# Addressing unmet clinical needs, practices and patient outcomes: the impact of EU-funded projects

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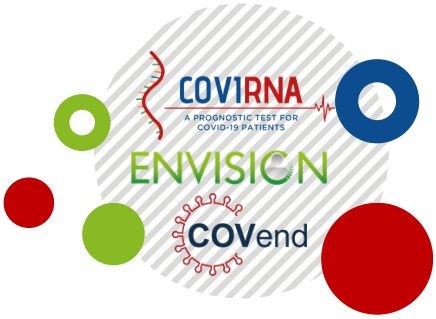


On 5 January 2023, the EU-funded projects COVIRNA, ENVISION, and COVend held a joint webinar on 'Addressing unmet clinical needs, practices and patient outcomes: the impact of EU-funded projects'. Experts presented their projects and addressed achievements and challenges regarding the impact of EU-funded projects on research and medical technology development. The webinar explored how research projects can contribute to improved clinical practices. It addressed the importance of patient and stakeholder engagement and what can be improved to effectively address clinical needs and deliver sustainable results for clinicians and patients. The webinar also showcased the Open Research Europe (ORE) that provides a platform for the publication of peer-reviewed research stemming from projects funded by the European Union.

## EU-funded projects aim to improve surveillance and care of COVID-19 patients

The webinar presented three projects, funded by the European Union, that aim to improve surveillance and care of COVID-19 patients. The **COVIRNA** project aims to develop a reliable, cost-efficient, easy-to-use in vitro diagnostic (IVD) test to improve COVID-19 patients' care, follow-up, and individualised surveillance. The diagnostic test is based on cardiovascular RNA biomarkers predictive of the clinical outcomes of COVID-19 patients. The second project, **COVend**, aims to deliver a new therapy for the clinical management of COVID-19 during mild and moderate stages, including the prevention of the disease progression to severe illness. Finally, the project **ENVISION** aims to develop an innovative digital tool, the Sandman.MD, that is a real-time plug-and-play app to monitor the treatment of COVID-19 patients in intensive care units (ICUs). This digital tool serves to support medical staff in 'smart decision-making' in ICUs.

## The FAIR Data Principles and GDPR

Participants discussed the FAIR Data Management principles, a fundamental aspect of research activities, especially EU-funded research projects. FAIR data stands for Findable, Accessible, Interoperable, and Reusable. It means that the research data collected and analysed should be made available for other users, in full compliance with General Data Protection Regulation (EU) 2016/679 (GDPR), further supporting research, data sharing and learning across organisations. Dr Yvan Devaux, COVIRNA project coordinator, highlighted the importance of the FAIR principles in research and how the COVIRNA consortium will make their data available for reuse after the project ends. He stated that to better address clinical needs and bring sustainable results to clinicians and patients, “FAIR principles shouldn't be neglected and be an inherent part of research projects". He also reported that the European Commission estimates that disrespecting the FAIR principles costs more than 10 billion euros per year in Europe.

GDPR issues were also debated, and specifically their different interpretation depending on the country in question. Additionally, in some cases the legal enforcement of GDPR compliance is missing and data owners’ privacy suffer. Participants stated that data and regulatory aspects in research projects have yet to receive the attention they require. Dr Jan Kloka, representing both the COVend and the ENVISION project, expressed excitement for the upcoming steps on processing and joint controllership with the clinics involved in his projects. He stated that “we should keep in mind that we have an ethical obligation to make the most of the collected data, as not wasting data taken from our patients is a key scientific principle".

## Patient and end user involvement is key to improving clinical practices

All participants agreed that involving patients and experts is fundamental to improving patients' quality of life and clinical practices. Dr Timo Brandenburger, Senior Physician at the Medical University of Dusseldorf highlighted that one of COVIRNA strengths is that it brings together a large variety of specialists, such as clinicians, researchers, biostatisticians, and IT experts, whilst considering patient perspectives at the different stages of the process. According to Ms Britt Sandberg, member of the board at Amazona, it is essential to involve patients from the very beginning of any research project, so that project outcomes can respond to real needs of patients. She and Ms Matilda Ersson, Project Manager at Amazona, presented the methodology of the REBECCA project as a best practice on how to engage patients in the research process.

There is still a big need for diagnostic, prognostic tests and new therapeutic tools. When answering how the COVIRNA project could improve clinical practices, Dr Brandenburger explained that the project is a great example of what could potentially be transferred from one disease area to another. For example, the COVIRNA diagnostic kit could be used to diagnose long COVID or cardiac diseases.

Regarding the commercialisation of EU-funded projects' products and innovations, Ms Matilda Ersson shared that often new solutions, systems or innovations, even if built from peer-reviewed information and solid scientific methodology, do not reach their full potential and the stage of commercialisation. In addition, Ms Ersson underlined that it is vital to plan for the longevity of the solution created by the project, and to plan for what happens when the project ends.

## Need for international and interdisciplinary collaboration in EU-funded projects

According to article 4 paragraph 2 of the European Commission Regulation (EC) No. 507/2006, unmet medical needs are "a condition for which there exists no satisfactory method of diagnosis, prevention or treatment in the Union". The European Commission, through its funding instruments and specifically the Research and Innovation Framework Programme, has allocated a significant budget to research addressing unmet medical needs. In this context, the speakers emphasised the crucial role of policy and decision-makers in securing sustainable funding and political commitment.

For Mr Ed Harding, Managing Director and Co-Founder of the Health Policy Partnership, the EU needs to focus on the strategic challenges that healthcare systems are facing as no country can address them on its own and international collaboration is the only way forward. EU-funded projects are a great example of both international and interdisciplinary collaboration. Ms Ersson was vocal about the need for multi-stakeholder engagement. She explained that patients receive the necessary care when they are considered ill; however, once treated, they are left outside the system. Research projects need to clearly define who are the patients, who are the stakeholders and who are the end-users.

## Open Research Europe (ORE) for a faster and more rigorous peer-reviewed publishing

In recent years, open science has become a priority within the European Union. To respond to this need, the European Commission created the **Open Research Europe (ORE)** platform offering rapid and transparent publishing. Ms Kelly Woods, Senior Associate Publisher at F1000, presented the platform that hosts publications on a variety of topics, including healthcare, and provides immediate open access to publications, which is an important requirement for Horizon Europe projects. The platform follows a rigorous procedure of peer review that ensures transparency and quality of published data. Although the platform is relatively new, it has achieved positive results including nearly 25,000 views for articles, over 6,000 downloads, and 300 mentions.

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