the AB of PLASTICHEAL, specifically with the figure of the designated External Independent Ethics Advisor (Josep Santaló) that will coordinate the ethical action, and will provide the External Independent Ethics Report. Section 5 provides further information on these issues.

ETHICS COMMITTEE	
PARTNER	**NAME**
UNIMAN	Cyrill Bussy
UAB	Susana Pastor
IGTP	Jose Antonio Domínguez Benítez
IMIB	Laura Martínez Alarcón
FIOH	Tiina Santonen

TABLE 10: ETHICS COMMITTEE

4.8. Gender Committee

The Gender Committee (GC) is composed by partners' representatives who have previously worked gender issues in research and science. The GC was constituted during the Kick-off meeting of the project and will have the following responsibilities:

- To monitor the inclusion of gender dimension in all research tasks of the project
- To guarantee enough representation of targeted groups in the AB
- To report to the Steering Committee the fulfilment of gender aspects and actions to be undertaken if needed

The GC will interact with the AB of PLASTICHEAL, specifically with the figure of the designated External Independent Gender Advisor (Carme Valls).

GENDER COMMITTEE	
PARTNER	**NAME**
UNIMAN	Cyrill Bussy
AIMPLAS	Raquel Llorens

Table 11: GENDER COMMITTEE

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4.9. Work Package Leaders and Task Leaders

Each Task Leader (TL) reports directly to a Work Package Leader (WPL) who is in charge of managing the Work Package as a self-contained entity. The scope of this responsibility includes the technical coordination and supervision of the Work Package, planning and control of the necessary activities, preparation of all relevant deliverables, collection of contributions from the beneficiaries participating in the task and participation in all meetings planned within the Work Package. The WPL assists the PC and shall inform the PC of any quality assurance related problems immediately.

WP1 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP1	UFZ	Thorsten Reemtsma
TASK	**PARTNER**	**NAME**
T1.1	AIMPLAS	Raquel Llorens
T1.2	UFZ	Thorsten Reemtsma
T1.3	FIOH	Julia Catalan

TABLE 12. WP1 LEADER AND TASK LEADERS

WP2 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP2	FIOH	Julia Catalan
TASK	**PARTNER**	**NAME**
T2.1	UFZ	Thorsten Reemtsma
T2.2	FIOH	Julia Catalan
T2.3	WU	Hans Bouwmeester
T2.4	FIOH	Julia Catalan

TABLE 13. WP2 LEADER AND TASK LEADERS

WP3 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP3	WUR	Hans Bouwmeester
TASK	**PARTNER**	**NAME**
T3.1	UFZ	Thorsten Reemtsma
T3.2	WU	Hans Bouwmeester
T3.3	WU	Hans Bouwmeester

TABLE 14. WP3 LEADER AND TASK LEADERS

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WP4 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP4	UNIMAN	Cyrill Bussy
TASK	**PARTNER**	**NAME**
T4.1	ULEI	Irina Estrela-Lopis
T4.2	UAB	Alba Hernández Bonilla
T4.3	UNIMAN	Cyrill Bussy
T4.4	UNIMAN	Cyrill Bussy

TABLE 15. WP4 LEADER AND TASK LEADERS

WP5 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP5	IMIB	Pablo Pelegrin
TASK	**PARTNER**	**NAME**
T5.1	UAB	Alba Hernández Bonilla
T5.2	IMIB	Pablo Pelegrin
T5.3	IMIB	Pablo Pelegrin
T5.4	IMIB	Pablo Pelegrin
T5.5	IMIB	Pablo Pelegrin

Table 16. WP5 Leader and Task Leaders

WP6 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP6	UAB	Alba Hernández Bonilla
TASK	**PARTNER**	**NAME**
T6.1	UAB	Alba Hernández Bonilla
T6.2	FIOH	Julia Catalan
T6.3	INSERM	Veronique Maguer-Satta
T6.4	UAB	Alba Hernández Bonilla
T6.5	UAB	Alba Hernández Bonilla

Table 17. WP6 Leader and Task Leaders

WP7 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP7	DTU	Steffen Foss Hansen
TASK	**PARTNER**	**NAME**
T7.1	DTU	Steffen Foss Hansen
T7.2	DTU	Steffen Foss Hansen
T7.3	UAB	Alba Hernández Bonilla

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T7.4	DTU	Steffen Foss Hansen
T7.5	UAB	Alba Hernández Bonilla

Table 18. WP7 Leader and Task Leaders

WP8 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP8	UAB-PRUAB	Ona Tribó
TASK	**PARTNER**	**NAME**
T8.1	UAB PRUAB	Ona Tribó
T8.2	UAB PRUAB	Ona Tribó
T8.3	UAB	Alba Hernández Bonilla
T8.4	UAB	Alba Hernández Bonilla
T8.5	AIMPLAS	Raquel Llorens

Table 19. WP8 Leader and Task Leaders

WP9 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP9	UAB	Alba Hernández Bonilla
TASK	**PARTNER**	**NAME**
T9.1	UAB	Alba Hernández Bonilla
T9.2	UAB	Alba Hernández Bonilla
T9.3	UAB	Alba Hernández Bonilla

Table 20. WP9 Leader and Task Leaders

WP10 LEADER AND TASK LEADERS		
WORK PACKAGE	**PARTNER**	**NAME**
WP10	UAB	Alba Hernández Bonilla
TASK	**PARTNER**	**NAME**
T10.1	UAB	Alba Hernández Bonilla
T10.2	UAB	Alba Hernández Bonilla

Table 21. WP10 Leader and Task Leaders

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5. Reports

The aim of this section is to describe the different categories of reports required for the PlasticHeal project. In the first part of the section the aim of the Contractual and Internal Reports is described, while in the second part of the section the procedure for preparation and quality assurance of the reports is explained in detail.

5.1. Categories of reports

Two categories of reports exist in the PlasticHeal project: a) Contractual Reports and b) Internal Reports.

A. Contractual Reports

Contractual reports are defined in the GA. They will be delivered to the EC. Beneficiaries will contribute to the preparation of these reports under the supervision of the Coordinator and the PC.

There are 3 categories of Contractual Reports (Deliverables, Periodic Report and Final Report):

- *Deliverables (D).* All project deliverables are associated with a specific work package task. It will be the responsibility of the Work Package Leader to coordinate the drafting of the deliverable and ensure the receipt of inputs of other partners where necessary. Annex G provides an overview of all the deliverables, the lead partner and the deadlines for submission to the EC.
- *Periodic Reports (PR*), one for each of the following 'reporting periods': RP1: from month 1 to month 18; RP2: from month 19 to month 36; RP3: from month 37 to 48 month. The Annex B provides the template.

