Project No. 101045956
Biomarker and AI-supported FX06 therapy to prevent progression from mild and moderate to severe stages of COVID-19

Deliverable 8.7

COVend cluster event

WP8 – Communication, dissemination & exploitation

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Revision history

Date	Authors	Revision
05/03/2025	Anastasiia Aksonova (accelCH)	Draft version
10/03/2025	Petra Wuelfroth (F4)	Revision
11/03/2025	Anastasiia Aksonova (accelCH)	Final version

Contents

Partner short names

GUF	Johann Wolfgang Goethe Universität Frankfurt am Main
accelCH	accelopment Schweiz AG
ESAIC	European Society of Anaesthesiology and Intensive Care
Fraunhofer	Fraunhofer Institute for Translational Medicine and Pharmacology ITMP
F4	F4 Pharma GmbH
TAU	Tampereen Korkeakoulusaatio SR
UCD	University College Dublin
UMCG	Universitair Medisch Centrum Groningen
MiDA	Medical Intelligent Data Analytics GmbH
UHW	University Hospital Würzburg
UNIPG	Universita degli Studi di Perugia
KC	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
ICS-HUB	Hospital Universitari de Bellvitge
UMFCD	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
CHUC	Centro Hospitalar e Universitario de Coimbra E.P.E.
APHP	Assistance Publique – Hôpitaux de Paris
MUMC	Maastricht University Medical Center+

Abbreviations

CEO	Chief Executive Officer
D	Deliverable
DCP	Plan for dissemination including communication activities
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EU	European Union
HEU	Horizon Europe
ICU	Intensive care unit
KPI	Key Performance Indicator
RBD	Receptor binding dimer
REA	Research Executive Agency
RSV	Respiratory syncytial virus
WHO	World Health Organisation

Executive Summary

This document represents Deliverable D8.7 from Work Package (WP) 8 Communication, dissemination & exploitation – COVend cluster event. It provides a comprehensive overview of the preparatory measures, event implementation and key conclusions, along with potential future collaborations that could enhance pandemic preparedness and advance effective therapeutic interventions for diseases related to or similar to COVID-19. These insights are based on the connections established with cluster projects during the event.

The report details the networking opportunities, knowledge exchanges and shared resources that emerged, as well as the future potential partnerships fostered through this initiative. It highlights key learnings from this collaborative effort, emphasising the impact of cross-project cooperation in strengthening the European Union's response to the COVID-19 pandemic.

The cluster event was designed to facilitate experience-sharing and knowledge exchange among EU-funded initiatives focused on COVID-19 research and innovation. Its preparation, execution and follow-up measures are documented in this publicly available report.

1 Introduction

The collaborative efforts among projects funded under the Horizon Europe call "HORIZON-HLTH-2021-CORONA-01" aim to enhance coordination and synergy in developing effective COVID-19 therapeutics. By fostering cooperation, these initiatives accelerate therapeutic development, optimise resource usage and facilitate knowledge sharing, ensuring a more efficient and streamlined approach. Collaboration also helps avoid duplication of efforts by exchanging lessons learned, identifying barriers and facilitators and strengthening cross-project cooperation. Moreover, interdisciplinary collaboration enhances knowledge transfer and data sharing in line with open science principles.

The COVend project has demonstrated its commitment to cross-consortium cooperation, experience exchange and open discussions by actively engaging in collaborative networks. This commitment was exemplified by the strategic organisation and execution of the cluster event "Highway to Health" in July 2023, which brought together other projects funded under the same initiative. The event featured a roundtable discussion, where key lessons learned and future directions were explored.

This report provides detailed insights into the event's preparation, execution and outcomes, as well as potential future collaborations that could strengthen pandemic preparedness and advance therapeutic interventions for diseases related to or similar to COVID-19.

2 Highway to Health Cluster & Policy Event

On 4 July 2023, the two project consortia of COVend and ENVISION, held a joint Cluster and Policy Event at the Representation of the State of Hesse to the EU in Brussels, Belgium. The Highway to Health Cluster & Policy Event was attended by over **50 stakeholders**, including policymakers, health authorities, clinicians and researchers. The aim was to review the scope and benefits of COVID-19 interventions, strengthen preparedness for potential future pandemics and identify ways to improve health systems

2.1 Preparation

2.1.1 Participants

The preparation phase began with the identification of potential participants and the establishment of contact with relevant stakeholders. The cluster projects were selected based on their alignment with the Horizon Europe call HORIZON-HLTH-2021-CORONA-01, ensuring a strong focus on advancing COVID-19 therapeutics and pandemic preparedness.

On 7 April 2021, the European Commission launched an emergency request for expressions of interest, marking the first such initiative under Horizon Europe. This call aimed to mobilize EU-funded research and innovation efforts to combat COVID-19 and mitigate the impact of emerging coronavirus variants. It was part of the broader European bio-defence preparedness strategy, HERA Incubator. A total of 11 projects involving 312 research teams from 40 countries were selected, addressing four key areas of the emergency call:

Acronym	Title	Lead partner	Partners
VACCINES & THERAPEUTIC CLINICAL TRIALS TO BOOST COVID-19 PREVENTION AND TREATMENT – EU funding: € 57 million			
ECRAID-PRIME	European Clinical Research Alliance on Infectious Diseases - PRIMary care adaptive platform trial for pandemics and Epidemics	Universitair Medisch Centrum Utrecht (NL)	4 partners: BE, FR, NL, UK
XVR011 Phase 2	ExeVir's XVR011, a best in class nanobody-based biology that broadly neutralizes SARS-COV-1 and SARS-COV-2	ExeVir Bio (BE)	5 partners: BE, DE, FR, IE
RBDCOV	RBD Dimer recombinant protein vaccine against SARSCoV2	HIPRA Scientific (ES)	13 partners: BE, DE, ES, IT, TR, UK
EPIC-CROWN-2	Equine Polyclonal antibodies Immunotherapy against COVID-19/SARS-CoV2–VOC	Fabentech (FR)	5 partners: DE, EL, ES, FR
iMPact	Novel, orally available immune modulator MP1032 with anti-SARS-CoV-2 and anti-cytokine activity	MetrioPharm AG (CH)	4 partners: AT, CH, DE, NL
COVend	Biomarker and AI-supported FX06 therapy to prevent progression from mild and moderate to severe stages of COVID-19	Johann Wolfgang Goethe Universitaet Frankfurt-am-Main (DE)	18 partners: AT, BE, CH, DE, ES, FI, FR, IE, IT, LT, NL, PT, RO, SI,

Figure 1. 6 out 11 projects funded under the HORIZON-HLTH-2021-CORONA-01, part of the HERA Incubator preparadness strategy

- **Clinical trials for therapeutics and vaccines** to boost COVID-19 prevention and treatment and further inform public health policy and clinical management.
- **Cohorts united against COVID-19 variants of concern** supporting activities that are enabling or contributing to the development of large scale, COVID-19 cohorts and networks worldwide, including beyond Europe's borders, forging links with European initiatives as a global response to the pandemic.
- **FAIR and open data sharing in support to European preparedness** for COVID-19 and other infectious diseases, to further develop and integrate platforms for the sharing of relevant research resources
- **Research infrastructure services for rapid research responses** to COVID-19 and other infectious disease epidemics, to set up and provide access to a comprehensive portfolio of relevant services

