



ECDC Management Board

Fourth Extraordinary Meeting 7 May 2021 (audioconference)

Adopted by the ECDC Management Board at its Fifty-second meeting, 16 June 2021

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Summary of Proceedings – ECDC Management Board Meeting

The Fourth Extraordinary meeting of the ECDC Management Board convened on 7 May 2021 as a virtual meeting due to the COVID-19 pandemic. During the meeting, the Management Board:

- ❖ adopted the programme of the meeting;
- ❖ discussed the proposed HERA Incubator Action Area 1 (Rapid detection of SARS-CoV-2 variants) related ECDC actions, and their impact on planned ECDC work. The Management Board agreed that ECDC would provide written answers to the main questions raised during the discussion.

Opening and welcome from the Chair (and noting the Representatives)

1. Anni Virolainen-Julkunen, Chair of the ECDC Management Board, welcomed all the participants to the Fourth Extraordinary meeting of the Management Board, which convened via audio conference. A special welcome was extended to Áslaug Einarsdóttir, newly appointed alternate, Iceland, and Ingrid Keller, newly appointed alternate, European Commission. Apologies had been received from Denmark and Liechtenstein.
2. The Chair recalled that the purpose of the meeting was to discuss the HERA Incubator implementation plan and the consequences for the current ECDC work plan. A note on the matter had been circulated to the Management Board ahead of the meeting.
3. The Chair then informed the Board that the Secretariat had asked for permission to exceptionally record the meeting for minute taking purposes and asked the Management Board members whether there were any objections to the meeting being recorded. No objections were raised.

Welcome from the Director, ECDC

4. Andrea Ammon, Director, ECDC, warmly welcomed the Management Board members and thanked them for taking the time to participate in the meeting despite the short notice. She added that this was an important session from ECDC's perspective as it provided the opportunity to better explain the consequences of the HERA Incubator before the next written procedure on amendments in the 2021 work programme and Financing Decision would be sent to the Board for approval.

Adoption of the draft programme (and noting the declarations of interest and proxy voting, if any) (*Document MB Extraordinary 04/01*)

5. The draft programme was adopted without changes.
6. Following the adoption of the programme, the Chair asked each member whether s/he wished to add any oral declaration(s) of interest to her/his Annual Declaration of Interest (ADoI) submitted previously. None were declared.

The Management Board adopted the draft programme.

HERA Incubator Action Area 1 (Rapid detection of SARS-CoV-2 variants) and ECDC (*Document MB Extraordinary 04/02*)

7. Before giving the floor to the European Commission and the ECDC Director for an introduction to the topic, the Chair clarified that the Management Board was not expected to take any decisions during the current meeting, but the purpose was to discuss the matter, and to give the Management Board members the possibility to ask questions or raise any concerns they may have.
8. John F Ryan, MB Member, European Commission, gave a brief introduction of the HERA Incubator and related ECDC actions. He explained that, in response to the COVID-19 pandemic and as part of the legal proposals for an EU Health Union, the European Commission had proposed to develop an EU health emergency preparedness and response authority, HERA. A public consultation on the proposal had been carried out and an impact assessment was ongoing. Discussions were currently taking place in the Member States' Steering Group that had been set up. The Commission was hoping to present the legal proposal later in 2021. In the meantime, the European Commission had launched the HERA Incubator in February this year, i.e. a bio-defence preparedness plan to tackle SARS-Cov-2 variants. The HERA Incubator focuses on five specific action areas: 1) Rapid detection of SARS-CoV-2 variants; 2) Swift adaptation of COVID-19 vaccines (investments in research and innovation); 3) Setting up a European Vaccine Trial Network

(VACCELERATE); 4) Fast tracking the regulatory approval process of adapted vaccines, and 5) Ramping up industrial production of COVID-19 vaccines against variants of concern.

9. He noted that the rapid detection of variants was crucial in this context, and a substantial budget (EUR 200 M) was therefore proposed to be allocated to Action Area 1. More than half of this budget was proposed to be transferred to ECDC to coordinate activities aimed at strengthening the detection and characterisation capacity for variants within and outside the EU. The Commission had worked closely with the ECDC in the past weeks to put forward a comprehensive plan to implement this considerable budget, and to propose activities that address the real needs in the Member States and that were in line with the political expectations. ECDC was considered the agency best placed to carry out these activities. He stressed that the substantial budget would help Member States reach the levels of surveillance capacity needed; this was an opportunity to invest in important infrastructure development and capacity building which would give benefits also for the future. He added that airport authorities were naturally very anxious to see Europe reopen, and the expectations in the society overall were also high. The activities foreseen under the HERA Incubator could help making that move to a more normal situation. Lastly, he thanked the ECDC for the note that had been shared ahead of the meeting, which explained well the proposed implementation plan.