This report must include the following:

(i) an explanation of the work carried out by the beneficiaries;

(ii) an overview of the progress towards the objectives of the action, including milestones and deliverables identified in GA Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out. The report must detail the exploitation and dissemination of the results and — if required in GA Annex 1 — an updated plan for the exploitation and dissemination of the results. The report must indicate the communication activities;

(iii) a summary for publication by the H2020 PROGRAMME;

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(iv) the answers to the 'questionnaire', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

- *Final Report (FR)* In addition to the periodic report, the coordinator must submit the final report within 60 days following the end of the last reporting period (see Annex C).

The final report must include the following:

a) a 'final technical report' with a summary for publication containing:
   i an overview of the results and their exploitation and dissemination;
   ii the conclusions on the action, and
   iii the socio-economic impact of the action;

b) (b) a 'final financial report' containing:
   i an 'individual financial statement' (see GA Annex 4) from each beneficiary, for the reporting period concerned. The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see GA Annex 2).
   The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see GA Annex 2). Amounts which are not declared in the individual financial statement will not be considered by the EC.
   If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.
   The individual financial statements of the last reporting period must also detail the receipts of the action (see GA Article 5.3.3).

Each beneficiary must certify that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see GA Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see GA Article 18) that will be produced upon request (see GA Article 17) or in the context of checks, reviews, audits and investigations (see GA Article 22), and
- for the last reporting period: that all the receipts have been declared (see GA Article 5.3.3);

ii an explanation of the use of resources and the information on subcontracting (see Article 13) and in-kind contributions provided

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by third parties (see GA Articles 11 and 12) from each beneficiary, for the reporting period concerned;

iii a **'summary financial statement'**, created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the request for interim payment.

iv a '**final summary financial statement'**, created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the request for payment of the balance and

v a 'certificate on the financial statements' (drawn up in accordance with GA Annex 5) for each beneficiary, if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see GA Article 5.2 and Article 6.2).

B. Internal Reports

Internal reports are key tools that serve to monitor the development of the project in terms of activities, use of resources as well as to document other activities during the project (i.e. Internal documents). Despite the fact that various categories of Internal reports exist in the PlasticHeal project, the Management Handbook only addresses the Internal Activity Reports since the other categories of internal reports are beyond the scope of this Handbook.

There are 2 categories of Internal Reports (Internal Activity Reports and Internal Financial Report):

- *Internal Activity Reports* (IARs) include a detailed description of the work progress and achievements for every WP and the related statement on the use of resources (including the person-months expended and an explanation of personnel costs, subcontracting and any major direct costs incurred by each beneficiary for the period). During the preparation stage the IARs will be used to evaluate the development of the D. They are updated by each beneficiary 6 months previously to PR delivery. IARs dissemination status should be strictly CO. They have issued versions, but they do not need to be reviewed in a formal process. The release dates of the IARs are:
  - IAR1: month 12 (01/04/2022)
  - IAR2: month 30 (30/09/2023)
  - IAR3: month 45 (31/12/2024)

The IAR is structured in 8 sections, corresponding to each WP in the project. Within each WP section, the reporting of activities presents the following structure:

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1. Work package objective
2. Progress summary for each Task defined in the Annex 1 during the reporting period. For each Task a table is provided with:
   a) a short description of the task, b) significant results and c) deviations and corrective actions.

For more details on the IAR structure, see Annex H of this Handbook.

The relationship among Contractual Reports and Internal Reports is represented in the following figure. At the end of each period a Periodic Report is submitted. The Periodic Report includes information from both categories of reports: Deliverables submitted during the period and Internal Activity Reports. Thus, the Periodic Report reflects the progress presented in the Deliverables as well as the activities carried out internally by partner's (IAR). At the end of the project The Final report is submitted to the EC.

- *Internal Financial Report (IFR)* are key tools that serve to monitor the development of the project in terms of use of resources as well as to document other financial issues during the project. Each Beneficiary should elaborate the corresponding IFR, including a detailed description of the use of resources, the person-months expended and an explanation of personnel costs, subcontracting and any major direct costs incurred for the period. IFRs dissemination status should be strictly CO. Due to the duration of the project, 3 IFR will be necessary on M12, M30 and M45.

The IFR is structured in several categories according to the nature of the costs. For more details on the IFR structure, see GA Annex 4 Model and see Annex D.

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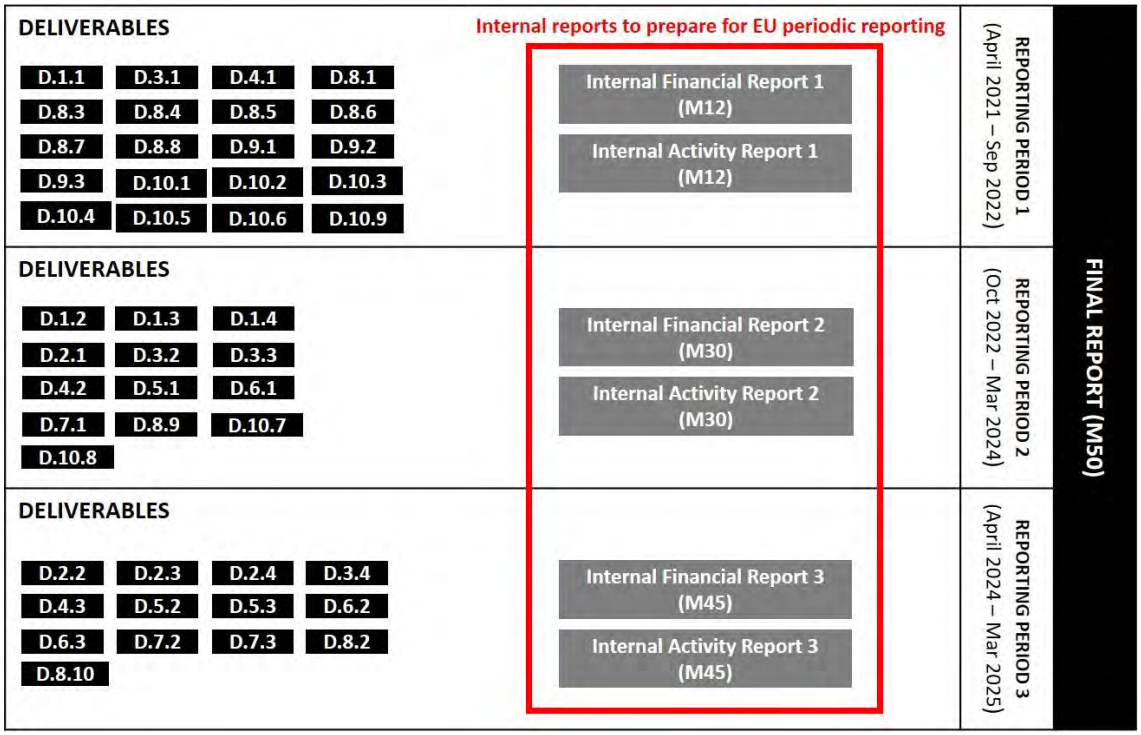

