

SC1-PHE-CORONAVIRUS-2B

ENVISION

Intelligent plug-and-play digital tool for real-time surveillance of COVID-19 patients
and smart decision-making in Intensive Care Units

Project No. 101015930

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Partner short names

AAW	app@work GmbH
accelCH	accelopment Schweiz AG
accelDE	accelopment Schweiz AG
CCHT	Spitalul Clinic Judetan De Urgenta Pius Brinzeu Timisoara
CHUC	Centro Hospitalar e Universitario de Coimbra E.P.E.
DPT	Central Hospital of Southern Pest National Institute of Hematology and Infectious Disease
ESAIC	European Society of Anaesthesiology and Intensive Care
GUF	Johann Wolfgang Goethe Universität Frankfurt am Main
ICS-HUB	Institut Catala de la Salut – Bellvitge University Hospital
iDA	Intelligent Data Analytics GmbH & Co. KG
KC	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
LMI	Löwenstein Medical Innovation GmbH & Co. KG
SE	Semmelweis Egyetem
TAU	Tampereen Korkeakoulusaatio SR
UCL	University College London
UMCG	Universitair Medisch Centrum Groningen
UMCL	Univerzitetni Klinicni Center Ljubljana
UMCM	Univerzitetni Klinicni Center Maribor
UMFCD	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
UNIPG	Università degli Studi di Perugia
UNITO	Università degli Studi di Torino

Abbreviations

CA	Consortium Agreement
D	Deliverable
DoA	Description of Action
EB	Executive Board
EC	European Commission
GA	Grant Agreement
GAP	Grant Agreement Preparations
H2020	Horizon 2020
M	Month
MS	Milestone
MST	Management Support Team
SC	Steering Committee
WP	Work Package
WPT	Work Package Team

Executive Summary

This deliverable is part of **Work Package (WP) 1, Task 1.1: Coordination and governance**, which aims to establish the project-internal bodies and management team and to set up external monitoring structures ensuring ethical and scientific oversight. Furthermore, the deliverable is a means of verification for **Milestone (MS) 1: Consortium bodies established and members of external advisory boards confirmed**.

The deliverable confirms that internal and external bodies have been established and decision-making processes are defined. Work contracts for internal bodies and NDAs for external members are in place.

Specifically, this deliverable shows:

- ◆ consortium internal bodies and roles
- ◆ consortium external advisory and monitoring boards
- ◆ decision making processes, tasks and responsibilities

Prior to the project start, i.e. during the application process and grant agreement preparation, the ENVISION Consortium already established clearly defined consortium bodies and progress monitoring processes. Members of the internal consortium bodies and external boards were appointed prior to the project start and during Month (M) 1–2 of the project according to the planned organisational structure.

