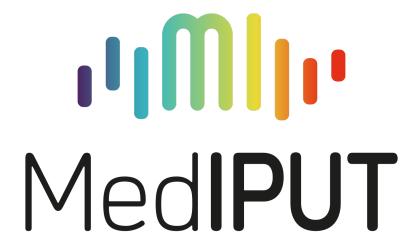
Project title: Medical Integrated Photonic Ultrasound Transducer

Project acronym: MED-IPUT

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## **D1.1: Project Management Handbook**

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# **Executive summary**

This deliverable describes the operational procedures, project governance and decision making for the MED-IPUT project.

## **Abbreviations**

DoA	Description of the action	WPL	Work Package Leader
EAB	External Advisory Board	MB	Management Board
EC	European Commission	СО	Coordinator
CA	Consortium Agreement		
IPR	Intellectual Property Rights		
GA	General Assembly		



## Disclaimer

The opinions stated in this report reflect the opinions of the author(s) and not the opinion of the European Commission.

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#### 1. Introduction

The project operational handbook summarises the decision-making and management procedures for the MED-IPUT project. These procedures are laid out in more detail in the Grant Agreement, Description of Action (DoA) and the Consortium Agreement (CA).

## 2. Project governance and decision-making

Project management procedures and responsibilities must be clearly defined to ensure high quality project output and the timely delivery of work. This section describes the MED-IPUT project's management procedures and shall serve as manual and guideline for all parties.

The project governance is based on rules and regulations described in Annex 1 of the Grant Agreement and in the CA. It is divided into three domains: decision-making, operational execution, and advice.

Decision-making, implemented through the General Assembly (GA) includes handling contractual issues regarding the Consortium Agreement, changes to the project work plan, budget and resource distribution policy, quality assurance policy, development of progress monitoring procedures, consortium structure, IPR policy and confidentiality issues.

Operational execution, implemented through the Management Board (MB) and the Coordinator Team, includes implementing decisions regarding execution of the work, following up on work done, providing logistics for all coordination tasks, coordinating, and supporting reporting, as well as financial and administrative management.

Advice, implemented through the External Advisory Board (EAB), will support all facets of the project, including technical, ethical and legal related aspects as well as exploitation and regulatory issues. The EAB assesses the performed work through dedicated meetings and reporting.

#### 2.1 Consortium

The project partners are listed in Table 1.

Table 1. MED-IPUT project partners

No.	Institution	Acronym	Country
1	Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek TNO	TNO	NL
2	Teknologian Tutkimuskeskus VTT OY	VTT	FI
3	Vermon SA	VERMON	FR
4	EIBIR gemeinnützige GMBH zur Förderung der Erforschung der biomedizinischen Bildgebung	EIBIR	AT
5	LIGENTEC SA	LGT	CH



### 2.2 Management structure

The management structure and interactions between the different project bodies are detailed in the following sections.

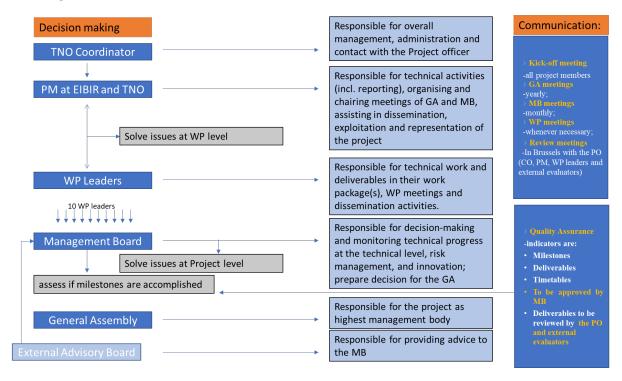


Figure 1. Governance structure

#### 2.2.1 General Assembly

The General Assembly is the decision-making body of the consortium and consists of one representative of each project partner (Table 2). It is chaired by the Coordinator (CO).

Table 2. Members of the MED-IPUT General Assembly.

