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

Deliverable 8.4

European trial networks webinar

WP 8 – Communication, dissemination & exploitation

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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
KC	Lietuvos Sveikatos Mokslu Universiteto Ligonine Kauno Klinikos
ICS-HUB	Hospital Universitari de Bellvitge
UMFCD	Universitatea de Medicina si Farmacie Carol Davila din Bucuresti
APHP	Assistance Publique – Hôpitaux de Paris

Abbreviations

ARDS	Acute Respiratory Distress Syndrome
COVID-19	Coronavirus Disease 2019
D	Deliverable
EU	European Union
ICU	Intensive Care Unit
GDPR	General Data Protection Regulation

Executive Summary

COVend successfully conducted a webinar with European clinical trial networks to share lessons learned from adapting COVID-19 trials to mechanism-based ARDS approaches. The event aligned with the commitment of COVend to open science and knowledge dissemination across the European research community.

The present document represents Deliverable 8.4 – European trial networks webinar and has been developed as part of WP 8 – Communication, dissemination & exploitation, Task 8.2: Dissemination of scientific and technological results.

This deliverable reports on the implementation and outcomes of the webinar "From COVID-19 to ARDS: Adapting our clinical trial to the real-world scenario" held on June 12, 2025. The webinar brought together 21 participants from major European clinical trial networks, including ECRIN, ESAIC CTN, and EU SOLIDACT/EU RESPONSE to exchange experiences on mechanism-based therapeutic development and pandemic preparedness.

Related deliverables:

- D8.2 Training material
- D1.6 Report on virtual meeting with the other successful projects working on COVID-19 therapeutics funded under the Horizon Europe call "HORIZON-HLTH-2021-CORONA-01"

1 Introduction

The COVend project, initiated in 2021 as part of the European Union's Horizon Europe programme, was originally designed to evaluate FX06 as a therapeutic intervention to prevent the progression of mild and moderate COVID-19 to severe stages. However, the rapidly evolving pandemic landscape, particularly the emergence of the Omicron variant in late 2021 and its reduced severity compared to previous variants, fundamentally altered the clinical trial environment. By mid-2022, the dramatic decrease in hospitalised COVID-19 patients suitable for recruitment made it clear that the original trial design was no longer feasible.

This challenge, rather than becoming an insurmountable obstacle, catalysed a strategic pivot that would ultimately strengthen the project's scientific foundation and broaden its potential impact. Drawing on the mechanistic understanding of FX06's action on endothelial dysfunction—a pathological feature common to various forms of acute respiratory distress syndrome (ARDS), not just COVID-19—the COVend consortium made the decision to expand the trial's scope from COVID-specific to mechanism-based ARDS therapy. This transition from the IXION study to IXION 2.0 represented a shift from pathogen-specific to host-directed therapeutic approaches.

The webinar "From COVID-19 to ARDS: Adapting our clinical trial to the real-world scenario," held on June 12, 2025, served as a crucial platform to share this transformative journey with the broader European clinical research community. The event brought together key stakeholders from major European clinical trial networks, including ECRIN, ESAIC CTN, EU SOLIDACT, and EU RESPONSE, to discuss the challenges, lessons learned, and implications for future pandemic preparedness.

1.1 Purpose and scope of the deliverable

This webinar fulfilled multiple objectives within Work Package 8 (Communication, dissemination & exploitation), specifically contributing to Task 8.2: Dissemination of scientific and technological results. By openly sharing both the scientific rationale and practical challenges of adapting a large-scale clinical trial mid-course, the COVend consortium aimed to contribute valuable insights to the European research infrastructure and foster collaborative approaches to addressing similar challenges in future health emergencies.

The timing of this webinar, in the project's final year, allowed for a comprehensive reflection on the entire adaptation process, from initial crisis to successful implementation of the revised protocol. This deliverable reports on the webinar's execution, key discussions, outcomes, and its contribution to advancing mechanism-based therapeutic approaches in critical care research across Europe.

2 Webinar Implementation

2.1 Key Implementation Milestones

The successful execution of the webinar required careful planning and coordination across multiple phases. **Table 1** outlines the key milestones in the webinar development and implementation process.