Through our outreach efforts, we successfully established contact and invited key cluster projects to participate in the event. These projects represent cutting-edge research and innovation in COVID-19 therapeutics and pandemic response:

1. **RBDCOV**: RBD Dimer recombinant protein vaccine against SARSCoV2
2. **XVR011 Phase 2**: ExeVir's XVR011, a best in class nanobody-based biology that broadly neutralizes SARS-COV-1 and SARS-COV-2
3. **EPIC-CROWN-2**: Equine Polyclonal antibodies Immunotherapy against COVID-19/SARS-CoV2–VOC

4. **iMPact**: Novel, orally available immune modulator MP1032 with anti-SARS-CoV-2 and anti-cytokine activity
5. **MOOD**: data-driven tools to tackle emerging health threats

Beyond the cluster projects, we engaged key representatives from European institutions, ensuring a comprehensive perspective on research progress, challenges, and policy frameworks. Ulla Närhi (Health Emergency Preparedness and Response, HERA), Patricia Urban-Lopez (Policy Officer at the EC), Andreas Holtel (Scientific Officer at the European Research Executive Agency, REA)
were invited to share their insights.
These experts provided valuable feedback on project progress, discussed challenges in research and clinical trials, and offered strategic guidance for overcoming barriers in therapeutic development. Additionally, given the policy relevance of the event, distinguished policymakers were invited to contribute to discussions on research infrastructure and healthcare innovation:

- Dr. Cristian-Silviu Buşoi, Member of the European Parliament.
- Dr. Alexandru Rogobete, Secretary of State at the Ministry of Health.

Their participation added political and regulatory perspectives, emphasising the importance of policy support for research funding, infrastructure development, and cross-border collaboration in pandemic preparedness.

Figure 2. Speaker profiles of Ulla Närhi, Patricia Urban-Lopez and Andreas Holtel

2.1.2 Agenda

When reaching out to potential event participants, we provided them with a preliminary agenda, inviting them to take part in designated session slots. Upon receiving their confirmations, we finalised the agenda, shaping it into the format shown in Figure 3. The key sessions included:

- **EU Initiatives: How Can We Prepare for Future Pandemics?**
  A **panel discussion** moderated by Dr. Jeanette Müller focusing on the role of EU initiatives in pandemic preparedness.
- **Vaccines, Therapies, and Digital Technologies: What Have We Learned to Face Future Pandemics?**
  Moderated by Dr. Petra Wülfroth, this session features a series of five cluster **project pitch talks**.
- **Secure and Sustainable Infrastructure for Research and Innovation: How to Improve Health, Society, and Economics in the EU**

Figure 3. Highway to Health cluster event programme

This **panel discussion**, chaired by Prof. Dr. Dr. Kai Zacharowski, brings together key experts, including invited policy representatives.

In addition to the panel discussions and pitch talks, we incorporated presentations from the COVend coordinator and consortium partners to provide deeper insights into the project.

To foster collaboration and knowledge exchange, we also introduced networking sessions in the form of a Projects Road Tour—a dedicated poster exhibition showcasing the participating cluster projects, along with posters from additional projects that were not present at the event. This format allowed participants to gain a broader perspective on the COVID-19 research landscape, explore various initiatives, and engage in in-depth discussions on project objectives, findings, and potential synergies.

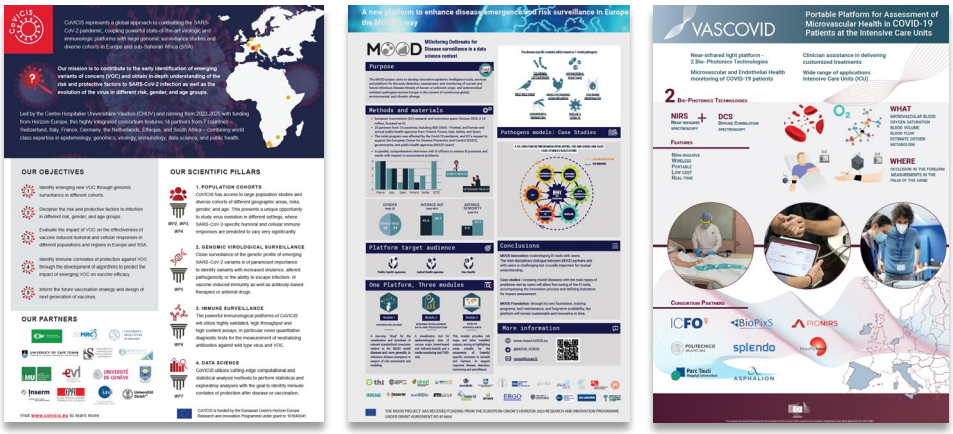

Figure 4. Some of the posters of the cluster projects displayed at the dedicated poster exhibition at the event

2.1.3 Promotional aids

We began our preparations by developing a comprehensive plan that outlined all the essential elements required for implementation to be tracked. To maximise our outreach efforts and promote the event effectively, we created a variety of promotional materials to be used during the preparatory, implementation and follow-up phases. These included:

- A **project poster** displayed alongside posters for other projects at the poster exhibition.
- An **event banner** prominently displayed at the event location in the photo area.
- An 8-page **brochure** featuring the event programme, infographics on the EU-funded projects landscape, participant profiles and information on the COVend and ENVISION projects, along with details about their digital channels. These brochures were distributed to attendees at the event start.
- Branded **name tags and slides**.
- A **pre-event social media campaign** highlighting speakers, the agenda, discussion topics, and more.
- **Social media live-posting** during the event onto the LinkedIn and Twitter channels.
- **Website news posts**.

These outreach efforts were further supported by participants' online networks, which actively engaged with and shared content across their projects' and institutions' social media channels and websites.

As the event was also streamed online, we actively promoted online registration to ensure it was accessible to those who couldn't attend in person.

