COHORT COORDINATION BOARD

Second Report

January 2024 – April 2025

Authors

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Executive Summary

This second edition of the Cohort Coordination Board Report provides a comprehensive overview of the Board's activities and outputs between 1 January 2024 and 30 April 2025. The Cohort Coordination Board has evolved significantly during this period, expanding its thematic scope outside of COVID-19, reinforcing its operational structures, and consolidating its role in new initiatives.

The report shows how the Cohort Coordination Board continues to serve as a collaborative forum enabling knowledge-sharing between European cohort studies, and how its impact has deepened following a shift in focus from COVID-19 to wider infectious diseases with epidemic or pandemic potential and a significant growth in members from 16 to the 27 permanent member projects now involved. Two new working groups focusing on artificial intelligence and mpox have also been established alongside the initial three working groups.

This report also outlines the key achievements of the Cohort Coordination Board, highlighting the progress that has been made as regards the specific elements identified in the SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, completed by members in 2023. These include the launch of the dedicated Cohort Coordination Board website; the development and population of the Central Data Repository with 217 studies covering COVID-19, mpox, and Avian Influenza A(H5N1); greater integration between the Cohort Coordination Board and the Trial Coordination Board; and the completion of extensive mapping activities. The Cohort Coordination Board also coordinated formal responses to the European Commission and European Medicines Agency on Long COVID and real-world data use in regulatory decision-making, and published a high-impact article on Post-Acute Infection Syndromes.

The sustainability of the Cohort Coordination Board is also discussed, focusing particularly on the inclusion of its activities into new projects: PIPELINE (focused on pregnancy and infant cohorts), PROACT EU-Response (regarding AI-driven target trial emulations), and BE READY NOW (a foundational initiative for a future European Pandemic Preparedness Partnership) and how these projects will enable the Cohort Coordination Board to continue to foster collaboration and harmonisation across European research initiatives, strengthen its connection with other mechanisms, and support the generation of scientific evidence and policy recommendations.

Table of Acronyms

Acronym	Description
AI	Artificial Intelligence
APT	Adaptive Platform Trial
CCB	Cohort Coordination Board
CDR	Central Data Repository
CS	Cohort Study
EC	European Commission
eCRF	Electronic Case Report Form
ECDC	European Centre for Disease Prevention and Control
ECRIN	European Clinical Research Infrastructure Network
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
H5N1	Avian Influenza A(H5N1)
ID	Infectious Disease
IDEPP	Infectious Disease with Epidemic or Pandemic Potential
PAIS	Post-Acute Infection Syndromes
PCC	Post COVID-19 Condition
PI	Principal Investigator
RCT	Randomised Controlled Trial
RSV	Respiratory Syncytial Virus
STI	Sexually Transmitted Infection
SWOT	Strengths, Weaknesses, Opportunities and Threats
TCB	Trial Coordination Board
ToR	Terms of Reference
WG	Working Group

1. Summary of Major Achievements

- January 2024: the Cohort Coordination Board (CCB) submitted a **joint response to the DG SANTE survey** on *"Research priorities for Long COVID"* from members ORCHESTRA, VERDI, SYNCHROS, RIVM Long COVID and UNCOVER, highlighting specifically the importance of identifying high-risk populations, understanding the impact of different variants, clarifying the impact on mental health, and developing a common data collection tool.
- January 2024: the **first joint Trial Coordination Board (TCB) and CCB was held** under the CoMeCT project discussing the future joint meetings and the results of the adoption of data standards survey from the dedicated CCB working group (WG). Seven joint meetings have been held in total in the reporting period.
- March 2024: the **CCB's dedicated website was launched** at https://cohortcoordinationboard.eu/, with sections featuring: Mission; History; Members; Resources; CDR; eCRF; Working Groups; Publications; News; Events; and Webinars & Videos.
- April 2024: Oral presentation at European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Global titled: ***Supporting synergies across European cohorts for optimal evidence generation: the case of the Cohort Coordination Board***. L.M. Canziani, R. Davis, R.L. Flett, G. Pantaleo, I. Abubakar, F. Incardona, G. Rinck, M. Kanerva, L. Maxwell, P. Caro Chinchilla, J.L. Peñalvo, A. Judd, Z.D. Pana, V.C. Simensen, E. Tacconelli.
- April 2014: **A video showcasing the activities of the CCB** was developed for dissemination. With the **contribution of the CCB members and the European Commission (EC)**, the video discusses the importance of observational studies, particularly in pandemic times, and highlights how the setting up of a dedicated cohort board has enhanced opportunities for collaboration across cohorts in Europe. The video was published by ESCMID in the build-up to the conference and then broadcast live at ESCMID Global 2024, and has since been uploaded to the CCB website.
- May 2024: CCB members attended the CoVICIS focus groups to support the development of the COVID Cohorts Technical Synthesis for Public Policy, published in April 2025.
- August 2024: **the CCB submitted joint feedback**, alongside members of the TCB, for the European Medicines Agency (EMA) paper titled *Reflection paper on use of real-world data in non- interventional studies to generate real-world evidence*.
- December 2024: **the CCB performed an extensive mapping of mpox cohorts in Europe, identifying 48 studies.** The preliminary results were included into *Report on Status of European Mpox Cohorts*, submitted to the EC. The final results have been formatted into a paper titled *Lessons from the European Mpox Outbreak: Strengthening Observational Research for Future Pandemic Preparedness,* submitted to Clinical Microbiology and Infection and currently under review. All cohort studies (CSs) with contact details were invited to engage with the CCB, and, by May 2025, nine cohort PIs had presented and subsequently joined the CCB.
- December 2024: Several CCB researchers participated in the generation **of standardised electronic case report forms** (eCRFs) responding to the Oropouche Virus outbreak in Latin America, convened by CONTAGIO. These CRFs are being developed for Acute Febrile Illness syndromes as well as for pregnant women and children cohorts (because of the potential of congenital abnormalities).
- January 2025: the CCB performed a **mapping of CSs relevant to Avian Influenza A(H5N1) (H5N1)** for inclusion into CoMeCT's Outbreak Response Board's report titled *H5N1 Research Priorities* and submitted to the EC.
- March 2025: a scientific publication, spear-headed by the Long COVID WG, titled "***Learning from Post COVID-19 condition for epidemic preparedness: a variable catalogue for future Post-Acute Infection Syndromes***" was published in Clinical Microbiology and Infection. Górska A, Canziani LM, Rinaldi E, Pana ZD, Beale S, Bai F, Boxma-de Klerk BM, de Bruijn S, Donà D, Ekkelenkamp MB, Incardona F, Mallon P,

Marchetti GC, Puhan M, Riva A, Simensen VC, Vaillant M, van der Zalm MM, van Kuijk SMJ, Wingerden SV, Judd A, Tacconelli E, Peñalvo JL. 31(3):380-388. doi: 10.1016/j.cmi.2024.12.001. Epub 2024 Dec 9. PMID: 39662824.