Figure 3. The relationship amongst different categories are represented in the following figure.

5.2. Preparation & Quality assurance procedures

A procedure for preparation and quality assurance of the project reports has been defined with the aim to monitor the elaboration of the reports. The procedure entails several stages that can only be considered passed when the report has been reviewed successfully. Careful planning of the required time schedule for these review iterations is an integral task for the deliverable author.

The following Table depicts the generic report maturity process and describes the 3 phases required to produce a particular report: 1. Preparation, 2. Revision, 3. Validation and Release.

Peer review will be the main mechanism for providing quality assurance. Each report will be subject to a peer review by at least one expert. Before issued to the EC, final approval of the quality of the report will be made by the PC. Finally, the report is released by the PC. The PC, the report author, and the reviewers will jointly maintain the due dates and check the contents if it meets the overall objectives and covers the scope.

Stage	Name	Description
1	**PREPARATION**	Adoption of the template, agreement on a document structure and content input.

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2	**REVISION**	Complete, structured and condensed document, prepared in first draft version by the respective editor, to be reviewed by the reviewers and the PC.
3	**VALIDATION and RELEASE**	Reviewed and updated complete document in second draft version, to be validated by the PC. Complete document in final version, to be released by the project manager and submitted to the EC.

Table 22. Stages of the generic report maturity process.

Procedure details for D, PR, FR and IFR are explained in the following sections.

5.2.1. Deliverables

This section describes the process of how the production of D is managed and controlled and when reviews shall be performed.

1. Preparation

The D author may provide a *tentative document structure*, *contents overview* and a *preliminary abstract* for co-ordination between the beneficiaries working on that document. The document structure will be mainly derived from the tasks described in the Annex 1 Description of the project but may be enhanced if necessary. The tasks will be detailed into actual activities with responsible and contributing team members. These activities will comprise all the preparatory work (literature research, reading, presentations and discussions, research team meetings) necessary to gain the insights and results required for the D. During the PREP stage, the Task Leader (TL) shall guarantee that each D accomplishes its preliminarily objectives and reaches the scope it should cover based upon the Project Work Plan and the respective A plans. If the author of the D is not the TL, the first complete draft version of the deliverable should be accepted by the TL prior to its submission to the reviewers (REV stage). If necessary, the TL will transmit the deliverable author any relevant comments and suggestions. Also, the Work Package Leader (WPL) will control the progress achieved for each of the deliverables included in their respective WP.

The template for D provides the following information on the first page (title page): Document identifier, title, version, date, author, and dissemination status. These data shall not be changed except updating it indirectly via the document properties. Template file for Deliverables can be found in Annex A.

2. Revision

The REV stage starts when the D author uploads a complete draft version for review to the OneDrive *repository* (see Annex E for a tutorial on OneDrive). Additionally, the author shall send a notification via email informing that the draft is ready for review to the PC and all other parties that may be involved.

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Access to the draft document should be provided with a link to OneDrive, instead of attaching the file in the email.

The D author informs the PC about the material to be reviewed. The reviewers for each report will be assigned by PC for each D. Other beneficiaries are welcome to provide a review as well. Each reviewer provides his review after one week. The reviews shall be content-oriented, qualitative, and not too extensive. Reviews should serve as a basis for information exchange. The author may also point out particular questions to the reviewers to actively solicit specific feedback on certain issues. The author in turn provides feedback to the reviewers (author's comments on the review). A discussion may then be needed to settle open issues (by phone, email, personal meetings).

In order to reach the VAL & REL stage, the author incorporates the 2nd round of corrections. The author should upload to OneDrive the final version of the D with the agreed changes and inform the PC for approval two weeks after the review.

3. Validation and release

The PC now checks if the deliverable meets the formal requirements regarding the file format, naming and versioning schemes. The PC will provide feedback to the author of the D regarding any deviation from the guidelines. In parallel, the Coordinator checks the deliverables and informs the PC *via* email about the acceptance (release authorization).

The PC finally prepares the release version, adopts the title page and performs the PDF conversion for final release. The Coordinator or PC then forwards the documents to the EC, thereby reaching the final REL stage.

The following figure shows the stages and timings of Deliverable preparation.

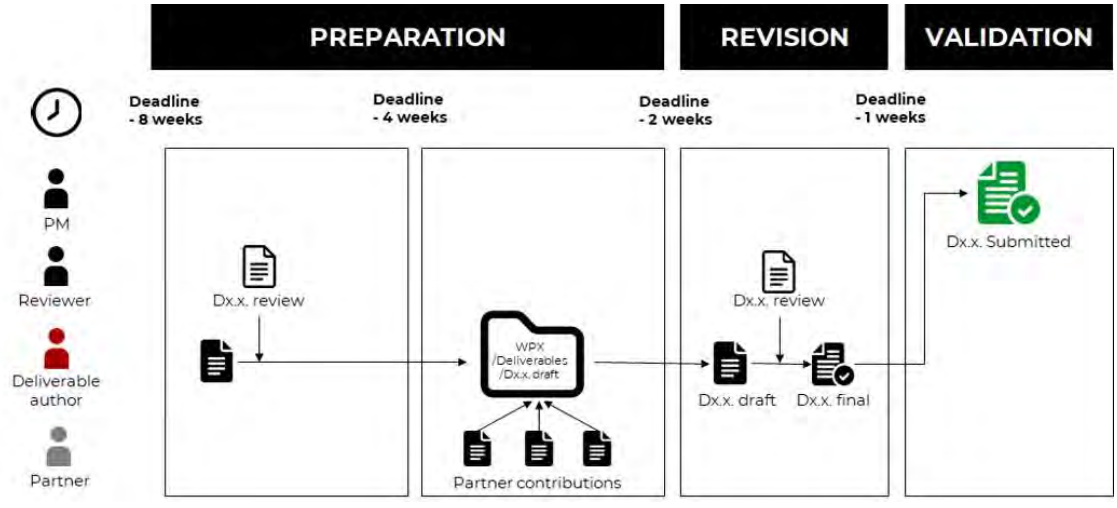

Figure 4. Preparation and Quality assurance procedure for Deliverables.

