VANGUARD	Title **VANGUARD Stakeholder Engagement and Dissemination Assessment Reports**	Deliverable Number **D9.3**
Project Number **874700**		Version **2**

H2020-SC1-2019-Single-Stage-RTD

VANGUARD - New Generation Cell Therapy: Bioartificial Pancreas to Cure Type 1 Diabetes

Deliverable D9.3

VANGUARD Stakeholder Engagement and Dissemination Assessment Reports

WP 9 – Stakeholder engagement, dissemination and exploitation

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Delivery date: 21/02/2024

Dissemination level: Public

Type: Report

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874700.

Revision History

Author Name, Partner short name	Description	Date
Julia Goetz (accelCH)	Draft deliverable	05/11/2023
Margaryta Schaltegger (accelCH)	Revision 1	18/02/2024
Julia Goetz (accelCH)	Revision 2	19/02/2024
Ekaterine Berishvili Berney (UNIGE)	Internal review	21/02/2024
Margaryta Schaltegger (accelCH)	Finalisation of version 1	21/02/2024
Margaryta Schaltegger (accelCH)	Addition of a footnote pointing out the acknowledgment of a publication on page 21. Finalisation of version 2	23/05/2024

Contents

Project Partners

accelCH	accelopment AG
CHU-LYON	Lyon Claude Bernard University
EMC	Erasmus University Medical Centre
ESOT-ELPAT	European Society for Organ Transplantation
KGM	Kugelmeiers AG
LMUM	Ludwig-Maximilians-Universität München
OSR	IRCCS Ospedale San Raffaele
UNIGE	University of Geneva
UNIUPO	Università degli Studi del Piemonte Orientale "Amedeo Avogadro"

1 Introduction

VANGUARD is a five-year project researching a new generation cell therapy by developing a bioartificial pancreas to cure type 1 diabetes. The project is of high societal relevance and thus requires a clear strategy and plan for its stakeholder engagement, communication and dissemination, to maximise its impact. This deliverable presents an evaluation of the stakeholder engagement, communication and dissemination activities implemented during the first 48 months of the VANGUARD project. While the Stakeholder Engagement and Dissemination Plan (SEDP – D9.2), submitted in February 2021 (project month 14) defines the activities planned for the entire project duration, not everything can be known and planned. Thus, an evaluation of the activities implemented this far is necessary to ensure that the SEDP remains effective and efficient.

While in the SEDP we presented the key components of the stakeholder engagement, communication and dissemination strategy, such as target audiences, messages, channels and tools, as well as measures to evaluate the implemented activities, herein we focus on the evaluation indicators defined in the SEDP to assess the effectiveness of the implemented activities during the VANGUARD project's first four years. Based on this assessment, suggestions for improvement and adaptation are made and envisioned to be implemented in both the ongoing and planned activities.

2 Goals

The overall aim of reporting and evaluating the stakeholder engagement, communication and dissemination activities of VANGUARD is to keep improving the effectiveness of the SEDP and maximise the project's reach and impact. With the help of this deliverable, the VANGUARD partners aim to:

- report on the stakeholder engagement, communication and dissemination activities implemented to date;
- present an assessment of the implemented activities based on the metrics defined in the SEDP;
- provide an outlook with suggestions for improvement and adaptation of activities, where needed.

This cycle of implementation, feedback, evaluation and adaptation is key to taking advantage of learning effects within the project and possibly also between past, current and future projects.

Figure 1:SEDP Cycle

3 Activities and impact assessment

The stakeholder engagement, communication and dissemination activities planned in VANGAURD are crucial to promote research results and gather awareness of new generation cell therapies among the scientific community, clinicians and healthcare experts, patients and patient advocacy groups, policy-makers, potential new collaborators and society as a whole.

In this section, we assess the project's varied range of stakeholder engagement activities first (Section 3.1), followed by the communication (Section 3.2) and dissemination activities (Section 3.3). Those activities implemented to date are covered below, whereas those that have yet to start will be described in the next periodic and final reports.

Stakeholder engagement

Raise awareness of the foreseen benefits of bioartificial pancreas transplantation

Communication

Multi-channel communication throughout the duration of the project

Dissemination

Dissemination to the research and practitioners communities to ensure knowledge transfer

3.1 Stakeholder engagement

Stakeholder engagement is defined as a process organisations undertake to connect with their stakeholders to gain a deeper understanding of their key audiences. It focuses on the systematic approach to identify, analyse and plan activities to listen to the stakeholders and to learn about their needs and requirements within the scope of the VANGUARD project and in general. Furthermore, the planned stakeholder engagement activities aim to consult regarding the solutions offered by VANGUARD and influence the key stakeholders.

3.1.1 Social media

To support VANGUARD's presence in online media and to promote dissemination and communication activities with interested external stakeholders, three project-related social media accounts have been set up on Facebook, Twitter (X) and YouTube. While the media channels are managed by UNIGE and accelCH, all partners are encouraged to use their organisation or personal accounts to further share VANGUARD posts to their existing and already established networks. Most efforts have been put

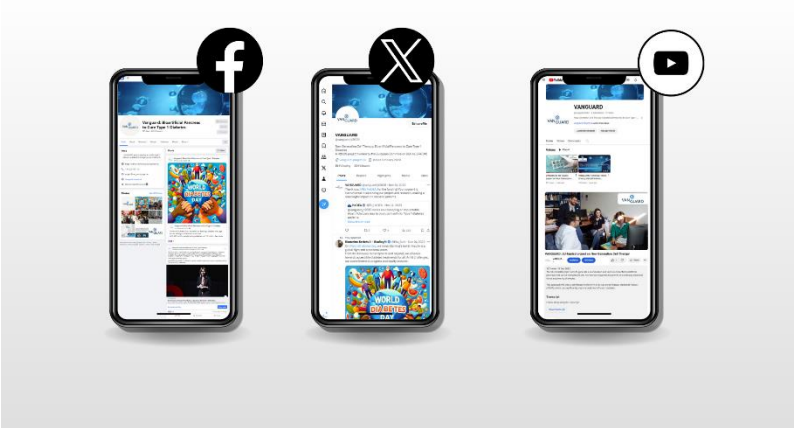
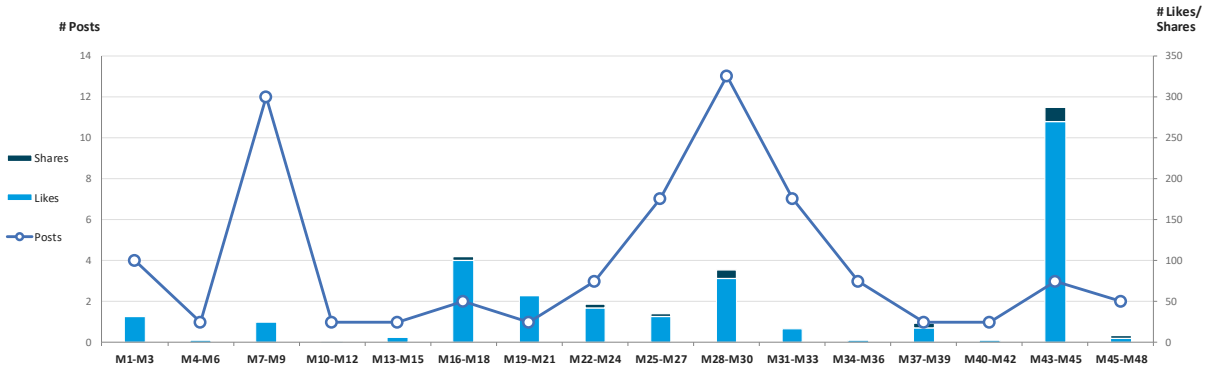