Table 1: Webinar Implementation Timeline

Milestone	*Target Date*	*Description*
Speaker Confirmation	By May 2	Approached and confirmed participation of internal speakers (Dr. Petra Wülfroth, Prof. Günther Eissner, Dr. Michael Nordine)
Webinar Materials Development	By May 9	Creation of branded event brochure with complete agenda, speaker bios, and webinar objectives
Network Identification & Outreach	May 12-16	Systematic identification and invitation of European clinical trial networks
Follow-up Communications	May 19-30	Second round of invitations emphasising no presentation requirements for network representatives
Technical Preparation	June 5-11	Platform testing, speaker briefings, and final logistics coordination
Webinar Execution	June 12	Live online webinar delivery (12:00-13:00 CET)
Post-Webinar Dissemination	June 13-20	Website recap publication and social media posts

2.2 Strategic Selection of European Clinical Trial Networks

The selection of participating networks was a critical component of the webinar's success. We employed a systematic approach to identify networks whose expertise would provide complementary perspectives on the challenges of adapting clinical trials from pandemic-specific to mechanism-based approaches. The selection process evaluated networks across four key dimensions:

1. **Relevance to ARDS/Critical Care Research**
2. **Experience with Adaptive Trial Designs**
3. **Pan-European Operational Capability**
4. **Pandemic Response Track Record**

Based on these criteria, eight networks were identified and invited:

ECRIN (European Clinical Research Infrastructure Network)

- **Selection rationale:** Unparalleled expertise in harmonizing regulatory and operational aspects of multi-country trials
- **Expected contribution:** Insights on cross-border patient recruitment and centralized support for investigator-initiated studies
- **Relevance to webinar:** Their experience directly addresses the challenges of scaling mechanism-based trials across EU member states

PERMIT (Personalised Medicine Trials Network)

- **Selection rationale:** Specialised knowledge in methodological frameworks for personalised and precision-medicine trials
- **Expected contribution:** Guidelines on biomarker stratification and adaptive design
- **Relevance to webinar:** Their expertise aligns with the pivot of COVend from pathogen-targeted to mechanism-targeted strategies

REMAP-CAP Network

- **Selection rationale:** Pioneers of adaptive platform trials in critical care settings
- **Expected contribution:** Practical insights on protocol amendments and real-time data monitoring
- **Relevance to webinar:** Direct experience with shifting platforms from acute pandemic focus to broader clinical contexts

ESAIC CTN (European Society of Anaesthesiology Clinical Trials Network)

- **Selection rationale:** Deep connections to intensive-care and anaesthesiology sites across Europe
- **Expected contribution:** Perspectives on ICU recruitment optimization and site readiness
- **Relevance to webinar:** Critical for addressing ARDS patient enrolment challenges

ISARIC Europe (International Severe Acute Respiratory and Emerging Infection Consortium)

- **Selection rationale:** Extensive experience in pandemic data harmonisation and rapid response
- **Expected contribution:** Insights on maintaining data quality post-pandemic

- **Relevance to webinar:** Valuable perspective on sustaining research engagement beyond emergency phases

VACCELERATE

- **Selection rationale:** Network of 500+ trial sites with expertise in rapid activation
- **Expected contribution:** Knowledge of site readiness assessments and master-service agreements
- **Relevance to webinar:** Insights on maintaining trial infrastructure during inter-pandemic periods

RECOVER

- **Selection rationale:** Focus on long-term COVID-19 sequelae and pathophysiology
- **Expected contribution:** Patient cohort and biobank perspectives
- **Relevance to webinar:** Complementary view on endothelial protection approaches and post-acute care

EU SOLIDACT and EU RESPONSE

- **Selection rationale:** Purpose-built adaptive platform trials created specifically for pandemic response, with proven experience in rapid trial deployment during COVID-19
- **Expected contribution:** First-hand insights on managing evolving pathogen variants and maintaining trial infrastructure for emerging infectious diseases
- **Relevance to webinar:** Direct experience transitioning from pandemic emergency response to sustainable preparedness models

The strategic selection of these networks ensured comprehensive coverage of the critical aspects needed for successful mechanism-based clinical trials in the European context, from regulatory harmonisation to practical recruitment challenges, and from adaptive design methodologies to sustainable infrastructure maintenance.

2.3 Webinar Format and Structure

The webinar was designed as a focused one-hour online event structured to maximise knowledge exchange while respecting participants' time constraints. The format comprised:

- **Opening (5 minutes)**: Welcome and introduction of speakers and panellists
- **Scientific Presentations (30 minutes)**: Three 10-minute presentations from COVend experts
- **Panel Discussion (25 minutes)**: Moderated discussion with network representatives

This structure was specifically chosen to balance the presentation of COVend and findings with interactive dialogue among European clinical trial experts, ensuring both knowledge transfer and collaborative problem-solving.

