COHORT COORDINATION BOARD

First Report 2022-2023

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Executive Summary

During pandemics, cohort studies (CSs) enable rapid exploration of disease epidemiology and effectiveness of interventions. However, differences in research protocols and how data are defined and structured can challenge data harmonisation and bias cross-study results. Support for the implementation of data harmonisation efforts is crucial to maximise the success of observational research, especially in the context of pandemic preparedness. Encouraged by the European Commission (EC), the Cohort Coordination Board (CCB) was established in April 2022. Members include European Union and nationally funded COVID-19 cohort projects and initiatives, EC and Executive Agencies (DG-RTD, DG-SANTE, HaDEA), the European Centre for Disease Prevention and Control, European Medicines Agency and other stakeholders. The CCB aims to identify synergies across cohorts, map common tasks, discuss hurdles and solutions, promote collaboration for optimising resources and reaching stronger powered results, and provide recommendations for priority areas to the EC.

Meetings are scheduled every 4 weeks with the participation of guest experts in the case of emerging scientific evidence. The CCB includes 58 representatives from 16 projects and institutions. In terms of thematic areas of relevance, consultation of the members revealed high interest in: virtual biobanking; metadata sharing platforms; standardisation/interoperability of data; and the definition of post-COVID-19 syndrome. Three working groups have been established focusing on: methodological flaws when setting up CSs during pandemics; definition of a core protocol to assess post-viral syndromes; and assessment of barriers to uptake of standard ontologies and vocabularies. During the first 20 months of activity, 23 meetings were held covering 35 thematic areas: 12 on CS results; 6 on data harmonisation; 5 on methodologies; 4 on pandemic preparedness; 4 on new collaborative proposals; 4 on networking opportunities. Projects have shared Data Management Plans and data dictionaries which has facilitated project start-up and new proposals for funding have been developed. The collaborative efforts were summarised in a White Paper on challenges of data sharing in European COVID-19 projects ("*Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response*" - Lancet Regional Health – Europe; https://www.sciencedirect.com/science/article/pii/S2666776222001636), and produced two new Horizon Europe financed projects.

Collaboration among cohort projects is particularly important due to the head start it can provide for the rapid activation of projects and, hence, optimal and prompt evidence generation for informing public health decisions, vital in a pandemic scenario. The CCB offers a trusted environment that allows for discussion on challenges encountered. Strategic and sustained coordination mechanisms are especially important during interpandemic phases for pandemic preparedness.

This report provides an overview of how the CCB has evolved from its inception during the pandemic phase to a consolidated body now formalised within the framework of an EU-funded project. It describes how the focus of the CCB has shifted from COVID-19 to the broader topic of pandemic preparedness in its two years of operation and considers the future sustainability and relevance of the Board against the constantly evolving epidemiological situation and increased coordination among main stakeholders.

Table of Acronyms

Acronym	Description
APT	Adaptive Platform Trial
CCB	Cohort Coordination Board
CS	Cohort Study
DG R&I	Directorate-General Research and Innovation (Department within the European Commission)
DG SANTE	Directorate-General Health and Food Safety (Department within the European Commission)
DMP	Data Management Plan
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
eCRF	Electronic Case Report Form
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
HaDEA	Health and Digital Executive Agency
HERA	Health Emergency Preparedness and Response
IDs	Infectious Diseases
TCB	Trial Coordination Board
WG	Working Group
WHO	World Health Organization
WP	Work Package

1. Background

The idea to create a Cohort Coordination Board (CCB) came as a result of the meeting, "*Cohorts united against COVID-19*", organised by the European Commission (EC) in February 2022. With almost 90 participants, the meeting brought together the EU-funded COVID-19 cohort projects, as well as other relevant initiatives, such as the European COVID-19 data platform. From the EC, participants from several Directorates-General (Research and Innovation (DG R&I), Health Emergency Preparedness and Response (HERA)) and Executive Agencies (Health and Digital Executive Agency (HaDEA), Research Executive Agency (REA)) were present, and participants from the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA). The meeting brought attention to the significant opportunity for constructive collaboration among COVID-19 cohort projects. It also showed the potential for stronger evidence in the field of disease prevention and treatment from the EU-funded cohorts when efforts are joined, for advanced harmonisation of data collection across cohorts, using the existing enabling tools and initiatives.

The CCB was established to resemble a similar format to the Trial Coordination Board (TCB) (https://covid19trials.eu/en/tcb), which creates a forum for projects running EU-funded clinical trials. The main goals of the CCB are to encourage knowledge-sharing between EU-funded COVID-19 projects, to spark partnerships, discuss similar challenges and reduce overlap between projects. This coordinated approach is also supported by the common deliverables foreseen in the more recently EU-funded COVID-19 cohort projects, as well as projects focused on epidemic and pandemic preparedness.

The CCB was initially created within the auspices of the EU-Funded ORCHESTRA project, with the CCB Chair as Evelina Tacconelli representing ORCHESTRA, and co-chairs Jose Luis Peñalvo and Ali Judd, representing respectively the unCoVer and VERDI projects. The University of Verona acts as secretary for the CCB.