Speaker/Guest			Role	Topic	Invitation		
Name	Position	Contact	Guest or Speaker?	Programme slot	Sent by	When	Reply (dropdown)
Alexandru Rogobete	Secretary of State at the Ministry of Health (Romania)	alexandru.rogobete@ms.ro, cor	Speaker	Policy Rountable	Elina	6/7/2023	Ready to participate
Cristian Dudu		cristian.dudu@ms.ro			Elina	5/22/2023	Pending
Nika Rituema	BE-READY project	jasurveillance@rivm.nl	Speaker	Cluster (EU initiatives for pandemic preparedness) + panel discussion	Anastasiia	6/1/2023	Pending
	ECRAID organisation	info@ecraid.eu	Speaker	Ploicy (The main current challenges in the treatment and management of infectious diseases) + Round Table	Anastasiia	6/2/2023	Pending
	BeYond-COVID project	by-covid-admin@elixir-europe.	Speaker	Cluster (Pitch talks - Data) or Policy - Round table	Anastasiia	6/3/2023	Pending
	ISIDORE project	contact@isidore-project.eu	Speaker	Cluster - Fighting COVID-19 – key results of European initiatives + Panel discussion	Anastasiia	6/4/2023	Pending
	VEO project	m.koopmans@erasmusmc.nl	Speaker	Cluster - Pitch talks - Data + Panel Discussion	Anastasiia	6/5/2023	Pending
Expert to be defined	MOOD project		Speaker	Policy Roundtable (science policy interface and decision making in France and Finland)	Anastasiia	6/6/2023	Ready to participate
Dub Timothe	MOOD project	mood@cirad.fr	Speaker	Cluster - Pitch talks - Data + Panel Discussion	Anastasiia	6/6/2023	Ready to participate
Dear Prof. Dr. Hans-Georg Kräusslich, Dear Prof. Dr. Dirk Heinz	NA-PATH initiative	hans-georg.kraeusslich@med.uni-heidelberg.de	Speaker	Policy - "The main current challenges in the treatment and management of infectious diseases" + Round table	Anastasiia	6/7/2023	Pending
Sareema, Keiko	JAAM, TCB	keiko.ueda@ecrin.org, Sareema.JAWAD@ecrin.org	Support in finding speakers		Anastasiia	6/8/2023	Pending
Ali, Ruth	CCB	ruthjoanna.davis@univr.it;, ali.judd@ucl.ac.uk	Support in finding speakers	Policy Rountable	Elina	5/6/2023	Pending

Legend
CLUSTER Registered
POLICY COVend cluster

Speaker/Guest				Role	Programme		Invitation			Comments
Name	Project/Organisation	Position	Contact	Guest or Speaker	Programme slot	Topic	Sent by	When	Reply (dropdown)	
Alexandru Rogobete	Ministry of Health (Romania	Secretary of State at the Ministry of Health (Romania)	alexandru.rogobete	Speaker	Policy	Policy Rountable	Elina	6/7/2023	Ready to participate	
Diana Stepanyan	ISIDORe	Director of External Affairs, European Research Infrastructure on Highly Pathogenic Agents (ERINHA)	diana.stepanyan@erinha.eu audrey.richard@erinha.eu jonathan.ewbank@erinha.eu	Speaker	Cluster	"EU initiatives for pandemic preparedness" - they proposed	Anastasiia	6/4/2023	Ready to participate	1) They are waiting for our reply 2) NOT COVERING COSTS - TO EXPLAIN
Dub Timothe	MOOD project	Research manager Infectious Disease Control and Vaccinations Unit Department of Health Security Finnish Institute for Health and Welfare	Timothee.Dub@thl.	Speaker	Cluster	"broad presentation of the MOOD project"	Anastasiia	6/6/2023	Ready to participate	1) NOT COVERING COSTS - TO EXPLAIN 2) +1 more speaker?
Wolfgang Brysch	iMPact	CEO at MetrioPharm AG (Chief Scientific Officer, Chief Medical Officer	POC - Stefanie Klare s.klare@metriopharm.com	Speaker	Policy	Would like to present the results of the clinical trial (?) panel discussion " Secure and sustainable infrastructure for research and innovation in health, data science, society, and economics in the European Union"	Anastasiia, Serena	6/5/2023	Ready to participate	1) Elina: I called his PM today, they will let us know more until next Friday. contact point: Stefanie Klare (s.klare@metriopharm.com 2) NOT COVERING COSTS - TO EXPLAIN
Cristian-Silviu Buşoi	European Parliament, Industry & Public Health		cristiansilviu.busoi @europarl.eu; cristina-mihaela.semanaru @europarl.europa.eu	Speaker (very important for chef)	Policy	Policy Roundtable	Elina	7/6/2023	Ready to participate	OK
Anaïs BELLEDANT	EPIC-CROWN-2 project	Representative	anais.belledant@fa berdech.com> ;	Speaker	Cluster	Cluster Pitch talks + Panel Discussion	Serena	6/6/2023	Ready to participate	1) They are waiting for our reply 2) NOT COVERING COSTS - TO EXPLAIN
Karin van Beek, Marko	ECRAID-Prime (Press Office)	Representatives	karin.vanbeek@ecraid.eu m.markov@umcutrecht.nl	Support in finding	Cluster	Cluster Pitch talks + Panel Discussion	Anastasiia	6/7/2023	To follow up	1) We are waiting for their reply 2) NOT COVERING COSTS - TO EXPLAIN

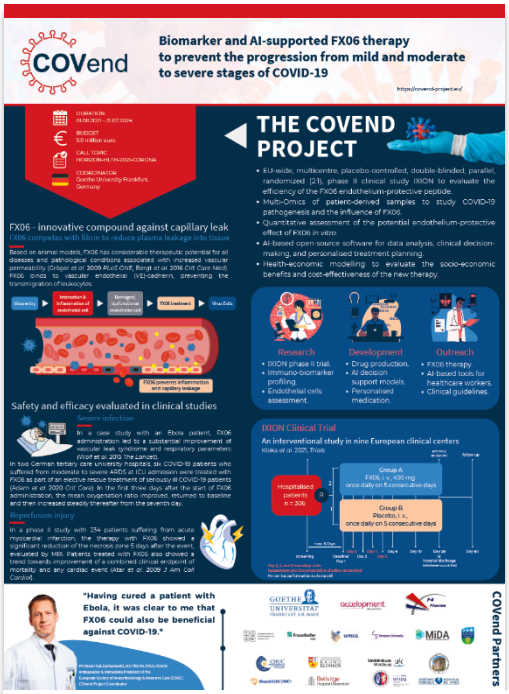

Figure 5. Higheay to Health cluster event preparatory and promotional materials: planning tools (top), COVend poster (bottom right), brochure (centre), examples of social media posts of a dedicated sociel media campaign (bottow right)

2.2 Implementation

The Highway to Health event took place on Tuesday, 4 July 2023, starting at 16:00 and continuing into the evening. Hosted at the Hessian Representation, the event provided a platform for discussions on European healthcare, pandemic preparedness, and the role of research and innovation in strengthening health systems. The programme featured expert panels, project presentations, and networking opportunities, engaging participants from various disciplines. The online audience were able to join the event and engage with the speakers as well.

Detailed Programme

16:00 – Registration & Refreshments

The event began with a registration and welcome session, allowing participants to check in, network and engage informally before the main discussions commenced.

16:30 – Visions in European Healthcare: Welcome to the Hessian Representation

The formal proceedings started with a welcome address by:

- Mr. Axel Wintermeyer
- Prof. Dr. Dr. Kai Zacharowski

This session set the stage for discussions on the evolving landscape of European healthcare policies, innovation and future priorities.

16:40 – EU Initiatives: How Can We Prepare for Future Pandemics?