- April 2025: the EuCARE project initiated collaboration with several other CCB members for a **study focusing on clinical outcomes of Post-Acute Infection Syndromes (PAIS)** (incidence, characteristics, and risk factors) to be compared between **SARS-CoV-2, Flu, and Respiratory Syncytial Virus (RSV)**, as well as on the analysis of inflammatory biomarkers. Collaboration is ongoing at the time of this report.
- April 2025: **the Central Data Repository (CDR) of the CCB was launched**, with a total of 217 studies targeting COVID-19, H5N1, and mpox. Mapping is ongoing to expand the number and focus of the studies included.

Progress of initial SWOT

These key achievements address many of the elements identified in the SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis that was carried out in March 2023. The expansion of the CCB beyond COVID-19 cohorts and greater integration with the TCB has provided a single voice to trial and cohort research in the broader context of pandemic preparedness facilitating a greater alignment of priorities and improved cohesion among different research initiatives. Figure 1 below outlines how the achievements relate to the SWOT analysis that was carried out in the first reporting period.

Legend

Green: Fully addressed

Orange: Partially addressed

2. Background

This is the Second Report of the CCB, covering the activities and outputs of the CCB from 1 January 2024 to 30 April 2025. For a greater understanding of the CCB's activities in general, and how it began, please see the First Report, published on 29 February 2024, and the dedicated website of the CCB. A brief overview of the CCB's activities from its conception in April 2022 can be seen in Figure 1.

Following the CCB's inclusion into the CoMeCT project in December 2024, the CCB expanded its focus outside of COVID-19 to include mpox and other infectious diseases with epidemic or pandemic potential (IDEPP). In 2025, the CCB's activities have also been included into the PIPELINE, PROACT EU-RESPONSE, and BE READY NOW projects, outlined in Section 7 of this report.

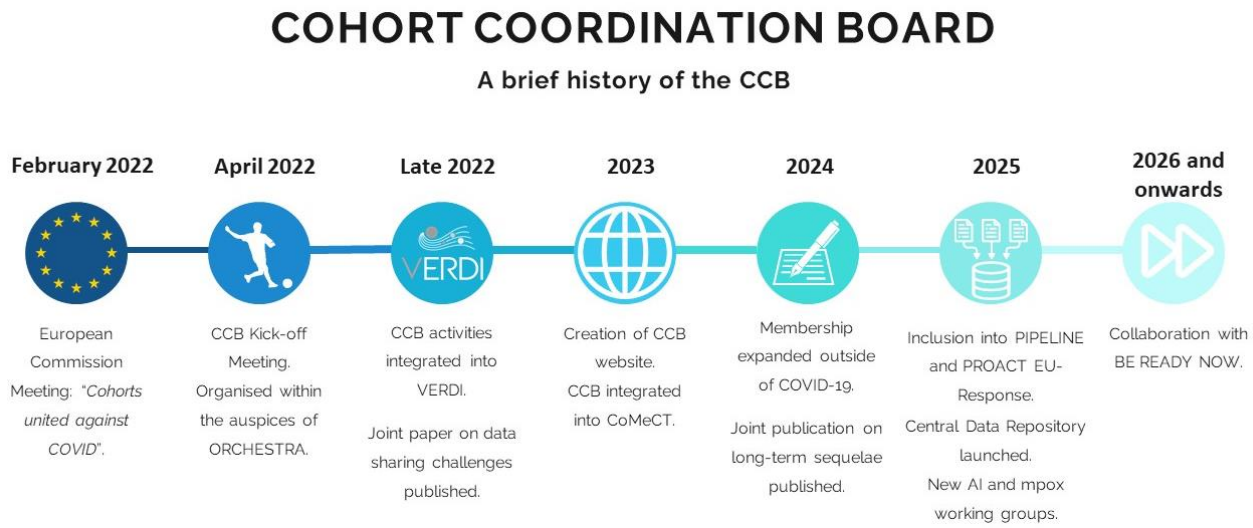

Figure 1 Timeline of CCB activities.

Table 1 lists the tasks relevant to the CCB by timeline and project.

Dates	Project	Task
29/04/2022 - 04/09/2022	ORCHESTRA	CCB launch and coordination activities
05/09/2022 - 31/10/2025	VERDI	Sub-task 7.1.1 Mapping Exercise and consolidation of the CCB
05/09/2022 - 31/10/2025	VERDI	Sub-task 7.1.2 Core dataset for MPX and STI prospective cohorts
05/09/2022 - 31/10/2025	VERDI	Sub-task 7.1.3 Dissemination and global synergies
01/12/2023 - 30/11/2026	CoMeCT	Task 1.3 Transitioning towards an expanded CCB
01/01/2024 - 30/11/2026	CoMeCT	Task 1.5 Implementation of CCB meetings
01/02/2024 - 30/11/2026	CoMeCT	Task 1.7 Alignment of cohorts and trials
01/12/2023 - 30/11/2026	CoMeCT	Task 3.1 Mapping of APTs and CSs - IDs with epidemic potential
01/12/2023 - 30/11/2026	CoMeCT	Task 3.3 Developing a Central Data Repository for APT and CS
01/01/2025 - 31/12/2027	PIPELINE	Task 1.4 Cluster within the pandemic preparedness research infrastructure in the EU
01/01/2024 – 31/12/2029	PROACT-EU RESPONSE	Task 18.1 Artificial intelligence supported systematic search of cohort studies and databases for TTEs Duration

Table 1 Timeline and tasks of the EU-funded projects pertaining to the CCB.

3. Scope and Composition

In 2024, the CCB expanded its membership to include European Union (EU) and nationally-funded projects conducting mpox cohort-based research, alongside the COVID-19 research projects and relevant initiatives already engaged. Additionally, members of the extended CCB include representatives from the European Centre for Disease Prevention and Control (ECDC), EMA, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the EC.

3.1 Terms of References

In March 2024, the updated Terms of Reference (ToR) for the CCB were finalised, having been developed in collaboration with the TCB to encourage alignment and synergy between the two boards, as foreseen within the CoMeCT project. The updated ToR also includes a Non-Disclosure Agreement (NDA), designed to protect any sensitive information shared during or following a CCB meeting. Members and guests are both invited to sign the NDA before attending their first CCB meeting.