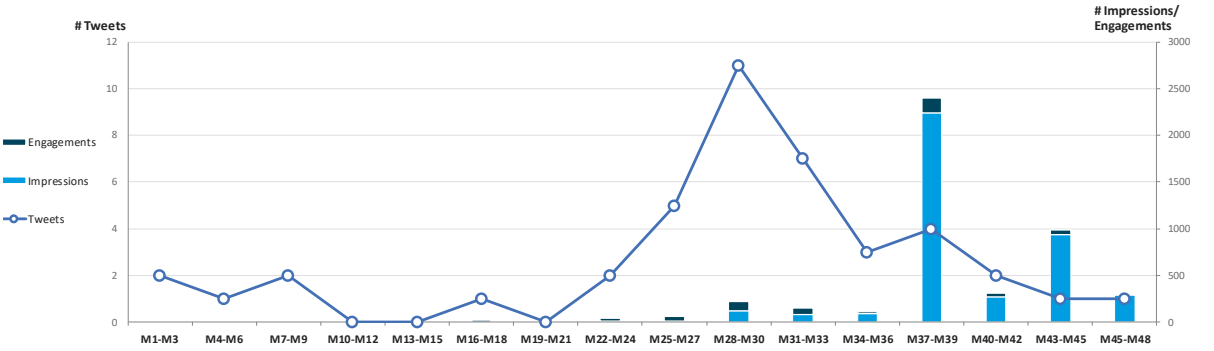
Figure 2: VANGUARD social media channels

into maintaining the Facebook and Twitter channels for regular communication and YouTube to share videos, for which most promotion so far was done through the project website, Facebook and Twitter channels rather than via YouTube itself.



	M1-M3	M4-M6	M7-M9	M10-M12	M13-M15	M16-M18	M19-M21	M22-M24	M25-M27	M28-M30	M31-M33	M34-M36	M37-M39	M40-M42	M43-M45	M45-M48
Posts	4	1	12	1	1	2	1	3	7	13	7	3	1	1	3	2
Likes	31	2	25	1	6	100	57	42	31	78	16	3	18	2	270	5
Shares	1	0	0	2	0	5	1	4	4	10	0	0	5	0	17	3

Figure 3: Facebook analytics



Tweets	2	1	2	0	0	1	0	2	5	11	7	3	4	2	1	1
Impressions	0	1	1	0	0	2	0	9	15	119	83	87	2236	271	935	291
Engagements	1	2	9	0	0	15	0	34	41	103	72	20	161	42	48	13

Figure 4: Twitter (X) analytics

Assessment:

The social media channels were monitored using each platform's own analytics tools (Facebook insights and Twitter analytics) and evaluated on a quarterly basis. Since the project start, the Facebook page has accumulated 605 followers and 585 likes. In total, there have been 17 Facebook posts which lead to a total of 314 likes, and 25 shares. Twitter has built up 89 followers during the same time. The total 37 posts have received a total of 4,048 impressions, 549 engagements and 85 likes.

As seen in the Facebook and Twitter analytics above, there is a sharp increase in the number of posts during M25-M33. This is due to VANGUARD social media campaigns launched during this period including partner introduction posts. However, we do not see a sharp increase in likes and interactions. In the past project year, we have focused on creating fewer posts but with content that is more interesting for our target audiences. According to the success indicators such as proportionally higher interactions and likes during M37-M48, this approach has proven to be successful. The most engaging post on Facebook was our coordinator's TEDxTbilisi presentation, and on Twitter it was the VANGUARD annual meeting held in Igls.

3.1.2 Patient engagement

Patient letter: UNIGE issued a Patient Sheet including information for patients and their relatives in July 2020 (M7). The Patient Sheet was created due to the high interest the project received via the website from patients and their families inquiring about the possibility to enrol in the study. The open letter from the VANGUARD coordinator, Ekaterine Berishvili was deemed necessary to manage the expectations of the patient target group and to inform them of the current status of the project.

Figure 5: Open patient letter

VANGUARD Roundtable Event: In May 2023, accelCH drafted a proposal for a patient-engagement event, the VAGUARD Roundtable Event, to be held on the occasion of World Diabetes Day (See SDEP, Section 3.2. World Diabetes Day Series). The draft was presented at the General Assembly meeting held in July 2023 in Milan, Italy, where all partners contributed to setting clear objectives and defining a structure for the event. It was agreed that the main objective of the event would be to educate and engage the audience about innovative diabetes treatments while raising awareness about the VANGUARD project, and the proposed treatments, and presenting realistic expectations for the commercialisation of the proposed treatment. The event will be delivered simultaneously in several partner countries and in local languages to maximise its impact. It will be structured as a roundtable discussion where VANGUARD partners take part as moderators presenting the project and topics of discussion; experts participate as relevant speakers, bringing different perspectives to the subject; and the public participates as an audience and asks questions on the project and treatments. It was collectively agreed that the date for the delivery date of the roundtable event will be postponed to 2024. In turn, partners agreed to feature VANGUARD at annual local events dedicated to diabetic patient engagement (see following paragraphs).

UNIGE and LMUM Diabetes Days: In November 2022 and 2023, UNIGE hosted Journée du Diabète – its annual event in Geneva, Switzerland, featuring the VANGUARD project. Furthermore, LMUM has hosted another patients-oriented event titled "Trends and advances in Type 1 diabetes" on November 27, 2023. During these events, diabetic patients and curious participants from the general public were presented with the latest R&D developments for the treatment of diabetes, among which was the VANGUARD project. For these occasions, a VANGUARD roll-up banner was developed by accelCH (see 3.2.3. Communication material).

OSR DIRitti a Voi: In February 2024, OSR will feature the VANGUARD project, as part of their annual event DRItti a Voi, a patient day organised by the OSR's Diabetes Research Institute. During the event young and senior researchers will present the latest VANGUARD developments through posters, videos and/or scientific booths, emphasising the impact of the project on patients and the treatment of diabetes type 1. For this occasion, tailored communication materials, such as an updated roll-up banner, flyers, and/or brochures will be developed.

Assessment:

The effectiveness of patient engagement events is measured by tracking the downloads and clicks of patient-focused materials and campaigns on our website, as well as by the attendance at patient-oriented events. Regarding the LMUM and UNIGE Diabetes Days, a combined total of 80 diabetic patients and interested parties participated in these events. For the VANGUARD Roundtable Event, we anticipate a minimum of 40 attendees, and for the DIRitti a Voi event, we expect at least 20 participants.

With two patient-events delivered, one patient letter available on the website, and two large events planned for the year 2024, the project is performing well in terms of patient engagement. Due to the COVID-19 pandemic outbreak, the project faced delays in R&D, resulting in some deviations from the initial plan detailed in the SEDP. Specifically, the World Diabetes Day Series, as described in the SEDP section 3.2, could not be carried out as originally planned. In turn, partners have delivered (or plan to) several patient-engagement events and a VANGUARD Roundtable Event is expected to be delivered in November 2024.