A panel discussion moderated by Dr. Jeanette Müller focused on the role of EU initiatives in pandemic preparedness. The discussion featured insights from:

- Dr. Patricia Urban Lopez
- Dr. Ulla Närhi
- Dr. Andreas Holtel

The European Commission representatives Dr. Patricia Urban Lopez and Dr. Ulla Närhi highlighted the role of the EU on pandemic preparedness. They noted that to achieve these objectives the following needs to be done: include science closely in the priority setting and decision-making for the response, use existing instruments for funding where feasible, improve coordination on clinical trial infrastructure at the EU level, commit to sustain strong regional clinical trial networks, sustain the trial network infrastructure during peace time, establish a platform for open data sharing during and outside pandemics, coordinate funding from multiple sources, and have a quick, effective, and coordinated funding mechanism in place when the pandemic hits.

Figure 6. Photos of Patricia Urban-Lopez and Ulla Närhi giving their presentations at the Highway to Health cluster event. Copyright for images: © Landesvertretung Hessen in Brüssel / Bernal Revert.

Followed by these presentations, the panel explored lessons from previous health crises and strategies to strengthen future pandemic response mechanisms. Dr. Jeanette Müller, charing the discussion with Dr. Patricia Urban Lopez, Dr. Ulla Närhi and Dr. Andreas Holtel, opens it with a look back at the pandemic and the important role the EU ecosystem plays in pandemic preparedness, looking at the various initiatives and existing frameworks that stakeholders have put in place to be better prepared in the future.

The talk provided valuable insight into the EU initiatives for pandemic preparedness. HERA was currently working on improving the preparedness for future pandemics, stressing the importance of cooperation between member states, and providing a call to action for the scientific and healthcare community to become involved in research and policy-making. It was highlighted that networks that are enactable in times of crisis, realistic structural thinking for the setup and maintenance of the networking, and follow-up activities in terms of feedback from agencies are all necessary.

Figure 7. Photo collage from Highway to Health – Policy and Cluster Event 2023 Copyright for images: © Landesvertretung Hessen in Brüssel / Bernal Revert.

17:25 – Highway to Health: Contribution of ENVISION and COVend

Presented by Prof. Dr. Dr. Kai Zacharowski, this session highlighted the contributions of the ENVISION and COVend projects. The discussion focused on their role in pandemic preparedness, therapeutic advancements, and collaborative research efforts.

17:40 – Vaccines, Therapies, and Digital Technologies: What Have We Learned to Face Future Pandemics?

Moderated by Dr. Petra Wülfroth, this session featured a series of five project pitch talks, each lasting 10 minutes. Speakers shared insights on how vaccines, treatments and digital health solutions can contribute to pandemic response and preparedness.

Figure 8. Graphic for Meet the Speakers from the event brochure profiling RBDCOV project coordinator, Ellia Torroella

The **RBDCOV** project aims to test the efficacy and safety of the HIPRA vaccine against COVID-19 in clinical trials. The goal is to develop a recombinant protein-based vaccine that can be licensed in Europe. The focus of the project is to generate robust data to demonstrate the safety of the vaccine and its ability to elicit a strong and durable immune response, particularly against novel variants. It also addresses challenges such as adaptation to different populations, including children, adolescents and immunocompromised individuals, and the development of a booster dose for future vaccination programmes. The project involves 12 partners and aims to engage European stakeholders. Elia Toroella gave an overview of her work on a new recombinant protein vaccine containing a receptor binding dimer (RBD) against SARS-CoV-2. The vaccine is designed to elicit a strong neutralising immune response and provide a high level of safety. RBDCOV has conducted clinical trials with various populations, including immunocompromised adults and in paediatrics. Dr Toroella highlighted the challenges the project has faced, such as the evolving dynamics of the pandemic and the regulatory framework. Key learnings include building collaborative networks and developing next-generation COVID-19 vaccines.

EPIC-CROWN-2 is a project focused on evaluating the effectiveness of an antiviral immunotherapy using equine antibodies in COVID-19 patients, including those with variant strains. The goal is to reduce ICU admissions and mortality rates. The project involves clinical trials, virology studies, and immune response assessment, coordinated by Fab'entech and collaborating with various institutions. It is part of the European trial network EU-RESPONSE and the multinational platform trial "Solid Act." Anais Belledant presented that EPIC-CROWN-2 is working to produce the antibodies to GMP standards and have demonstrated efficacy against variants of concern in preclinical studies. EPIC-CROWN-2 outlined plans to launch a 400-patient multi-center Phase 2 clinical trial in Q3 2023 to assess the clinical benefits of the antibody treatment called FBR-002. Anais Belledant noted that FBR-002 has shown potent neutralising activity against Delta, Omicron, and other variants of SARS-CoV2 in addition to a favourable safety profile.

Figure 9. Graphic for Meet the Speakers from the event brochure profiling EPIC-CROWN-2 Project Manager, Anais Belledant.

Dr. Timothée Dub
MOOD Project Expert

Timothee is a research manager at the Finnish Institute for Health and Welfare. He is responsible for deputy coordination of the Monitoring Outbreaks for Disease surveillance in a data science context (MOOD) Horizon 2020 project. His work focuses on vector-borne, emerging infectious, and vaccine preventable diseases, and climate change's impact on disease emergence in Finland. He plays an active role in training and supervising junior epidemiologists and promoting collaboration in public health in Europe and neighbouring countries.

Figure 10. Graphic for Meet the Speakers from the event brochure profiling MOOD Project Expert, Timothee Dub.

The **MOOD** project aims to develop innovative tools for the early detection and surveillance of infectious diseases in Europe. It focuses on improving epidemic information systems, data exchange and collaboration between the animal, human and environmental health sectors. The project also emphasises sustainability and ethical standards. With the help of EU funding, data analysis will be used to improve event-based surveillance and support public health authorities. The project plans to establish a non-profit association called MOOD Epi-Platform INPA to ensure the sustainability of the platform and the further development of the epidemiological tools in the long term. Timothee Dub presented the data-driven tools and platform for improved epidemiological education and disease surveillance in Europe and beyond. The approach focuses on co-designing solutions that meet the needs of end users in public and animal health settings. MOOD has developed services to improve access to standardised, queryable datasets for epidemiological studies and early detection of health threats. This is to support epidemiologists and other specialists to better use data for public health. MOOD also outlined plans to unify the Epi platform to ensure long-term sustainability.

ExeVir is a biotechnology company specialising in the development of novel antibody therapeutics to combat viral infections. ExeVir's approach is based on the use of llama antibodies known as nanobodies or VHHs (Variable Heavy Chain Domains of heavy-chain-only antibodies). These nanobodies have advantageous properties such as small size, high stability and the ability to target hard-to-reach sites. Through the use of its nanobody technology, ExeVir is actively involved in the discovery and development of therapeutic solutions for various viral infections, with a particular focus on respiratory syncytial virus (RSV) and other emerging infectious diseases. Its ultimate goal is to provide effective treatments that address unmet medical needs and significantly improve patient outcomes. Through its research and development efforts, ExeVir aims to contribute to the advancement of antiviral therapies and make a significant impact in the field of infectious diseases. Fiona Du Monceau discussed the use of llama nanobodies to develop novel antibody therapies against viruses such as SARS-CoV-2. She explained the advantages of the technology, such as small size, high stability and ability to reach hard-to-reach sites. She further reported on the COVID-19 programme with the antibody XVR011, which is currently in phase 1/2 trials. The company highlights focus areas such as respiratory syncytial virus and underlines its commitment to meeting unmet patient needs.