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5.2.2. Periodic Report

This section describes the process of how the production of the PR is managed and controlled and when reviews shall be performed. The periodic report shall contain the necessary information for the EC to evaluate the state of implementation of the project, the respect of the work plan, the financial situation of the project and whether the project's objectives have been achieved or are still achievable.

- Periodic reports ***must*** be submitted on M20, M38 and M50.
- A periodic report should normally contain a maximum of 15 pages, excluding deliverables. Please use font Times New Roman 11 or equivalent.
- The technical part should contain a concise statement of the tasks undertaken and a forecast for the next reporting period. Any problems encountered during the period and possible deviations from project plans must be covered.
- Progress report must be accompanied by the deliverables due in the reporting period as well as other relevant annexes (such as feasibility studies, networking reports, maps, all technical and financial documentation requested by the EC in previous letters, etc.).

1. Preparation

The required structure for PR and other comments for its preparation are provided in Annex B.

PR are responsibility of the Coordinator, with the collaboration of the corresponding TL. Each TL is in charge of creating a OneDrive folder structure to collect contributions. Since the information is structured in Task sections, the template file is the same for each Task. Each TL should create a subfolder into their T folder in OneDrive containing the template. Then the TL should inform the beneficiaries about the file via email, asking for contributions. In the figure 5, beneficiary contributions are represented by the bottom row of documents. Contributions should be done through different files uploaded to the subfolder or in specific parts of the template document, depending on the instructions given by the TL. After the deadline for contributions, the TL integrates the inputs and may ask the beneficiaries for more information if necessary.

2. Revision stage

Once the T section is reviewed by the TL, he or she should upload the file to the PR subfolder in Tx.x. Then the TL is in charge of merging all the sections from the different T in order to create the first version that will be reviewed by the PC.

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3. Validation stage

The PC now checks if the PR meets the requirements regarding the file format, naming and versioning schemes. The PC finally prepares the final version.

5.2.3. Final Report

This section describes the process of how the production of FR is managed and controlled and when reviews shall be performed.

The PC will make sure that it describes or contents (see Annex C):

- The project objectives, key deliverables and outputs.
- The background, problems and objectives (as foreseen in the proposal) and the expected longer-term results (as anticipated at the start of the project).
- The project management process, the working method, the problems encountered, the partnerships and their added value, including comments on any significant deviations from the work plan.
- Technical progress per Action, main deviations, problems and corrective actions implemented.
- Evaluation of Project Implementation and analysis of benefit.
- Project Specific Indicators.
- Comments on the financial report.

1. Preparation

FR is responsibility of the PC, with the collaboration of the corresponding TL and WPL. Each TL is in charge of creating a OneDrive folder structure to collect contributions. Since the information is structured in Task (T) sections, the template file is the same for each T. Each TL should create a subfolder into their T folder in OneDrive containing the template. Then the TL should inform the beneficiaries about the file via email, asking for contributions. In the figure 5, beneficiary contributions are represented by the bottom row of documents. Contributions should be done through different files uploaded to the subfolder or in specific parts of the template document, depending on the instructions given by the TL. After the deadline for contributions, the WPL integrates the inputs and may ask the beneficiaries for more information if necessary.

2. Revision stage

Once the T section is reviewed by the TL, he or she should upload the file to the FR subfolder in Tx.x. Then the WPL is in charge of merging all the sections from the different T in order to create the first version that will be reviewed by the WPL and PC.

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3. Validation stage

The PC now checks if the FR meets the requirements regarding the file format, naming and versioning schemes. In parallel, the Coordinator checks the FR and informs the PC via email about the acceptance. The PC finally prepares the final version.

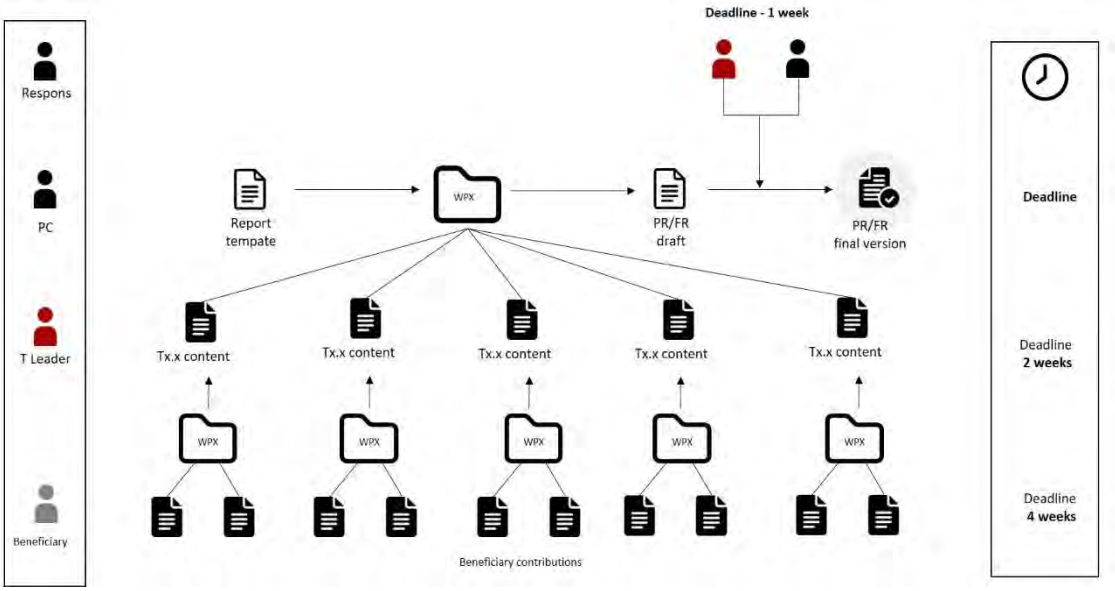

Figure 5. Preparation and Quality assurance procedure for the PR and FR.