3.2 Communication

Communication is a strategic process throughout the project's lifetime to promote the project to diverse audiences and to society as a whole. The focus of communication lies on informing of and promoting the project and its achievements (European IPR Helpdesk, 2018).

All planned communication activities aim to create awareness about the project and its results as well as generally establish a network to which subsequent activities can reach out to. As a result, stakeholder engagement, dissemination and exploitation of project results will be facilitated as well as accelerated and the outreach will be increased.

3.2.1 VANGUARD website

The project website (vanguard-project.eu) first launched in February 2020 (M2) continues to function as the main platform where project progress and outcomes is shared.

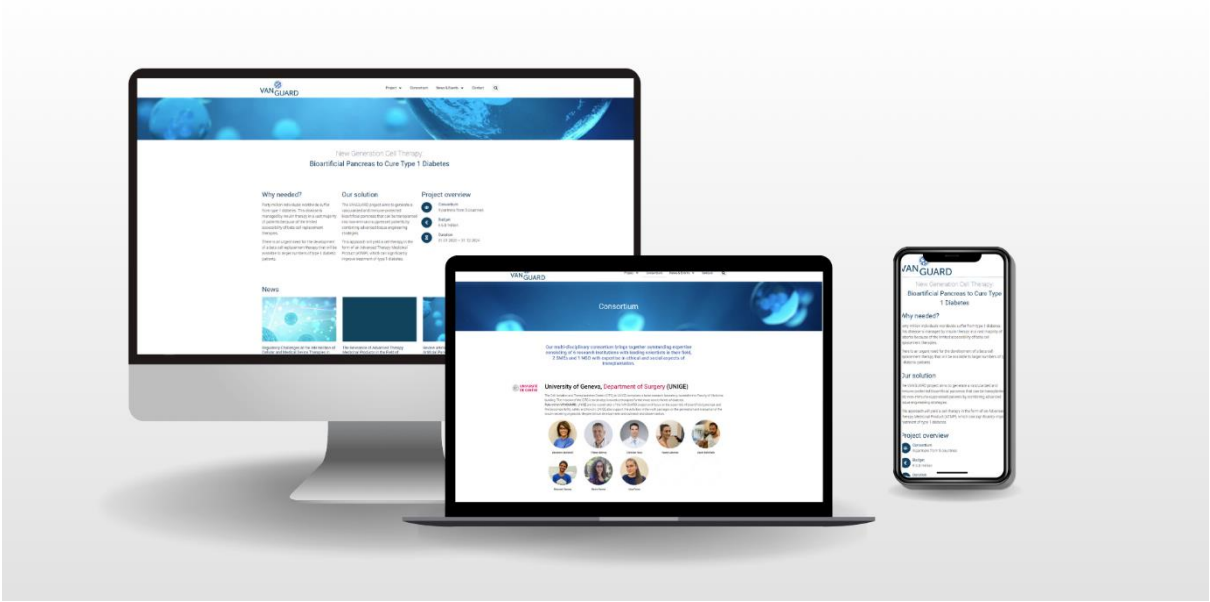
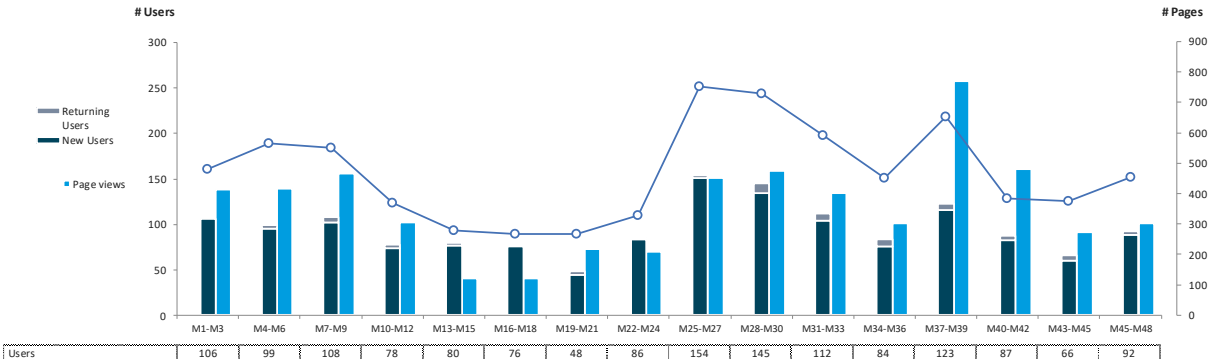


Figure 6: VANGUARD website



Users	106	99	108	78	80	76	48	86	154	145	112	84	123	87	66	92
New Users	106	95	102	74	77	76	44	84	151	134	104	76	116	83	60	88
Sessions	161	189	184	124	93	89	89	110	252	244	198	151	219	129	126	152
Average session duration (sec.)	150	184	148	113	55	21	208	56	85	147	43	49	45	40	123	78
Page views	412	415	467	305	121	122	216	209	450	475	400	303	770	481	272	303
Top pages viewed	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home	Home
	Partners	Project	Partners	Partners	Partners	Partners	Partners	Partners	Ethics WS	Partners	Partners	Partners	Partners	Partners	Overview	Overview
	Project	Partners	Project	Outcomes	Patient Info	Infographic	News	Outcomes	Partners	News	Outcomes	Outcomes	News	Project	Consortium	Consortium
	News	Contact	News	News	Outcomes	Outcomes	Outcomes	Project	News	Outcomes	Outreach	News	Project	News	News	News

Figure 7: VANGUARD project website online statistics

Assessment:

The impact and reach of the website are monitored via Google Analytics which are extracted and evaluated every three months. The numbers of visitors and sessions have remained overall steady (Figure 7). In total, since the website has been first launched there are an average of 96 users and 358 pages viewed per month. The most viewed pages over the whole duration are the Overview (738 views), Consortium (737 views) and the News (372 views) page. These numbers are in line with our targets of 100 visitors per set out in the SEDP.

This shows that regularly implemented changes and updates have maintained traffic on the VANGUARD website with a continuously high number of new users visiting the page. To further increase traffic on the website which in turn creates more awareness and interest for the project we will continue to create new content related to new results and outcomes which will be implemented over the next reporting period to further increase the number of users and pages viewed. Additionally, to increase the interest of patients and their families while maintaining expectations, a dedicated patient area including FAQs is currently being developed.

3.2.2 Media

Press releases: To engage and keep all stakeholders updated on the most noteworthy events and ground-breaking advancements of the project, VANGUARD plans to publish press releases as official statements. A first press release (figure 8) was already written by UNIGE and accelCH for the kick-off of the project and distributed to all partners to disseminate using their own channels which was further published via CORDIS. The press release was structured in a way that allowed each partner to adapt its content for their organisations' contribution to the project.

News: To further keep stakeholders up to date on new outcomes, publications, materials and events, VANGUARD regularly posts shorter news pieces to the project website (figure 9). The aim of the news texts is to keep different target audiences informed that the project is moving forward and to increase interest and retention on the website (i.e. regular visits to the page). To date, 28 news articles have been published on the project website which have also been shared via the project's social media channels.

Events: The events page of the project website has been updated to showcase occasions linked to the VANGUARD project activities and type-1 diabetes-related events in general. This includes internal closed meetings of the consortium as well as open access events organised by project partners for various types of stakeholders. Keeping the events section updated generates additional website traffic and establishes the project website as a repository for diabetes type 1-related events.

