

Meeting Information and Agenda

Meeting to Discuss and Develop Recommendations for the Future Utility of RV144
for Presentation to the Ministry of Public Health, Thailand

Meeting Information

Background and Objectives

At the conclusion of the last Global HIV Vaccine Enterprise Coordinating Group meeting on 1 October, 2009, the Group – following a recommendation from Dr. Supachai Rerks-Ngarm of the Thai Ministry of Public Health – called for a meeting of international experts to develop recommendations for the future utility of RV144. These recommendations are for presentation to the Thai Ministry of Public Health in May 2010. The objective of this meeting, therefore, is to convene a group of international experts to develop these recommendations. Following the meeting, through conference calls, the recommendations will be refined for presentation to the Ministry in May.

Meeting Dates: 16 – 18 March, 2010

Venue: Plaza Athenee (Royal Meridien Hotel) Bangkok

<http://www.royalmeridienbangkok.com/>

61 Wireless Road, Bangkok Thailand 10330

Hosts: Dr. Alan Bernstein, Global HIV Vaccine Enterprise

Dr. Catherine Hankins, UNAIDS: The Joint United Nations Programme on HIV/AIDS

COL. Jerome Kim, U.S. Military HIV Research Program

Dr. Saladin Osmanov, World Health Organization

Dr. Supachai Rerks-Ngarm, Ministry of Public Health, Thailand

For ground transportation reservations (to/from airport) and hotel room reservations at the Plaza Athenee, please contact:

Mr. Bruce Merrell, Armed Forces Research Institute of Medical Sciences (Bangkok)

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Confirmed Participants:

1. Ms. Chutima Akaleephan, Health Intervention & Technology Assessment Program, Thailand
2. Ms. Charla Andrews, USAMC-AFRIMS
3. Dr. Michael Benenson, USAMC-AFRIMS
4. Dr. Alan Bernstein, Global HIV Vaccine Enterprise
5. Dr. Suwat Chariyalertsak, Chiang Mai University
6. Dr. Robert Chen, U.S. Centers for Disease Control and Prevention
7. Dr. Joseph Chiu, USAMC-AFRIMS

8. Dr. Sunate Chuenkitmongkol, sanofi Pasteur
9. Dr. Mark de Souza, U.S. Military HIV Research Program/AFRIMS
10. Dr. José Esparza, The Bill & Melinda Gates Foundation
11. Mr. Kevin Fisher, AIDS Vaccine Advocacy Coalition
12. Dr. Alan Fix, National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health
13. Dr. Donald Francis, Global Solutions for Infectious Diseases
14. Dr. Catherine Hankins, UNAIDS: The Joint United Nations Programme on HIV/AIDS
15. Dr. Sujarti Jatanasen, Ministry of Public Health, Thailand
16. Prof. Jaranit Kaewkungwal, Mahidol University
17. Prof. Stephen Kent, The University of Melbourne
18. Dr. Chirasak Khamboonruang, Ministry of Public Health, Thailand
19. COL. Jerome Kim, U.S. Military HIV Research Program
20. Dr. Prayura Kunasol, Ministry of Public Health, Thailand
21. Dr. Yupin Lawanprasert, Thai FDA
22. Mr. Carter Lee, Global Solutions for Infectious Diseases
23. Ms. Pattara Leelahavarong, Health Intervention & Technology Assessment Program, Thailand
24. Dr. Jean-Louis Excler, International AIDS Vaccine Initiative
25. Dr. Ruth Macklin, Albert Einstein College of Medicine
26. Dr. Michael Martin, U.S. Centers for Disease Control and Prevention
27. Dr. Timothy Mastro, Family Health International
28. Dr. Bonnie Mathieson, Office of AIDS Research, U.S. National Institutes of Health
29. Ms. Margaret McCluskey, U.S. Agency for International Development
30. Mr. Bruce Merrell, Armed Forces Research Institute of Medical Sciences
31. COL. Nelson Michael, U.S. Military HIV Research Program
32. Ms. Patricia Morgan, USAMC-AFRIMS
33. Dr. Chawetsan Narwat, Ministry of Public Health, Thailand
34. Dr. Viseth Ngauy, USAMC-AFRIMS
35. COL. Sorachai Nitayaphan, AFRIMS
36. Dr. Saladin Osmanov, World Health Organization
37. Ms. Myra Ozaeta, Global HIV Vaccine Enterprise
38. Dr. Punnee Pitisuttithum, Mahidol University
39. Dr. Nakorn Premisri, Ministry of Public Health, Thailand
40. Dr. Sawat Ramaboot, Thai Muslim Medical Association
41. Dr. Supachai Rerks-Ngarm, Ministry of Public Health, Thailand
42. Dr. Chitr Sithiamorn, Chulalongkorn University
43. Dr. Donald Stablein, The EMMES Corporation
44. Dr. Yot Teerawattnanon, Health Intervention & Technology Assessment Program, Thailand
45. Ms. Nusara Thaitawat, USAMC-AFRIMS
46. Dr. Prasert Thongchareon, Ministry of Public Health, Thailand
47. Mr. Nimit Tienudom, AIDS-Access Foundation
48. Dr. Paijit Warachit, Ministry of Public Health, Thailand