The CCB has been active since the Kick-off Meeting on the 29th of April 2022, and has expanded both through the addition of new cohorts, and with its inclusion into EU-funded projects. Originally, the CCB was managed within the ORCHESTRA project (https://orchestra-cohort.eu/), then, in September 2022, the activities related to pandemic preparedness were adopted into the VERDI project (https://verdiproject.org/), under Task 7.1, which foresees the consolidation of the CCB with a view to streamlining synergies among cohorts in terms of preparedness plans, with a focus on Monkeypox (MPX) and Sexually Transmitted Infections (STIs). In November 2023 the Grant Agreement for the CoMeCT project was signed, which includes the coordination and expansion of the CCB. The project officially began on the 1st of December 2023. Figure 1 details the timeline of the CCB history.

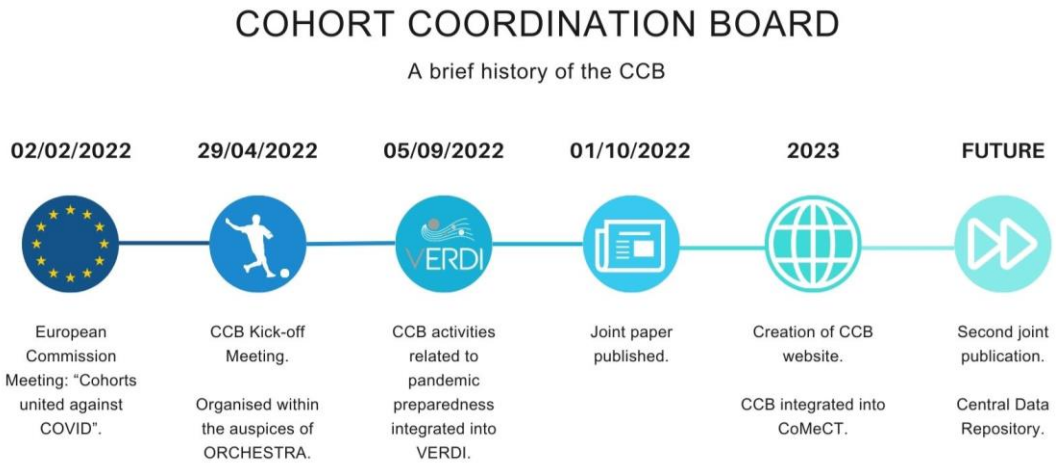

Figure 1

Table 1 displays the CCB tasks and timelines by 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 (CDR) for APT and CS

Table 1

1.1 Scope and Composition

The CCB includes EC representatives, all the EU-funded projects conducting COVID-19 cohort-based research, other nationally-funded COVID-19 cohort-based research projects, relevant initiatives such as the European COVID-19 Data Platform, EU agencies (EMA, ECDC, HaDEA), the European Federation of Pharmaceutical Industries and Associations (EFPIA) and other relevant stakeholders when appropriate. The board is organised into two levels, namely with a core group and an extended group who participate as the need arises and according to the topic of discussion.

1.2 Objectives and Organisation

The overarching objectives of the CCB were developed during the first year of activity and are as follows:

1. Provide an update on the status of ongoing cohort studies, including early results and final outcomes;
2. Avoid overlapping and duplication of efforts (not only in cohort research but also in the creation of tools and infrastructures);
3. Combine forces to achieve better results (e.g., larger sample sizes, stronger powered results, and wider dissemination);
4. Share approaches to overcome commonly encountered obstacles (e.g., shipment of samples across national borders, lack of common dictionaries, electronic tool to link anonymous patient IDs to multiple samples and Work Packages (WPs));
5. Organise training activities for best practices within sub-working groups of interest;
6. Share documents of relevance for cohorts and with a view to greater harmonisation (Data Management Plans (DMPs), Data Sharing Agreements, Material Sharing Agreements, Informed Consent);
7. Make recommendations to the EC for future research in the area of COVID-19.

1.3 Core Group Members

The CCB core group currently has 16 permanent member organisations, including both EU and nationally-funded projects conducting COVID-19 cohort-based research. The European Commission also participates with observer status with representatives from DG R&I, DG SANTE, and HADEA.

The activities of the CCB are organised into three Working Groups (WGs) which are detailed in the next section.

See the full list of current CCB participants in Table 2.