Ms. Fiona Du Monceau
Chief Operating Officer, ExeVir

Fiona is COO of ExeVir Bio. She brings nearly 20 years of experience in life sciences to the role. Previously, she led various teams at Eli Lilly, launching products across multiple therapeutics areas. She also worked for McKinsey & Company covering healthcare clients in the US and Europe and worked in business development at GSK Biologicals. Fiona has an MBA from Harvard Business School and a MSc in Management from the Solvay Business School.

Figure 11. Graphic for Meet the Speakers from the event brochure profiling ExeVir Chief Operating Officer, Fiona Du Monceau.

Overall, the presentations offered valuable insights into the COVID-19 treatment landscape and showcased European innovations that can help improve preparedness. In the discussion, we could highlight technical challenges, lessons learned and the importance of coordination.

18:40 – Refreshments & Project Road Tour

A break and networking session, where participants had the opportunity to explore ongoing projects at the poster exhibition, discuss ideas with peers and establish potential collaborations.

19:00 – Secure and Sustainable Infrastructure for Research and Innovation: How to Improve Health, Society, and Economics in the EU

This panel discussion, chaired by Prof. Dr. Dr. Kai Zacharowski, brought together key experts, including:

- Dr. Alexandru Rogobete
- Dr. Cristian-Silviu Bușoi
- Dr. Patricia Urban Lopez
- Dr. Ulla Närhi
- Dr. Andreas Holtel
- Ms. Cathy Weynants

The final panel of the event chaired by Prof. Dr. Dr. Zacharowski and attended by the esteemed panelists Dr. Alexander Rogobete, Dr. Patricia Urban Lopez, Dr. Ulla Närhi, Dr. Andreas Holtel, Ms. Cathy Weynants and Dr. Cristian-Silviu Busoi held productive discussions regarding the impact of the current European pandemic and the measures that can be taken with regards to healthcare. It was concluded that remaining proactive and encouraging connectivity and digitalisation will benefit the broader health sector. It was also highlighted that politicians and clinicians need to have a strong network with each other in order to strengthen European healthcare. The panel concluded by presenting hopeful views for the future of European healthcare.

20:00 – Walking Dinner & Networking

The event concluded with an informal networking dinner, providing attendees with the opportunity to continue discussions, build collaborations and reflect on key takeaways from the sessions.

Key Takeaways from the Event

- European healthcare strategies were a focal point, with discussions on policy frameworks and funding opportunities.
- Pandemic preparedness and response remained central, emphasising research collaborations and technological advancements.
- Innovative digital health solutions and therapeutic developments were showcased through project presentations.
- Networking opportunities facilitated interdisciplinary exchange, strengthening ties between researchers, policymakers, and industry stakeholders.

2.3 Results

2.3.1 Panel discussion on EU initiatives for pandemic preparedness

Figure 12. Photo of discussion panel on EU initiatives. From left to right : Jeanette Müller (acceICH), Ulla Närhi (HERA), Patricia Urban-Lopez (Policy Officer), Andreas Holtel (Scientific Officer) © Landesvertretung Hessen in Brüssel / Bernal Revert.

Key points raised by the panellists Ulla Närhi (Health Emergency Preparedness and Response, HERA), Patricia Urban-Lopez (Policy Officer at the EC), Andreas Holtel (Scientific Officer at the European Research Executive Agency, REA) included that the EU has established new bodies to coordinate threat monitoring, countermeasure development, and funding specifically for pandemics. However, continued efforts are needed to achieve robust preparedness. Horizon Europe research programmes aim to support projects across the spectrum from basic research through clinical trials and implementation. Collaboration and coordination of funding streams between Horizon Europe, member states, and other EU programs is crucial. The panellists noted that networks of research centres and clinical trial sites that can be rapidly activated during health crises need to be sustained. Quick access to financing, when threats emerge, is essential. Regulatory processes must enable accelerated development and approval of medical countermeasures while upholding safety and efficacy standards. Pan-European digital infrastructure for real-time surveillance, open data sharing, clinical decision support, and other functionalities are required to mount a coordinated response. Substantive involvement of scientific experts and stakeholders in preparedness planning and policymaking is likewise key. While progress has been made, continued efforts are required to close gaps and align systems across the EU.
Overall, the panel provided insights into EU-level initiatives underway to strengthen preparedness, as well as areas needing further action through collaborative efforts between member states, researchers, healthcare providers, and other partners.

2.3.2 Benefits of the panel discussion on pandemic preparedness for EU-funded COVID-19 projects

The perspectives shared during the EU Readiness Panel at the Highway to Health Cluster & Policy Event highlighted important opportunities for ongoing COVID-19 therapy projects such as COVend and other Horizon Europe funded initiatives.
The overview of emerging bodies such as HERA highlights the importance of projects keeping abreast of and engaging with new EU-level programmes specifically focused on accelerating pandemic research and response. Understanding HERA's decision-making priorities and processes could help projects position themselves to take advantage of future funding or regulatory support. The emphasis on coordinating funding streams also highlights the potential for projects to collaborate when applying for joint support through Horizon Europe and other instruments such as the EU4Health programme. This could help overcome the financial hurdles for large-scale clinical trials that need to be implemented quickly in the event of future health crises. The focus on real-time data sharing highlights

the need for projects to proactively adopt digital platforms and common data standards. A shared repository of clinical, genetic and epidemiological data would enable a more flexible, networked response to pandemic threats. In addition, the focus on regulatory efficiency underscores the importance of projects working hand-in-hand with decision-makers to balance safety guarantees with crisis response capacity. Sharing lessons learned from practice can lead to balanced policies.
In summary, by applying the perspectives highlighted during the panel discussion at the EU level, COVID-19 projects may be better able to use tools, strategies and collaborations needed to maximise their impact when health threats inevitably re-emerge. Participation in the broader EU ecosystem will accelerate solutions.