2.4 Webinar Content Overview

The webinar delivered a comprehensive examination of the evolution of COVend and IXION from a COVID-19-focused project and clinical trial to a mechanism-based approach for treating Acute Respiratory Distress Syndrome (ARDS).

2.4.1 Scientific Presentations

Scientific Rationale for Mechanism-Based Approaches in Infectious Diseases Dr. Petra Wülfroth (F4 Pharma) presented FX06 as a platform therapeutic targeting endothelial dysfunction. She emphasised the advantages of host-directed therapies over pathogen-specific approaches and explained how the mechanism of action of FX06 makes it applicable across multiple respiratory conditions.

From Clinic to Research: A Bidirectional Relationship Prof. Günther Eissner (University College Dublin) shared findings from mechanistic research conducted in parallel with clinical work. He demonstrated how integrating mechanism understanding early in trial design enhances both clinical outcomes and scientific knowledge generation.

Clinical Implementation and Trial Coordination Dr. Michael Nordine (Johann Wolfgang Goethe University Frankfurt) provided practical insights into the clinical challenges of recruiting patients with mild-to-moderate ARDS. He shared key lessons learned and strategies for mitigating these challenges in future ARDS trials.

2.4.2 Panel Discussion

The panel discussion moderated by Dr. Elina Nürenberg-Goloub (GUF) brought together representatives from major European clinical trial networks to address critical questions about pandemic preparedness, regulatory frameworks, and collaborative approaches. Key themes explored included:

- The evolution of clinical trial networks' roles during and after the pandemic
- Regulatory and contractual hurdles in conducting rapid multi-centre trials
- Data sharing challenges across European countries
- Strategies for maintaining trial infrastructure and readiness between pandemics
- The value of interdisciplinary collaboration in European clinical trial projects

The discussion fostered a rich exchange of experiences and perspectives, with network representatives providing candid assessments of both successes and ongoing challenges in the European clinical research landscape.

3 Key Outcomes and Findings

3.1 Major Insights

The webinar yielded critical insights into the challenges and opportunities for conducting mechanism-based clinical trials in Europe, particularly in the context of pandemic preparedness and ARDS research.

3.1.1 Four Fundamental Challenges for European Clinical Trials

Dr. Inge Christoffer Olsen (EU SOLIDACT and EU RESPONSE) crystallised the discussion by identifying three major hurdles that must be overcome when running trials rapidly:

- **Regulatory hurdles** - The complex and varied regulatory landscape across European countries significantly delays trial initiation
- **Contractual challenges** - Multi-party agreements and institutional negotiations create substantial time barriers
- **Funding constraints** - Securing and maintaining adequate funding for trials, especially during inter-pandemic periods
- **Data sharing** - The fragmentation of data protection regulations in the EU creates significant obstacles for multi-centre trials requiring real-time data integration.

3.1.2 The Critical Balance: Speed Versus Understanding

Prof. Jacques Demotes (ECRIN) provided a nuanced perspective on the relationship between rapid clinical trials and mechanistic understanding. He noted that **"Clinical trials are mechanism-agnostic"** and that the most successful COVID-19 trials were **"very pragmatic just addressing the question: is this drug working or not - usually via in-hospital mortality at day 28."** However, he emphasized that while this approach delivered rapid answers during the acute pandemic phase, understanding mechanisms remains crucial for:

- Selecting appropriate drugs for future trials
- Building a knowledge base for pandemic preparedness
- Enabling adaptation to evolving pathogens and clinical presentations

3.1.3 Mechanism-Based Approaches: A Paradigm Shift

The webinar highlighted how the evolution of COVend from COVID-19 to ARDS exemplifies the value of mechanism-based therapeutic development. Dr. Petra Wülfroth's presentation of FX06 as a platform therapeutic targeting endothelial dysfunction demonstrated how understanding the underlying pathophysiology enables:

- Application across multiple conditions (viral infections, septic shock, reperfusion injury)
- Preparation for unknown future pathogens
- More informed trial design based on biological rationale
- Potential for broader therapeutic applications beyond initial indications

3.1.4 The Challenge of Disease Evolution

Dr. Inge Christoffer Olsen highlighted a critical lesson about adapting to disease evolution: **"We started out in the Delta version and then ended up in Omicron, and these are very different situations and diseases."** This observation underscored why mechanism-based approaches offer advantages over pathogen-specific strategies, as they target fundamental pathophysiological processes rather than specific viral variants.