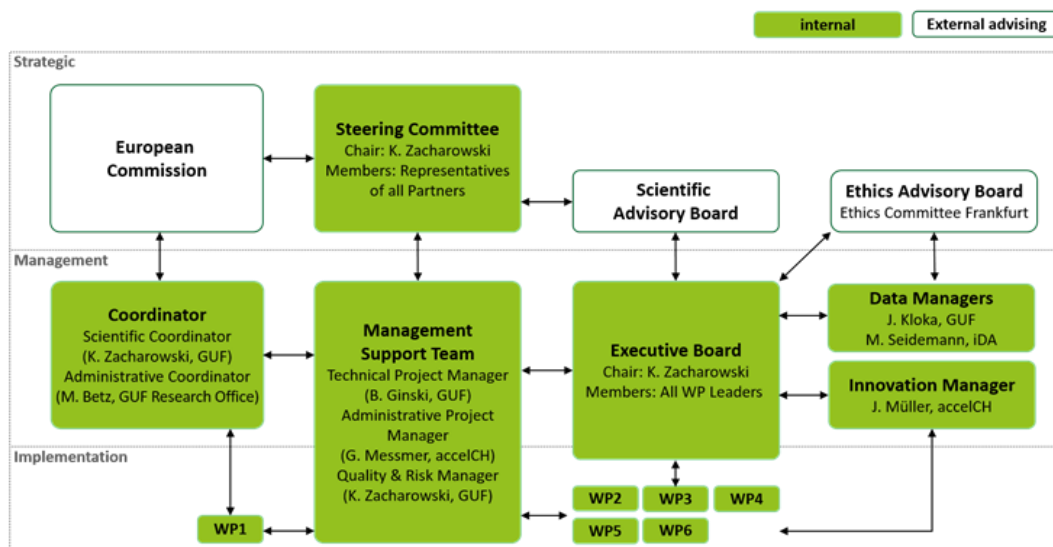


Figure 1: Organisational chart

1 Organisational Overview

1.1 Internal bodies and roles

The **Coordinator** of ENVISION is the Johann Wolfgang Goethe University Frankfurt. Prof. Kai Zacharowski (GUF) is the **Scientific Coordinator** of the project, supported by the **Administrative Coordinator** at the GUF Research Office. The scientific coordinator acts as the intermediary between the consortium bodies and the European Commission and the Project Officer respectively. The **Steering Committee (SC)** is the strategic decision-making body. The SC is chaired by Prof. Kai Zacharowski and is composed of (at least) one representative for each participating organisation. The **Executive Board (EB)** is the operational coordination and decision-making body. The EB is supported by the Management Support Team to monitor the progress of work in the WPs and their interactions. The EB consist of all **WP-leaders** – GUF, AAW; iDA, UMCG, and accelCH. The **Management Support Team (MST)** is responsible for daily operations and implementation of the project. The MST is composed of the **Technical Project Manager**, the **Administrative Project Manager** and the **Quality & Risk Manager**. The **Work Package Team (WPT)** for each of the 7 WPs is responsible for delivering their respective tasks. Their leaders and co-leaders will monitor their timely execution and oversee the planned activities to ensure quality of work, achievement of deliverables and contribution to reports. The **Data Managers** have been appointed to monitor the lifecycle of the data collected during the ENVISION project the data protection processes. The **Innovation Manager** is responsible for advising on the overall innovation management and will be assisted by the MST.

1.2 External boards

The **Scientific Advisory Board (SAB)** advises the consortium on scientific and technological matters, discusses the project progress with WP leaders and reviews relevant project documents and results. The SAB currently consists of two confirmed members external to the ENVISION Consortium, who are experts in the research areas covered by the project. The **Ethics Advisory Board (EAB)** monitors the ethical compliance of ENVISION with relevant regulations.

1.3 1st Point of Contact

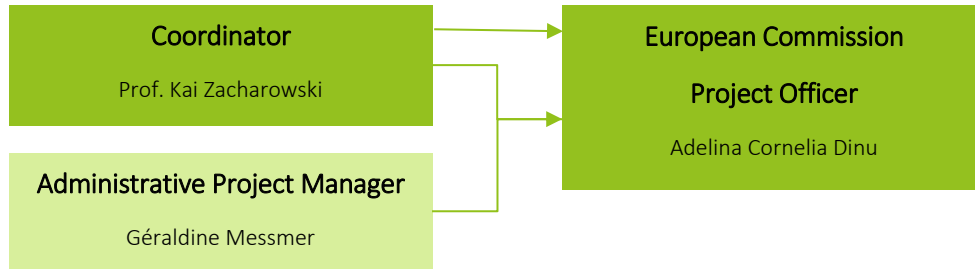
To facilitate communication within the consortium, a 1st point of contact is available for specific topics.

Management and Communication		
Medical and patient related questions	Project Coordinator	Kai Zacharowski
Technical questions	Technical Project Manager	Benjamin Ginski
Administrative questions	Administrative Project Manager	Géraldine Messmer
News and media related questions	Project Communications	Géraldine Messmer
Exploitation, innovation, collaboration	Innovation Manager	Jeanette Müller

IT and Data Management		
Sandman app	Team leader at AAW	Dominik Wegner
IT infrastructure	Team leader at iDA	Constantin Luster mann
Data management (medical/clinical)	Data Manager	Jan Andreas Kloka
Data management (technology/IT)	Data Manager	Marc Seidemann
Medical devices in ICUs	Team leader at LMI	Peter Kremeier

2 Coordinator

The Coordinator is the intermediary between the consortium and the European Commission, i.e. the EC's Project Officer appointed to this project, Adelina Cornelia Dinu. During the Grant Agreement Preparations (GAP) it has been agreed on with the Project Officer that the Administrative Project Manager is allowed to communicate updates and issues on behalf of the Coordinator to the PO, however, the Coordinator must be included in all communication to the PO.



The Coordinator, supported by the MST, is responsible for:

- ♦ monitoring compliance by the Parties with their obligations,
- ♦ keeping the address list of consortium members and other contact persons updated and available
- ♦ collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Funding Authority
- ♦ transmitting documents and information related to the project but were exclusively received by the Coordinator to any other partner concerned
- ♦ administering the financial contribution of the Funding Authority and fulfilling the financial tasks described in Section 7.3 of the CA.
- ♦ providing, upon request, the partners 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 partners to present claims.