49. Dr. Carol Weiss, U.S. Food & Drug Administration
50. Dr. Bruce Weniger, U.S. Centers for Disease Control and Prevention
51. Dr. Ryan Wiley, SHI Consulting

Regrets:

1. Dr. Vincent Ahonkhai, The Bill & Melinda Gates Foundation
2. Dr. David Brandling-Bennett, The Bill & Melinda Gates Foundation
3. Dr. Donald Burke, University of Pittsburgh
4. Dr. Mariam Claeson, World Bank
5. Prof. David Cooper, National Centre in HIV Epidemiology and Clinical Research, Australia
6. Dr. Lawrence Corey, HIV Vaccine Trials Network
7. Dr. Ray Dolin, Harvard University and Massachusetts General Hospital
8. Dr. Pat Fast, International AIDS Vaccine Initiative
9. Dr. Peter Gilbert, Statistical Center for HIV/AIDS Research and Prevention
10. Dr. Karen Goldenthal, U.S. Food and Drug Administration (Retired)
11. Dr. Barton Haynes, Duke University
12. Dr. Timothy Holtz, U.S. Centers for Disease Control and Prevention
13. Dr. Margaret Johnston, National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health
14. Prof. Dwip Kitayaporn, Mahidol University
15. Dr. Robert Kohberger, Wyeth (retired)
16. Dr. Pisake Lumbiganon, Khon Kaen University
17. Dr. Julie McElrath, HIV Vaccine Trials Network
18. Dr. Devan Mehrotra, Merck & Co. Inc.
19. Dr. Gary Nabel, National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health
20. Dr. Sean Philpott, Mount Sinai School of Medicine
21. Prof. Helen Rees, University of the Witwatersrand
22. Dr. Wasima Rida, National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health
23. Dr. Michael Robertson, Merck & Co., Inc.
24. Dr. Kiat Ruxrungtham, Thai Red Cross
25. Dr. Jerald Sadoff, Aeras Global TB Vaccine Foundation
26. Dr. Steven Self, Statistical Center for HIV/AIDS Research and Prevention
27. Mr. Anil Soni, The Clinton Foundation
28. Prof. Ruengpung Sutthent, National HIV Repository and Bioinformatics Center
29. Dr. Viroj Tangcharoensathien, Ministry of Public Health, Thailand
30. Mr. Mitchell Warren, AIDS Vaccine Advocacy Coalition
31. Dr. Janet Wittes, Statistics Collaborative, Inc.