10. Andrea Ammon, Director, ECDC, provided further details on the proposed activities under the HERA Incubator Action Area 1 and their impact on the ECDC work plan for 2021. She explained that the proposed implementation plan consisted of three main parts with different implementation mechanisms. Firstly, it is proposed to maintain, and if possible expand, the shorter-term support to EU/EEA countries for access to high-capacity WGS services through an external contractor (including limited use of the contract by the Western Balkan countries and Turkey). For 2021, the total budget of this activity is estimated to EUR 27 M (EUR 21 M from the EU budget, and EUR 6 M from the ECDC budget). She presented the current use of the existing framework contract and stressed that more countries could benefit from this support to detect not only known variants of concern (VOCs) but also potentially not yet known variants. She recalled that the Management Board had recently approved additional budget for this activity through written procedure to allow more countries to be involved.

11. Secondly, it is suggested to implement an infrastructure support programme to develop and/or enhance national WGS and RT-PCR infrastructure. This part would be implemented through grants based on national applications. The proposed budget for 2021 is EUR 83 M to be transferred to ECDC. She explained that using grants would allow for a bottom-up approach where countries specify their needs and thereby allowing for more tailor-made functionalities than with a tender procedure. The reimbursement rate for grants is 90% of the eligible costs; the 10% to be financed by the Member State can consist of the participating institutes' own resources, including costs for staff resources, or from financial contributions from third parties. She added that equipment purchase costs could be considered as an eligible cost under certain conditions that needed to be clarified¹. Concerning the timeline, she noted that the invitation to submit applications was planned to be dispatched towards the end of May and the Member States would have 6 weeks to submit their proposals back to ECDC. The implementation would start beginning of October 2021 and all activities would need to be completed by 30 September 2022.

12. Thirdly, the plan includes a cross-border capacity-building support programme for training, twinning and WGS and RT-PCR standardisation to be put in place following a call for tender. The budget for this part amounts to EUR 2 M in 2021. The Director stressed that together with the infrastructure support programme, the capacity building support is an important investment for the future as it will upgrade the diagnostic capabilities in the Member States, which is in line with the objectives of the ECDC molecular surveillance roadmap from 2015.

13. The Director then explained the impact of the proposed activities on the ECDC 2021 work plan. She clarified that the implementation of the HERA Incubator activities would require a significant portion of ECDC procurement resources in 2021. In particular, to be able to implement the national infrastructure support programme, ECDC would need to de-prioritise a significant number of planned activities and contracts that require procurement expertise. Out of 285 remaining procurement actions in 2021,

¹ ECDC clarified thereafter with DG Budget that treatment of full equipment purchase cost is an eligible cost based on the nature of the action and the context of the use of such equipment.

approximately 95 would be prioritised. These include important activities such as the Fellowship Programme, the VEBIS (Vaccine Effectiveness, Burden and Impact Studies for infectious respiratory diseases) project, the SARI surveillance project and the COVID-19 related activities. The remainder of the planned actions would either be pursued in Q3/Q4 2021, postponed to 2022 or in some instances cancelled. She anticipated that the budgetary impact in 2021 would be limited, especially if normal procurement activities can be resumed in Q3/Q4. Some activities in 2022 could, however, be delayed, and the objective was to take this into account already in the SPD 2022. She added that ECDC had reached out to other independent decentralised EU Agencies, executive Agencies as well as the European Commission with requests for seconding competent colleagues for a limited period to support the Centre. So far, the contacted entities had confirmed that they were unable to support ECDC, even temporarily, but this possibility would still be looked into.

14. Lastly, the Director explained that without the described de-prioritisation of part of the ECDC 2021 work plan, it would not be possible for ECDC to execute the HERA Incubator activities as proposed. In this case, the HERA Incubator activities would be limited to the continued implementation and expansion of the outsourced WGS support, and possibly some limited training activities. In conclusion, she reiterated that ECDC was hoping to go forward with the proposed implementation plan as it considered it an important step forward in the implementation of molecular surveillance in the EU, which would serve not only for COVID-19 but also for other pathogens in the future. She asked the Management Board members to indicate, as far as possible, in which direction they would prefer to go.