5.2.4. Internal Activity Reports

This section describes the process of how the production of the IAR is managed and controlled and when reviews shall be performed. They shall contain the necessary information for the EC to evaluate the state of implementation of the project, the respect of the work plan, the financial situation of the project and whether the project's objectives have been achieved or are still achievable.

- Internal activity reports ***must*** be submitted on M12, M30 and M42.
- An internal activity report should normally contain a maximum of 15 pages, excluding deliverables. Please use font Times New Roman 11 or equivalent.
- The technical part should contain a concise statement of the tasks undertaken and a forecast for the next reporting period. Any problems encountered during the period and possible deviations from project plans must be covered.
- Internal activity report must be accompanied by the deliverables due in the reporting period as well as other relevant annexes (such as feasibility studies, networking reports, maps, all technical and financial documentation requested by the EC in previous letters, etc.).

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1. Preparation

The required structure for IAR and other comments for its preparation are provided in Annex H.

IAR are responsibility of the Coordinator, with the collaboration of the corresponding WPL. Each WPL is in charge of creating a OneDrive folder structure to collect contributions. Since the information is structured in WP sections, the template file is the same for each IAR. Each WPL should create a subfolder into their WP folder in OneDrive containing the template. Then the WPL should inform the partners about the file via email, asking for contributions. In the figure 6, partner contributions are represented by the bottom row of documents. Contributions should be done through different files uploaded to the subfolder or in specific parts of the template document, depending on the instructions given by the WPL. After the deadline for contributions, the WPL integrates the inputs and may ask the beneficiaries for more information if necessary.

2. Revision stage

Once the WP section is reviewed by the WPL, he or she should upload the file to the IAR subfolder in IAR.x. Then the WPL is in charge of merging all the sections from the different IAR in order to create the first version that will be reviewed by the PC.

3. Validation stage

The PC now checks if the IAR meets the requirements regarding the file format, naming and versioning schemes. The PC finally prepares the final version.

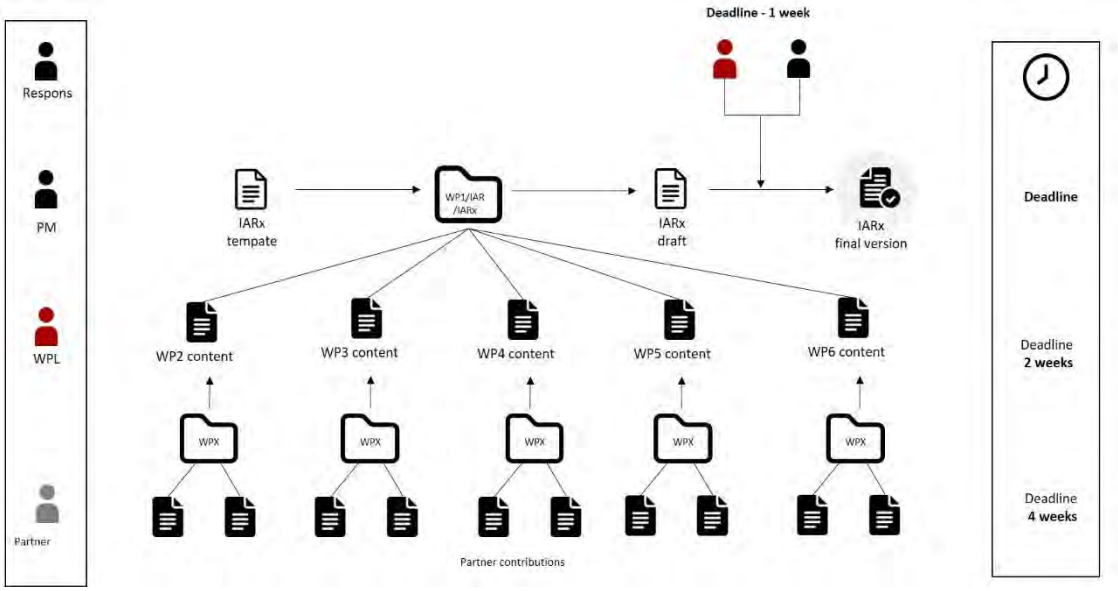

Figure 6. Preparation and Quality assurance procedure for IARs.

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5.2.5. Internal Financial Reports

This section describes the process of how the production of IFR is managed and controlled and when reviews shall be performed.

1. Preparation

Each Beneficiary will be responsible of generating the corresponding financial report according with their activities and costs generated. Each Beneficiary is in charge of creating an IFR using the template provided in Annex D. Once the IFR is filled, the Beneficiary sends the document to the Coordinator.

2. Revision

The Beneficiary's IFR is reviewed by the Coordinator to check out that all corresponding fields have been filled properly.

3. Validation

Once the IFR from the beneficiary is validated by the Coordinator, IFR will be saved.

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6. Document naming conventions

Documents will be named following the structure [Type#]-[org] _[ShortTitle].[extension], where:

- [Type] represents the type of document (deliverable, periodic report, internal activity report, internal financial report or review)
- # is the reference or order number
- [org] is the organization in charge of the task
- [ShortTitle] is a short descriptive title
- [extension] is the file extension.

The date may also be added with the format [YYYY]-[MM] as well as the revision number with the format revXXX.

File formats should be MS Office (.docx, .pptx) for draft versions and .pdf for final versions.

The table below provides example of these naming conventions for the different file's type.

Document Type, Template	Naming Convention	DocID example	File name example
Deliverables, [D]	[D#]-[org] _[ShortTitle].[extension]	D8.2-UAB	D8.2-UAB_Quality-Plan.doc
Periodic Report, [PR]	[PR#]-[org]-[YYYY][MM].[extension]	PR1-UAB-2021-20	PR1-UAB-2021-20.doc
Internal Activity Report, [IAR]	[IAR#]-[org]-[YYYY]-[MM].[extension]	IAR-UAB-2019-12	IAR-UAB-2019-12.doc
Internal Financial Report, [ICR]	[IFR#]-[org]-[YYYY]-[MM].[extension]	IFR-UAB-2019-12	IFR-UAB-2019-12.doc
Review, [RV]	RV-[org]_[DocID]rev[Rev#].[extension]	RV-SYN_ID7-UAB-01rev100	RV-SYN_ID7-UAB-01rev100.doc

Table 23. Summary of document types and their naming conventions for the PlasticHeal project.