3.2 Objectives

The overarching objectives of the CCB, updated for 2025, are as follows:

- To improve the understanding of the cohort landscape in Europe and of the role cohorts can play in supporting pandemic preparedness research;
- To promote the use of cohort data to inform randomised controlled trials (RCTs);
- To avoid the overlap and duplication of efforts and promote synergies among projects and initiatives implementing observational cohorts to support Europe response and preparedness;
- To improve the uptake of data standards and to harmonise data standards that have been adopted across cohorts and trials;
- To share approaches to overcome commonly encountered obstacles (e.g., shipment of samples across national borders, lack of common data dictionaries, electronic tool to link anonymous patient IDs to multiple samples and clinical data) in prospective cohorts;
- To share documents of relevance for cohorts and with a view to greater harmonisation (Data Management Plans, Data Sharing Agreements, Material Sharing Agreements, Informed Consent);
- To combine projects to achieve stronger powered results and support data sharing and innovative study designs (e.g., simulation trials);
- To organise training activities for best practices in cohorts;
- To identify research unmet needs and inform stajeholders, research centers, and founders;
- To support the CoMeCT Coordination Board by providing latest evidence on cohort-based research projects focusing on new and remerging IDEPP.

3.3 Core Group Members

At the end of April 2025, the CCB core group had 27 permanent member organisations. Twelve new projects have joined since January 2024: CoMeCT, CONTAGIO, VEBIS, German Mpox Cohort, VIHMAR, ITM Antwerp Mpox Cohort, MoVIHvax, MPOX-ICONA, Monkey Vax, MOSAIC, MICE, and MPOX CARE. Mpox CSs were invited to join following a mapping activity performed within the CoMeCT project (see Section 5.3). The EC also participates in the CCB with observer status with representatives from Directorate-General Research and Innovation (DG R&I), Directorate-General Health and Food Safety (DG SANTE), Health Emergency Preparedness and Response Authority (HERA), and Health and Digital Executive Agency (HaDEA) alongside representatives from the ECDC, EFPIA, and EMA (Table 2). A complete list of the core CCB members, including full project names, is available on a dedicated page on the CCB website.

Table 2 CCB participants as of May 2025

Core CCB

PROJECT REPRESENTATIVES:		EUROPEAN COMMISSION:
CoMeCT	**MPOX CARE**	**DG R&I**
Victoria C Simensen	Francisco Jover Diaz	Patricia Urban Lopez
Trine S Ofitserova	**MPOX-ICONA**	Romina Escobar
Nina Langeland	Valentina Mazzotta	Evelyn Depoortere
Monica Falk	**NICB**	**HADEA**
Catherine Fleming	Patrick Mitchell	Carina Pereira
CONTAGIO	**NMCB**	Sevasti Sketa
Thomas Jaenisch	Jos Bosch	Carlos Arauzo
Lauren Maxwell	**ORCHESTRA**	**DG Sante**
COVICIS	Evelina Tacconell	Marta Valenciano
Giuseppe Pantaleo	Lorenzo Maria Canziani	Sigrid Weiland
Song Ding	Anna Górska	Stefan Schreck
Agostino Riva	Alessandro Visentin	**HERA**
Karen Hoehn	Alessia Savoldi	Corinna Hartung
ECRAID	Massimo Mirandola	Teresa Chavarria
Marc Shamier	**REACT**	**Extended CCB**
Ankur Krishnan	Pilar Caro Chinchilla	**ECDC**
EMBL-EBI	**RIVM Long COVID**	Howard Needham
Gabi Rinck	Sophie van Wingerden	Ajibola Omokanye
END-VoC	**SYNCHROS**	**EFPIA**
Ibrahim Abubakar	Josep Maria Haro Abad	Magda Chlebua
Gemma Castaño-Vinyals	**UNCoVER**	Katarina Nedog
EuCARE	Jose Luis Peñalvo	**EMA**
Francesca Incardona	**VACCELERATE**	Eugenia Di Meco
German Mpox Cohort	Zoi Pana	Marco Cavaleri
Christoph Boesecke	**VEBIS**	Stephanie Buchholz
ITM Antwerp	Anthony Nardone	
Christophe Van Dijck	Esther Kissling	
LONG COVID	**VERDI**	
Marie Kanerva	Ali Judd	
Gunther Meinlschmidt	Carlo Giaquinto	
MICE	Gabija Morkunaite	
Nadim Cassir	Daniela Paolotti	
Monkey Vax	Moira Spyer	
Liem Binh Luong	Charlotte Jackson	
MOSAIC	Claire Thorne	
Xavier Lescure	Alessandra Nazeri	
MoVIHvax	**VIHMAR**	
Beatriz Mothe	Robert Güerri	
	Andreas Meyerhans	

4. Activities

4.1 Meetings

From January 2024 to April 2025, 11 meetings were held. At every meeting, the CCB welcomed members and external guests to share information, promote events of interest, and discuss common challenges (full list available in Table 3).

Table 3 List of meetings and topics.

Topic	Date	Presenter (affiliation)
What is the ECDC/EMA Vaccine Monitoring Platform?	26/01/2024	Piotr Kramarz (ECDC) and Catherine Cohet (EMA)
Darwin EU	26/01/2024	Andrej Segec (EMA)
Short update from the ECDC activities on Emergency Preparedness and Response	26/01/2024	Emmanuel Robesyn (ECDC)
Update from the COMECT Kick-off Meeting	26/01/2024	Evelina Tacconelli (ORCHESTRA)
Rapidly informing clinical questions to complement trials: the target trial emulation framework for pandemic preparedness	23/02/2024	Inge Olsen and Alain Amstutz (EU-Response)
EMA workshop on generating clinical evidence for treatment and prevention options for Long-COVID	23/02/2024	Stephanie Buchholz (EMA)
From I-MOVE to VEBIS network: Monitoring COVID-19 and influenza vaccine effectiveness in the EU/EEA	19/03/2024	Camelia Savulescu and Baltazar Nunes (VEBIS)
Presentation of the European project CONTAGIO	19/03/2024	Thomas Jaenisch (CONTAGIO)
A pharmacometric platform study to select effective SARS-CoV-2 antivirals and optimise their dosing	16/04/2024	James Watson (The Infectious Diseases Data Observatory)
Invitation for cohorts to join COVICIS focus groups	16/04/2024	Karen Hoehn (COVICIS)
Pregnancy and pandemic preparedness: considerations for data capture	11/06/2024	Claire Thorne (VERDI)
Latent Transition Analysis accurately describes post-COVID condition dynamics at 3, 6, 12, and 18 months. Results from the Orchestra prospective international cohort	11/06/2024	Anna Gorska (ORCHESTRA)
Outbreak Data Collection Initiative	24/09/2024	Frank Hulstaert (Belgian Health Care Knowledge Centre)
Feedback from the END-VOC General Assembly on 4th July 2024	24/09/2024	Sarah Beale (END-VOC)
Using population-based cohorts to study long lasting symptoms following COVID-19	29/10/2024	Lill-Iren Schou Trogstad (Norwegian Institute of Public Health)
Call for inputs: Global Consultation on the Draft Principles of Open Science Monitoring	29/10/2024	Ania Gorska (ORCHESTRA)
Mpox cohort presentations (first round)	21/11/2024	Christophe Van Dijck (ITM Antwerp mpox cohort), Beatriz Mothe (MoVIHvax), Christoph Boesecke (German Mpox Cohort),

