ECDC Advisory Forum

Minutes of the Extraordinary Advisory Forum meeting
Stockholm, 9 December 2016

Contents

Opening and welcome

1. Andrea Ammon, Acting Director, ECDC opened the session and welcomed all participants. The Management Board had asked the Advisory Forum (AF) for its views on the potential benefits and risks associated with ECDC collaborating with the DRIVE Consortium. After the teleconference, feedback would be provided to the Management Board in writing.

2. Mike Catchpole, Chair and Chief Scientist, ECDC, welcomed the participants and explained that although there was an Advisory Forum teleconference scheduled for 14 December, the general view was that discussions on this issue would take too long to accommodate within the scheduled meeting and therefore an extraordinary meeting had been scheduled. ECDC was seeking the AF's views on involvement with the IMI2 Drive Consortium project with a particular emphasis on scientific independence. Members of the DRIVE Consortium were also participating in the conference call: Javier Diez-Domingo, Public coordinator of DRIVE; Cedric Mahe, EFPIA coordinator of DRIVE; Caterina Rizzo, Public Health Institute of Italy, Member of DRIVE Consortium, and Hanna Nohynek, Public Health Institute of Finland, Member of DRIVE Consortium. He thanked the participants for their feedback and comments received in advance of the teleconference. Apologies had been received from Croatia, Denmark, Estonia, Hungary, Iceland, Italy, Latvia, Lithuania, Malta, Poland, Romania, Spain, Sweden and the European Public Health Association (EUPHA). He asked if there were any declarations of interest.

3. Marianne Van der Sande, Alternate, Netherlands said that the Netherlands were participating in the ADVANCE Consortium and had been involved in the DRIVE kick-off meeting for non-Consortium partners.

4. Jean-Claude Desenclos, Member, France, said that he was participating in the ADVANCE review panel and chairing an evaluation group in support of ECDC.

5. Hanne Nøkleby, Observer, Norway said that she had a colleague in her group who was keen to join the DRIVE Consortium but it would depend on the outcome of the current AF teleconference.

6. Mike Catchpole, Chair and Chief Scientist, ECDC, noted that Finland was already member of the Consortium, and therefore its declaration of interest was implicit.

7. Osamah Hamouda, Member, Germany, noted that Germany was also participating in the ADVANCE Consortium but that he was personally not involved.

Item 1. Presentation by the DRIVE Consortium

8. Javier Diez Domingo, Public Coordinator of DRIVE, gave a presentation on the IMI2 Drive proposal entitled *DRIVE governance and the role of the European Federation of Pharmaceutical Industries and Associations (EFPIA).* This presentation had been sent to participants on 8 December 2016.

9. Mike Catchpole, Chair and Chief Scientist, ECDC, clarified that the IMI2 call had been developed by IMI and that ECDC was not involved. IMI had simply consulted ECDC about the governance aspects. He opened the floor for questions.

10. Paul Cosford, Member, UK, referring to Slide 8 on DRIVE project governance, asked for confirmation of his understanding that the Steering Committee (with 50% EFPIA membership) would oversee the communication of the reporting and the study outcomes.

11. Marianne Van der Sande, Alternate, Netherlands, referring to Work Package 6 (Project Management) being led by EFPIA and non-EFPIA members, pointed out that there was an arrow directly connecting Work Package 6 with the Studies Work Package 0, indicating that the study activities would not really be protected by a firewall. She also asked about the definition of public in the 'public consortium' and wished to know who would be included, pointing out that 'non EFPIA' did not just refer to public health institutes and that the definition of public was more than just 'not industry'. She felt that there was only a relatively minor role for the public health institutes in the various work packages and was concerned about scientific independence.

12. Jean-Claude Desenclos, Member, France asked for confirmation that EFPIA would not be involved in the design or conducting of the studies or the reporting of results.