3 Steering Committee / General Assembly

3.1 Tasks and Communication

The SC is the **strategic decision-making body** of the consortium. All partners have agreed to abide by all decisions of the SC. This does not prevent partners from submitting a dispute for resolution in accordance with provisions for the settlement of disputes as described in Section 11.8 of the Consortium Agreement (CA).

The meetings of the SC (General Assembly) will take place as planned in the Description of Action (DoA) in M3, M6, M8, M14 and M20. During the kick-off meeting in December 2020, the SC has decided to increase the frequency of meetings and that they should be held online. Two thirds (2/3) of the SC must be present. The draft meeting minutes taken by GUF/accelCH will be shared with all partners within maximum 10 days after the meeting. The consortium can comment on the minutes before a final version is uploaded to the shared repository.

3.2 Members

Partner	Representatives
GUF	Kai Zacharowski, Lea Grebe, Benjamin Friedrichson, Benjamin Ginski, Jan Andreas Kloka
SE	Janos Gal, Krisztina Madach
DPC	Ilona Bobek, Andrea Csepe
UNIPG	Edoardo De Robertis, Gianmaria Cammarota
UNITO	Luca Brazzi
KC	Andrius Macas, Vilma Traskaite, Laura Pekiene, Ramune Jakubauskaite, Lina Simonyte
CHUC	Francisco Maio Matos, Patrícia Couceiro
UMFCD	Dana Tomescu, Mihai Popescu
UMCL	Matjaž Jereb
UMCM	Andreja Möller Petrun, Doroteja Batorek
ICS-HUB	Rafael Mañez
UCL	Mervyn Singer
accelCH	Jeanette Müller, Géraldine Messmer
AAW	Jörg Wegner, Dominik Wegner, Stefan Hüttemann, Peter Rybczyk
IDA	Hamedo Ayadi, Marc Seidemann, Constantin Luster mann, Kayla White, Peter Nahrgang
LMI	Peter Kremeier, Thomas Reins
TAU	Hannu Nieminen, Alpo Värri, Antti Kallonen, Milla Juutinen, Mark Van Gils
UMCG	Thea Van Asselt, Maarten J. Postma, Hanneke Vervoort
ESAIC	Cathy Weynants, Jennifer Rose, Julia Dowell
accelDE	Andrea Jahraus
CCHT	Dorel Sandesc, Ovidiu Bedreag

3.3 Strategic decision-making

The following conditions apply to the decision-making process of the SC:

- ◆ A quorum of two-thirds (2/3) of the SC is required.
- ◆ Each of the 21 partners has one vote i.e. must be represented by at least one representative of their organisation to vote. Absent members are not entitled to vote.
- ◆ Decisions will be taken by a two-thirds majority of the votes, with a veto right for all partners.

The following decisions can notably be taken by the SC:

- ◆ Proposals for changes to Annexes 1 and 2 of the Grant Agreement (GA) to be agreed by the European Commission;
- ◆ Modifications to Attachment 1 of the CA (Background Included);
- ◆ Evolution of the consortium (entry or withdrawal of project partners);
- ◆ Appointment of new members of consortium internal and external bodies.

4 Executive Board

The Executive Board is the **operational coordination and decision-making body** of the consortium and consists of the representatives of the work package leading partner. The EB implements the decisions of the SC and is responsible for:

- ◆ assisting the Coordinator and the Steering Committee and facilitating their work,
- ◆ monitoring the interaction between the Work Packages and their achievements,
- ◆ collecting information on the project progress, reports and other deliverables,
- ◆ organising Executive Board meetings and drafting the minutes of Executive Board meetings,

- ◆ preparing memos of decisions to be taken by the Steering Committee and assist the Steering Committee in executing these decisions,
- ◆ transmitting project related documents and information via the protected web-based platform to the Steering Committee,
- ◆ supporting the Coordinator in preparing meetings with the Funding Authority and in preparing related data and deliverables,
- ◆ preparing the content and timing of press releases and joint publications by the consortium or proposed by the Funding Authority in respect of the procedures of the Grant Agreement Article 29.

Monthly web calls are planned between the Work Package leaders.