		Roberto Güerri (VIHMAR) and Valentina Mazzotta (MPOX-ICONA)
Updates from CONTAGIO	21/11/2024	Thomas Jeanisch (CONTAGIO)
CoVICIS's Technical Synthesis for Public Policy and Cohorts Policy Insight Series	14/01/2025	Karen Hoehn (COVICIS)
Presentation of the Monkey Vax project	14/01/2025	Liem Binh Luong (MonkeyVax)
Launch of the Open Stakeholder Group on Long COVID	11/02/2025	Cristina Pepato (Intellera, consultant for DG Sante)
Mpox cohort presentations (second round)	11/02/2025	Xavier Lescure (MOSAIC) and Nadim Cassir (Mpox Imported Cases Epidemiology (MICE))
MPX-ICONA's vaccine research plan	11/02/2025	Valentina Mazzotta (MPX-ICONA)
Presentations of the MPOX CARE project	08/04/2025	Francisco Jover (MPOX CARE)
INTEGRATE – LMedC WP3 Outcomes	08/04/2025	Lydia-Hanaa Faris (INTEGRATE – LMedC)
Post-COVID research in the Netherlands: Creating an online metadata dictionary	08/04/2025	Dana Rouland (Post-COVID Network Netherlands)

4.2 Working Groups

The CCB currently has five WGs, designed to provide a dedicated space and time to discuss and evaluate key themes in detail, leaving space in the main meetings for other pertinent themes of discussion. In early 2025, two new WGs were established, focussing on the use of Artificial Intelligence (AI) in cohort design, and mpox. At every CCB meeting, the WG Chairs update the wider CCB members on their activities and progress. Outside of the routine CCB meetings, the WGs meet amongst themselves regularly.

4.2.1 Working Group on leveraging cohort data for the design and conduct of clinical trials

Chair: Lauren Maxwell (CONTAGIO-ECRAID)

This WG, initially titled Working Group on epidemiological analyses and methodology when setting up observational studies in Pandemic times but retitled for a clearer focus, aims to discuss and understand better the role of CSs with regards to preparedness plans. The WG includes representatives from several projects and the EC.

The WG focusses on understanding the role CSs have in providing results and guidance for the clinical response to COVID-19, and what a modern, pandemic-ready, observational platform model might look like. Based on collective experience from a range of infections including those caused by SARS-CoV-2, mpox, multi drug resistant organisms and HIV, the WG examines how to establish new CSs in the most effective and pragmatic way, to maximise impact, timeliness and sustainability, in the context of limited resources. This WG also creates dialogue surrounding the benefits of observational studies, highlighting that they can generate questions for trials and provide estimates for trial feasibility; provide real world comparison arms for some trials; generate data on key patient subgroups who may not be targeted by trials or for whom trials may be unfeasible; follow patients after trial exit to provide long term safety and effectiveness evidence; and provide insight into issues of trial generalisability.

Over the course of 2024, the focus of the WG has evolved to focus on better understanding how we can encourage reuse of cohort data in clinical trials. The WG started the development of a survey to better understand TCB and CCB member recommendations and experiences in using cohort data for the design and

conduct of RCTs in COVID-19 and mpox response. The survey was distributed to members of the CCB and TCB at the beginning of 2025. The survey results will be analysed, shared with the CCB and TCB, and submitted as an Open Access publication that includes the survey results and the related recommendations from the CCB and TCB.

4.2.2 Working Group on Post-Acute Infection Syndromes

Chair: José Luis Peñalvo (unCoVer)

This WG, initially focussed on Post COVID-19 Condition (PCC), has been constantly growing in members and contributing projects, including more than 30 representatives from major past- and currently-funded EU and national projects such as ORCHESTRA, unCoVer, VERDI, EuCARE, END-VOC, VACCELERATE, and COVICIS, along with public health institutions such as the Norwegian Institute of Public Health (NIPH) and the Dutch National Institute for Public Health and the Environment (RIVM). Extended membership involves national coordinators of COVID-19 and Long COVID cohorts, the TCB, World Health Organization, National Institute of Health - National Institute of Allergy and Infectious Diseases, EMA, and patient advocacy groups. The WG was established to map and align PCC related research efforts from observational cohorts, enhance data quality, promote interoperability, and support standardised data collection across studies. In 2024, following evolving research needs and the prioritisation of pandemic preparedness, the WG transitioned into a broader scope addressing PAIS, reflecting the need to generalise methodologies and collaborative frameworks beyond, and learning from, PCC. Monthly expert meetings continue to serve as a space for knowledge exchange, harmonisation of research approaches, and coordination of data infrastructure development, as well as collaborative work. A key output of the WG is the ongoing development of guidelines for robust observational research on PAIS, focusing on clinical characterisation, epidemiology, and evaluation of care strategies resulting in a joint publication in the March 2025 issue of Clinical Microbiology and Infection, outlining the methodological foundations for harmonised research on PCC and potential future PAIS "Learning from post-COVID-19 condition for epidemic preparedness: a variable catalogue for future post-acute infection syndromes" (doi: 10.1016/j.cmi.2024.12.001). This work has also been presented at international forums, including the ESCMID Global conference held in Vienna in April 2025. The WG plans to continue shaping collaborative, transnational responses to the long-term effects of infectious diseases (IDs) and improving preparedness for future health challenges.