CORE CCB		
EC Funded Projects		**European Commission**
COVICIS	**ORCHESTRA**	**DG R&I**
Giuseppe Pantaleo	Evelina Tacconelli	Patricia Urban Lopez
Song Ding	Lorenzo Maria Canziani	Evelyn Depoortere
Milo Puhan	Alessandro Visentin	**HADEA**
Agostino Riva	**RECODID**	Romina Escobar
Hester Kuipers	Thomas Jaenisch	Carina Pereira
ECRAID	Lauren Maxwell	**DG SANTE**
Marc Shamier	**SYNCHROS**	Marta Valenciano
Ankur Krishnan	Josep Maria Haro Abad	Sigrid Weiland
END-VOC	Ellen Vorstenbosch	**EXTENDED CCB**
Ibrahim Abubakar	**unCoVer**	**Policymakers**
Gemma Castaño-Vinyals	Jose Luis Peñalvo	**ECDC**
Patricia de Llobet	Gloria Soriano	Howard Needham
Alexei Yavlinsky	**VACCELERATE**	Ajibola Omokanye
EUCARE	Zoi Pana	**Regulators**
Francesca Incardona	**VERDI**	**EMA**
Chiara Mommo	Ali Judd	Eugenia Di Meco
Iuri Fanti	Carlo Giaquinto	Marco Cavaleri
Maurizio Zazzi	Deenan Pillay	**EFPIA**
Sara Gandini	Gabija Morkunaite	Magda Chlebua
Sara De Benedittis	Daniela Paolotti	**Boards**
Pontus Nauclér	Moira Spyer	**Trial Coordination Board**
EMBL-EBI/RECODID	Charlotte Jackson	Victoria C Simensen
Gabi Rinck	**REACT**	Hanne Løvdal Gulseth
Guy Cochrane	Pilar Caro Chinchilla	Signe Flottorp
LONG COVID	**NICB**	
Marie Kanerva	Patrick Mitchell	
Gunther Meinlschmidt	**RIVM Long COVID**	
NMCB	Sophie van Wingerden	
Jos Bosch	Merlin van Loenen	

Table 2

2. Activities

2.1 Meetings

Overall, 23 meetings have been held. At every meeting, the CCB welcomes members and external guests to share information, promote events of interest and spark discussion around similar challenges. A list of meeting topics is available in Table 3.

Topic	Date	Presenter (project, stakeholder, affiliation)
European COVID-19 Data Portal	10/06/2022	Gabriele Rinck (EMBL-EBI/ReCoDID)
EMA Questions: Lab capacity – anti viral resistance monitoring	10/06/2022	Eugenia Di Meco (EMA)
COVICIS presentation: Assessment of Anti-SARS-CoV-2 Neutralizing Antibodies Extracted from Dried Blood Spot Cards	22/07/2022	Craig Fenwick (Lausanne University Hospital, CHUV)
Patient Advocacy Groups (PAGs) EU Survey	02/09/2022	Zoi Dorothea Pana (VACCELERATE)
Proposals Cohort Studies (Point Prevalence Survey; Persistent Covid systems)	02/09/2022	Evelina Tacconelli (ORCHESTRA)
Work of ECRAID and relevancy to CCB	23/09/2022	Lauren Maxwell and Ankur Krishnan (ECRAID)
Publication on Long-COVID in JAMA	14/10/2022	José Luis Peñalvo (unCoVer)
MOSAIC Study	14/10/2022	Evelina Tacconelli (ORCHESTRA)
VERDI – WP7 – Mpox	16/12/2022	Charlotte Jackson (VERDI)
Shared deliverables: what are they and how can they be shared	16/12/2022	Patricia Urban-Lopez (European Commission)
Horizon Europe Calls: Overview of relevant calls	16/12/2022	Lorenzo Maria Canziani (ORCHESTRA)
Horizon Europe REACT project	27/01/2023	Pilar Caro Chinchilla (REACT)
WHO study - use of antibiotics in COVID-19 treatment and relation to comorbidities	27/01/2023	Francesca Incardona (EU-CARE)
1-day COVID-19 hospital point prevalence study	27/01/2023	Evelina Tacconelli (ORCHESTRA)
Publication: "Host immunological responses facilitate development of SARS-CoV-2 mutations in patients receiving monoclonal antibody treatments"	17/02/2023	Samir Kumar-Singh (ORCHESTRA)
RIVM Long COVID-onderzoek study	17/02/2023	Siméon de Bruijn (Dutch Public Health Centre for Epidemiology & Surveillance)
Future pandemic preparedness – activities and collaborations	10/03/2023	Ibrahim Abubakar (END-VOC)
EuCARE SCHOOLS study result	31/03/2023	Sara Gandini (EuCARE)
ORCHESTRA at ECCMID	31/03/2023	Evelina Tacconelli (ORCHESTRA)
ECRAID Perpetual Cohorts	21/04/2023	Marc Bonten (ECRAID)
Impact of incorporating semantic standards into COVID-19 study metadata on data transformation, analysis and federated learning in a large multi-country consortium	21/04/2023	Eugenia Rinaldi and Caroline Stellmach (Charite/ORCHESTRA)
Survey on standards for data collection/harmonization	21/04/2023	Lauren Maxwell (RECODID)