No.	Acronym	Name of GA representative	
1	TNO	Rob Jansen, Suhendan A. Van Zoelen	
2	VTT	Paivi Heimala, Yisbel Marin	
3	VERMON	Bogdan Rosinski, Dominique Gross	
4	EIBIR	Peter Gordebeke	
5	LGT	Anton Stroganov, Andreas Frigg	

The members of the GA are required to be duly authorised to deliberate, negotiate and decide on all matters which fall under the responsibility of the GA as laid out in the CA.

The GA will discuss and decide on major modifications of the consortium membership (e.g., entry of new partners, withdrawal of partners), work plan, project's budget, unresolved management issues and intellectual property rights (Table 3). Furthermore, the GA will also decide on requests for amendments to the Grant Agreement after prior consultation and agreement has been granted by the European Commission.

The decisions are taken by majority vote – two-thirds (2/3) of the votes casted. Each partner has one vote. For deliberation and voting a quorum of two-thirds (2/3) must be met; if this condition is not met, another ordinary meeting shall be convened within 15 calendar days.



The GA will be convened on a regular basis annually by its chair, the CO. In addition, extraordinary meetings can also be convened at any time upon written request of any project partner. Each project partner should be represented at the meeting by its designated representative (Table 2) or by their proxy if the former is not available.

Table 3. Decisions to be taken by the General Assembly (GA) (Article 6 of the CA).

Content,	Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed
finances, and	by the Granting Authority
intellectual	Changes to the Consortium Plan
property rights	Modifications or withdrawal of Background in Attachment 1 (Background
	Included)
	Additions to Attachment 3 (List of Third Parties for simplified transfer according
	to Section 8.3.2)
Evolution of the	Entry of a new Party to the Project and approval of the settlement on the
consortium	conditions of the accession of such a new Party
	Withdrawal of a Party from the Project and the approval of the settlement on
	the conditions of the withdrawal
	Proposal to the Granting Authority for a change of the Coordinator
	Proposal to the Granting Authority for suspension of all or part of the Project
	Proposal to the Granting Authority for termination of the Project and the
	Consortium Agreement
Breach,	Identification of a breach by a Party of its obligations under this Consortium
defaulting party	Agreement or the Grant Agreement
status and	Declaration of a Party to be a Defaulting Party
litigation	Remedies to be performed by a Defaulting Party
	Termination of a Defaulting Party's participation in the consortium and
	measures relating thereto
	Steps to be taken for litigation purposes and the coverage of litigation costs in
	case of joint claims of the parties of the consortium against a Party (Section
	7.1.4)
la the sees of shell	ished tooks as a result of a desision of the Conoral Assembly, Manchen shall

In the case of abolished tasks as a result of a decision of the General Assembly, Members shall rearrange the tasks of the project partners concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

## 2.2.2 Management board

The Management Board (MB) is the operational body and comprises the CO (chair), all Work Package leaders (WPLs) (Table 4).

The MB is the interface between work packages and the GA and will be responsible for monitoring the technical progress of the project, quality assurance, and the ad-hoc coordination of scientific and technological activities.



Table 4. Members of the MED-IPUT Management Board.

Role	Main representative	Partner
Coordinator	Rob Jansen	TNO
Project Manager	Suhendan A. van Zoelen, Peter Gordebeke	TNO, EIBIR
WP1	Rob Jansen, Suhendan A. van Zoelen, Peter Gordebeke	TNO, TNO, EIBIR
WP2	Maurits v. d. Heiden, Peter Harmsma	TNO
WP3	Yisbel Marin	VTT
WP4	Andreas Frigg	LGT
WP5	Paul van Neer	TNO
WP6	Dominique Gross	VERMON
WP7	Peter Gordebeke	EIBIR

The MB will meet monthly by teleconference to ensure close monitoring of progress and quality assurance.

### 2.2.3 External Advisory board

An External Advisory Board (EAB) will be set up in the early stages of the project to advise the consortium on ethical and related legal issues as well as on exploitation and regulatory matters.