4.2.3 Working Group on data standardisation across cohort studies and clinical trials

Chair: Lauren Maxwell (CONTAGIO-ECRAID)

The WG aims at encouraging data standardisation across CSs and clinical trials, learning from the experiences of the initiatives within the CCB and TCB. In 2024, a survey was circulated to understand which standard ontologies were used by the CCB cohorts and TCB trials. The survey was designed to create a baseline for efforts in the CoMeCT Consortium to improve the uptake of data standards and coordination in the standards that have been adopted, and to generate preliminary recommendations from researchers to the EC to facilitate the uptake of standards. A position paper was drafted in collaboration with all CCB and TCB members to ensure the broadest possible feedback on related recommendations to the EC and other funders of ID research. The paper addresses unmet needs in terms of how data standards are adopted and coordinated across cohorts and clinical trials. The standards paper was submitted to Open Research Europe and it is currently under revision. This WG has now connected with related WGs from the European Open Science Cloud and ESCMID. The WG will contribute to the 2026 European Open Science Cloud Winter School and is in the process of drafting a standards-focused session for ESCMID 2026 and a stand-alone, online training with ESCMID.

4.2.4 Working Group on the use of artificial intelligence in cohort design

Co-chairs: Thomas Jaenisch (CONTAGIO) and Anna Górska (CoMeCT)

AI is an emerging and transformative tool that is increasingly being integrated into all domains of life, including CSs in ID. The CS pipeline is multistage, complex, time- and labour-intensive, spanning structured eCRF design, variable selection, prospective data standardisation, quality control, statistical analysis,

visualisation, and concluding with meta-research and evidence synthesis. These final steps often form the foundation for designing new observational studies. AI has the potential to support and streamline each stage of this pipeline by reducing time and labour requirements while also improving data quality and consistency. However, AI also introduces unique ethical and methodological considerations that must be addressed.

The goal of the WG is to foster peer learning, critical review, and collaborative development of methodologies applying AI throughout the entire observational cohort research pipeline. The group brings together 35 members: clinicians, ID researchers, and methodological experts, including those from the areas of medical informatics, bioinformatics, data science, and statistics. Members come from a broad range of European research institutions and CCB-affiliated projects.

As of April 2025, three WG meetings have been held.

- The first meeting focused on results from a participant survey assessing experience with AI tools and identifying which phases of the CS pipeline are most time-consuming and potentially benefit most from automation.
- The second meeting explored AI applications in systematic reviews and meta-analyses.
- The third meeting addressed AI-driven crosswalks between data standardisation ontologies, particularly involving the OMOP (Observational Medical Outcomes Partnership) Common Data Model, and initiated a broader discussion that will continue in the next session.

Looking ahead, the WG plans to publish a review article on the use of AI across the CS pipeline to map current practices, identify opportunities, and highlight open challenges.

4.2.5 Working Group on mpox

Co-chairs: Xavier Lescure (MOSAIC) and Zoi Pana (VERDI)

Following the global outbreak of mpox in 2022-2023, and the subsequent outbreak in the Democratic Republic of the Congo and surrounding countries in August 2024, the CCB established a WG focused on this specific disease, to support the development of standardised data collection tools and encourage the consideration of vulnerable and underserved populations. This WG was recently established, with its first meeting to be held in June 2025. Members include representatives from VERDI, MOSAIC, German Mpox Cohort, MPX-ICONA, ITM Antwerp, VIHMAR, MoVIHvax, Monkey Vax, VEBIS, and MICE. The main aim is to map the current efforts across European countries enrolling patients with acute mpox infection (cohorts) - both adult and pediatrics - and involving different clades (narrative review, a living document), explore key clinical biological and immunological variables in a coordinated manner to help build a foundational dataset that can support in depth immunological research (focus on post infectious immune response), support the development and harmonisation of standardised datasets and protocols for mpox and align and synergise with existing initiatives already moving in this direction. The WG activities include also assessment of outpatient mpox management and explore the use of telemedicine tools, which could also be validated for future outbreaks. The WG has been involved in a collaborative effort with the COMECT project and substantially contributed to the manuscript titled *Lessons from the European Mpox Outbreak: Strengthening Observational Research for Future Pandemic Preparedness,* submitted to Clinical Microbiology and infection and currently under review. The group is also actively working with ISARIC to inform syndromic surveillance approaches and standard mpox eCRFs.

5. CCB Website

On 4 March 2024, the CCB website was published at www.cohortcoordinationboard.eu. The website aims to increase the visibility of the CCB activities and enable accessibility to useful resources and toolkits. It provides a brief history of the CCB, a list of the members and relevant resources and documents. It also features a blog section which keeps the audience updated with the latest news from the CCB and events calendar. Since the website launch, 30 posts have been published. A key feature of the website is the CDR, launched on 17 April 2025, and discussed in detail below.

5.1 Central Data Repository

Within the VERDI project, the CCB developed the CDR, an open and accessible repository for metadata of CSs of mpox and sexually transmitted infections (STIs). Through the CoMeCT project, the CDR has expanded to be populated with metadata from CSs, RCTs and Adaptive Platform Trials (APTs) targeting IDEPP. The mapping activities described later in this section provide the metadata to be uploaded: Study design, Time and Location, Pathogen, Disease, Population, Setting, Intervention, Funder and (presence of) Biobanking.

CDR Design

The CDR was designed through the Persona Exercise, a methodology of extraction feature requirements for informatics tools by facilitating communication between the domain experts and IT specialists.

The primary functionality of the CDR is to enable users to find studies that match specific study designs, time and geographical parameters, populations, pathogens, disease or infection type, setting, and information on collected bio-samples, which is achieved through the interactive filters in the left panel (Figure 3).