3.1.5 Proactive Pandemic Preparedness

A transformative insight emerged from the discussion on maintaining readiness between pandemics. Dr. Petra Wülfroth challenged the reactive paradigm: **"We don't have to wait for the next pandemic. We could be active in the meantime."** She proposed studying mechanism-based therapies in current diseases with similar underlying pathophysiology, such as dengue fever, which shares endothelial inflammation and capillary leak syndrome with COVID-19 and ARDS.

This proactive approach offers multiple benefits:

- Maintains active trial infrastructure and expertise
- Generates valuable data on mechanism-based therapies
- Keeps clinical teams engaged and trained
- Builds evidence for rapid deployment in future emergencies

3.1.6 The Human Cost of Pandemic Response

Prof. Bernard Cholley (ESAIC CTN) provided sobering insights into the healthcare system's capacity for emergency response: **"We learned from the previous pandemic that anaesthesiologists are a key component of the healthcare system in such situations because they are able to transform into critical care physicians."** However, he cautioned about sustainability: **"The trauma was deep, and we all experienced that many healthcare professionals left the world of intensive care after this episode."** This highlights the need for:

- Sustainable models for surge capacity
- Support systems for healthcare workers
- Institutional memory preservation without causing burnout
- Balanced approach to maintaining preparedness

3.1.7 ARDS: An Underrecognized Opportunity

Dr. Michael Nordine's clinical insights revealed that many mild-to-moderate ARDS cases in European hospitals go undetected on general wards, representing missed opportunities for intervention. This finding suggests that:

- Increased ARDS awareness could improve patient outcomes even outside pandemic contexts

- Better diagnostic protocols on general wards are needed
- Mechanism-based therapies could address a broader patient population than initially recognized
- Investment in ARDS research provides dual benefits for routine care and pandemic preparedness

These major insights collectively demonstrate that successful adaptation of clinical trials requires not just technical solutions but a fundamental shift in how we approach therapeutic development, trial infrastructure, and collaborative research in Europe.

3.1.8 Cross-Network Consensus

Despite their different organizational focuses and experiences, several consensus points emerged across the networks:

- **Infrastructure Persistence**: All networks agreed on the critical importance of maintaining "warm" trial infrastructure between emergencies, though they acknowledged the funding and organisational challenges this presents.
- **Regulatory Harmonisation**: Every network identified regulatory complexity as a fundamental barrier, suggesting this should be a priority for European policy makers.
- **Data Integration**: The technical and legal challenges of data sharing were universally recognised as impediments to both routine and emergency research.
- **Human Factors**: Networks emphasised that sustainable preparedness must account for healthcare worker wellbeing and cannot rely solely on emergency surge models.
- **Value of Mechanistic Understanding**: While acknowledging the success of pragmatic trials, all networks recognised that mechanistic insights enhance preparedness and enable more sophisticated trial designs.

3.1.9 Network Recommendations for Future Preparedness

The collective network perspective suggested several key recommendations:

- **Establish permanent funding mechanisms for inter-pandemic trial infrastructure**
- **Develop European-level harmonization for data sharing agreements**
- **Create standardized protocols for mechanism-based trials that can be rapidly adapted**
- **Build systematic approaches for maintaining clinical research expertise without burnout**
- **Invest in diseases with similar pathophysiology to maintain active learning**

These network perspectives demonstrate that successful pandemic preparedness requires not just maintaining technical capacity but fundamentally reimagining how European clinical research infrastructure operates during both emergency and routine conditions. The COVend webinar

succeeded in bringing these diverse viewpoints into productive dialogue, creating a foundation for future collaborative approaches to mechanism-based clinical trials.

4 Dissemination Activities

4.1 Immediate Outputs

The webinar dissemination strategy encompassed both pre-event promotion and post-event knowledge sharing, coordinated by Anastasiia Aksonova (accelCH).

Pre-Webinar Promotion:

- Professional event announcements via COVend LinkedIn channel (214 followers) – **Figure 1**
- Collaborative promotion with ESAIC communications team, leveraging their extensive network reach
- Targeted invitations to European clinical trial networks via Email
- Branded event materials featuring speaker profiles and registration information – **Appendix**