TV: VANGUARD has also been presented on a Georgian TV channel – First Channel – by the project's coordinator Ekaterine Berishvili on 24 April 2023. By talking about the role of stem cells in the treatment of complicated type 1 diabetes in the Georgian language, the coordinator could reach thousands of viewers from various audience groups including the general public in Georgia. Furthermore, the broadcasting featured a synchronous translation into sign language. Such activities are crucial for making sure that the results of scientific projects such as VANGUARD are inclusive and can reach wider audiences.

Figure 8: VANGUARD first press release

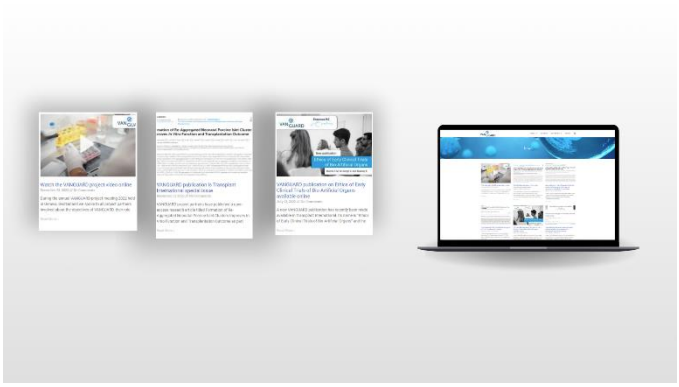


Figure 9: Example news texts and news page

Assessment:

Due to data protection regulations, we do not have access to the views generated by the press release on external platforms like CORDIS, but through the news page on the VANGUARD website, this first press release gathered 37 views. While not many, the number of views is also to be considered bearing in mind that the website was at its very first stages at this point and the project was at its infancy, without an established community of interested stakeholders. The 28 news texts collectively received 482 views.

From other experiences, the press release and news texts could have had more outreach if shared further by the partners through their organisations' well-established channels and media connections. This will be a point that will be more emphasised for future press releases and news texts to increase the outreach, interest and impact of our outcomes and activities.

Broadcasting through national Georgian television has generated an important outreach opportunity as 89.1% of the Georgian population watch TV at least once a week, according to research by Georgian Public Broadcaster in 2021. However, it is challenging to measure the actual impact and estimate the exact number of audiences reached.

3.2.3 Communication materials

It is crucial to produce content introducing details of the VANGUARD project in various forms and complexity in order to maximize the reach of different types of stakeholders. Therefore, a number of VANGUARD digital and print materials have been created since the start of the project. The available materials have all been published on the VANGUARD website's outreach page and documented as part of the public deliverable D9.4 *VANGUARD Communication Portfolio* submitted in October 2022 (M34).

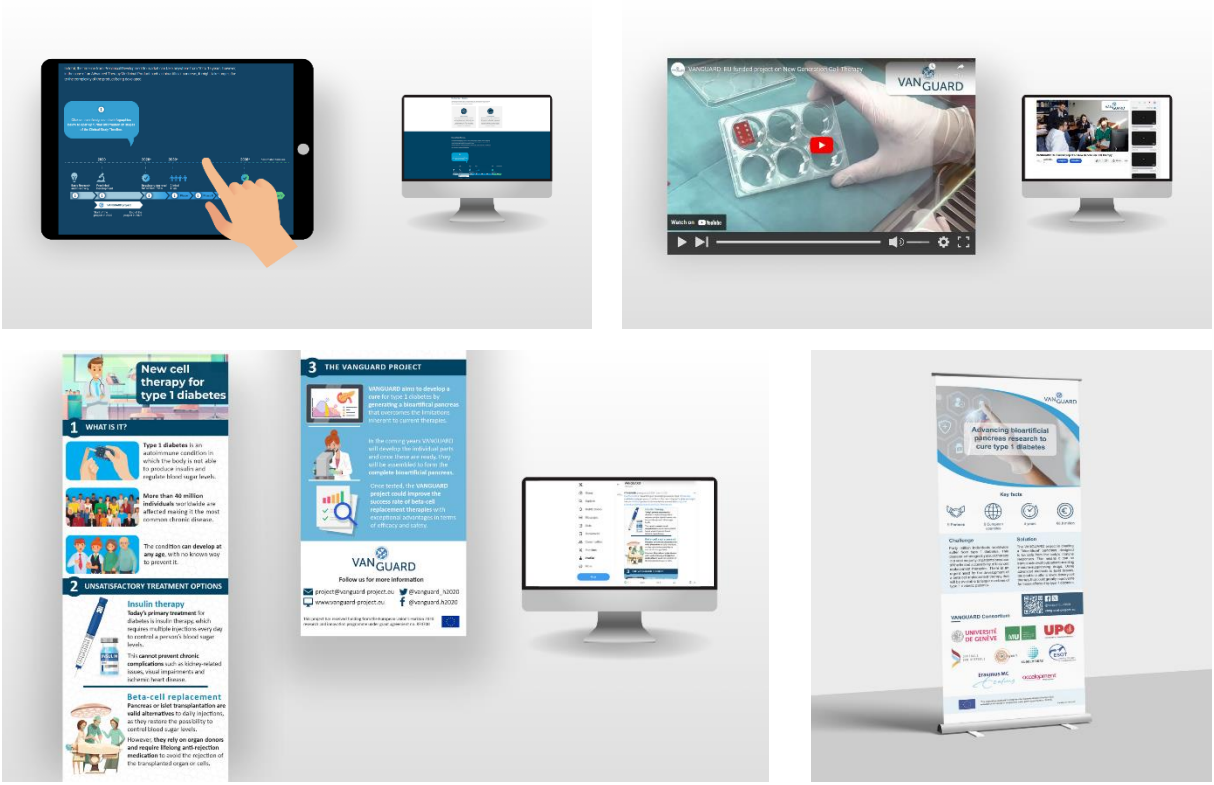


Figure 10: VANGUARD communication materials

Digital visual material: accelCH supported by project partners develop digital visual material and graphics to bring the objectives of the project and the research aims closer to the general public and to explain complex content in an easy-to-understand way. In June 2021 (M18) accelCH and UNIGE created a VANGUARD infographic titled New cell therapy for type 1 diabetes. Further digital materials such as the animated concept chart for researchers and the interactive clinical study timeline for patients will further facilitate different audiences to better understand the project. The digital visual materials are available to download on the outreach page and has been shared via the project's social media channels. Further visual and audio-visual material is planned for the VANGUARD project as defined in the SEDP.

VANGUARD project video: During the annual VANGUARD project meeting 2022 held in Geneva, Switzerland, accelCH recorded video material and interviews with the work package leaders to create an introductory video to the VANGUARD project. The recorded material highlights the issue, the project's objectives, approach, involved partners and the potential impact of the overall project. The final video was published on the project website's outreach page and on YouTube in December 2022 and further distributed via the project's and partners' social media channels.

VANGUARD roll-up banner: In October 2023 (M46), accelCH developed an informative roll-up banner, visualising VANGUARD's ambition and key facts for the general public and diabetic patients. Using very simple language, the banner highlights the main challenge for the treatment of diabetes type 1 and presents the solution proposed by the VANGUARD project. Additionally, it also features essential details about the VANGUARD project such as the number of partners and their logos, the funding duration, the total grant amount received, and the number of participating countries in the research. The roll-up banner was created for events such as local patient days by UNIGE in Geneva, Switzerland (Journée du Diabète), LMUM in Münich, Germany (Trends and advances in Type 1 diabetes), and OSR, Milan, Italy (DRItti a Voi).