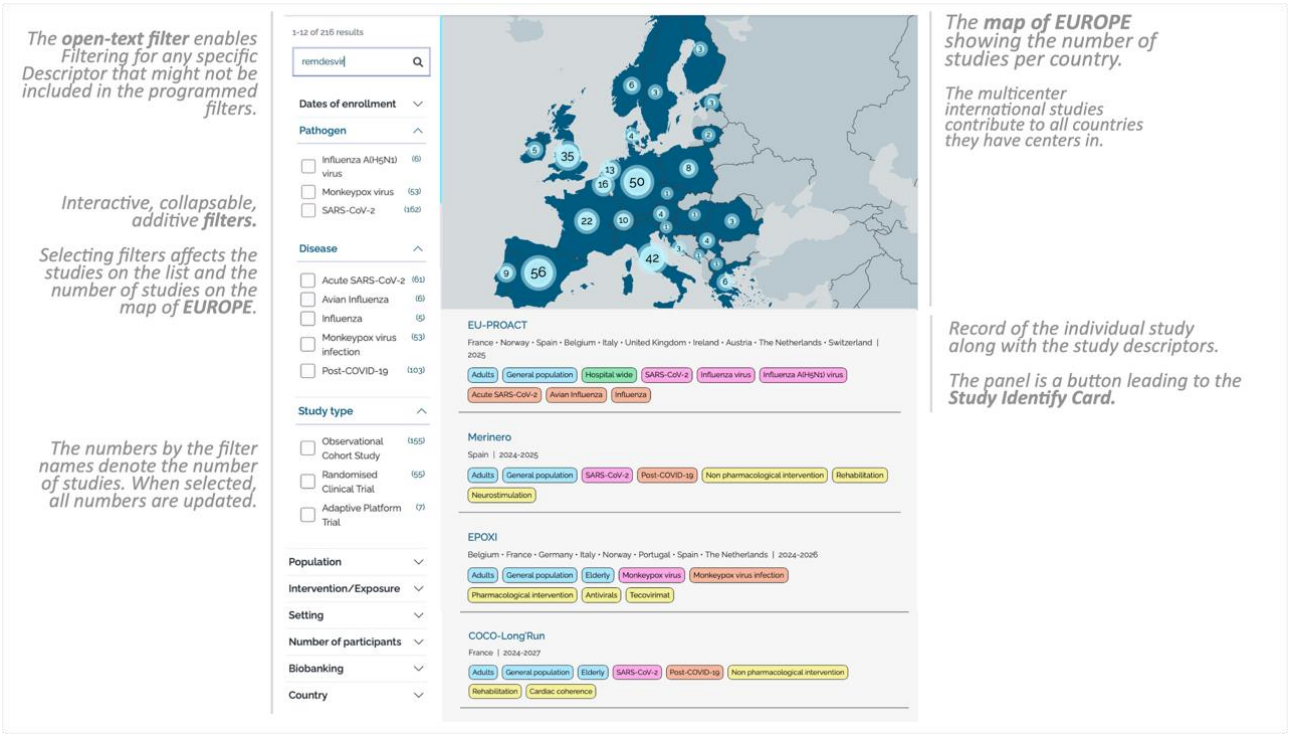

Figure 3 CDR view.

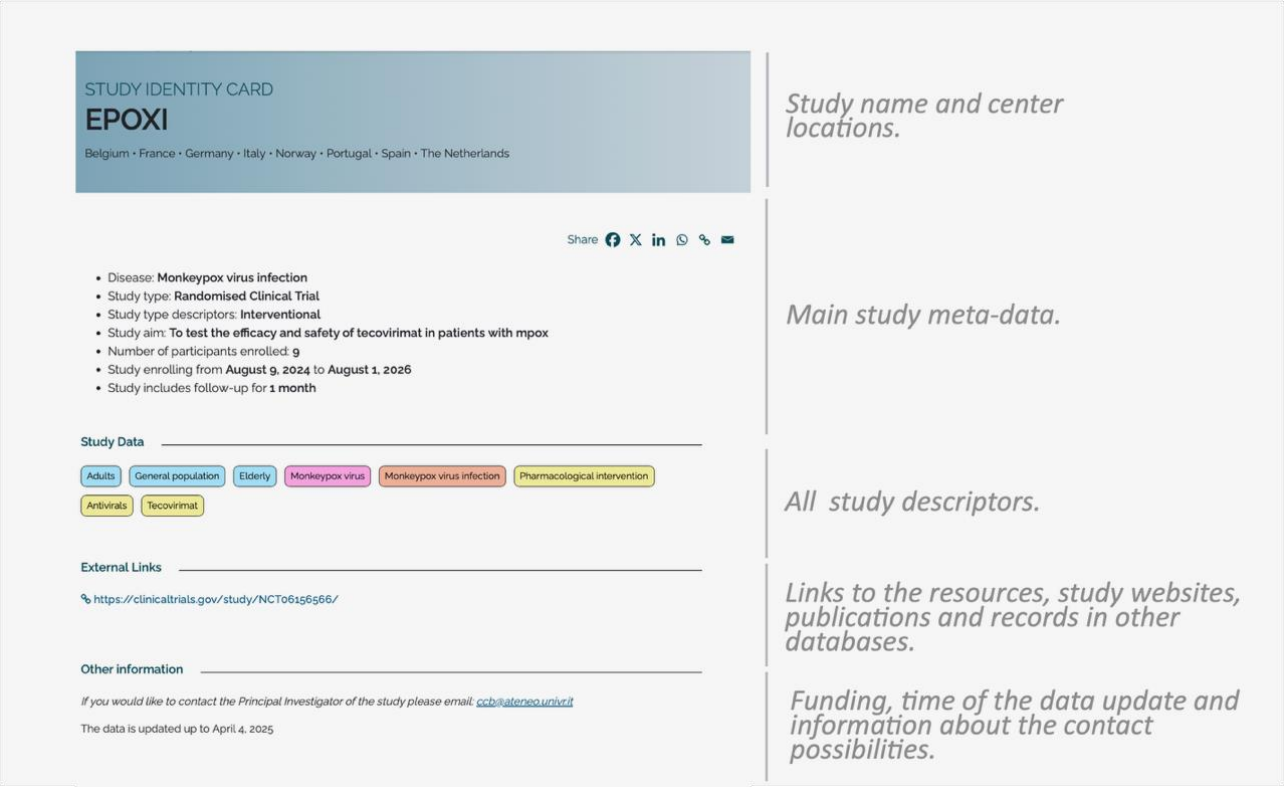

Figure 4 Exemplary Study Identity card.

Mapping Methodology

The mapping is performed using multiple data sources. For CSs, searches are conducted in PubMed, Scopus, ClinicalTrials.gov and the European Clinical Research Infrastructure Network (ECRIN) Clinical Research Metadata Repository. Ongoing or recently closed RCTs and APTs are primarily identified through ClinicalTrials.gov, ECRIN, the Clinical Trials Information System (CTIS) and the International Standard Randomised Controlled Trial Number databases. All searches are complemented by partner consultation to avoid publication bias. The whole process is human-supervised but largely automated, thus enabling frequent updates and sustainability beyond the projects' lifecycle, as per the overall aim of these activities.

The search strategy initially focused on a pathogen-specific approach and involved both the generation of search strings and the use of free-term searches, when relevant. To enhance the comprehensiveness of the mapping, a complementary syndromic approach on a case-by-case basis is being considered, which will allow a broader range of studies to be captured.