The EAB consists of:

EAB Members		
Name	Function	Institute/remarks
Nico de Jong (tbc)	US expert / PIC expert	
Mathias Fink / Srirang Manohar (tbc)	US expert / PA experts	
Antonio Pifferi or Paola Taroni (tbc)	Optical	Polytechnic University of Milan
TBC	Medical expert: US	US: focus on 3.5 MHz - abdominal imaging -> radiology / gynecology

### 2.2.4 Project Coordinator

The CO (TNO) acts as intermediary between the Parties and the Granting Authority, the European Commission (EC). It is the main point of contact for the EC and responsible for the overall scientific, technical and financial management (including payments to partners) of the MED-IPUT project.

The CO is also tasked with the technical review of deliverables and milestones and financial reporting. The Coordinator is supported by EIBIR, forming together the Coordination Team. The Coordination Team acts as the point of contact for consortium members for administrative, non-scientific matters, and is responsible for the day-to-day management of the Project including collecting deliverables, milestones and facilitating the review process.

The specific tasks for which the Coordination Team is responsible are:



- monitors compliance of project partners with their obligations under the Consortium Agreement and the Grant Agreement;
- keeps the address list of project partners and other contact persons updated and available;
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Granting Authority;
- preparing the meetings, proposing decisions and preparing the agenda of General Assembly meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings;
- transmitting promptly documents and information connected with the Project to any other Party concerned;
- administering the financial contribution of the Granting Authority to the Beneficiaries and fulfilling the financial tasks described in Section 7.2 of the CA;
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims;
- providing a copy of the Grant Agreement and its Annexes to the Associated Partner.

## 2.3 Preparation and organisation of meetings

The General Assembly meetings

#### Organisation and notification of meetings

The General Assembly shall meet at least once every year in ordinary meetings, and at any time in extraordinary meetings at any time upon written request of any project partner. The meetings may also be held by tele- or videoconference or other telecommunication means.

The chairperson will give written notice of a meeting to each member of the GA as soon as possible and no later than 30 calendar days preceding an ordinary meeting and 14 calendar days preceding an extraordinary meeting.

#### Agenda of the meeting

The agenda of the meeting shall be prepared and sent to each member by the chairperson no later than 14 calendar days preceding the meeting, or 7 calendar days before an extraordinary meeting. Any agenda item requiring a decision by must be identified as such on the agenda.

Any member may add an item to the original agenda by written notice to all of the other Members no later than 5 calendar days preceding the meeting and 2 days preceding an extraordinary meeting. During the meeting of the General Assembly its members present (or represented by a proxy) can unanimously agree to add a new item to the original agenda.

### Quorum and voting rules

The General Assembly shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum). If the quorum is not reached, the chairperson of the General Assembly shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of members is present or represented.



Each member present or represented (by a proxy) in the meeting shall have one vote. In case a project partner has been declared a Defaulting Party (as per CA paragraph 4.3) they are no longer allowed to vote.

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast. The decisions will only be binding after the CO sends a notification to all Members. The CO will keep records of the votes and make them available to the Parties on request.

#### Minutes of the meeting

The CO shall produce minutes of each General Assembly meeting and represent the formal record of all decisions taken. He/she shall send draft minutes to all members within 30 calendar days of the meeting. The minutes shall be considered as accepted if, within 15 calendar days from receipt, no project partner has sent an objection, by written notice, to the Coordination Team with respect to the accuracy of the draft minutes. The CO shall send the accepted minutes to all the Members and shall retain copies of them.

#### Other meetings

Additional meetings for specific issues, tasks or WPs will be organised as required. Whenever possible, meetings will be held via tele- or videoconference or other telecommunication means.

#### 2.4 Internal communication

The project internal communication aims at keeping the partners regularly informed about the project status, work planning and all other issues that are important in order to obtain appropriate transparency and to increase synergy of cooperation.

WPLs will be responsible for the WP internal communication and maintain the communication with the Coordination Team. The Coordination Team will be the key address of the internal communication between WPs. Relevant information related to any issues will be communicated to the Coordination Team, who will be responsible for distributing this information to all partners involved and for the GA, where relevant.



**Figure 2. Internal Communication structure** 

All partners will actively and timely inform the CO on changes of their contact details, contact persons or changes in any other information needed for executing the project. The CO will update the data on regular basis and will make this information available for all partners.

#### 2.4.1 Sharepoint: document repository and collaboration platform

TNO provides access to a Microsoft Sharepoint environment for acting as a document repository and collaboration platform.