Assessment:

The outreach page where all materials are made available has received 171 views. On social media, the posts related to communications materials on Facebook received 171 impressions, 7,172 reach and 73 engagements. On X (Twitter), they received 2,499 impressions, 131 impressions, 11 likes and 8 shares. Since its publication, the project video has been watched 124 times with a total watch time of 6.5 hours.

The visual and audio-visual materials have a notable impact due to their ability to distil intricate data and concepts into visually appealing and easy to follow format. By presenting information through a combination of text, visuals, audio, video and design elements, the materials make it easier for the audience to grasp key points quickly. Additionally, sharing on social media platforms extends its reach and impact contributing to more accessible and engaging communication, fostering a deeper understanding of complex topics and driving meaningful engagement with the audience.

3.3 Dissemination

Dissemination is "the public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium." The focus of dissemination lies on making the obtained knowledge and the results available for others to use (European IPR Helpdesk, 2018). The consortium aims to disseminate the project results to a wide scientific audience. Future research projects should be able to use VANGUARD results to build up on the knowledge generated, bringing cell therapy treatment research forward towards market implementation.

3.3.1 Conferences, workshops and events

Conference participation: Members of the VANGUARD project participated in several conferences to present their latest progress through oral and poster presentations. By M48, there have been 39 VANGUARD oral presentations and 6 scientific posters reported by the partners. The full list is kept updated on the VANGUARD outcomes page.

Oral Presentations

- **"Beyond beta cell replacement: bioengineering the endocrine pancreas"** presented by Ekaterine Berishvili (UNIGE), Transplant Immunology and Innovations in Immunotherapies, 22.12.2023, Paris, France
- **"Construction endocrine a base prevascularisee et explantable de diabete de type 1"** presented by Funny Lebreton (UNIGE), 23ème Réunion Annuelle de la Société Francophone de Transplantation, 08.12.2023, Brest, France.
- **"Clinical translation and implementation of a bio-artificial pancreas: a qualitative study exploring the perspectives of people with type 1 diabetes"** presented by Dide de Jongh (EMC), Annual Dutch Diabetes Research Meeting, 02.11.2023, Wageningen, The Netherlands.
- **"Bioartificial endocrine pancreas generated from human placenta for Type 1 Diabetes treatment"** presented by Kevin Bellofatto (UNIGE), IPITA-IXA-CTRMS Joined congress 2023, 27.10.2023, San Diego, USA
- **"Hydrogel-based, prevascularized, retrievable endocrine construct to treat Type 1 Diabetes**" presented by Fanny Lebreton (UNIGE), IPITA-IXA-CTRMS Joined congress 2023, 27.10.2023, San Diego, USA
- **"Bioartificial Pancreas to Cure Type 1 Diabetes"** presented by Ekaterine Berishvili (UNIGE), Fokus Patient Transplantation Forum, 11.10.2023, Stockholm, Sweden
- **"Transgenic porcine neonatal islets expressing human PD-L1 reduce immune cell activation and cellular rejection in humanized NSG mice with type 1 diabetes"** presented by Yutian Lei (LMUM), EASD 2023, 02-06.10.2023, Hamburg, Germany
- **"Hydrogel-based, prevascularized, retrievable endocrine construct to treat Type 1 Diabetes"** presented by Fanny Lebreton (UNIGE), ESOT2023, 19.09.2023, Athens, Greece
- **"Bioengineering Of Vascularized Insulin-Secreting Organoids For Type 1 Diabetes Cell Therapy"** presented by Laura Mar Fonseca and Vanguard consortium (UNIGE), ESOT2023, 19.09.2023, Athens, Greece
- **"Engineering Vascularized Endocrine Pancreas for Type 1 Diabetes"** presented by Kevin Bellofatto (UNIGE), ESOT2023, 18.09.2023, Athens, Greece
- **"Small Organs Large Aspirations. Next Generation Organoids"** State of the Art Lecture presented by Ekaterine Berishvili (UNIGE), ESOT2023, 18.09.2023, Athens, Greece

- **"Generation Of Vascularized Endocrine Constructs For Type 1 Diabetes"** presented by Laura Mar Fonseca and Vanguard consortium (UNIGE), ESOT2023, 19.09.2023, Athens, Greece
- **"Clinical translation and implementation of a bio-artificial pancreas: a qualitative study exploring the perspectives of patients with type 1 diabetes"** presented by Dide de Jongh (EMC), ESOT Congress 2023, 18.09.2023, Athens, Greece
- **"Single-Cell RNA sequencing analysis of human amniotic epithelial cells to decipher the mechanisms of immunomodulation they confer to pancreatic islets"** short oral communication presented by Juliette Bignard and VANGUARD consortium (UNIGE), ESOT Congress 2023, 18.09.2023, Athens, Greece
- **"Generation of a bioartificial pancreas for Type 1 diabetes"** presented by Ekaterine Berishvili (UNIGE), TREPID meeting, 01.06.2023, Biarritz, France
- **"Neonatal porcine pseudo-islets display an improvement in vitro function and transplantation outcome"** presented by Mohsen Honarpisheh (LMUM), DDG Kongress, 17-20.05.2023, Berlin, Germany
- **"Clinical translation and implementation of a bio-artificial pancreas: a qualitative study exploring the perspectives of patients with type 1 diabetes"** presented by Dide de Jongh (EMC), Clinical & Health Science Day, 09.05.2023, Rotterdam, The Netherlands
- **"Regenerative Medicine & Bio-Engineered Approaches to β-cell Replacement"** postgraduate course presented by Ekaterine Berishvili (UNIGE), EDS 2023, 22.04.2023, Tbilisi, Georgia
- **"Generation of a bioartificial pancreas for Type 1 diabetes"** presented by Ekaterine Berishvili (UNIGE), Congrès national de la Société Francophone du Diabète, 21.03.2023, Montpellier, France
- **"Overexpression Of hPD-L1 In Neonatal Porcine Islets Improves Long-Term Xenograft Survival In Humanized NSG Mice"** presented by Yutian Lei (LMUM), 12th EPITA Symposium, 24.01.2023, Innsbruck-Igls, Austria
- **"Biomarkers for Rejection"** presented by Olivier Thaunat (CHU-LYON), 12th EPITA Symposium, 23.01.2023, Innsbruck-Igls, Austria
- **"Organoids for the treatment of diabetes: "Fact or Fiction"?"** presented by Ekaterine Berishvili (UNIGE), 45th SITO National Congress, 24.10.2023, Trieste, Italy
- **"Ethics of early phase clinical trials of bio-engineered organs: points to consider"** presented by Dide de Jongh (EMC), EACME conference, 17.09.2022, Varese, Italy
- **"Generation of Prevascularized Endocrine Constructs to Treat Type 1 Diabetes"** presented by Ekaterine Berishvili (UNIGE), 29th International Congress of The Transplantation Society (TTS 2022), 10-14.09.2022, Buenos Aires, Argentina
- **"Protecting islet functional viability using amniotic epithelial cells"** presented by Fanny Lebreton (UNIGE), University of Geneva Diabetes Faculty Center (DFC) monthly seminar, 05.09.2022, Geneva, Switzerland
- **"The 'soft impacts' of bio-artificial organ transplantation"** presented by Dide de Jongh (EMC), 16th World Congress of Bioethics (IAB), 22.07.2022, Basel, Switzerland
- **"Introduction to Islet Organoids"** presented by Ekaterine Berishvili (UNIGE), The 10th NICE/EPITA Islet Isolation and Beta Cell Replacement Workshop, 20.06.2022, Oslo, Norway