2.3.3 Assessment of the collaboration potential for COVend based on the pitch talks session

At that time, the COVend project focused on evaluating the drug FX06 to treat mild to moderate COVID-19 disease and prevent progression of the disease to severe cases. It was concluded that collaboration with other EU-funded projects looking at COVID-19 therapies and response tools could be of great benefit to COVend. It could accelerate learning, strengthen study operations and maximise the impact of project results.
The Highway to Health Cluster & Policy Event provided an opportunity to identify synergies with several complementary Horizon Europe projects. For example, networking with **RBDCOV** and its focus on recombinant protein vaccines could support COVend's efforts to determine optimal FX06 delivery mechanisms and evaluate efficacy in different populations. RBDCOV has valuable experience in conducting clinical trials in immunocompromised patients and paediatrics. The collaboration could help COVend determine the optimal dosing and administration methods for FX06 in different demographic groups. RBDCOV's insights into the regulation and monitoring of next-generation vaccine technologies could also help COVend track the impact of FX06. Meanwhile, **EPIC-CROWN-2** is working on polyclonal antibody therapies that could offer a perspective on treating more severe COVID-19 cases, complementing COVend's focus on mild to moderate cases. As both projects are conducting multicentre clinical trials, coordinating patient recruitment in overlapping regions could increase recruitment numbers and efficiency. Sharing phase 2 trial protocols could also help COVend plan future trials. **MOOD**'s epidemiological dashboards and disease surveillance tools could help COVend identify patient populations for trials and monitor real-world trends relevant to FX06 use and efficacy. Collaboration on data standards, APIs and sharing frameworks could yield new insights. **ExeVir**'s expertise in developing novel nanobody antibody therapies could be valuable to COVend in the future. Sharing knowledge on regulatory approval processes and insights on clinical trial design could be mutually beneficial. Jointly exploring combinations of novel antibody therapies with FX06 could lead to improved patient outcomes.
There are many opportunities to integrate complementary knowledge across projects to accelerate learning, optimise trial operations and strengthen COVend's contribution to better pandemic preparedness. However, realising these synergies requires continuous engagement between consortia, which is facilitated by the EU institutions providing collaboration platforms, incentives and support. Pooling expertise is key to addressing future health crises.

PROJECT OUTLINE	RELEVANCE	COLLABORATION OPPORTUNITIES	POTENTIAL BENEFIT
RBDCOV Project COVID-19 recombinant protein vaccine development	Research on biomarkers of immunogenicity and immune response	• Exchange insights on immune signatures triggered by COVID-19 • Integrate biomarker work to identify FX06 response correlates • Develop aligned monitoring approaches for treatment response	Inform mechanistic work in WP5 on immunologic dynamics Identify subgroups most likely to respond to and benefit from FX06
ExeVir Clinical trial of novel COVID-19 nanobody therapy	Experience with innovative delivery methods and formulations	• Share techniques for next-generation FX06 formulations • Compare trial data on combining monoclonal antibodies with FX06 • Discuss strategies for transitioning intravenous therapeutics	Inform development of more convenient FX06 administration Increase understanding of using multi-therapy approaches with FX06
2 Clinical trial of equine polyclonal antibody therapy for COVID-19	Focus on treatment of later stage COVID-19 disease	• Exchange clinical data on treating different disease severities • Discuss aligning therapies into a clinical care pathway • Cooperate on treatment guidelines and regulatory submissions	Build evidence for FX06's use within multi-therapy protocols Strengthen position in clinical guidelines and formularies
iMPact a better therapy for Covid patients Clinical trial of oral immunomodulator for COVID-19	Experience with oral delivery methods and target groups	• Exchange techniques on transitioning intravenous therapeutics • Integrate datasets to reveal subgroups for oral vs. intravenous (IV) therapy • Discuss evolving to oral administration for FX06	Inform efforts to develop oral dosage forms for convenience Identify which patients gain the most from IV FX06 delivery

Figure 13. Collaboration opportunities for sharing knowledge on innovative therapies, biomarkers, and study design

In particular, the COVend project could benefit from sharing knowledge with initiatives such as RBDCOV, ExeVir (XVR011 Phase 2 clinical trial), EPIC-CROWN-2 and iMPact. While their therapeutic approaches differ from those of the FX06 therapy candidate, their experience in developing innovative solutions for COVID-19 could inform future efforts to optimise and expand the use of FX06 therapy. The focus of RBDCOV on generating evidence on a recombinant COVID-19 protein vaccine could provide valuable perspectives for evaluating efficacy in different populations, which could support real-world implementation of FX06 therapy. Insights from RBDCOV research on biomarkers of immunogenicity and immune response could help identify correlates of protection and response to treatment that would complement mechanistic analysis in COVend WP5. Sharing knowledge about immune system dynamics and signatures triggered by COVID-19 infection and different therapies could support COVend efforts to elucidate the mechanism of action of FX06. Incorporating findings from the RBDCOV biomedical analysis (RBDCOV WP5 - Immune monitoring and clinical data analysis) could help develop tailored monitoring approaches to determine which patient subgroups are most likely to benefit from treatment with FX06. Meanwhile, the XVR011 Phase 2 clinical trial work (ExeVir) on novel nanobody therapies could provide innovative techniques for next-generation FX06 formulations and delivery methods. Comparison of clinical trial data could provide insights into combining monoclonal antibodies with FX06 to improve treatment outcomes. In addition, the development of polyclonal antibody therapies through EPIC-CROWN-2 may provide an outside perspective on the treatment of later-stage COVID-19 disease, building on the mild to moderate focus of COVend. Knowledge sharing could strengthen the overall evidence base for the use of FX06 as part of a multi-therapy clinical pathway. Finally, the experience of iMPact with oral immunomodulators

could help identify opportunities for switching FX06 from intravenous administration to more convenient routes of administration in the future. Comparative assessments could identify target groups most likely to benefit from FX06's unique therapeutic focus.

2.3.4 Panel discussion on secure and sustainable infrastructure for healthcare, research, and society

Figure 14. Photo of Secure and sustainable infrastructure for healthcare, research, and society panel. From left to right: Kai Zacharowski (GUF), Andreas Holtel (Scientific Officer), Ulla Närhi (HERA), Patricia Urban-Lopez (Policy Officer, Cathy Weynants (ESAIC)

The Highway to Health Cluster & Policy Event included a roundtable discussion focused on the COVID-19 pandemic review and ways to improve healthcare infrastructure, connectivity and coordination in the EU. It was moderated by Kai Zacharowski (GUF).

Cristian Silviu Busoi (Member of the European Parliament), Alexandru Rogobete (Secretary of State at the Ministry of Health in Romania), Alexander Holtel (Scientific Officer, REA), Ulla Närhi (HERA), Patricia Urban-Lopez (Policy Officer at the EC), and Cathy Weynants (CEO of ESAIC) emphasised the need for increased investment in health systems, including digital infrastructure, research capacity and workforce development. Greater alignment of health policies and regulations between Member States was mentioned as an important goal. Rapid access to funding, both from national budgets and EU programmes, was highlighted as essential for health crises. The benefits of greater networking between clinicians, researchers and policymakers were discussed. Pan-European networks that can quickly share expertise and resources in emergencies are invaluable. However, realistic planning is needed to establish and maintain such collaborations. Several panellists underlined that interoperability of health data and moving away from paper records remains a challenge. While progress has been made, further efforts are needed to digitise systems and enable appropriate data exchange. There was agreement on the importance of learning from pioneering countries and organisations that have advanced digitisation and integrated healthcare. Bilateral cooperation and showcasing best practices can accelerate progress on a broad scale. Involving patients and health professionals in research and policymaking was identified as crucial. Their perspective from practice leads to better outcomes and acceptance of reforms. Communication and outreach should be improved.