Every project member will be able to read and up-/download documents.



## 3. Quality assurance

#### 3.1 Quality assurance

The CO leads the quality management procedures. Assuring the quality of the project is a joint responsibility of all partners. As part of the quality procedures, the CO is tasked with:

- documenting and assessing the project's progress and evaluating the contribution of the ongoing results to the project's overall objectives
- monitoring budget use
- identifying any deviations from DoA (content and timeline) at an early stage
- initiating appropriate actions as soon as possible should deviations occur.

Key elements in following the project's progress and quality are the qualitative and quantitative assessment of milestones and deliverables. Deliverables and milestone reports are submitted for an internal review to the Coordination Team for approval and agreement to ensure their quality throughout the project.

Project partners should make any quality assurance issues known to their WPLs. If the issues cannot be solved within the WP, WPLs will bring it to the Coordination Team, who will develop a mitigation strategy and, if necessary, propose it for decision by the GA.

Quality assurance issues will be discussed within the monthly meetings and telephone conferences.

#### 3.2 Deliverables and milestones

Deliverables and milestones have to be prepared and submitted according to the time schedule listed in the DoA.

Templates for deliverables and milestones are provided by the Coordination Team on Sharepoint.

Depending on their nature (e.g., public), Deliverables and Milestone reports will also be made public on the project's webpage, once approved by the EC.

Parties responsible for deliverables, as indicated in Grant Agreement Annex 1, are required to submit a draft of the respective deliverable in an editable text document (e.g. .docx) to the CO three weeks prior to submission in order to allow sufficient time for review. The Coordination Team will send regular reminders to the responsible partners as regards the preparation and punctual submission of deliverables.

Most deliverables are written reports. Deliverables that are of type other than written reports, such as deliverable type "others", should also be accompanied by a short report, so that the EC has a record of their existence.

For all deliverables submitted for review, comments and edits by the reviewer should be made without delay, preferably leaving the author(s) around five to seven working days to update the deliverable accordingly if necessary, and to provide the final version to the CO, who will then submit it to the EC.

Parties responsible for milestones, as indicated in Grant Agreement Annex I, are required to submit a written proof of achievement of the milestone to the Coordination Teamin the specified delivery month and no longer than 10 days from the achievement of the milestone.

Usually, a milestone is used as a project checkpoint to validate how a project is progressing and revalidate the work. A milestone is the end of a stage that marks the completion of a WP or phase. There is no direct task associated with it (although preparing a milestone can involve significant work).



Shifting or delay of deliverables or milestones is possible but should be avoided. Such deviations need to be justified to the EC (e.g., necessary meeting took place at a later date, new developments, delays due to COVID-19, etc.). A detailed explanation and plan as to how the deliverable or milestone will be fulfilled in the near future has to be provided then approved by the EC.

## 4. Project reporting

Reporting to the EC is a contractual obligation for all project partners as described in the Grant Agreement at Article 21.

All financial reporting is completed electronically, therefore partners should confirm with their Legal Entity Appointed Representatives (LEARs) that the rights to sign electronically have been appropriately assigned (i.e., to the appropriate financial signatory or FSIGN) to ensure there are no delays in the reporting and payment process.

The Reporting contains two parts (Grant Agreement Article 21):

- 1. Continuous reporting
- 2. Periodic reporting: technical reports and financial statements

## 4.1 Continuous reporting

The project partners must continuously report on the progress of the action (e.g., deliverables, milestones, outputs/outcomes, critical risks, indicators, etc; if any), in the Portal Continuous Reporting tool and in accordance with the timing and conditions it sets out (as agreed with the EC). The status of continuous reporting will be submitted to the EC with every periodic report.

### 4.2 Periodic reporting: technical reports and financial statements

The progress and fulfilment of tasks according to the Description of Action will be evaluated by the European Commission over 3 reporting periods (Table 9), and every periodic report needs to be submitted within 60 days after the end of each reporting period.