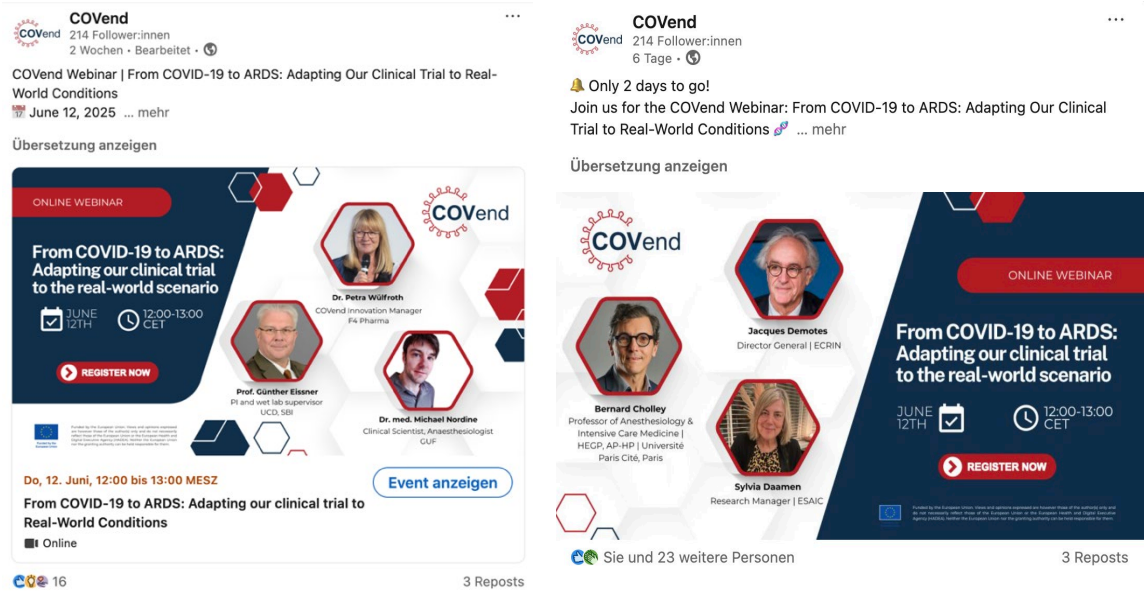

Figure 1: Two LinkedIn posts announcing the COVend clinical trial networks webinar

Webinar Documentation:

- Complete video recording of the 1-hour webinar session
- Full transcript of presentations and panel discussion
- Participant attendance report with organisational affiliations
- Webinar presentation materials

Post-Webinar Dissemination:

- Comprehensive recap article published on the COVend project website
- LinkedIn post summarising key insights and takeaways – Figure 2
- Full video of the webinar available on the COVend website
- Follow-up communications to network representatives

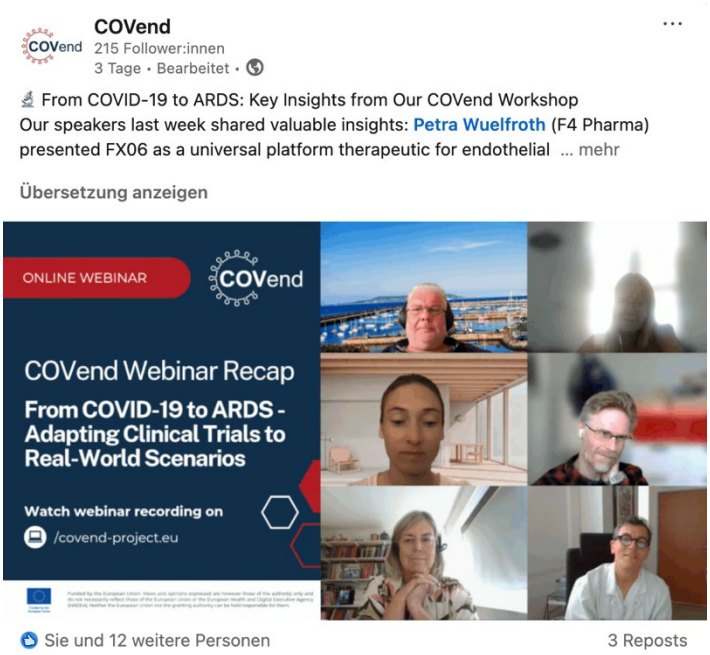

Figure 2: LinkedIn post summarising the COVend clinical trial networks webinar

4.2 Reach and Engagement

Direct Participation: The webinar counted 21 participants and successfully engaged representatives from major European clinical trial networks, including confirmed participation from:

- ECRIN (European Clinical Research Infrastructure Network)
- ESAIC CTN (European Society of Anaesthesiology Clinical Trials Network)
- EU SOLIDACT
- EU RESPONSE

Social Media Metrics: The pre-webinar LinkedIn posts achieved 40 reactions, 1130 impressions and 6 reposts (as of 20/06/2025). We also achieved extended reach through ESAIC's professional network. The post-webinar LinkedIn achieved 14 reactions, 347 impressions and 4 reposts in only three days.