Overall, the EU must continue to provide guidance and incentives to Member States while respecting their autonomy over health systems. Closer integration and coordination will strengthen pandemic preparedness and everyday health services. However, concrete action and funding commitments are essential to turn plans into reality.

2.3.5 Benefits of the panel discussion on infrastructure and healthcare for EU-funded COVID-19 projects

The perspectives shared during the second roundtable at the Highway to Health Cluster & Policy Event reveal valuable lessons for ongoing COVID-19 therapy projects such as COVend and other Horizon Europe funded initiatives.
The emphasis on greater connectivity and collaboration between clinicians, researchers and health authorities across the EU highlights the importance of fostering strong networks between projects. COVID-19 consortia have much to gain from the regular transnational exchange of expertise, data and best practice. Similarly, the focus on gathering evidence from the field highlights the need for projects to involve patients, healthcare workers and other stakeholders in their research and clinical trials. Their input helps to maximise the potential of new therapies and tools for effective use in practice. Calls for better coordinated funding streams and accelerated research timelines are relevant for projects planning clinical trials and seeking regulatory approvals. A more harmonised and faster EU environment for developing therapies would support projects to deliver effective solutions more quickly. In addition, the attention given to the digitisation of healthcare infrastructure highlights the value of projects proactively integrating digital medicine, such as telemedicine, predictive analytics and data-sharing platforms into their approaches. Forward-looking solutions will be crucial.
In summary, the perspectives expressed during the roundtable highlight meaningful opportunities for funded consortia to improve their coordination, field engagement, regulatory efficiency and use of enabling technologies. COVID-19 projects have much to gain from multi-stakeholder dialogues on strengthening pandemic preparedness and response in the EU. Applying this knowledge can accelerate progress.

2.3.6 Results of the networking discussions

During the networking session at the Highway to Health Cluster & Policy Event, participants had fruitful discussions on how to improve coordination between EU institutions and national health authorities to respond more effectively to health emergencies such as pandemics. The COVend organising committee collected the main recommendations. The overarching theme was to improve integration between EU and national systems through joint planning, regulatory alignment and rapid, centralised decision-making structures to enable rapid joint action when pandemics and crises occur.

Figure 15. Photo of networking session © Landesvertretung Hessen in Brüssel / Bernal Revert.

Specifically, the EU institutions and national health authorities could better coordinate their efforts to respond quickly to public health emergencies

- by establishing clear protocols and channels for sharing public health information and intelligence between the European Centre for Disease Prevention and Control (ECDC), national health authorities and the World Health Organisation (WHO),
- creating a common EU pandemic early warning and surveillance system that integrates data sources from all Member States,

- setting up coordinated EU stockpiling of medical countermeasures and supplies, with deployment plans to affected areas,
- developing evidence-based EU clinical management guidelines for emerging infectious diseases that member states can adapt,
- increasing capacity for and interoperability of genomic sequencing across borders to swiftly detect emerging disease variants,
- harmonising procedures for clinical trial approvals across member states to accelerate development of vaccines and therapeutics,
- improving EU scientific advisory capacity to provide rapid, coordinated guidance to national policymakers during health crises,
- leveraging digital tools and platforms for real-time information sharing, monitoring, resource allocation, and crisis communications,
- creating a common EU pandemic preparedness and response fund to provide surge financing to national healthcare systems when needed.

2.3.7 Media campaign for Highway to Health

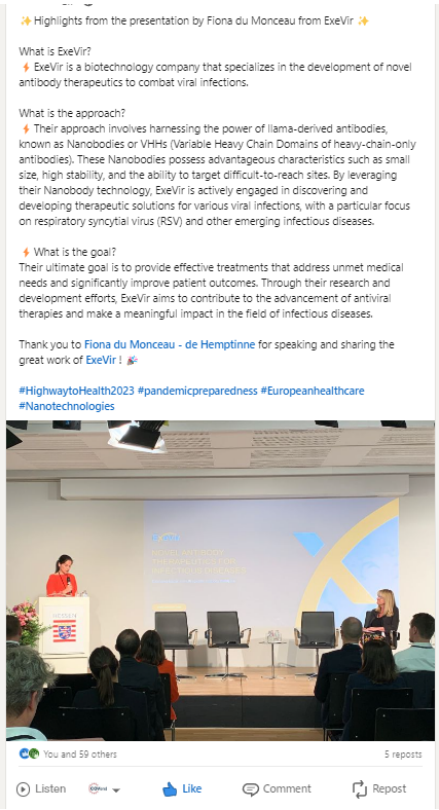

Figure 16. Screenshot of social media post highlighting ExeVir CEO, Fiona Du Moneau's presentation

The event was promoted online on both the COVend and the co-host, ENVISION social media channels, LinkedIn and Twitter as well as their websites. This campaign served to promote the policy and cluster event to the scientific community, healthcare providers and policymakers, to encourage registration and to inform attendees on the programme and guest speakers. The campaign ran from 15 June to 7 July 2023, beginning with an announcement post, followed by registration reminders, speaker profiles, information for virtual attendees, live updates during the event, ending with a post thanking attendees for their participation with a link to the full recap posted on the COVend and ENVISION websites.

The event was posted live on the ENVISION project's LinkedIn page and immediately reposted by COVend. Each speaker was introduced and details of the talks were provided as well as all key highlights from the discussion panels.

Over the course of the campaign, we received 352 reactions, 24 reposts and 4371 impressions (Figure 17 and 18). Visitors came in from relevant industries, the top being Strategic Management Services (20.4%), followed by Chemical Manufacturing (13.6%), Hospitals and Healthcare (11.7%) and Government Administration (11.7%). Job functions of those we reached and engaged with include Business development (35%), Program and Project Management (21.4%), Media and Communication (11.7%), Community and Social Services (9.7%), Research (9.7%) and Healthcare Services (5.8%).

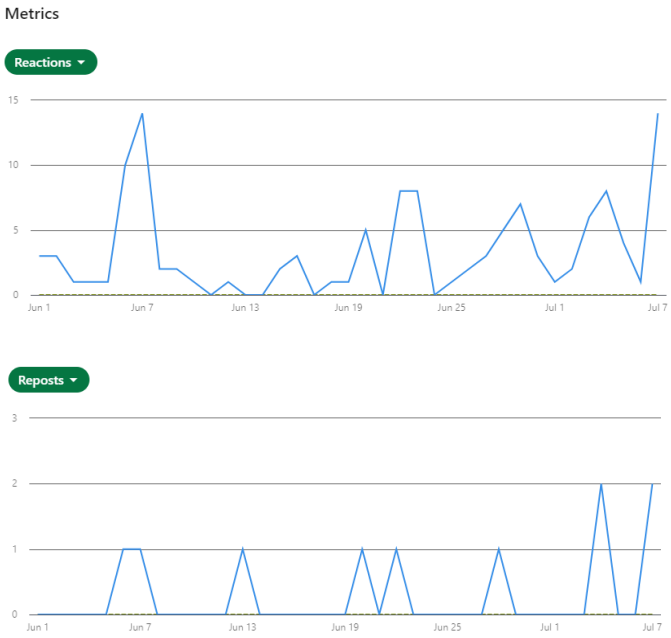

Figure 17. Screenshot of reaction and reposting metrics over the course of the campaign.