13. Javier Diez Domingo, Public Coordinator of DRIVE, responding to the questions, explained that the blue part of the slide with the Work Packages represented the important tasks for the development of the studies. For example, the Communication Work Package would not communicate on anything that had not been accepted by the Independent Scientific Committee. The role of the Steering Committee

would be to organise the protocol so that deliverables were sent to the IMI on time and resolve any conflicts which may arise. In response to the comment by the Netherlands on the blue arrow marked 'Activities coordination' connecting with the red Work Package 0 (Studies), he explained that this mainly involved coordination of deliverables to the IMI from a structural point of view rather than for scientific transmission of information. He also pointed out that the model presented was the result of extensive discussions within the Consortium and with EFPIA and ECDC and, as such, it differed significantly from the model which had initially been accepted by the IMI. With regard to the issue of a protective firewall for Work Package 0 (Studies), considerable effort had been made to ensure independence and, once deliverables were released, all contacts between EFPIA and Studies would have to be made in writing so that EFPIA input to the deliverables and the project would be transparent. He reiterated that there were two different workloads – the blue Work Packages involving the collection of information and improving of know-how, and the red Studies Work Package, which would be independent and controlled by the Independent Scientific Committee to avoid bias. He stressed that this was a first draft and that it could be modified to accommodate stakeholder requirements and was not final. Responding to the question on the definition of 'public' he explained that the 'public consortium' referred to all those who had participated in Stage 1 (see Slide 4), together with all the public health institutes in the DRIVE project.

14. Paul Cosford, Member, UK asked for clarification on Mr Diez Domingo's response regarding communication and reporting – who would ultimately decide what was published, and whether everyone approved?

15. Javier Diez Domingo, Public Coordinator of DRIVE, explained that the plan was to work together with EFPIA on the design of the platform for reporting (in the blue Work Packages 1-6) in order to achieve rapid results and the best infrastructure for data collection and pooled analysis. This infrastructure would then be used in the red Studies Work Package 0, but there would be no interaction with EFPIA on how to report.

16. Jean-Claude Desenclos, Member, France asked what the actual role of the people working in the Consortium would be if they would only be contributing 'in kind'.

17. Javier Diez Domingo, Public Coordinator of DRIVE, said that the main objective of DRIVE was to create a sustainable platform that could be used by all the public health institutes in Europe and the European Medicines Agency. The studies conducted would provide evidence that this could be done and would maintain and sustain the platform. The EFPIA role would be to create all the infrastructure in blue, to undertake quality control and audits for these structures and to review all the deliverables in order to give feedback. The EFPIA contribution to DRIVE would cover the time of those participating in the project.

18. Cedric Mahe, EFPIA Coordinator of DRIVE, clarified that in other projects EFPIA had traditionally made 'in kind' contributions corresponding to half of the project cost, however, because most of activities would be carried out by public health institutes and public consortiums, the in kind contribution would only be one fifth of the cost in this case. The rest would be monetary contributions in order to be able to scale up the data collection (0.2 FTE per year per company). EFPIA would support discussions on quality control with regulatory authorities and work on brand identification and knowledge sharing with the public consortium to ensure that it obtained the appropriate data sets.

19. Marianne Van der Sande, Alternate, Netherlands asked for further clarification regarding the role of EFPIA in the Work Packages. If Work Packages 2, 3 and 4 were being co-led by EFPIA, then it would appear that it was impossible for the firewalled Studies Work Package 0 to be scientifically independent.

20. Derval Igoe, Alternate, Ireland asked whether the Quality Control and Audit Committee had an influence over scientific content when raising concerns with the Steering Committee, and what type of quality control and audit considerations they could influence.

21. Javier Diez Domingo, Public Coordinator of DRIVE, responding to the question from the Netherlands about the scientific independence of the Studies Work Package 0, explained that there were tools (in the blue Work Packages) which were important to the whole project although they would definitely not influence the scientific studies. For example, all protocol development took place in the red Studies Work Package 0. It was important to develop tools for the study site selection, and to understand vaccine effectiveness by type, it was important to assess how vaccines were being used and where. Therefore guidelines and protocols needed to be developed for these purposes. There were also plans to develop apps to integrate different results coming from the various studies. So each of the Work Packages would have a list of different tasks but these should definitely not influence scientific independence.