- **"Bioengineering of a vascularized endocrine pancreas to cure type I diabetes"** presented by Ekaterine Berishvili (UNIGE), Spring 2022 Beta Cell Replacement Consortium Meeting, 23.05.2022, Los Angeles, USA
- **"Ethics of first-in-human transplantation trials of bioartificial organs"** presented by Dide de Jongh (EMC), 14th World Conference on Bioethics, Medical Ethics and Health Law conference, 07.03.2022, Porto, Portugal
- **"Engineering a bioartificial pancreas"** presented by Ekaterine Berishvili (UNIGE), Séance commune SFT / ESAO, 21ème Congrès Annuel de la Société Francophone de Transplantation, 08.12.2021, Geneva, Switzerland
- **"Ethical considerations for responsible research and clinical development of chimeric bioartificial pancreases"** presented by Dide de Jongh (EMC), 6th Tissue Engineering and Regenerative Medicine International Society (TERMIS) World Congress, 16.11.2021, Maastricht, The Netherlands
- **"Biofabrication of a functional Vascularized Endocrine Pancreas"** presented by Antonio Citro (OSR), IPITA, 20-23.10.2021, online
- **"Homemade hydrogel from human amniotic membrane improves islet transplantation outcomes in diabetic immunodeficient mice"** presented by Kevin Bellofatto (UNIGE), IPITA, 20-23.10.2021, online
- **"Human amniotic epithelial cells immunomodulatory properties protect islets against inflammatory cytokines in vitro"** presented by Fanny Lebreton (UNIGE), IPITA, 20-23.10.2021, online
- **"The road toward a new Pancreas: from organoids to bio-engineered pancreas"** presented by Ekaterine Berishvili (UNIGE), ESAO – ESOT Joint Session- New challenges in organ replacement. ESAO Congress 2021, 10.09.2021, London, UK
- **"A systematic review of ethical issues of the use of organoids in research and clinical care"** presented by Dide de Jongh (EMC), European Association of Centres of Medical Ethics (EACME), 9-11.09.2021, Cluj-Napoca, Romania
- **"Super-Pancreas"** presented by Ekaterine Berishvili (UNIGE), Specialty Update Symposium-What is new in the translational pipeline? 20th Congress of ESOT, 29.08.2021, Milan, Italy
- **"Generation of Endocrine Pancreas Using Placental Derivatives"** presented by Ekaterine Berishvili (UNIGE), State-of the-Art session- Cell and Biomaterials based Technologies in GI Bioengineering: Approaching the Bedside. ISCT 2021, 28.05.2021, New Orleans, online
- **"Generation of a bioartificial pancreas for type 1 diabetes"** presented by Ekaterine Berishvili (UNIGE), La néphrologie du futur" symposium, 15.04.2021, Lyon, France

Scientific Posters

- **"Definition and optimization of new protocol for chimeric spheroids generation to bioengineer a bioartificial human pancreas (hBAP) for type 1 diabetes"** scientific poster by Francesco Campo, Cataldo Pignatelli, Matteo Monieri, Alessia Neroni, Federica Casalnuovo, Fanny Lebreton, Kevin Bellofatto, Ekaterine Berishvili Berney, Cristina Olgasi, Antonia Follenzi, Silvia Pellegrini, Antonio Citro, Lorenzo Piemonti, PhD Meeting 2023 in Mario Negri Institute, 29-30.06.2023, Milano, Italy
- **"Definition and optimization of new protocol for chimeric spheroids generation to bioengineer a bioartificial human pancreas (hBAP) for type 1 diabetes"** scientific poster by Francesco Campo, Cataldo Pignatelli, Matteo Monieri, Alessia Neroni, Federica Casalnuovo, Fanny

Lebreton, Kevin Bellofatto, Ekaterine Berishvili Berney, Cristina Olgasi, Antonia Follenzi, Silvia Pellegrini, Antonio Citro, Lorenzo Piemonti, Ospedale San Raffaelle scientific retreat 2023, 08-11.03.2023, Baveno, Italy

- **"Early-phase clinical trials of bio-artificial organ technology: a systematic review of ethical issues"** scientific poster by Dide de Jongh (EMC), 12th EPITA Symposium, 22-24.01.2023, Innsbruck-Igls, Austria
- **"Early-phase clinical trials of bio-artificial organ technology: a systematic review of ethical issues"** moderated scientific poster presented by Dide de Jongh (EMC), European Cell Therapy and Organ Regeneration Section (ECTORS) 3rd Meeting, 29.09.2022, Rotterdam, The Netherlands
- **"In vitro generation and characterization of human bioartificial pancreas for type 1 diabetes treatment"** scientific poster by Cataldo Pignatelli, Federica Casalnuovo, Francesco Campo, Alessia Neroni, Fanny Lebreton, Kevin Bellofatto, Ekaterine Berishvili, Cristina Olgasi, Antonia Follenzi, Silvia Pellegrini, Antonio Citro, Lorenzo Piemonti, Ospedale San Raffaelle scientific retreat, 10-12.01.2022, Baveno, Italy
- **"A systematic review of ethical issues in organoids research for use in transplantation"** scientific poster by Dide de Jongh (EMC), presented at the 20th Congress of ESOT, 29.08.2021, Milan, Italy

VANGUARD ethics workshop: Erasmus MC organised a VANGUARD Ethics Workshop titled "Ethics of early clinical trials in regenerative medicine in transplantation" in February 2022 (M26) to discuss research ethics issues (first-in-human trials, handling of sensitive human data and samples, returns of individual research results and incidental findings) as well as ethical issues associated with future clinical implementation of the VANGUARD bioartificial pancreas in particular, and regenerative medicine in the field of organ transplantation in general.