Presentation Gut Microbiome and Infectious Diseases	12/05/2023	Elda Righi (ORCHESTRA)
Invitation to Cluster Event and Policy Event in Brussels on 04/07/2023; organised by the EU-funded projects, COVend and ENVISION.	12/05/2023	Elina Nürenberg-Goloub (COVEND/ENVISION)
Presentation about the New Cohort Atlas Design and the BY-COVID open call, a funding opportunity for data hubs	30/06/2023	Gabriele Rinck (EMBL-EBI/ReCoDID)
Feedback from "Research to Policy" meeting on Post-Covid Condition organised by DG R&I	30/06/2023	José Luis Peñalvo (unCoVer)
Feedback from "Lessons-learned workshop on Clinical Trials in Public Health Emergencies" meeting organised by the EMA	21/07/2023	Evelina Tacconelli (ORCHESTRA)
Data Preparedness for future Pandemic and Epidemic risks: The role of the WHO Hub for Pandemic and Epidemic Intelligence	21/07/2023	Oliver Morgan (World Health Organization (WHO))
Estimating COVID-19 burden of disease: evidence gaps	22/09/2023	Ajibola Omokanye (ECDC)
Results from survey on standards for data collection/harmonization	22/09/2023	Priya Shreedhar (RECODID)
Discussion: Outcome of sharing Data Management Plan	22/09/2023	Song Ding (COVICIS)
ORCHESTRA Science Challenge	22/09/2023	Katharina Appel (ORCHESTRA)
COordinating MEchanism for Cohorts and Trials (CoMeCT)	13/10/2023	Evelina Tacconelli (ORCHESTRA)
COVID in Ireland and future directions	13/10/2023	Patrick Mitchell (National Irish COVID Biobank (NICB))
"The incidence and risk factors of selected drug prescriptions and outpatient care after SARS-CoV-2 infection in low-risk subjects: a multicenter population-based cohort study"	13/10/2023	Federico Banchelli and Elena Berti (ORCHESTRA)
Feedback from meeting of Network of Expertise on Long COVID (NELC) on 18/09/2023	24/11/2023	Stefan Schreck (European Commission)
National expertise and research infrastructure for post-COVID and other post-acute infection syndromes in the Netherlands	15/12/2023	Jos Bosch (Netherlands ME/CFS Cohort and Biobank Consortium (NMCB))

Table 3

2.2 Working Groups

Following the first meetings of the CCB, certain recurring themes for discussion became evident. The WGs were designed to provide a dedicated space and time to discuss and evaluate these themes in detail, leaving space in the main meetings for other pertinent themes of discussion.

Three WGs have been formed: the first focusses on epidemiological analyses and methodology during the setup of observational studies in pandemic times, the second on Long COVID and the third on data standardisation across cohorts and trials. 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.

Working Group on epidemiological analyses and methodology when setting up observational studies in Pandemic times

Chair: Ali Judd (VERDI) (Former Chair) Lauren Maxwell (RECODID) and Milo Puhan (COVICIS) (Current Co-chairs)

This WG aims to discuss and understand better the role of CSs with regards to preparedness plans. The WG currently comprises 32 representatives from various projects including ORCHESTRA, ReCoDID, VERDI, EuCARE, CoVICIS, unCoVer, END-VOC, VACCELERATE and ECRAID.

The WG focusses on understanding the role CSs had 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, MPX, 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. The WG is currently organising the writing and submission of a scientific paper summarising the main results.

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.

Working Group on Long COVID

Chair: José Luis Peñalvo (unCoVer)

This WG includes 27 representatives from various projects including ORCHESTRA, unCoVer, VERDI, EuCARE, END-VOC, VACCELERATE, COVICIS, as well as institutions such as the Norwegian Institute of Public Health (NIPH) and the Dutch National Institute for Public Health and the Environment (RIVM), among others. Extended membership outside of the CCB core group includes national coordinators of COVID and Long COVID cohorts; Trial Coordination Board; WHO; National Institute of Health - National Institute of Allergy and Infectious Diseases; EMA; Patient association groups.

This WG is actively mapping out the efforts of the CCB partners on Long COVID. The primary goal is to facilitate mutual learning and foster collaborative partnerships. The ultimate objective is to enhance the quality of data, promote interoperability, and work towards the establishment of standardised data collection methods. This, in turn, will result in a more precise definition of Long COVID, contributing to better prevention and care strategies for those affected by this condition. Over time, the WG has developed into a platform for expert discussions and regular updates. It serves as a space for brainstorming sessions, the presentation of initial findings, and the creation of a repository containing up-to-date information and results. Within the WG, valuable insights garnered from previous studies are shared with newer projects focused on Long COVID. Issues such as the diversity of study designs and varying analytical methods are addressed as the primary challenges impacting the comparability of findings across studies and the interoperability of databases.