22. Cedric Mahe, EFPIA Coordinator of DRIVE, responding to the question on the role of the Quality Control and Audit Committee and its influence on study design, said that in the governance model they

had been careful to distinguish between scientific content and process. The Quality Control and Audit Committee was more concerned with the process because it was necessary to report to the European Medicines Agency on the quality and integrity of data. Usually, EFPIA would generate the data themselves, but when done through partners some form of reassurance would be required. For example, the Committee could request some form of data control/analysis or site visits by third parties. However, this would not have any impact on the scientific process and could also be very useful for the interpretation of the data.

23. Mike Catchpole, Chief Scientist, ECDC, asked about the significance of the red arrow entitled 'Approval of scientific deliverables (TBD)' on Slide 9.

24. Javier Diez Domingo, Public Coordinator of DRIVE, explained that there could be some deliverables which would not need to be approved by the Independent Scientific Committee such as apps or other minor, non–technical deliverables. The plan was to sit with the Committee at a later stage and go through all the deliverables in order to identify minor tasks/non-technical deliverables that they might not need to approve.

ECDC position on the IMI2 DRIVE proposal and questions to AF

25. Mike Catchpole, Chief Scientist, ECDC, reiterated ECDC's position as seeing post-authorisation studies as being within the ECDC mandate, as approved by the Management Board, and that the preferred financing arrangements would be that there was a public funding scheme which was independent of industry. The ECDC Management Board had recognised, however, that it would require time and extensive consultation to achieve such a process and ECDC would only be involved prior to satisfactory completion of such consultations if the pre-requirements for scientific independence defined by the Advisory Forum were met.

Closed session

26. Jean-Claude Desenclos, Member, France, inquired about the composition of the proposed Quality Control and Audit Committee.

27. Mike Catchpole, Chief Scientist, ECDC, responded that he did not think it would include exclusively EFPIA members and that indeed this would not be desirable. Referring to the briefing paper distributed before the audio conference, he noted that there had been a number of written responses to the questions from those unable to participate. In particular, Spain had provided detailed answers, distributed to all AF Members, and was against ECDC participating in the second stage. Other Member States had sent emails simply stating that they supported the views of the AF Member for Spain. However, these comments were made before the details of the governance model had been received by the Consortium. He therefore encouraged AF Members to give their views on whether the DRIVE Consortium's governance model satisfied the pre-requisites defined by the Advisory Forum for ECDC engagement in the project.

28. Franz Allerberger, Alternate, Austria, said that although the scientific independence was not an issue for him, the fact remained that a public/private partnership was not a suitable platform for vaccine evaluation. It was not appropriate that EFPIA was investing EUR 2.5 billion into the project and this fact would almost certainly be picked up by the media. If vaccine efficiency studies were to be objective they would have to be funded solely by public authorities.

29. Paul Cosford, Member, UK, agreed with Austria's comments. He could see that the undertaking of the studies was largely independent, however the Steering Committee was composed of 50% industry and this Committee would oversee the reporting/communications strategies for the studies. It was therefore difficult to imagine that industry would have no influence on the quality and feasibility of the studies and the reporting/publication. He was not convinced that the proposed governance model met the requirements of industry not having a decision-making role in the design, analysis and publication of results. With regard to the public private partnership, it was not a problem for resources to be provided from industry to fund this process, provided that industry did not have an influence on how the money was used. He would therefore favour a cost recovery model. He also agreed that the enormous resources being invested would imply that industry had an influence on the process and he did not see the appropriate safeguards in place to prevent this.

30. Hanne Nøkleby, Observer, Norway, agreed with the UK comments and pointed out that it was not just a question of real independence but also perceived independence. She noted that the Advisory

Forum was an interested party, yet it was still having problems understanding the model and roles of stakeholders. It was therefore doubtful that anyone else would be able to understand the model.

31. Marianne Van der Sande, Alternate, Netherlands, said that the Consortium did seem to have made efforts to guarantee scientific independence, but her main concern was still the fact that EFPIA was a co-cordinator in the Work Packages which could be perceived as a conflict of interest. It was clearly in everyone's interests to try and find a way to work together because otherwise industry would go ahead on its own and this could potentially destroy many of the public networks.