4.1 Members

Role	Representatives	Partner
WP1 Leader	Kai Zacharowski, Lea Grebe, Benjamin Friedrichson, Benjamin Ginski, Jan Andreas Kloka	GUF
WP2 Leader	Jörg Wegner, Dominik Wegner, Stefan Hüttemann, Peter Rybczyk	AAW
WP3 Leader	Hamedo Ayadi, Marc Seidemann, Constantin Lustermann, Kayla White, Peter Nahrgang	iDA
WP4 Leader	Kai Zacharowski, Lea Grebe, Benjamin Friedrichson, Benjamin Ginski, Jan Andreas Kloka	GUF
WP5 Leader	Thea Van Asselt, Maarten J. Postma, Hanneke Vervoort	UMCG
WP6 Leader	Jeanette Müller, Géraldine Messmer, Andrea Jahraus	accelCH/accelDE
WP7 Leader	Kai Zacharowski, Lea Grebe, Benjamin Friedrichson, Benjamin Ginski, Jan Andreas Kloka	GUF

4.2 Operational decision-making

The following conditions apply to the decision-making process of the EB:

- ◆ A quorum of two-thirds (2/3) of the EB is required.
- ◆ Each project partner has one vote. Absent partner members are not entitled to vote.
- ◆ Decisions will be taken by a simple majority of the votes.

5 Management Support Team

The Management Support Team assists and facilitates the work of the Executive Board and the Coordinator for executing the decisions of the SC as well as the day-to-day management of the Project. The MST consists of three members, the Technical Project Manager, the Administrative Project Manager and the Quality & Risk Manager. They support the Coordinator and all partners to ensure the interaction and progress of the work packages runs smoothly on a daily basis. Specifically their tasks include:

- ◆ Implementing innovation and quality and risk management with dedicated tools
- ◆ Collecting input for regular reports and finances following standardised processes
- ◆ Monitoring and tracking of deliverables with dedicated tools
- ◆ Organising meetings and preparing minutes using EU project proven templates
- ◆ Facilitating knowledge and document sharing on a secure web-based tool
- ◆ Advising the Executive Board on management related issues and necessary measures

The Technical and the Administrative Project Manager have weekly web conferences to coordinate tasks and share updates. The MST plus further representatives of GUF and accelCH/accelDE meet on a monthly basis to discuss relevant topics and the general progress of the project. The outcomes of the meetings will be shared and discussed with the Executive Board and/or the Steering Committee respectively.

5.1 Members

Role	Representative	Partner
Technical Project Manager	Benjamin Ginski	GUF
Administrative Project Manager	G�eraldine Messmer	accelCH
Quality & Risk Manager	Kai Zacharowski	GUF

6 Work Package Teams

The WP Teams are responsible for delivering their respective tasks. Their leaders and co-leaders will monitor their timely execution and oversee the planned activities to ensure quality of work, achievement of deliverables and contribution to reports. Several WP Teams have combined meetings and work closely together as even participants overlap within these work packages. The combined teams ensure the organised and seamless interaction of these work packages.

6.1 Members

Work Package Team WP1 (Management)

WP Team 1 (Management) has been included in the MST meetings.

WP-Lead	WP Co-Lead	Participant
GUF	accelCH/accelDE	iDA

Work Package Team WP2 + WP3 (Sandman + ICT)

WP-Lead	WP Co-Lead	Participant
AAW (WP2)	LMI (WP2)	GUF, iDA, ESAIC (WP2)
iDA (WP3)	TAU (WP3)	GUF, LMI (WP3)

Work Package Team WP4 (Clinical Validation)

WP-Lead	WP Co-Lead	Participant
GUF	AAW	all Clinical Partners, iDA, LMI, ESAIC

Work Package Team WP5 + WP7 (Assessment + Ethics)

WP-Lead	WP Co-Lead	Participant
UMCG (WP5)	GUF (WP5)	ESAIC (WP5)
GUF (WP7)	ESAIC (WP7)	all Clinical Partners (WP7)

Work Package Team WP6 (Communication + Dissemination)

WP-Lead	WP Co-Lead	Participant
accelCH/accelDE	ESAIC	GUF, AAW, iDA, LMI, TAU, UMCG

7 Data Managers

Two data managers have been appointed prior to the project start to represent both a medical and technical perspective and expertise on data management. The data managers monitor the data handling and protection of the data that will be collected during the project.

Role	Representative	Partner
Medical data manager	Jan Andreas Kloka	GUF
Technical data manager	Marc Seidemann	iDA

8 Innovation Manager

The Innovation Managers support and feedback on the planned measures and their long-term impact for commercial and non-commercial exploitation. The Innovation Managers in cooperation with the WP leaders will monitor the implementation of standards to assess the impacts and potential contributions of results on key European standardisation activities.