15. Following the introduction, the Management Board members were invited to express their views in a tour-de-table session. Overall, the Management Board expressed wide support for the proposed implementation. One member stressed the importance of moving fast with the detection of variants and adaptation of vaccines; this was important from a public health perspective but also from the political point of view as it gave hope for a return towards a more normal life. With regards to the infrastructure support programme, one MB member asked whether there was some overarching concept of how samples were going to be selected, analysed, and managed. He added that the best value for money would be to work together by doing common assessments of how to look at variants in different settings, etc. Another member stressed that the project needed to be well integrated into the public health infrastructure in each country and linked to other parts of the public health activities (e.g. bioinformatics, public health response). Some concerns were raised regarding the tight timeline for submitting the grant applications. There were also questions on how outputs would be monitored and how potential conflicts of interest would be handled. With regards to the capacity building support programme, one member asked how the work could be divided between countries to accelerate the characterisation work of VOCs. Concerning the impact of the HERA Incubator activities on the ECDC's work plan, several Management Board members requested additional information on the activities to be de-prioritised. There were also questions on the current sequencing capacity in the Member States and the percentage of countries using the short-term WGS support.

16. In response to some of the comments, John F Ryan agreed that the monitoring was indeed crucial, and Member States would need to be able to show that the money had been wisely spent. Concerning the conflict of interest, he noted that this should be handled by ensuring lack of CoI between people making decision on budget distribution, and people receiving money. ECDC will need to ensure there is no conflict of interest by not being involved in the drafting of countries' applications.

17. The Director thanked for the support expressed by the Management Board members. Concerning the monitoring of outputs, she added that there will be mandatory reports to show that Member States deliver on objectives, but these objectives will be different between countries depending on their individual proposal. Responding to a question on which laboratories were involved in the sequencing work, she clarified that the EU reference laboratory network referred to in the Commission legal proposal was not yet in place but ECDC would be working with the existing network of national reference laboratories. With regards to staff resources, she explained that the Commission had allowed ECDC to advance the recruitment of 15 FTEs (out of the 73 FTEs included in the EC legal proposal for strengthening the ECDC mandate) from 2022 to 2021. It should be kept in mind though that these FTEs would need to serve also for other tasks in coming years. Lastly, she recalled that the implementation of the additional budget provided by the HERA incubator will require amendments of the ECDC 2021 Work Programme and Financing Decision; a written procedure would therefore be circulated to the Management Board for

approval in the next couple of weeks pending the approval by the European Commission of the reallocation of the 2021 budget to the longer-term HERA Incubator activities.

18. Following the discussion, the Management Board agreed that ECDC would send written responses to the main questions raised following the meeting, as well as further information on the prioritisation of ECDC procurements².

The Management Board discussed the proposed HERA Incubator implementation plan and its impact on the ECDC 2021 work plan. The Management Board agreed that ECDC would provide written answers to the main questions raised during the discussion.

Any other business

19. The Chair thanked the European Commission and the ECDC for the information provided and the Board Members for their active participation.

20. The next regular Management Board will take place remotely on 16 June 2021.

² The requested written information was shared with the Management Board on 11 May 2021.

Annex: List of Participants

Country/Organisation	Representative	Status
Austria	Bernhard Benka	Member
Belgium	Lieven De Raedt	Member
Croatia	Bernard Kaić	Member
Cyprus	Irene Cotter	Member
Czech Republic	Jozef Dlhý	Alternate
Finland	Anni Virolainen-Julkunen (<i>Chair</i>)	Member
Finland	Taneli Puumalainen	Alternate
France	Anne-Catherine Viso	Alternate
Germany	Hans-Ulrich Holtherm	Member
Greece	Panagiotis Arkoumanas	Member
Hungary	Ágnes Dánielisz	Member
Ireland	Colette Bonner	Member
Italy	Francesco Maraglino	Member
	Sandro Bonfigli	Alternate
Lithuania	Audrius Ščeponavičius	Member
Luxembourg	Jean-Claude Schmit	Member
	Thomas Dentzer	Alternate
Malta	Patricia Vella Bonanno	Member
The Netherlands	Ciska Scheidel	Member
Poland	Dariusz Poznański	Member
Portugal	Rui Portugal	Member
Portugal	Cristina Abreu Santos	Alternate
Romania	Andrei Baciú	Member
	Paul Daniel Iordache	Alternate

Country/Organisation	Representative	Status
Slovakia	Peter Zsapka	Alternate
Slovenia	Mario Fafangel	Alternate
Spain	Pilar Aparicio Azcárraga	Member
Sweden	Johan Carlson	Member
	Andreas Johansson	Alternate
European Parliament		
	Zofija Mazej Kukovič	Member
	Maria Eleni Koppa	Member
European Commission		
DG SANTE	John F. Ryan	Member
DG SANTE	Isabel de la Mata Barranco	Alternate
DG SANTE	Ingrid Keller	Alternate
DG RTD	Barbara Kerstiëns	Member
EEA Countries		
Iceland	Ásthildur Knútsdóttir	Member
	Áslaug Einarsdóttir	Alternate
Norway	Øystein Riise	Member