With the intention of promptly sharing insights from their own experiences to enhance ongoing design activities, the idea of creating a comprehensive guidance document for crafting CSs emerged as a highly valuable contribution. Presently, the WG is crafting an initial draft subsequent to agreement on a concept note that remains closely aligned with collective expertise. The primary objective of this Master Protocol is to provide empirically-driven guidance for conducting robust observational research into post-viral syndromes, using Long COVID as an illustrative case example. This protocol seeks to present a comprehensive framework for designing observational studies that encompass the following key objectives: 1) Characterising the natural progression of the syndrome, including clinical manifestations, risk factors, trajectory, and underlying mechanisms; 2) Exploring the epidemiological dimensions of the syndrome, including prevalence and incidence rates, identification of risk factors, and recognition of vulnerable population groups; and 3)

Assessing the efficacy of management and treatment approaches. The WG hopes for this document to serve as a stimulus in expanding the understanding of Long COVID, ultimately leading to refined strategies for devising effective surveillance systems not only for Long COVID but also for potential future post-viral syndromes. This collaborative effort is hoping to bolster the preparedness of European and international health systems.

Within a collaborative project led by ORCHESTRA and VERDI, the WG is also looking into the creation of an Electronic Case Report Form (eCRF) for general post-viral syndromes.

Working Group on data standardisation across cohort studies and clinical trials

Chair: Lauren Maxwell (ReCoDID)

This WG was developed following the circulation of a survey developed by Lauren Maxwell (Heidelberg University Hospital) to the members of the CCB and TCB. This survey aimed to understand which standard ontologies are used by the CCB cohorts and TCB trials. The survey was designed to create a baseline for efforts in the recently funded CoMeCT Consortium (discussed later in this report) 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 preliminary position paper has been drafted. The paper addresses unmet needs in terms of how data standards are adopted and coordinated across cohorts and clinical trials.

2.3 Dissemination Activities

The CCB provides a forum in which members can share information regarding relevant training opportunities and scientific events. To date, members of the CCB have been invited to the events illustrated in table 4.

EVENT	LOCATION	DATE	FURTHER INFORMATION
SYNCHROS Final Conference	Barcelona	02/06/2022	https://synchros.eu/synchros-final-conference/
Data standardization: Establishing semantic interoperability of data in ORCHESTRA	Online	14/6/2022	
ORCHESTRA Science Challenge[1]	Online	9/2022-4/2023	Second run: July – October 2023
ReCoDID Stakeholder Meeting	Cambridge	17-19/10/2022	
Scientific Symposium "COVID-19 variants and the next pandemic"	Barcelona	06/06/2023	https://www.isglobal.org/en/-/endvoc-scientific-symposium-on-covid-variants-and-the-next-pandemic
Highway to Health — visions in European Healthcare	Brussels	04/07/2023	
EUCARE Annual meeting - Preparedness brainstorming session	Tel-Aviv	23-24/10/2023	

Table 4

[1] This event involved the ORCHESTRA cohort opening up their database before their study closed, to share data. They encouraged other cohorts to propose possibilities for data sharing and as a result many applications for data sharing were received and accepted. Topic areas were: fragile populations, therapy algorithms and vaccination efficacy.

The CCB has participated in multiple events since its conception, to share results and engage in potential collaboration between its experts and other ongoing initiatives. Table 5 details the events where the CCB's work has been presented.

EVENT	LOCATION	DATE	PRESENTER	PRESENTATION TITLE
European Public Health conference	Berlin	09/11/22	Evelina Tacconelli, José Luis Peñalvo	CCB Special Edition as part of unCoVer´s final Conference
EU/US Long Covid meeting	Online	13/12/22	Evelina Tacconelli	Research evidence on epidemiology, symptoms, treatment of long COVID
Research to policy meeting on Post-Covid Condition	Online	31/05/23	José Luis Peñalvo	Working group on Long COVID: an initiative from the Cohort Coordination Board
Data privacy, data property, and data sharing: an interdisciplinary dialogue for post-pandemic transnational research - A workshop organised by the EuCARE project	Geneva	19–20 June 2023	Ruth Joanna Davis and Lorenzo Maria Canziani	Ethics requirements in an EU-funded research project: The case of ORCHESTRA and the role of the CCB
PHEG Network of Expertise on Long COVID	Online	19/09/23	José Luis Peñalvo	Cohorts Coordination Board: Working Group on Long COVID
ECCMID, the European Congress of Clinical Microbiology and Infectious Diseases 2024	Barcelona	27-30/04/24	Evelina Tacconelli	Supporting synergies across European cohorts for optimal evidence generation: the case of the Cohort Coordination Board.

Table 5

The CCB website has recently been published at www.cohortcoordinationboard.eu. It aims to increase the awareness of the CCB's activities and enable accessibility to useful resources and toolkits.

2.4 Outputs

The CCB's main outputs related to data harmonisation, dissemination and training have been highlighted in the section below.