Role	Representative	Partner
Innovation Manager	Jeanette Müller	accelCH
Innovation Manager	Andrea Jahraus	accelDE

9 Scientific Advisory Board

The Scientific Advisory Board (SAB) advises the ENVISION consortium on scientific and technological matters. Information on the progress of work, results and the newsletter will be made available to the SAB members for review.

The SAB has been appointed and is steered by the Executive Board. The SAB assists and facilitates the decisions made by the SC (General Assembly). All confirmed SAB members have signed a non-disclosure agreement (NDA), which in turn has been signed by the Coordinator on behalf of the consortium, as defined in the Consortium Agreement (CA). The SAB will attend the SC meetings but have no voting rights.

9.1 Members

Name and position	Expertise	Recent publications
Prof Stefan De Hert Professor of Anesthesiology and Director of Research at the Department of Anesthesiology of the University Hospital of Ghent.	Prof De Hert was vice chairman of the Department of Anesthesiology at the Antwerp University Hospital and professor of Anesthesiology at the University of Antwerp for over 10 years. From 2007 to 2010 he acted as Professor of Cardiothoracic and Vascular Anesthesiology at the University of Amsterdam and Director of the Division of Cardiothoracic and Vascular Anesthesiology at the Academic Medical Center in Amsterdam. He acted as president of ESAIC until 2020.	<ul style="list-style-type: none"> • COVIDSurg Collaborative. <i>Elective surgery cancellations due to the COVID-19 pandemic: global predictive modelling to inform surgical recovery plans</i>. Br J Surg. 2020 Oct;107(11):1440-1449. doi: 10.1002/bjs.11746. • De Hert S, et al. <i>Pre-operative evaluation of adults undergoing elective noncardiac surgery: Updated guideline from the European Society of Anaesthesiology</i>. Eur J Anaesthesiol. 2018 Jun;35(6):407-465. doi: 10.1097/EJA.0000000000000817. • Redfern N, Clyburn P, Grigoras I, Calleja P, Mellin-Olsen J, Novak-Jankovic V, Bobek I, De Hert S, Zacharowski K, De Robertis E. <i>Getting old</i>. Eur J Anaesthesiol. 2020 Dec;37(12):1081-1083. doi: 10.1097/EJA.0000000000001266.

<p>Dr Tomas Tamošuitis Head of Neurosurgery Intensive Care Department at the Kaunas Clinics, Lithuania</p>	<p>Dr Tamošuitis is an anaesthesiologist-resuscitator. He worked in the UK, both in the public and private sector since 2004. He returned to Lithuania in 2012 to work at the Lithuanian University Hospital Kaunas Clinics, where he now holds the position of head of department of neurosurgery and intensive care.</p>	<ul style="list-style-type: none"> • Rimaitis M, Bilskienė D, Tamošuitis T, Vilcinis R, Rimaitis K, Macas A. <i>Implementation of Thromboelastometry for Coagulation Management in Isolated Traumatic Brain Injury Patients Undergoing Craniotomy</i>. Med Sci Monit. 2020 Jul 4;26:e922879. doi: 10.12659/MSM.922879. • Gravesteijn BY, et al.; CENTER-TBI collaborators. <i>Machine learning algorithms performed no better than regression models for prognostication in traumatic brain injury</i>. J Clin Epidemiol. 2020 Jun;122:95-107. doi: 10.1016/j.jclinepi.2020.03.005. • Pranskunas A, Tamosuitis T, Balciuniene N, et al. <i>Alterations of conjunctival glycocalyx and microcirculation in non-septic critically ill patients</i>. Microvasc Res. 2018 Jul;118:44-48. doi: 10.1016/j.mvr.2018.02.004.
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10 Ethics Advisory Board

The Ethics Advisory Board (EAB) is an independent body composed of GUF’s Ethics Committee, chaired by **Prof Dr Sebastian Harder**. Prof Harder is a member of the ethics commission of Hessen State Medical Association since 2003 and its chairman since 2007. In 2016, he was elected Chairman of the Ethics Committee of the Department of Medicine at Goethe University by the Departmental Executive Committee.

The role of the EAB is to:

- ◆ Support the preparation of ethics-related documents;
- ◆ Review ethics-related documents;
- ◆ Monitor ethical compliance of VANGUARD research with relevant regulations.