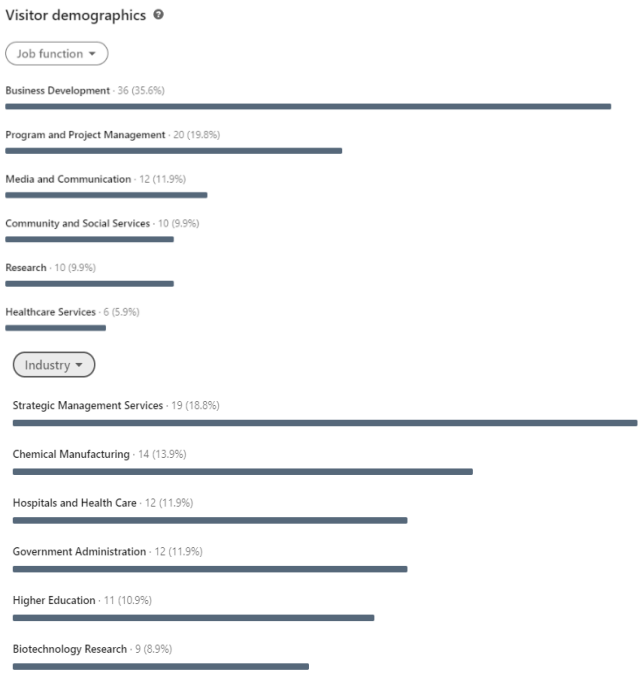

Figure 18. Screenshot of Visitor demographics by job function and industry

Engaging in continuous collaboration with complementary initiatives on social media is a powerful platform for fostering meaningful relationships and cultivating future mutually beneficial collaborations. Our shared objective remains resolute: to bring an end to the persistent health threat of COVID-19 while continually refining best practices and enhancing pandemic preparedness.

By leveraging the vast reach and connectivity of social media, we can unite diverse stakeholders, organisations and individuals dedicated to combating the pandemic's challenges. Through open

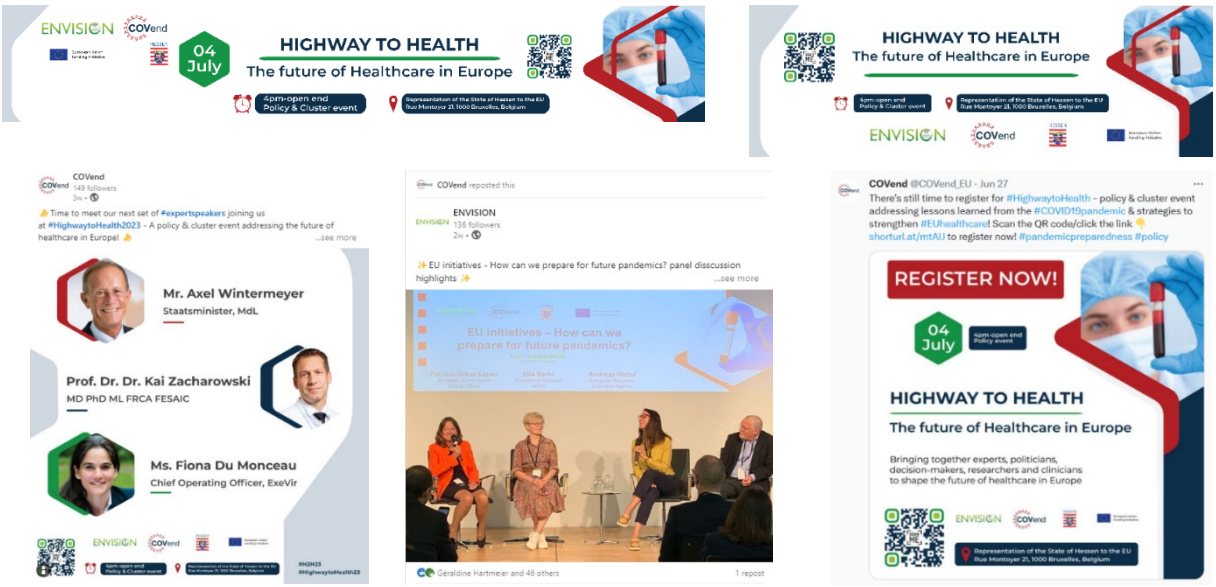

Figure 19. Graphics and posts created for the Highway to Health social media campaign

dialogue, knowledge exchange, and collective brainstorming, we can pool our collective expertise and resources to develop innovative solutions and strategies.
The social media campaign was supported by publishing detailed content on both projects' websites. These outreach efforts were further supported by participants' online networks, which actively engaged with and shared content across their projects' and institutions' social media channels and websites. As part of the media strategy, individual emails were sent to participants, including thank-you messages and follow-up communications with relevant resources shared after the event.

3 Summary and outlook

The collaborations and progress towards partnerships described in this report demonstrate COVend's commitment to maximising impact by working with complementary initiatives. By breaking down silos and pooling expertise across projects, consortia can achieve more together than they can on their own. While COVID-19 continues to pose urgent health challenges, the window for meaningful solutions depends on a coordinated and multifaceted response from the research community. COVend recognises that collaboration across clinical trials, data platforms and geographic networks will produce faster results. Ongoing engagement through virtual meetings, conferences and joint workshops allows for the identification of mutually beneficial overlaps between COVend and other funded projects. Coordinating patient cohorts, integrating complex datasets and navigating the regulatory environment will become more robust through collaboration. Developing best practices for key pandemic response capabilities will strengthen collective preparedness.

The future collaboration opportunities for COVend were identified according to the knowledge sharing on Innovative Therapies, Biomarkers, and Study Design. Collaboration for data security, interoperability, high-quality and integration of data sets is crucial not only for legal compliance, building trust with clinical trial participants and stakeholders but for increasing the impact, specificity and applicability of the results for therapeutic development that can positively contribute to pandemic preparedness and response. Regular communication, sharing of resources, and alignment of data protection practices will help ensure that clinical data is handled responsibly and ethically across the EU research landscape. Additionally, staying informed about updates and guidance from European and national regulatory agencies is important for timely adaptation, re-structuring, and efficient use of resources for all projects.

Challenges such as coordination complexities and aligning different project timelines remain. To sustain and improve collaborative efforts, the EU should continue to foster a culture of cooperation, streamline communication channels, and incentivise joint initiatives. Platforms for the exchange of ideas between consortia can identify innovative ways forward. The strengths of one can compensate for the weaknesses of the other. To overcome a crisis like COVID-19, it is necessary to work shoulder-to-shoulder as a community. COVend remains committed to enriching partnerships wherever synergies arise. By working together, the project can improve and expand its impact on patients and populations.