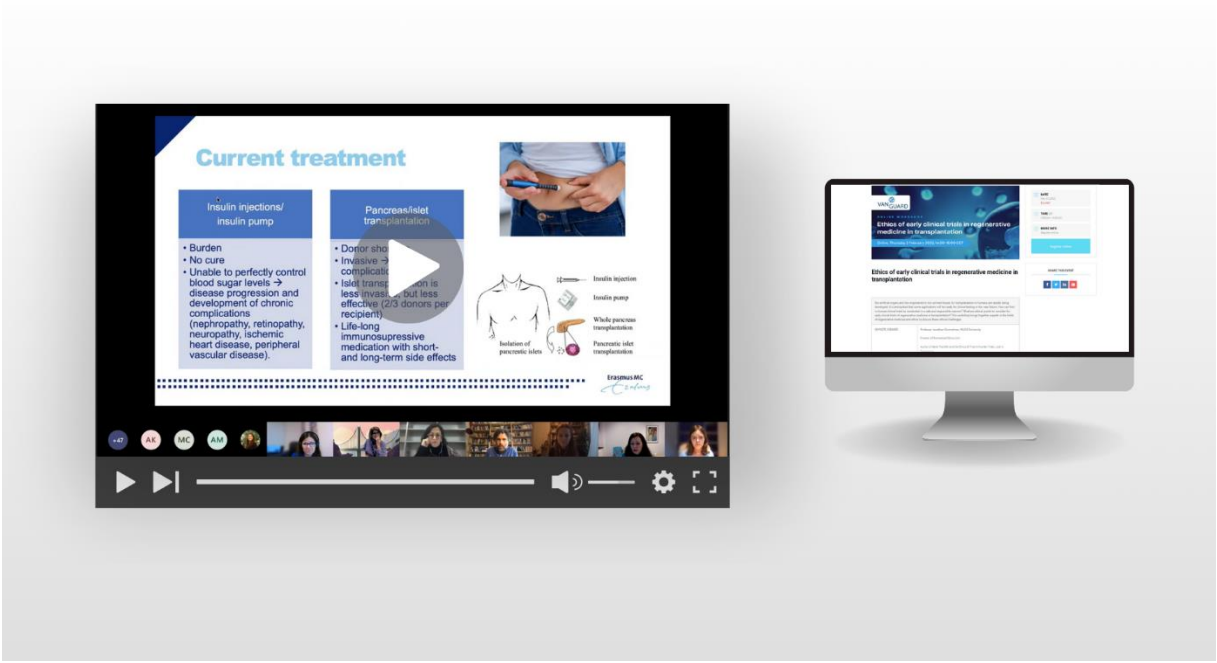


Figure 11: Screenshots from the ethics workshop recording (left) and the events page (right)

The 2-hour workshop consisted of presentations from an invited keynote speaker, showcases of regenerative medicine applications by three EU Horizon 2020 projects (VANGUARD, OrganTrans and BraV3) as well as a panel discussion. This virtual workshop brought together 74 participants and experts in the fields of regenerative medicine and ethics and the recording is available on the VANGUARD YouTube channel as well as ESOT's own platform.

Together We Win Workshop: as part of the 12th EPITA Symposium, VANGUARD partners KUGELMEIERS and Erasmus MC organised a workshop in form of a roundtable lunch session titled *Together we win - combine European resources to tackle regulatory hurdles towards islet-cell ATMPs*. This event hosted on January 24, 2023, welcomed 20 representatives from the scientific community and provided a platform for experience exchange in their research on pancreas and islet transplantation from the regulatory perspective. In particular, the participants identified common problems and discussed possible solving strategies for regulatory, law and ethical questions.

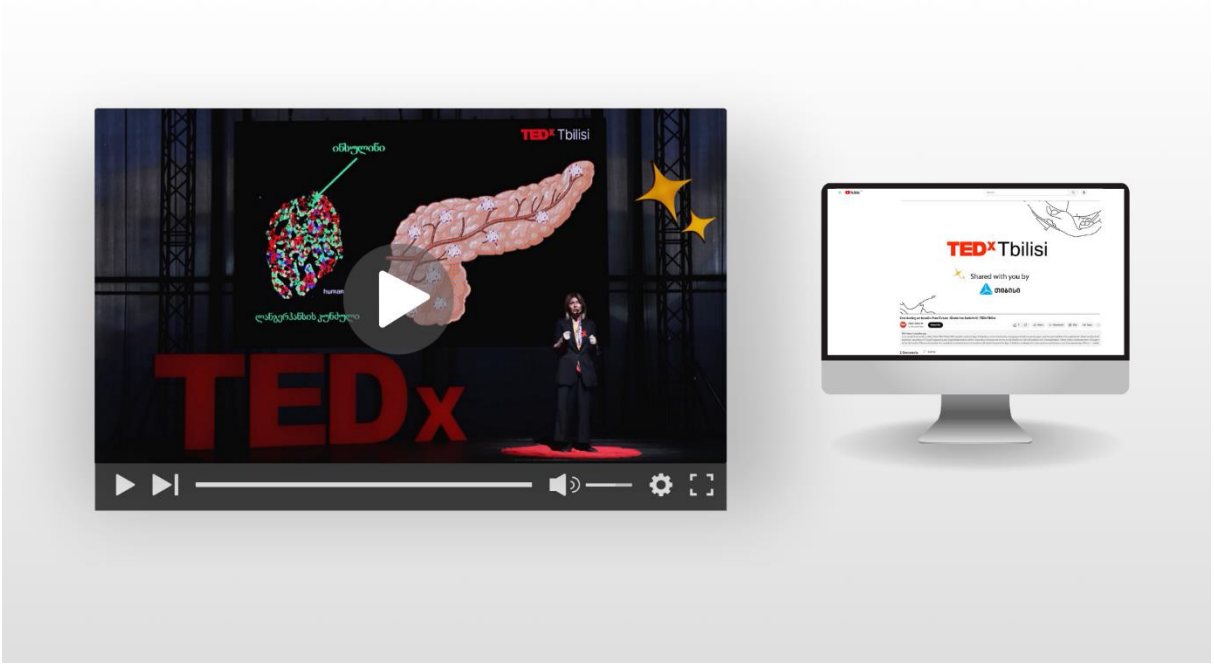


Figure 12: Screenshot from the VANGUARD TEDx talk by VANGUARD coordinator, Ekaterine Berishvili

TEDxTbilisi: The VANGUARD coordinator, Ekaterine Berishvili presented the VANGUARD project in form of a TEDx talk titled *Envisioning an Insulin-Free Future* as part of *Defining Moments* theme. This talk held on April 22, 2023, in Tbilisi, Georgia, was given in Georgian at a standard TEDx event organised by local licensed event coordinators for a wide range of local residents using the TED conference format. To date, the video of the TEDx Talks recording uploaded in July 2023 (M43) has been viewed 950 times.

Assessment:

By the end of the M48, 39 conference participations have already been recorded, exceeding the set target of 10 conference contributions by the end of the project. This is thanks to the remarkable research activities of the partners and their willingness to present their results and share with the scientific community. Moreover, further results will become available in the later stages of the project generating more opportunities for dissemination activities.

The effectiveness of the project event is assessed by tracking the number of participants/audiences reached in an event and their level of satisfaction – where possible – which is measured via feedback surveys. At present, the VANGUARD TEDxTbilisi event has engaged an audience of at least 950 individuals. The 74 participants who joined for the VANGUARD Ethics Workshop exceed expectations from the evaluation metrics defined in the SEDEP (20 participants).The recording of the ethics workshop available on YouTube has received 128 views. Additionally, a publication on the results and discussions from the workshop titled *Organoids: a systematic review of ethical issues* was developed by Erasmus MC which was published in July 2022 (M31) in Stem Cell Research & Therapy. The workshop Together We Win during the EPITA Symposium has gathered 20 participants from scientific community as expected.

3.3.2 Publications

The academic partners in VANGUARD have already led several publications in peer-reviewed journals (see Table 1). Currently, 25 VANGUARD publications have been published and further publications are planned. The up-to-date list of all VANGUARD publications is published on the project website's outcomes page.