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7. Meetings

Efficient means of communication, fixed project physical meetings and virtual meetings will be organized to guarantee a constant control, monitoring and coordination among the beneficiaries and towards the project governance body. To guarantee a constant control in physical meetings, each participant will have to sign the meeting agenda (using the template provided in Annex I). Control of the virtual meetings will be also ensured through the appropriated means.

7.1. Categories of meetings

There are different meeting categories depending on their nature and objectives. The organizer responsible for each category of meeting, attendants, format and frequency are detailed in the following table.

Meeting category	Organizer	Attendants	Format	Frequency
Consortium meetings	UAB	Beneficiary representative	Physical	Annual
Review meetings	UAB	EC officer & external evaluators	Physical	M20, M38, M50
Steering Committee meetings	UAB	Beneficiary representative	Physical	Annual
Executive Board	UAB	WP leaders	Virtual	Monthly (2nd Thursday of the month)
WP Follow-up meetings	WPL	WP leader + WP members	Physical	Annual
			Virtual	Monthly or bimonthly

Table 24. Meeting categories.

7.2. Procedures

In this section the stablished procedure for carrying out Presential and Virtual meetings is explained. See below Figure 7 representing the procedures for Presential and Virtual meetings.

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1. Notice

Date and location for the Presential meeting should be agreed in advance with attendants via Doodle polls. Once a date is defined the organizer should notice the meeting attendants *via* email. Each meeting category has a specific periodicity defined in the Annex 1.

2. Preparation

Meeting Agendas are created collaboratively within WP members. Beneficiaries contribute to the agendas in order to report the status of work and issues to be discussed.

3. Execution

During the meeting, two types of documents may be used: Presentations and working documents. Presentations not only serve as meeting documentation but are an important building block for dissemination (e.g. slides from conference presentations, conference posters…). The template for presentations including the main information about the project and the consortium should be used in meetings. The Presentations template can be found in Annex F.

4. Post-processing

The meeting organizer is the responsible for the creation of the meeting minutes. They are used to disseminate minutes from project meetings and they contain the agenda, a summary of the topics covered during the meeting and, most importantly, the actions agreed by the members. The meeting organizer is also in charge of uploading the document to OneDrive and share the link among beneficiaries for a final review. Also, the .doc file will be uploaded by the organizer and stored in OneDrive.

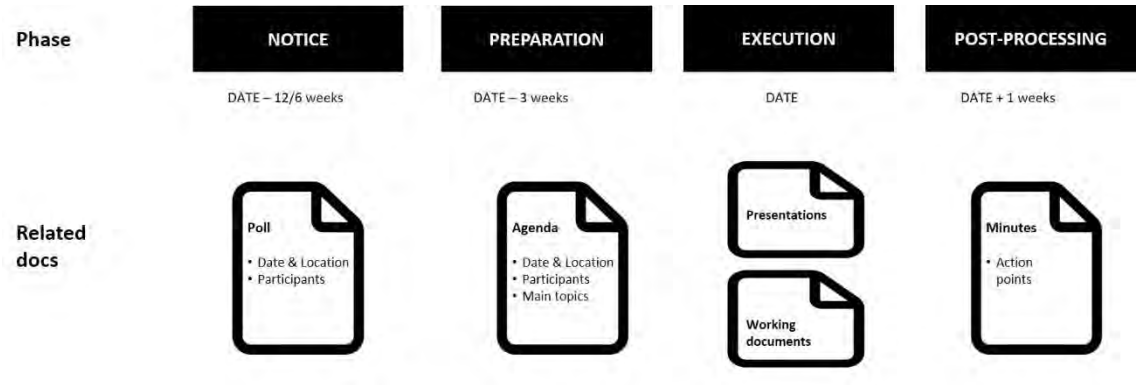

Figure 7. Meeting procedure.

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8. Risk Management

Risk management is a project management tool to assess and mitigate events that might adversely impact the project, in order to increase the likelihood of success. This section presents the process for implementing proactive risk management. Risk management deploys methods for identifying, analysing, prioritizing, and tracking risk drivers.

The purpose of the described procedures for risk management process pursues to find, quantify and handle risks that could jeopardize the work programme of the project. In order to support the achievement of the project's overall objectives, the purpose of quality assurance process is to ensure the quality and timely delivery of the project's various components.

8.1. Definitions

Risk is a measure of the inability to achieve overall project objectives within defined cost, schedule, and technical (performance and quality) constraints and has two components:

- Probability of failing to achieve a particular outcome
- Consequences of failing to achieve that outcome

For processes, risk is a measure of the difference between actual performance of a process and the known best practice for performing that process.

Risk Event

Risk events are those events that, if they go wrong, could result in problems in the development of the expected research results, production and assessment of the prototypes, and dissemination of the results. Risk events should be defined to a level such that the risk and causes are understandable and can be accurately assessed in terms of likelihood/probability and consequence to establish the level of risk.

Type of Risk

A Technical Risk is the risk associated with the evolution of the research results and the prototype development affecting the level of performance necessary to meet the requirements of the GA Annex 1.

A Cost Risk is associated with the ability of the project to achieve its cost objectives as determined in the GA Annex 1.

- Risk that the cost estimates and objectives are not accurate and reasonable
- Project execution will not meet the cost objectives as a result of a failure to mitigate technical risks

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Schedule Risks are those associated with the adequacy of the time estimated and allocated for the development, production, and fielding of the system. Two risk areas bearing on schedule risk are:

- Schedule estimates and objectives are not realistic and reasonable
- Program execution will fall short of the schedule objectives as a result of failure to mitigate technical risks

Risk Ratings

This is the value that is given to a risk event (or the overall project) based on the analysis of the likelihood/probability and consequences of the event. Risk ratings of *Low*, *Moderate*, or *High* shall be assigned based on the following criteria:

- Low Risk: Has little or no potential for increase in cost, disruption of schedule, or degradation of performance. Actions within the scope of the planned project and normal management attention should result in controlling acceptable risk.
- Moderate Risk: May cause some increase in cost, disruption of schedule, or degradation of performance and/or quality. Special action and management attention may be required to control acceptable risk.
- High Risk: Likely to cause significant increase in cost, disruption of schedule, or degradation of performance and/or quality. Significant additional action and high priority management attention will be required to control acceptable risk. This type of risk may be subject to a report to EC.