The studies are de-duplicated and the metadata are extracted automatically. The inclusion criteria are:

- study performed in at least one centre in Europe;
- active in the last 3 years,
- targeting at least one pathogen of interest;
- study design: CS or RCT. APT is here considered a sub-type of RCT.

The studies, along with all extracted metadata, are compiled into a dedicated database and provided to clinical researchers for manual screening and review. Finally, from the accepted studies, the contacts of the principal investigators (PIs) are extracted. The PIs are then contacted with a request to submit their study's metadata via an Online Form on the CCB website. A final quality check is performed before publicly sharing the data. In the case of no reply from the PI, the metadata is extracted from public sources by the team at the University of Verona.

The present version

As of May 2025, the CDR contains 217 studies (RCT and CS) targeting COVID-19, H5N1, and mpox. Mapping of CSs on C. trachomatis and N. gonorrhoeae will be included on the CDR shortly. Mapping will also be updated regularly, to identify any recently published relevant studies.

The next subparagraphs provide details of each of the topics mapped and included in the current CDR.

5.2 COVID-19 Mapping

In line with the CCB's original aim to map and coordinate cohort-based COVID-19 research initiatives, in December 2024 a mapping activity was conducted to identify CSs related to both acute COVID-19 and PCC, with at least one participating centre located in Europe and active since 1 January 2022. Studies that addressed treatment in acute COVID-19, as well as treatment and natural history in PCC were prioritised. No final report was developed, as only the latest still ongoing studies were selected, but all studies are available to view on the CDR.

The mapping identified 54 studies on acute COVID-19, of which 14 were prospective and 18 were multicentre studies. The majority (50) enrolled adult participants, while 17 included immunocompromised individuals. The studies were conducted in a variety of clinical settings: 41 in hospitals, seven in emergency departments, three in intensive care units, and 37 in primary care settings or outpatient clinics. Finally, 36 studies investigated antivirals, including 25 on Remdesivir, 23 on Nirmatrelvir/Ritonavir, and 22 on monoclonal antibodies.

The PCC mapping identified 49 CSs, the majority of which were prospective (45) and single-centre (33). These cohorts enrolled between 19 and 641,407 participants. The earliest studies began on January 1, 2020, and the most recent started on October 7, 2023. Completion dates ranged from January 3, 2022, to December 11, 2024. The studies were conducted across 18 European countries. Germany was the most represented, with 21 studies having at least one participating centre there, followed by the United Kingdom (8), Belgium (5), and Spain (4). Most cohorts (44) focused on the general population, with 43 enrolling adults and eight (16.3%) including paediatric participants. Additionally, two studies involved rehabilitation settings.

5.3 Mpox Mapping

Following the declaration of the mpox outbreak in the Democratic Republic of the Congo (DRC) and surrounding countries as a Public Health Emergency of International Concern in August 2024, an emergency initial mapping activity of CSs on mpox in Europe after 1 January 2018 was performed. A total of 37 CSs were identified from PubMed and by expert consultation, leveraging the cohort network present within the CCB. The details of these studies were presented in the *Report on Status of European Mpox Cohorts,* a document submitted to the EC on 14 October 2024. The initial results of this mapping were also included into the *CoMeCT assessment of the European research response to the 2024 mpox outbreak: policy brief for the European Commission*, submitted by CoMeCT's Outbreak Response Board in September 2024.

Report overview

Briefly, the report identified the following gaps in mpox research:

- Limited follow-up data available for most of the cohorts, with few studies assessing long-term sequelae and immune response,
- Limited geographical representation, with most of the studies being conducted in Western Europe and no cohorts identified in Northern, Eastern or Southeastern Europe,
- Lack of information on the implementation (or development) of standardised data dictionaries,
- Lack of linkage with national surveillance registries,
- Missing information on funding sources.

For this reason, the following recommendations for future research were discussed:

- Innovative study design, including approaches such as embedding RCTs within CSs (also known as trial within cohort – TwiC) to streamline enrolment and ensure comprehensive follow-up,
- Implementation of CSs targeting individuals at high risk for STIs,
- Enhance data interoperability and harmonise study designs between CSs and RCTs, to ensure data re-use and enable prospective meta-analyses of individual patient data,
- Greater integration between CSs and national registries,
- The widespread adoption of the STROBE checklist (*STrengthening the Reporting of OBservational studies in Epidemiology*) and the sharing of data dictionaries.

Expanding the mpox mapping

A second iteration of the mpox mapping activity was performed on 10 December 2024 and included updates of the previous data sources as well as four additional ones: the ECRIN clinical research metadata repository, Clinicaltrials.gov, CTIS, and Scopus. A total of 11 CSs were added, increasing the total to 48 identified studies. The metadata of these studies have been added to the CDR. The PIs have also been invited to present their study in CCB meetings and, as of April 2025, nine PIs have presented and subsequently joined the CCB as permanent members. A paper titled "*Lessons from the European Mpox Outbreak: Strengthening Observational Research for Future Pandemic Preparedness*" has been drafted following the mapping activity and was submitted for publication in an indexed journal in early May 2025. The manuscript further explores the gaps in the European research response and offers possible solutions for future pandemic preparedness research.

5.4 H5N1 Mapping

Following the outbreak of human cases of H5N1 across the United States and Canada in late 2024, the CCB, alongside the TCB, completed a mapping activity to identify CSs, RCTs and APTs specifically investigating H5N1 with at least one active site in Europe since January 2022. The results were included into the Outbreak Response Board's second report titled *H5N1 Research Priorities* and submitted in March 2025.

Report overview

Overall, five APTs focused on therapeutics were identified through the consultation of networks. None of these trials specifically addressed H5N1, but rather adopted a syndromic approach to identify acute respiratory distress syndrome, community acquired pneumonia or respiratory viral infections. Among them, one APT is ongoing since 2018 and enrolled 8442 patients so far, while two others are ongoing since 2020 and July 2024 and included 100 and 291 patients, respectively. One prospective CS conducted in Spain with the aim of assessing vaccination effectiveness was identified. The study enrolled 135 patients and had a follow-up of 6 months. No other recently published CSs investigating H5N1 were found.

The following recommendations for future research were discussed:

- assess infection and immunity dynamics using standardised protocols,
- investigate disease progression and outcomes across diverse populations,
- enhance genomic surveillance and data integration for timely variant detection,
- prioritise research on the immunogenicity, safety, and long-term protection of avian influenza vaccines,
- address gaps in zoonotic vaccine approval, particularly for underserved populations,
- evaluate the effectiveness and safety of antivirals and monoclonal antibodies,
- develop robust predictive models for pandemic preparedness that incorporate behavioural, policy, and epidemiological data.