32. Carlos Dias, Member, Portugal, also agreed with comments by the UK and noted that not every aspect had been clarified in the governance model. It was not really clear what the impact of the results would be on industry and what their concerns were.

33. Jean-Claude Desenclos, Member, France said that although the Consortium had made an effort to demonstrate that they would ensure independence through the Independent Scientific Committee, he still had concerns and would also have preferred a purely public approach. The vaccines were funded by national governance so it was difficult to understand why industry should be involved in technical and quality control activities and the Steering Committee. He also pointed out that there was a serious problem in France with lack of confidence in vaccines and a campaign had been run recently to try and restore confidence. Some of those involved had had contact with industry and this had undermined the whole campaign. He warned that a similar situation could arise with the DRIVE initiative.

34. Jan Kyncl, Member, Czech Republic, agreed with the Spanish position and the comments made by Austria and UK. He added that the whole project was currently moving out of the scientific and into the political domain.

35. Osamah Hamouda, Member, Germany, agreed with Austria that ideally the vaccine effectiveness studies should be funded entirely by public resources, however this was an unlikely scenario. The governance model showed that significant efforts had been made to meet the requirements but at the present time they had not been met. He understood that this was the beginning of the process but had similar doubts to those expressed by Norway and France on the perceived influence of industry and its detrimental effect. It would not be possible to present and explain the current model to the public and claim that it was independent.

36. Outi Lyytikänen, Alternate, Finland, said that Finland also had concerns about independence but believed that it was important to find a way to move forward.

37. Derval Igoe, Alternate, Ireland, agreed with the major considerations concerning perception and the involvement of industry which would also be a difficult issue for Ireland. The governance model as currently proposed was very complex and would be very hard to sell.

38. Mike Catchpole, Chief Scientist, ECDC, concluded that there had been significant focus during discussions on the issue of scientific independence. The AF had identified the Consortium's significant efforts to put in place a model to meet the requirements, but the model was difficult to understand and there were still concerns, particularly with regard to communications and reporting where there would not be sufficient independence. Perception was also a serious issue for those working with vaccines/vaccine hesitancy at present. One other point raised by the Management Board had been the opportunity costs of ECDC involvement. ECDC's financial regulation prohibit it from receiving resources, funds or staffing to support engagement in such projects and, although it was difficult to know the full level of engagement, based on experience to date it would probably require a substantial commitment from ECDC's experts in the field of influenza and respiratory diseases. This would mean that if ECDC was to take the lead in the Independent Scientific Committee, it would probably have to put on hold other activities in the field, such as enhanced influenza surveillance and work associated with the introduction of the RSV vaccine. He therefore asked the AF Members whether they would find it appropriate for another public health institute to take the lead in the Independent Scientific Committee and if not, whether they had a view on the benefits of being involved in brand-specific effectiveness studies versus ECDC's work plan covering enhanced influenza surveillance activities and the introduction of the RSV vaccine.

39. Jean-Claude Desenclos, Member, France, argued that, from a public health perspective, brand-specific effectiveness studies were not a high priority compared to issues such as effectiveness by age, time since immunization and according to the influenza vaccine status during previous seasons.

40. Carlos Dias, Member, Portugal, expressed support for the comments made by France. He was concerned that investment in this type of research could backfire in the short and medium term.

41. Marianne Van der Sande, Alternate, Netherlands, understood ECDC's dilemma but felt that it was crucial that ECDC should take the lead.

42. Hanne Nøkleby, Observer, Norway, agreed that ECDC should take the lead if a decision was made to go ahead, however she was not sure that it represented a good use of ECDC resources as there was a great deal of other work to be done in the field of influenza.

43. Outi Lyytikänen, Alternate, Finland, agreed that ECDC should take the lead role.

44. Mike Catchpole, Chief Scientist, ECDC, thanked the participants for their input and feedback and for finding the time to discuss this crucial issue. He hoped to be able to distribute a paper the following week and provide a written procedure to the Management Board before Christmas.