8.2. Risk Management and Responsibilities

Each beneficiary has the responsibility to report immediately to their respective TL and the PC any risk situations that may conflict with the project objectives or their successful completion. Changes in time schedule of deliverables or in the allocated budget must be reported to the corresponding Task Leader and to the Project Coordinator. In case of problems or delays, the Management Board will be consulted and it can install task forces to implement the necessary corrective actions. It will establish risk mitigation plans to reduce the impact of the risk occurring.

Conflicts will be solved at the lowest level possible, and preferably amicably. If an agreement cannot be reached at a Task or WP level, then the Project Coordinator will mediate. If that is not satisfactory, then the Management Board (MB) will take a decision, and if necessary the MB will ask for the authorization of the EC. In the Consortium Agreement (CA), signed by all the beneficiaries before the start of the project, are formalized the rights, obligations, relationships and procedures within the Consortium, as well as any

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other relevant issue. The procedures concerning the settlement of unsolved disputes are described in the article 11.8 of the CA.

8.3. Risk Management Process

Figure 8 shows, in general terms, the overall risk management process that will be followed. Each of the risk management functions shown in Figure 8 is discussed in the following paragraphs, along with specific procedures for executing them.

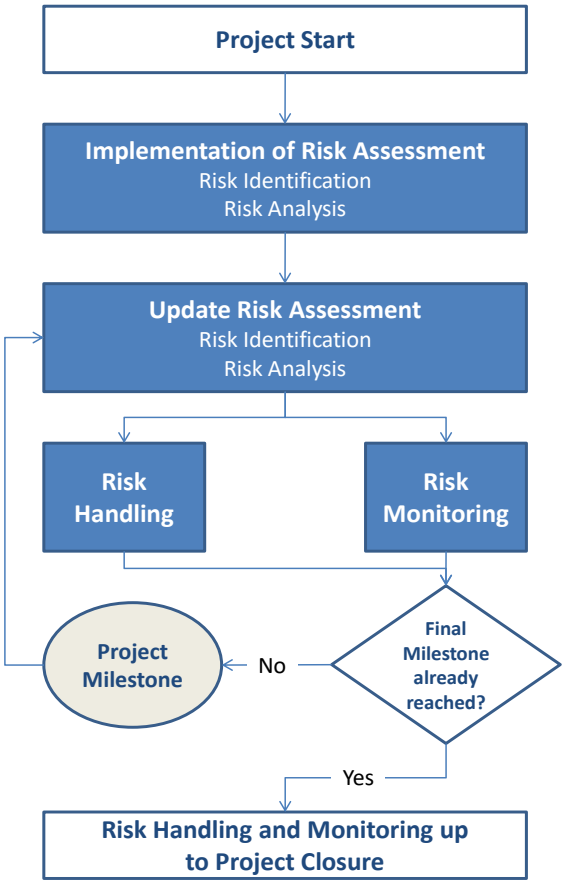

Figure 8. Risk Management Process

8.4. Risk Assessment

Risk assessment includes the identification of critical risk events/processes, which could have an adverse impact on the project, and the analysis of these events/processes to determine the likelihood of occurrence/process variance

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and consequences. Risk assessment is an iterative process. Each risk assessment is a combination of risks identified/analysed in the previous phase and the identification/analysis of risks on current milestones according to the GA Annex 1.

8.4.1. Risk Identification

Risk identification is the first step in the assessment process. The basic process involves searching through the entire project plan to determine those critical events that would prevent the project from achieving its objectives. Risks will be identified by all individuals in the project, particularly by the Task Leaders.

The basic procedure of identifying risks consists of the following steps:

1. Understand the requirements and the overall project quality and performance goals. Examine the operational (functional and environmental) conditions under which the values must be achieved by referring or relating to the GA Annex 1.
2. Identify the processes and activities (tasks) that are needed to produce the results.
3. Evaluate each activity/task against sources/areas of risk.

8.4.2. Risk Indicators

Following indicators are helpful for identifying risks (non-exhaustive list):

- Lack of stability, clarity, or understanding of requirements: Requirements drive the research and the design of the prototypes. Changing or poorly stated requirements guarantees the introduction of performance, cost, and schedule problems.
- Insufficient or inadequate resources: People, funds, schedule, and tools are necessary ingredients for successfully implementing a process. If any are inadequate, to include the qualifications of the people, there is risk.
- Communication is a critical success factor for PlasticHeal. Failure to provide (push) available information actively as well as to demand (pull) required information actively will both introduce considerable risk.

8.4.3. Risk Handling

After the project's risks have been identified and assessed, the approach to handle each significant risk must be developed. There are essentially four techniques or options for handling risks:

- Avoidance (application of tasks in order to avoid the risk event)
- Control (watch the environmental conditions for influences to an already assessed risk)

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- Transfer (application of tasks to set a risk to a lower level)
- Acceptance (the consequences of the risk event are accepted)

Results of the evaluation process and how to handle shall include:

- What must be done
- Level of effort required and estimated costs
- Proposed schedule showing the proposed start date
- Time phasing of significant risk reduction activities, including completion date
- Their relationship to significant Project activities/milestones
- The person responsible for implementing and tracking risk handling measurements (usually the responsible Task Leader)

8.4.4. Risk Monitoring

Risk monitoring systematically tracks and evaluates the performance of risk-handling actions. It is part of the Project Manager's and the Task Leaders' function and responsibility and will not become a separate discipline. Essentially, it compares predicted results of planned actions with the results actually achieved to determine the status and the need for any change in risk-handling actions.

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8.5. Potential Risks and Contingency Plans

Several potential risks of the PlasticHeal project have been identified and evaluated before the start of the project. A detailed description is provided in the Annex 1, Part B. The proposed contingency plans are summarized in Table 20.