- Several initiatives for data harmonisation and sharing have been organised in the CCB. **ORCHESTRA** connected its data standardisation experts and representatives with data management teams of **EuCARE** and **END-VOC**, whose projects were funded in October 2021 and May 2022 respectively, with a view to harmonise COVID-19-related information. Specifically, the ORCHESTRA Data Dictionary containing 3730 variables (questions and answer value sets) coded with international standards was shared with the representatives of EuCARE and END-VOC who then adapted their studies accordingly.
- **REACT**, funded in August 2022, and **ORCHESTRA** standardisation experts collaborated concerning the harmonisation approach used. REACT focuses on SARS-CoV-2, influenza and respiratory syncytial virus (RSV) infections. The REACT dataset was mapped to the ORCHESTRA variables to check for possible matches. In particular, for variables that covered the same topic but in a different format, the whole list of possibly corresponding ORCHESTRA variables was provided, such as in the case of tobacco and alcohol consumption, treatment, symptoms and comorbidities.
- **EuCARE**, working on the school cohorts, and the ORCHESTRA **Beneficiary RER-ASSR**, running the school cohort CoV-Stories, collaborated on aligning data standards.

- **COVICIS** and **ORCHESTRA** WP5 explored a possible combined analysis of the results on healthcare workers.
- **ORCHESTRA** explored synergies with **VACCELERATE** in relation to the potential of HCW cohort within the future vaccination trial landscape and preparedness programmes. VACCELERATE coordinates one of the largest volunteer registries for vaccine trial participation in Europe and ORCHESTRA WP5 coordinated with the VACCELERATE leadership to promote the Volunteer Registry among the HCW cohorts, in the participating centres where the VACCELERATE Volunteer's Registry is active (France, Germany, Italy, Spain). Moreover, thanks to the contacts of ORCHESTRA WP5 HCW cohort in Romania, the VACCELERATE Volunteer's Registry was activated for Romania in M30. All the participants from the HCW cohorts in Barcelona, Bologna, Bucharest, Cluj, Iasi, Munich, Oviedo, Paris, Turin, Timisoara, and Verona received communication packages via email, local website or during local events about how they can volunteer for COVID-19 vaccination clinical trials, using the VACCELERATE Volunteer's Registry.
- The CCB members with cohorts on vaccines collaborated with the **EMA funded project ROC 20 CVM "Safety monitoring of COVID-19 vaccines in the EU"** disseminating the information to its partners regarding the web-based app "COVID-VACCINE-MONITOR" to track adverse events following vaccination.
- ORCHESTRA organised an on-line **training workshop on "Data standardization: Establishing semantic interoperability of data in ORCHESTRA".** Invitations were extended to all EU projects participating in the CCB.
- Two representatives from ORCHESTRA attended the training workshop organised by EuCARE **"Data privacy, data property, and data sharing: an interdisciplinary dialogue for post-pandemic transnational research".**
- A scientific publication summarising challenges in data sharing was developed during the CCB meetings and published in high ranked journal. Tacconelli E, Gorska A, Carrara E, Davis RJ, Bonten M, Friedrich AW, Glasner C, Goossens H, Hasenauer J, Abad JMH, Peñalvo JL, Sanchez-Niubo A, Sialm A, Scipione G, Soriano G, Yazdanpanah Y, Vorstenbosch E, Jaenisch T. **Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response**. Lancet Reg Health Eur. 2022 Oct;21.
- Two papers are under finalisation, on eCRF for long term sequelae assessment post viral infections and on the importance of cohort design in pandemic times.
- The CCB abstract was accepted for an oral presentation at ECCMID 2024: **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.
- **A video showcasing the activities of the CCB** has been developed for dissemination. With the **contribution of the CCB members and the European Commission**, 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 will be broadcast at ECCMID 2024 and before as part of the CCB dissemination activities for public and scientific audiences and will be uploaded to the CCB website after the event.

3. SWOT Analysis

At the end of March 2023, all members were invited to complete a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis to understand the impact of the CCB over its first year in action and discuss how it can maintain progress and improve for the future.

Figure 2

3.1 Strengths

Among the strengths identified, members highlighted the trusted and secure environment created within the CCB, enabling open information exchange, in particular, the sharing of preliminary results, and open discussions surrounding challenges and solutions, in line with CCB Objectives 1 and 4. This secure environment within the CCB also enables members to discuss topics that they may not necessarily have knowledge in, and to comfortably ask questions to better understand the issues at hand: this then leads to suggestions of presentations in future meetings to discuss these topics in further detail, filling knowledge gaps within the CCB and updating members on new processes. The CCB has developed WGs for the investigation of specific topics that were frequently discussed in the initial CCB meetings to create dedicated space and time for these important topics. The WGs, formed upon various expertise and interest, were also identified as a strength, due to the in-depth analysis into these topics and the greater understanding of best-practices enabled, in line with CCB Objectives 4 and 5.

During the SWOT analysis, members also highlighted the inclusion of diverse project types as an important strength, encouraging synergy by sharing key learnings, documents of relevance and preliminary results, as

in CCB Objectives 1, 4 and 5. In fact, 16 projects participate regularly in the CCB meetings, each with different structures and aims. As well as diverse project types, the CCB also houses projects with staggered starting dates, enabling information sharing; knowledge of lessons learned and documents of relevance from older projects, and updates of changes and developments from newer projects, following CCB Objectives 4 and 5. The CCB was also identified as dynamic and flexible, able to understand changing situations, discuss and adapt, all vital characteristics in regards to pandemic preparedness.