Breakout Groups:

Group 1: Clinical Trial Design and Statistics (for screening of candidate vaccines versus efficacy licensure trial and trial endpoints)

1. COL. Jerome Kim (Co-Chair)
2. Dr. Donald Stablein (Co-Chair)
3. Dr. Michael Benenson
4. Dr. Sunate Chuenkitmongkol
5. Dr. Jean-Louis Excler
6. Dr. Michael Martin
7. Prof. Jaranit Kaewkungwal
8. Dr. Nakorn Premsri
9. Dr. Chitr Sithiamorn
10. Dr. Carol Weiss

Rapporteur: Ms. Vivalya Khonghakul

Group 2: Ethical, Regulatory and Community Issues

1. Dr. Ruth Macklin (Chair)
2. Ms. Charla Andrews
3. Mr. Kevin Fisher
4. Dr. Yupin Lawanprasert
5. Ms. Patricia Morgan
6. Dr. Chawetsan Namwat
7. Dr. Saladin Osmanov
8. Dr. Punnee Pitisuttithum
9. Dr. Supachai Rerks-Ngarm
10. Ms. Nusara Thaitawat
11. Mr. Nimit Tienudom

Rapporteur: Ms. Elizabeth Shoaf

Group 3: Public Health and Future Access (including demand assessment, production and delivery)

1. Dr. Catherine Hankins (Chair)
2. Ms. Chutima Akaleephan
3. Dr. Robert Chen
4. Dr. Joseph Chiu
5. Dr. Suwat Chariyalertsak
6. Dr. José Esparza
7. Dr. Donald Francis
8. Dr. Sujarti Jatanasen
9. Dr. Prayura Kunasol
10. Mr. Carter Lee
11. Ms. Pattara Leelahavarong
12. Ms. Margaret McCluskey
13. Dr. Viseth Ngauy
14. Dr. Sawat Ramaboot
15. Dr. Yot Teerawattnanon
16. Dr. Paijit Warachit
17. Dr. Ryan Wiley

Rapporteur: Ms. Laura Sadowski

Group 4: Science and Vaccine Development

1. COL. Nelson Michael (Chair)
2. Dr. Alan Bernstein
3. Dr. Mark de Souza
4. Dr. Alan Fix
5. Prof. Stephen Kent
6. Dr. Chirasak Khamboonruang
7. Dr. Timothy Mastro
8. Dr. Bonnie Mathieson
9. COL. Sorachai Nitayaphan
10. Dr. Prasert Thongchareon
11. Dr. Bruce Weniger

Rapporteur: Dr. Wai Lin Htun

Proposed Agenda

16 March, 2010

0530 – 0830 Breakfast at your leisure (complimentary for hotel guests; Rain Tree Cafe, Plaza Athenee Hotel)

Moderator: Dr. Alan Bernstein

0830 – 0900 Welcome Remarks (Plaza Athenee Hotel, Star room 29 on the 29th Floor)

- Dr. Alan Bernstein
- Dr. Catherine Hankins
- COL. Jerome Kim
- Dr. Saladin Osmanov
- Dr. Paijit Warachit

0900 – 0930 Update on RV144

- COL. Jerome Kim

0930 – 1000 Discussion/Q&A

1000 – 1015 Break (Plaza Athenee Hotel, Star room 29 on the 29th Floor)

1015 – 1030 Statement of Meeting Objectives, Review of Meeting Format and Procedures, and Introduction of Breakout Group Chairs

- Dr. Supachai Rerks-Ngarm

1030 - 1200 Introductory Presentations by Breakout Group Chairs

Includes a broad presentation of the issues to be addressed by each group, general implications of the Thai Trial for the area of focus, and questions to be answered over the course of the meeting.