6. Dissemination Activities

The CCB provides a forum in which members can share information regarding relevant training opportunities and scientific events. The CCB participated in multiple events from January 2024 to May 2025, to share results and engage in potential collaboration between its experts and other ongoing initiatives. Table 4 lists all meetings where the CCB was presented in the reporting period.

Table 4: Meetings where CCB was presented

EVENT	LOCATION	DATE	PRESENTER	PRESENTATION TITLE
The Infectious Diseases Data Observatory and CoMeCT	Online	11/3/2024	Evelina Tacconelli	**Oral presentation** The role of CCB
ESCMID Global	Barcelona	30/4/2024	Evelina Tacconelli	**Oral presentation**: Supporting synergies across European cohorts for optimal evidence generation: the case of the **CCB** **Video showcasing the activities of the CCB (**broadcast live – now on the CCB website.
Network of Expertise on Long COVID	Online	26/6/2024	Evelina Tacconelli	**Oral presentation:** Long Covid research priorities – Perspective of projects funded under Horizon Europe
CCB Networking Event at Demystifying Long COVID Conference	Barcelona	21-22/11/2024	Lorenzo Maria Canziani and Giulia Marchetti	**Oral presentation:** Long COVID Working Group & EUCARE Post-COVID Study
PIPELINE Kick-off	Paris	3-4/4/2025	Evelina Tacconelli	**Oral presentation:**. CCB and the pandemic preparedness research infrastructure in the EU

Events attended by CCB members

- COVICIS Cohort Focus Group Discussions on 30 May 2024 with the aim of collecting cohort participants' expertise, experience and observations into a policy brief for informing policy-makers and civil society.
- Italian Conference on AIDS and Antiviral Research in Rome on 20 June 2024. More information at: https://www.icar2024.it/
- Demystifying Long COVID Conference in Barcelona from 21 to 22 November 2024. More information at: https://academicmedicaleducation.com/meeting/demystifying-long-covid-international-conference-2024
- The Science of Pandemics: Past, Present, and Evidence-Based Strategies for the Future in Rome on 29 November 2024. More information at: https://eucareresearch.eu/eucare-schools-event/
- Launch of the Open Stakeholder Group on Long COVID on 15 February 2025.

7. Future Steps

This period has also seen the inclusion of the CCB's activities into multiple new projects, namely PIPELINE (GA 101155852), PROACT EU-Response (GA 101156304) and BE READY NOW (Prop 101226682).

7.1 PIPELINE

PIPELINE (Pregnancy and Infant PrEparedness pLatform IN Europe), was launched on 1 January 2025 and will run until the end of December 2028. It aims to develop a dedicated pregnancy-infant preparedness platform for adaptive trials and improve pandemic preparedness for these underserved populations. The CCB is involved in Task 1.4 *Cluster within the pandemic preparedness research infrastructure in the EU*, which entails the further development of automated search methods to populate the CDR with new clinical studies which include pregnant women and infants, and focus on prevention and treatment of infections which may have relevance to preparedness. The CCB will support and facilitate the extension of the search to other mapping initiatives outside Europe (such as the CONTAGIO project). Task 1.4 also involves the development of guidelines for the use of the CDR and of other linked initiatives by PIPELINE partners. Furthermore, PIPELINE Work Package 1 and PIPELINE-RSV trial representatives will participate in routine CCB meetings.

7.2 PROACT EU-Response

PROACT EU-Response (A European Proactive Adaptive Clinical Trials Network within EU-Response), which launched on 1 January 2025, aims to prepare Europe for future pandemics by strengthening upon existing networks of experts and civil society focused on clinical therapeutic platform trials within hospital inpatient settings across Europe. The CCB will support Task 18.1 *Artificial intelligence supported systematic search of cohort studies and databases for Target Trial Emulations*, specifically with regards to identifying CSs suitable for target trial emulations. Within this task, once CSs are identified and collaborations established, core datasets are to be harmonised across CSs to conduct pooled analyses.

7.3 BE READY NOW

The CCB has also been involved in a recent HORIZON Programme Cofund Action proposal for the BE READY NOW project, submitted on 25 November 2024. The proposal aims to set up the basis of the future European Partnership for Pandemic Preparedness, which will gather 74 organisations from 24 countries, including public funding agencies, public health institutes, clinical networks, ministries and research infrastructures active in pandemic preparedness. BE READY NOW will align stakeholders in pandemic preparedness around shared research priorities to foster a coordinated and efficient research landscape, producing sustainable scientific, health, and socio-economic benefits. Building on the infrastructures, projects and initiatives supported by the EC and Member States, BE READY NOW will establish and sustain an "ever-warm" research ecosystem, capable of pivoting swiftly in response to emerging health threats. This ecosystem will include an innovative, ever-warm EU-wide network of networks of clinical research sites, which the CCB will support. The CCB is involved particularly in Work Package 12, Task 12.5 *Run clinical studies through the Ever-Warm Network of Networks targeting a specific infection in the peacetime with case studies as an exercise for epidemics*.

8. Conclusions

Over the past 16 months the CCB has undergone a significant transformation, expanding its focus beyond COVID-19 research to include other IDEPP. Significant work has been performed in several key areas: long-term sequelae of IDs, promoting the use and adoption of data standards, and defining the role of CSs in informing RCTs and APTs. Furthermore, activities performed within VERDI and CoMeCT have contributed to bringing new members to the CCB and allowed for the creation of two new WGs, one dedicated to the role of AI in cohort design and another focused on mpox. These efforts have been crucial for the CCB expansion and consolidation as a key stakeholder in the European research landscape. This is exemplified by the CCB's inclusion into three new EU-funded projects. Alignment with the TCB has enabled a synergy between the boards and strengthened research recommendations to both the EC and EMA, particularly as regards the extensive and responsive mapping activities based on shifting epidemiological scenarios. The visibility of the CCB has also grown dramatically, with its presentation at ESCMID Global in April 2024, the finalisation of the CCB website and its being featured on the CoMeCT communication channels. The launch of the CDR also represents a significant milestone that enhances visibility of the CCB, as relevant studies are invited to contribute their metadata and stakeholders are invited to use the tool to support their own initiatives. Furthermore, the CDR reinforces the long-term sustainability of the CCB as an entity striving to align preparedness initiatives across Europe.

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