Table 1. VANGUARD Publications

No.	Title	Lead	Journal	Published
1	Targeting Toll-Like Receptor 4: a promising strategy to prevent type 1 diabetes occurrence or recurrence	Alibashe-Ahmed M. , Berney T. , Giovannoni L. , Berishvili E.	CellR4 2022	27.05.2020
2	Immunomodulatory Properties of Amniotic Membrane Derivatives and Their Potential in Regenerative Medicine	Wassmer CH, Berishvili E.	Current Diabetes Reports, 2020	10.06.2020
3	Treatment of COVID-19 Pneumonia: the Case for Placenta-derived Cell Therapy	Berishvili E, Kaiser L, Cohen M, Berney T, Scholz H, Floisand Y, Mattsson J.	Stem Cell Reviews and Reports, 2020	21.07.2020
4	Engineering of Primary Pancreatic Islet Cell Spheroids for Three-dimensional Culture or Transplantation: A Methodological Comparative Study	Wassmer CH, Bellofatto K, Perez L, Lavallard V, Cottet-Dumoulin D, Ljubicic S, Parnaud G, Bosco D, Berishvili E, Lebreton F.	Cell Transplantation, 2020	04.08.2020
5	Generation of insulin-secreting organoids: a step toward engineering and transplanting the bioartificial pancreas	Wassmer CH, Lebreton F, Bellofatto K, Bosco D, Berney T, Berishvili E.	Transplant International, 2020	27.08.2020
6	I've got you under my skin	Berney T, Berishvili E.	Nature Metabolism, 2020	07.09.2020
7	Organoïdes sécréteurs d'insuline : des «super-îlots» comme premier pas vers le pancréas bioartificiel[1]	Lebreton F, Wassmer CH, Bellofatto K, Berney T, Berishvili E.	Medical Sciences, 2020	07.10.2020
8	Mechanisms of Immunomodulation and Cytoprotection Conferred to Pancreatic Islet by Human Amniotic Epithelial Cells	Lebreton F, Hanna R, Wassmer CH, Bellofatto K, Perez L, Othenin-Girard V, de Tejada BM, Cohen M, Berishvili E.	Stem Cell Reviews and Reports, 2021	06.10.2021
9	Efficient and safe correction of hemophilia A by lentiviral vector-transduced BOECs in an implantable device	Olgasi C, Borsotti C., Merlin S, Bergmann T, Bittorf P, Adewoye A B, Wragg N, Patterson K, Calabria A, Benedicenti F, Cucci A, Borchiellini A, Pollio, B, Montini E., Mazzuca D M,	Molecular Therapy - Methods & Clinical Development, 2021	10.12.2021

[1] The editor's correction, where the acknowledgment of the project was included, was added to another issue of the journal (see erratum at the bottom of page 9).

		Zierau M, Stolzing A, Toleikis P, Braspenning J, Follenzi A.		
10	Bio-Engineering of Pre-Vascularized Islet Organoids for the Treatment of Type 1 Diabetes	Wassmer CH, Lebreton F, Bellofatto K, Perez Lisa, Cottet-Dumoulin D, Andres A, Bosco D, Berney T, Othenin-Girard V, Martinez de Tejada B, Cohen M, Olgasi C, Follenzi A, Berishvili E.	Transplant International, 2022	21.01.2022
11	Advances and challenges of endocrine pancreas bioengineering	Hanna R, & Berishvili E	Current Opinion in Endocrine and Metabolic Research, 2022	01.04.2022
12	Ethics of Early Clinical Trials of Bio-Artificial Organs	de Jongh D, Massey EK, Bunnik EM	Transplant International, 2022	06.07.2022
13	Organoids: a systematic review of ethical issues	de Jongh D, Massey EK, the VANGUARD consortium, Bunnik EM	Stem Cell Research & Therapy, 2022	23.07.2022
14	Bioengineering the Vascularized Endocrine Pancreas: A Fine-Tuned Interplay Between Vascularization, Extracellular-Matrix-Based Scaffold Architecture, and Insulin-Producing Cells	Pignatelli C, Campo F, Neroni A, Piemonti L, Citro A	Transplant International, 2022	25.08.2022
15	From islet of Langerhans transplantation to the bioartificial pancreas	Berney T, Wassmer CH, Lebreton F, Bellofatto K, Mar-Fonseca L, Bignard J, Hanna R, Peloso A, Berishvili E.	La Presse Médicale, 2022	03.10.2022
16	Early-Phase Clinical Trials of Bio-Artificial Organ Technology: A Systematic Review of Ethical Issues	Dide de Jongh, Emma K. Massey, Antonia J. Cronin, Maartje H. N. Schermer, Eline M. Bunnik and the VANGUARD Consortium	Transplant International, 2022	31.10.2022
17	Formation of Re-Aggregated Neonatal Porcine Islet Clusters Improves In Vitro Function and Transplantation Outcome	Honarpisheh M, Lei Y, Zhang Y, Pehl M, Kemter E, Lange A, Wolf E, Wolf-van Buerck L, VANGUARD consortium, Seissler S	Transplant International, 2022	22.12.2022
18	Generation of Prevascularized Endocrine Constructs to Treat Type 1 Diabetes	Bellofatto K, Lebreton F, Wassmer CH Fonseca L, Hanna R, Berishvili E.	Transplantation, 2022	09.2022
19	Therapeutic potential of fetal liver cell transplantation in hemophilia A mice	Merlin S, Akula S, Cottonaro A, Garcia-Leal T, Serrano LJ, Borroni E, Kalandadze V, Galiano R, Borsotti C, Liras A, Sanchez MJ, Follenzi A.	Haematologica, 2023	26.01.2023
20	Guidelines to Analyze Preclinical Studies Using Perinatal Derivatives	Pires AS, Bollini S, Botelho MF, Lang-Olip I, Ponsaerts P, Balbi C, Lange-Consiglio A, Fénelon M, Mojsilović S, Berishvili E, Cremonesi F, Gazouli M, Bugarski D, Gellhaus A, Kerdjoudj H, Schoeberlein A.	Methods and Protocols, 2023	25.04.2023

21	Legal and Regulatory Challenges for Emerging Regenerative Medicine Solutions for Diabetes	Thom RL, Cronin AJ, VANGUARD Consortium.	Transplantation, 2023	26.09.2023
22	Clinical Translation of Bio-Artificial Pancreas Therapies: Ethical, Legal and Psychosocial Interdisciplinary Considerations and Key Recommendations	de Jongh D, Thom RL, Cronin AJ, Bunnik EM, Massey EK.	Transplant international, 2023	18.09.2023
23	Hydrogel-based, prevascularized, retrievable endocrine construct to treat Type 1 Diabetes	Bellofatto K, Lebreton F, Hanna R, Fonseca L M, Bignard J, Galvan V, Peloso A, Berney T, Compagnon Ph, VANGUARD Consortium, Berishvili E.	Transplantation, 2023	10.2023
24	Vascularized endocrine pancreas for type 1 diabetes	Bellofatto K, Lebreton F, Fonseca L M, Hanna R, Bignard J, Galvan V, Peloso A, Berney T, Compagnon Ph, VANGUARD Consortium, Berishvili E.	Transplantation, 2023	10.2023
25	Regulatory Challenges at the Intersection of Cellular and Medical Device Therapies in Europe: The Case of the Bioartificial Pancreas	Cronin AJ, Thom RL.	Law, Technology and Human, 2023	21.11.2023

Assessment:

With 24 peer-reviewed and 1 non-peer-reviewed publications published and additional manuscripts currently in review and being planned, the partners are well on track to reaching the set target of 25 expected peer-reviewed manuscripts by the end of the project, especially considering that more publications are expected towards the later stages of the project when further results become available.