Another strength identified was the CCB's focus within the EU but with a global awareness and perspective, sharing information across larger networks and supporting future pandemic preparedness through knowledge gathering and information sharing.

Members also mentioned the benefits of the CCB having rotating chairing and presenting responsibilities, promoting a shared ownership and participatory approach.

Finally, the CCB has created itself as a single forum, providing an overview of cohort research and allowing stakeholders to have a constant understanding of the current activities and summary of the updates from each member, supporting CCB Objective 1.

3.2 Weaknesses

The main weakness identified within the CCB was a lack of dedicated resources for the activities and maintenance of the Board, limiting the scope of collaboration and the future expansion of the CCB. This lack of resources also elongates the time necessary for some processes, such as writing articles, communication of events/surveys, and creation of administrative documents and reports.

CCB members also mentioned the lack of any shared deliverable or WP as a weakness, and the lack of a common cohorts' strategy. Indeed, the lack of specified common objectives and outputs limits the efficacy of the efforts of the teams thus posing a challenge to achieving CCB Objective 2. Moreover, from a strategic point of view, the differences in the aims of the projects limits possible collaboration if not addressed directly.

In addition to this, the absence of a formal engagement between the CCB and TCB was identified as a weakness. This was suggested as a limit to the possible formation of synergy between the Boards and avoidance of overlap, which is in contrast with CCB Objective 2. In detail, in the field of pandemic preparedness, one way to rapidly identify at-risk populations is to enrol individuals in long-term/perpetual cohorts. Finally, members also suggested limited stakeholder/patient/industry involvement as a weakness within the CCB, as input from these groups could provide greater awareness of challenges faced and knowledge surrounding possible solutions, as in CCB Objective 4.

3.3 Opportunities

Through the analysis, members suggested that the CCB could encourage more efficient harmonisation of data collection across the cohorts. As an example, CCB members have discussed the benefits of sharing DMPs across the CCB cohorts, thus improving transmissibility of data, reducing time spent developing DMPs, and ensuring sustainability of results. Harmonisation of data enables the analysis of similar studies to be pooled, increasing the impact and reliability of results, in line with CCB Objectives 2, 3 and 4.

The CCB works to facilitate connections between organisations, and members highlighted that a stronger link with the TCB would benefit both Boards, reducing overlap and creating synergy between these organisations, and solidifying connections across cohorts and clinical trial networks, in line with CCB Objectives 2, 3, 4 and 5. Another opportunity identified was the use of cohorts for running investigational trials. As stated before, the collaboration between the TCB and the CCB could help to identify platforms (such as running cohorts) to enrol individuals with specific characteristics.

An important opportunity highlighted by members was to expand to global dimensions and create connections outside of Europe (i.e., the United States of America, Low-Middle Income Countries), encouraging innovation and improvement of methods by learning from diverse organisations from countries with different cultures and priorities. This expansion could be foreseen to include also non-COVID, cohort-based projects. Another suggestion was, in the case of emerging unmet clinical needs, that the CCB could offer a space for cohorts to discuss additional sub-studies, for example, with extended follow-up or additional clinical outcomes, in line with CCB Objectives 1 and 3.

Following on from the weakness identified regarding lack of stakeholder involvement, members suggested information could be more bidirectional, with stakeholders providing more input into the CCB and sharing their own results and knowledge; this may result in more effective recommendations from and for the EC, due to the various perspectives considered, in line with CCB Objective 6.

3.4 Threats

The main perceived threat is a lack of resources, which limits the impact and sustainability of the CCB. Members also discussed the risks of adding new cohorts, which might alter the secure environment created and limit collaboration. Another threat highlighted by members was the shift of focus from COVID-19, as the impact on public health vanishes and it is not considered a priority anymore, causing focus to shift, funding to cease, and studies to end.

3.5 Action Plan

The CCB has created a platform for information exchange and interdisciplinary collaboration, but this collaboration is limited by a lack of dedicated resources. The CCB has an opportunity to think more strategically about the cohort landscape in the EU, in terms of what is required to strengthen infectious disease (ID) preparedness, and how cohorts have a role to play in understanding ID preparedness.

The CCB has discussed multiple times the idea of a “perpetual cohort”, to continue once funding has finished to provide information and guidance. The CCB will consider further how to create a perpetual yet simple cohort to provide answers immediately to the EC as soon as an important public health issue arises. At the moment this type of alert system does not exist, especially for IDs with pandemic potential.

The information gathered through this SWOT has helped us understand how to further consolidate and expand the CCB. As a way to combat the threat of lack of resources, and take advantage of the opportunity identified to link the CCB and TCB, the project CoMeCT was proposed. This project, discussed in detail below, began on the 1st of December and supports both Boards to create a stronger and wider impact, encouraging the sustainability of the Boards. CoMeCT will also enable the CCB and TCB to expand to identify and invite any cohorts targeting IDs with pandemic potential. CoMeCT also foresees increased engagement with stakeholders, another weakness identified earlier in this analysis.