- Dr. Catherine Hankins (Public Health and Future Access)
- Dr. Ruth Macklin (Ethical, Regulatory and Community Issues)
- COL. Nelson Michael (Science and Vaccine Development)
- COL. Jerome Kim and Dr. Donald Stablein (Clinical Trial Design and Statistics)

1200 - 1300 Breakout Groups Meet

- Public Health and Future Access (Plaza Athenee Hotel, Atheneum 1 on the 6th floor)
- Ethical, Regulatory and Community Issues (Plaza Athenee Hotel, Atheneum 2 & 3 on the 6th floor)
- Science and Vaccine Development (Plaza Athenee Hotel, Atheneum 7 on the 6th floor)

- Clinical Trial Design and Statistics (Plaza Athenee Hotel, Atheneum 6 on the 6th floor)

1300 - 1400 Lunch (Plaza Athenee Hotel, Rain Tree Cafe on the ground floor)

1400 – 1500 Breakout Groups Meet

1500 – 1515 Break (Plaza Athenee Hotel, Star room 29 on the 29th Floor)

1515 – 1800 Report on Group Discussion and Proposed Way Forward For Group
The objective of this plenary discussion is for each group representative to share the output of their discussion and to solicit comments from participants of other groups.
 (Plaza Athenee Hotel, Star room 29 on the 29th Floor)

- Public Health and Future Access Group Representative
- Ethical, Regulatory and Community Issues Group Representative
- Science and Vaccine Development Group Representative
- Clinical Trial Design and Statistics Group Representative

1800 - 1900 Break

1900 Dinner (Plaza Athenee Hotel, The View Restaurant on the 4th floor)

17 March, 2010

0530 – 0830 Breakfast at your leisure (complimentary for hotel guests; Rain Tree Cafe, Plaza Athenee Hotel)

Moderator: *Dr. Saladin Osmanov*

0830 – 0900 Recap of Key Points from Day 1 and Review Objectives for Day 2 (Plaza Athenee Hotel, Star room 29 on the 29th Floor)

- Dr. Saladin Osmanov

0900 – 0920 Presentation of RV144 Cost Utility Analysis Findings

- Health Intervention & Technology Assessment Program, Thailand

0920 – 1035 Breakout Groups Meet

1035 – 1055 Break (6th floor)

1055 – 1250 Breakout Groups Meet

- 1250 – 1350 Lunch (Plaza Athenee Hotel, Rain Tree Cafe on the ground floor)
- 1350 – 1520 Breakout Group Recommendations and Presentation Development
- 1520 – 1535 Break (Plaza Athenee Hotel, Star room 29 on the 29th Floor)
- 1535 – 1820 Report on Group Discussion and Proposed Way Forward For Group
The objective of this plenary discussion is for each group representative to share the output of their discussion and to solicit comments from participants of other groups.
- Public Health and Future Access Group Representative
 - Ethical, Regulatory and Community Issues Group Representative
 - Science and Vaccine Development Group Representative
 - Clinical Trial Design and Statistics Group Representative
- 1820 – 1900 Break
- 1900 Dinner (Plaza Athenee Hotel, the View restaurant on the 4th floor)

18 March, 2010

- 0530 – 0830 Breakfast at your leisure (complimentary for hotel guests; Rain Tree Cafe, Plaza Athenee Hotel)

Moderator: Dr. Supachai Rerks-Ngarm

- 0800 – 0815 Recap of Key Points from Day 2 and Review Objectives for Day 3 (Plaza Athenee Hotel, Star room 29 on the 29th Floor)
- Dr. Saladin Osmanov
- 0815 – 0915 Public Health and Future Access: Presentation of Recommendations and Discussion
- Dr. Catherine Hankins
- 0915 – 1015 Ethics and Regulatory Issues: Presentation of Recommendations and Discussion
- Dr. Ruth Macklin
- 1015 – 1030 Break (Plaza Athenee Hotel, Star room 29 on the 29th Floor)
- 1030 – 1130 Science and Vaccine Development: Presentation of Recommendations and Discussion
- COL. Nelson Michael
- 1130 – 1230 Clinical Trial Design and Statistics: Presentation of Recommendations and Discussion

- COL. Jerome Kim and Dr. Donald Stablein

1230 – 1330 Lunch (Plaza Athenee Hotel, Rain Tree Café on the ground floor)

1330 – 1445 Outline Next Steps

- COL. Jerome Kim

1445 – 1500 Closing Remarks

- Dr. Supachai Rerks-Ngarm

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