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
1	In vitro long-term models of transformation for a given organ prove non-useful to unravel MNPLs-induced carcinogenesis	WP6	Use of a battery of stablished models for particulate NMs developed by CRCL and UAB partners covering a wide range of potential MNPLs target organs will be included. The establishment of other models highly prone to transformation / genetically compromised have been already considered as alternatives
2	Long-term cell culture reproducibility may be challenged if no common robust and homogeneous protocol is followed	WP6	An implemented protocol developed at UAB for nanomaterials will be adapted/optimized for MNPLs. The consortium will work with this MNPLs long-term protocol in all cases. Workshops and constant communication will be carried out to ensure full know-how transfer, mainly between UAB and CRCL.
3	Difficulty to detect unlabelled MNPLs in biological matrices, especially tissue samples	WP4	Metal and fluorescent tagged MNPLs will be used in parallel to unlabelled MNPLs to mitigate this risk.
4	Impossibility to include in the biomonitoring study a human population exposed to MNPLs at known high levels to aid in the	WP2	CDK patients undergoing haemodialysis will be included in the study as the 'positive control' population group, since their blood come in direct contact with plastic haemodialysis filters

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Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
	development of analytical methodologies		several days per week. This population group will serve to optimize the methods to identify MNPLs exposure and effects
5	Low relevance of generated data, DNELs and HRA for regulatory bodies.	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	PLASTICHEAL will follow ECHA guidance on information requirements and chemical safety assessment, and specifically on DNELs and HRA, occupational and consumer exposure assessment, and REACH. WHO guidance on immunotoxicity risk assessment for chemical will also observed. Moreover, there will be a continuous direct interaction with regulators (with JRC support).
6	Critical inputs expected from the WPs into PLASTICHEAL HRA framework are delayed	WP7	WP leaders will have ad hoc meetings to unblock information flows and a SC meeting will reduce communication risks
7	MNPLs quantity in urine, blood or faeces samples of human populations exposed by inhalation may be too low to be detected	WP2	EBCs and/or sputum samples will be collected from these populations, as these samples are expected to contain the highest inhaled MNPLs levels. Alternatively, released chemicals (e.g. phthalates) could be used as indirect MNPLs exposure biomarkers.

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Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
8	The number of volunteers per exposed group is too low to allow making conclusions	WP2	Experience acquired from the HBM4EU project on the required minimal group sizes, optimized study design and procedures to maximize enrolment of volunteers in the studies will ensure the appropriate performance of the biomonitoring studies. Also, several companies have already supported PLASTICHEAL and express their wiliness to be PLASTICHEAL liaison with workers. The partner AIMPLAS is in close contact with industry and will find alternatives if needed. Alternatively, consumer organizations, worker unions NGOs, public administrations, or workers' associations can be explored to be the PLASTICHEAL liaison with the occupationally exposed population.
9	Background levels of airborne contaminants are too high compared to MNPLs' levels to identify the carrier function of the latter.	WP2	Alternative studies using Drosophila models (WP4) and ALI-based in vitro experiments (WP5) have already been considered.
10	Weak or absent immune activation by MNPLs incubation alone.	WP5	Use of MNPLs together with cytokines, bacterial ligands or bacterial infection Study of immune cells from human patients with chronic inflammatory processes that will have an altered basal immune signalling, allowing to determine the effect of MNPLs on the modulation of established immune responses. Study of inflammasome activation as a sub-clinic inflammatory response and will focus on non- primed markers of inflammation (as the release of HMGB1 or mitochondrial DNA)

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Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
11	Global coronavirus sanitary crisis affects the development of the project	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Remote meetings will be organized, and tasks related to in-silico work will be prioritized in case of confinement.
12	Difficulty to detect unlabelled MNPLs in environmental samples	WP1	External exposure will be determined for occupational environments among others where high concentrations are expected. A battery of sample preparation techniques also for enrichment is available.
13	Difficulty to detect unlabelled MNPLs in human samples like blood, urine	WP1	Various particle analysis techniques with high sensitivity will be available to detect MNPLs. In addition, proxy parameters including dissolved compounds for internal particle exposure will be identified making direct particle analysis unnecessary
14	No toxicity of MNPLs is detected using the available in vitro assays	WP3	A broad panel of assays is available in the consortium. If no effects are detected this is important input to the human risk assessment.
15	No changes in the MNPL characteristics following digestion in	WP3	Assessment of the protein corona on MNPL is not frequently studied. The proteomics facilities as WUR are state-of - the art. Yet, this parameter is not included in the risk assessment, so if

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Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
	the gastrointestinal tract can be detected using LC-MS/MS		not detected it will not affect the way a risk assessment will be performed
16	Dosimetry is a critical issue for the in vitro studies, especially in working with low density MNPLs	WP3, WP4, WP5, WP6	If this is a problem reversed incubation (cells on top), dynamic flow models or others will be explored as done previously in the literature
17	In vitro or in vivo translocation data of MNPLs following oral and inhalation is not available (or too low to be detected)	WP3	Use of literature data on external exposure and in vitro and in vivo studies on MNPLs or metal nanoparticles will be used
18	No PKB model for partico kinetics can be developed	WP3	Several suggestions for particle specific PBK models are currently being explored, for instance in the H2020 BIORIMA and NanoInformaTIX projects.
19	Critical inputs expected from the WPs into PLASTICHEAL HRA framework are delayed	WP7	WP leaders will have ad hoc meetings to unblock information flows and a SC meeting will reduce communication risks. Should challenges arise (e.g. delay of critical input from the project), we will use data and information generated outside the project to the extent possible.

Table 20. Global risks and corresponding contingency plans for the PlasticHeal project.

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9. Management tools

To address different needs regarding project development, such as document storage, coordination, collaborative work, communication, progress control, etc.

The table shows the different tools defined to be used for different purposes.

Name	Aim
OneDrive	File hosting service
Microsoft Teams	Meeting and work environment
Doodle®	Event scheduling, Polls

Table 21. Management tools in PlasticHeal project

OneDrive

OneDrive has been selected as the platform for daily collaborative work on documents. Specific Action folders and subfolders have been created, among which those for dissemination matters. The platform is supported by UAB at

Microsoft Teams

The virtual meetings of the project are carried out through videoconferences. They will be held through Teams. Furthermore, we have created the PlasticHeal Team with different channels for each work package that will allow direct communication among the people involved as well as the possibility to share multiple applications for collaborative work.

Doodle

Meeting scheduling will be voted using Doodle. The meeting organizer will share the doodle link by email with the attendants. Also, beneficiary's availability for specific periods (for example, summer holidays) can be informed through Doodle.

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List of annexes

Annex A: Template Deliverables

Annex B: Template Periodic Report (Part B)

Annex C: Template Final Report Technical

Annex D: Template Internal Financial Report (Excel)

Annex E: OneDrive tutorial

Annex F: Template Presentations

Annex G: Work Plan (Excel)

Annex H: Template Internal Activity Report

Annex I: Agenda

Annex J: Teams tutorial

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