**Table 5. Periodic reports** 

Period 1 (M1-M15)	Period 2 (M16-M30)	Period 3 (M31-M42)
1 January 2023 - 31 March	1 April 2024 – 30 September	1 October 2025 – 30 June 2026
2024	2025	

Templates for the periodic report and detailed instructions for the reporting will be provided by the Coordination Team well in advance and will also be uploaded on Teamwork.

Both **periodic reports** must include the following:

- a) a 'periodic technical report' containing an overview of the action implementation. It must be prepared using the template available in the Portal Periodic Reporting tool.
- b) a 'periodic financial report' containing:
  - i) a 'financial statement' (see Grant Agreement Annex 4) from each partner for the reporting period concerned. The financial statement must detail the eligible costs and contributions for each budget category and, for the final payment, also the revenues for the action (see Articles 6 and 22 of CA). The partners must declare all eligible costs, even if they exceed the amounts indicated in the estimated budget (see Grant Agreement Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account.
    - Each partner certifies that:



- (1) the information provided is full, reliable and true.
- (2) the costs declared are eligible.
- (3) the costs and contributions can be substantiated by adequate records and supporting documents (Grant Agreement Article 20) that will be produced upon request (Grant Agreement Article 19) or in the context of checks, reviews, audits, and investigations (Grant Agreement Article 25)
- ii) an explanation of the use of resources (or detailed cost reporting table, if required).

The final report must be submitted within 60 days after the end of the project. Details and deadlines for communication and delivery of all templates, deliverables, etc. will be sent to the partners in due course to allow for required preparations of the report.

In addition, for the **final report** must include any declared revenues, if any. 'Revenue' is all income generated by the action, during its duration (Grant Agreement Article 4), for beneficiaries that are profit legal entities.

### 4.3 Reporting obligations

The periodic and final reports will be submitted to the EC by the CO. The reports consist of the relevant reporting information provided by all project partners.

Each project partner must provide the following documents to the CO at the end of each reporting period:

- Summary of the periodic activity, including dissemination and publications
- Activity Reports
  - All WPLs fill in the periodic activity report for their respective WP based on the input of the WP partners.
  - It is important that the WPLs outline the connection between the WPs, discuss possible solutions to issues, name the deviations from the original work plan and give a description of alternative plans how to reach the aims, highlight the reached goals, discuss upcoming issues, etc.

Templates for this will be provided by the Coordination Team, who will then merge the WP reports.

Each partner will also complete the financial forms on the EC's online reporting platform.

#### 4.3.1 Useful information

**Periodic Report**: Describing real added value of the work performed is important to show that the aims per WP have been achieved.

**Direct costs**: Direct costs are eligible costs which can be attributed directly to the project and are identified by the partner as such, in accordance with its accounting principles and usual internal rules.

Personnel costs: the personnel costs are calculated on a <u>daily basis</u> as follows: *daily rate for the person multiplied by number of day-equivalents worked on the action* (rounded up or down to the nearest half-day). The <u>daily rate</u> must be calculated as: *annual personnel costs for the person divided by 215*.

The number of day-equivalents declared for a person must be identifiable and verifiable (as per Article 20 Record-keeping in the Grant Agreement).

The total number of day-equivalents declared, for a person for a year, cannot be higher than 215.



For each person concerned, cost MAY INCLUDE the following:

- fixed salary
- fixed complements, if they are unconditional entitlements for the person (e.g., family allowance and contributions to medical insurance schemes set out in national law, complementary pension plan contributions set out in the collective labour agreement)
- variable complements, e.g., bonuses, if:
  - they are paid based on objective conditions set out, at least, in the internal rules of the beneficiary
  - they are paid in a consistent manner, i.e., not just for actions supported by EU grants,
    and
  - o where applicable, subject to the specific eligibility conditions for supplementary payments (see specific cases below)
- social security contributions (mandatory employer and employee contributions)
- taxes linked to the remuneration (e.g., income tax withholding)
- other costs and payments linked to the remuneration if they are justified and registered as personnel costs in accordance with the beneficiary's usual remuneration practices (e.g., benefits in kind like company car made available for the private use, lunch vouchers).