4. CoMeCT – COordination MEchanism for Cohorts and Trials

The CCB core team worked on a project proposal submitted on the 12th of April 2023 to the Horizon Europe call for a Coordinating Support Action (CSA) under HORIZON-HLTH-2023-DISEASE-03-05. The proposal passed the evaluation phase and, in November 2023, the Grant Agreement was signed, with the project officially launching on the 1st of December 2023. The project foresees the linking up of the running coordination initiatives (TCB and CCB) into one single, coherent coordination mechanism for Adaptive Platform Trials (APTs) and CSs, as well as developing an Outbreak Response Board to liaise with the two other Boards and activate timely action. Its activities will liaise with all key stakeholders of the IDs research landscape going beyond the research institutions and articulating with policymakers (e.g., the EMA, the Clinical Trials Coordination Group, ECDC), funders (e.g., BE-READY, GloPID-R, IHI, EDCTP3, DG R&I, HERA), industry (EFPIA), and patient organisations. The project structure of CoMeCT includes three WGs on Exploration (mapping), Harmonisation and Innovation, and Communication. The WGs will inform agendas and discussions in the Coordination Board, and help shape research directions and consolidate ideas and innovation. All cohorts that are currently participating in the CCB will be invited to join this coordination mechanism and the CCB will maintain the same leadership team and WGs. Table 6 shows the CoMeCT Partners.

Organisation	Position
Norwegian Institute of Public Health (NIPH)	TCB Chair
Ecraid Foundation (Ecraid)	APT infrastructure
European Clinical Research Infrastructure Network (ECRIN)	JAAM Chair
University of Verona (UNIVR)	CCB Chair
Institut national de la santé et de la recherche médicale (INSERM)	Outbreak Response Board
Fondazione Penta ONLUS (PENTA)	Pediatric Network
University of Cologne (UHC)	VACCELERATE Trial Network

Table 6

The objectives for CoMeCT are as follows:

1. To expand on European coordination mechanisms and supportive processes and policies, to facilitate coordination of research and innovation actions, exchange of good practices, and coherent stakeholder engagement across APTs and CSs.
2. To expand the Joint Access Advisory Mechanism (JAAM), supporting coordination through the independent scientific assessment of therapeutic compounds and vaccines and providing recommendations for the most appropriate APTs and vaccine trials.
3. To develop and maintain an overview of relevant APTs and CSs, and facilitate engagement with external stakeholder networks and organisations.
4. To enable GDPR-compliant cross-study identification, assessment, and reuse of participant level data from European APTs and CSs. To share operational best practices and monitor progress of clinical research methodologies and data analytical approaches.
5. To ensure coherent communications and visualise coordinated stakeholder engagement and dialogue across APTs and CS and coordinating networks and projects.
6. To monitor and report progress to CoMeCT's objectives, ensure compliance with contractual obligations (EC Grant Agreement and consortium agreement) and develop a sustainability plan to ensure ongoing coordinating mechanism.

The CCB tasks within CoMeCT are as follows:

1. Align with TCB under a common coordinating infrastructure for a more integrated approach.
2. Continue to map the cohort landscape and involve also relevant non-COVID cohorts, for example, IDs with endemic potential.
3. Update Terms of Reference and Confidentiality Disclosure Agreements for CCB.

4. Continue regular meetings and participate in CoMeCT Coordination Board meetings (CCB/TCB/ORB and other stakeholders (e.g., DG R&I, DG SANTE, HERA, ECDC, GloPID-R, WHO, EMA, patient organisations, and industry representatives).
5. Contribute to harmonisation of data collection (DMPs, eCRF templates, automated eCRF mapping, recommendations for data re-use, etc.).
6. Continue to showcase CCB activities under the overall coordination of CoMeCT.
7. Support the mapping procedure for the extension of the CCB Central Data Repository, created within VERDI, to include APTs and CSs.

5. Conclusions

Health emergencies, such as epidemics or pandemics, can have a massive impact on public health and society. Thus, coordinating efforts allows for a more effective response and helps limit the spread of infections and minimise their effects. It is therefore necessary to generate a strategic pool of scientific-technical knowledge and experiences to enable a coordinated, joint and immediate response to any scientific emergency affecting public health.

The CCB offers a trusted and proactive environment that allows for discussion on challenges encountered (expanding scientific knowledge to accelerate the development of effective treatments, vaccines and diagnostics by sharing data and research results; and to design more effective prevention and response approaches). Strategic and sustained coordination mechanisms are especially important during interpandemic phases for ID preparedness. Furthermore, establishing international norms and standards for the management of health emergencies ensures that responses are consistent and standardised, which, in turn, facilitates cooperation and communication between different agencies. The CCB has succeeded in creating the framework and the path to work jointly in this regard, and linking up with the TCB within the CoMeCT project will enable even greater collaboration and a more coordinated response.

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