5. Impact Assessment

5.1 Achievement of Objectives

The webinar successfully achieved all primary objectives (**Table 2**), creating a productive forum for knowledge exchange and collaborative problem-solving among European clinical trial networks. By achieving these objectives with 21 participants from major European clinical trial networks, the webinar demonstrated the value of bringing together diverse perspectives to address common challenges in clinical research infrastructure and pandemic preparedness.

Table 2: Major objectives were achieved in the COVend clinical trial networks webinar

Objective	*Achievement*
Knowledge Transfer Between Networks	The webinar facilitated bidirectional knowledge transfer across multiple levels: • COVend shared concrete lessons from adapting a COVID-19 trial to a mechanism-based ARDS approach • ECRIN contributed insights on balancing pragmatic trial needs with mechanistic understanding • ESAIC CTN shared critical perspectives on ICU capacity and healthcare worker sustainability • EU SOLIDACT/EU RESPONSE provided evidence of how pathogen evolution validates mechanism-based approaches. The interactive panel format enabled networks to learn from each other's experiences, creating cross-pollination of ideas that extended beyond bilateral exchanges.
Best Practices Shared	Participants exchanged actionable best practices across key areas: • **Trial Design**: Mechanism-based approaches that remain relevant despite pathogen evolution • **Recruitment Strategies**: Dr. Nordine's insights on identifying ARDS patients on general wards • **Infrastructure Maintenance**: Strategies for keeping trial networks "warm" between emergencies • **Regulatory Navigation**: Approaches to managing multi-country approval processes • **Data Integration**: Workarounds for GDPR fragmentation challenges. These practices were grounded in real experience, making them immediately applicable to participants' ongoing work.
Challenges Identified And Discussed	The webinar achieved exceptional clarity in articulating fundamental barriers: 1. Regulatory hurdles across different European jurisdictions 2. Contractual complexities in multi-centre collaborations 3. Funding constraints for maintaining inter-pandemic readiness 4. Data sharing blockages due to country-specific GDPR implementations. Beyond identification, participants engaged in substantive discussion about potential solutions, creating a shared understanding of priorities for systemic improvement.
Future Collaboration Opportunities Explored	The webinar catalysed several collaboration pathways: • **Proactive Research**: Study mechanism-based therapies in diseases like dengue during inter-pandemic periods • **Shared Infrastructure**: Networks expressed interest in pooling resources for trial readiness • **Methodological Alignment**: PERMIT's frameworks for adaptive design could be applied to mechanism-based trials • **Cross-Network Learning**: Opportunities identified to share protocols, training materials, and operational solutions. The webinar established a foundation for ongoing dialogue, with continued interest in mechanism-based approaches to pandemic preparedness.

5 Conclusions and Outlook

The COVend webinar successfully brought together 21 participants including representatives from major European clinical trial networks, validating the value of mechanism-based approaches for both pandemic preparedness and routine ARDS treatment. The event demonstrated how the evolution of COVend from COVID-19 to ARDS exemplifies a sustainable model for therapeutic development that transcends specific pathogens.

Key achievements included identifying four fundamental barriers to European clinical research (regulatory, contractual, funding, and data sharing), establishing consensus on the need for "warm" trial infrastructure between pandemics, and creating a foundation for ongoing collaboration among networks.

5.1 Critical Questions Requiring Future Action

The webinar highlighted several urgent questions that must be addressed:

- **ARDS Recognition**: How can we increase detection of mild-to-moderate ARDS cases on general wards and engage patient advocacy to raise awareness?
- **Healthcare Sustainability**: What models can maintain surge capacity without causing the trauma and exodus of healthcare professionals witnessed during COVID-19?
- **Infrastructure Integration**: How can we harmonise biobanking, sample sharing, and data exchange protocols across European countries while respecting GDPR?
- **Proactive Preparedness**: Which endemic diseases with similar pathophysiology (e.g., dengue, sepsis) could serve as training grounds for mechanism-based therapeutics?
- **Regulatory Evolution**: What European-level frameworks could enable rapid trial adaptation while maintaining scientific integrity?

The core message of the webinar - that we need not wait for the next pandemic but can act now through mechanism-based research - provides a clear path forward. Transforming this vision into reality will require coordinated action to address these systemic challenges while protecting the well-being of the healthcare workforce that makes clinical research possible.