#### You MAY NOT INCLUDE:

- any part of the remuneration which has not been an actual cost for you (for example, salaries reimbursed by a social security scheme or a private insurance in case of long sick leave or maternity leave)
- payments of dividends to employees (profit distribution in the form of dividends)
- variable complements based on commercial targets or fund-raising targets (because neither incurred in connection with the work of the action, nor necessary for its implementation)
- arbitrary bonuses (i.e., bonuses which are not paid based on objective conditions3 set out, at least, in the internal rules of the beneficiary or bonuses that are not paid in a consistent manner)
- bonuses that depend on budget availability on the specific project (e.g. paid only if there are remaining funds in the budget of a project).

**Timesheets:** Regardless of a person works exclusively on the project or not, monthly timesheets must be completed and kept by each project partner. If more persons from the same partner work on the project, a separate timesheet must be completed. It is necessary to have one timesheet per month. The timesheets have to be signed by the person carrying out the work and the supervisor/project leader in your institution (generally, this is the main responsible contact person of the project partner). You can use your own (electronic) timesheets or templates or use as an example the templated provided by the Coordinator on the Teamwork platform. In any case, it is important that each timesheet includes the following necessary information:

- Full name of the partner organisation
- Full name of the individual working in the project
- Title of the project
- Project account number should be indicated
- Time period concerned (for instance on daily, weekly, monthly basis) according to the partner's normal practice.
- Number of hours claimed for the project. All hours claimed must be able to be verified in a reliable manner



 Full name and signature of the working person and the supervisor (person in charge of the project)

Note that all your administrative/general work must also be added to your WPs in your time sheet (e.g., kick-off, any other meetings, phone conferences, reporting, etc.).

*IMPORTANT NOTES*: If you are engaged in more than one EU project, you have to keep a time sheet where working hours for all EU PROJECTS and NON-EU ACTIVITIES are listed. The European Commission and the external auditor will certainly demand an exact record of these hours worked per project.

It is important to assign the working hours to a specific WP as the personnel costs and the person months are billed by WP.

**Travel and subsistence allowances**: Actual travel and related subsistence costs related to the project may be considered as direct eligible costs. They have to be adequately recorded.

**Other costs**: Costs for group dinners and exclusive catering services are often not accepted as eligible costs.

For specific questions on reporting please refer to the annotated Grant Agreement or contact the Project Office for further guidance.

#### 4.3.2 Publications

All publications, including any scientific publications relating to foreground, are to be listed, and have to be reported. The list of publications will be made available in the public domain, thus demonstrating the added-value and positive impact of the project to the European Community.

Publications must be "Open access" and made available via a repository (e.g., Zenodo).

All publications (e.g., articles in scientific, conference presentations, presentations, etc.) and dissemination materials (press, websites, flyers, etc.) must mention the following:

- The funding sentence: "This project received funding from the European Union under Grant Agreement number 101092947 (Med-IPUT). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them."
- <u>The disclaimer</u>: "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union. Neither the European Union nor the granting authority can be held responsible for them."
- EU funding emblem:



For publications which also were supported by other grants, e.g., Swiss national grants from SERI for LGT, their respective funding acknowledgements must be respected also.

With regard to scientific publications published after the final report, details, references and an abstract, or a pre-print version of the publication must be provided to the Commission at the latest two months following publication.

Rules regarding internal review of publications (as per Consortium Agreement Article 8.4.2)



Prior notice of any planned publication shall be given to the other partners at least 45 calendar days before publication. Any objection to the planned publication shall be made by written notice to the Coordination Team and the partner(s) proposing dissemination within 30 calendar days after receipt of the notice. Justified objections may include adverse effects to the protection of the objecting partner's results or background, significant harm to their legitimate interests, or the inclusion of confidential information. Objections must request necessary modifications and include proposed remedies. A partner may request a delay up to 90 days from submission of an objection. If objections have been addressed, publication is allowed after 90 days. Project partners should not include a partner's unpublished results or background without their prior written approval.

## 5. Financial management

Finances and partner payments are handled by the CO, TNO.

The total requested EC contribution is **EUR 2,541,413**.

The pre-financing amounts to 35% of the requested EC contribution. The Interim payments from EC are scheduled after Period 1 and Period 2. At the end of Period 3 Beneficiaries will receive the final payment.