Expert Consultation on the

Use of Placebos in Vaccine Trials



WHO Library Cataloguing-in-Publication Data

Expert consultation on the use of placebos in vaccine trials.

1.Vaccines – standards. 2.Placebos – therapeutic use. 3.Clinical trial 4.Ethics.

5.Communicable diseases. I.World Health Organization.

ISBN 978 92 4 150625 0 (NLM classification: QW 805)

© World Health Organization 2013

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications –whether for sale or for noncommercial distribution– should be addressed to WHO Press through the WHO web site (www.who. int/about/licensing/copyright_form/en/index.html).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Printed in (Geneva, Switzerland)

Expert Consultation on the

Use of Placebos in Vaccine Trials



Table of Contents

	07
	08
	09
	11
search Ethics Principles	
rations relevant to the General Use of Placebos	
rations for the Use of Placebos in Vaccine Research	
se of Placebos	15
where Placebos may be Acceptable	
	19
ommendations	
commendations	
	22
of Participants	
ected Guidance and Regulations on the Use of Placebos in	
ical Research	
rnative Trial Designs in lieu of Individually Randomized Controlled Trials	
luding Placebo-Controlled Trials)	
Vaccine Trials in Thailand	
MS (2002) International Ethical Guidelines for Biomedical Research	
trol Vaccines	
umococcal Vaccine Trial in Bangladesh	
avirus Vaccine Trials in India	
	search Ethics Principles rations relevant to the General Use of Placebos rations for the Use of Placebos in Vaccine Research se of Placebos where Placebos may be Acceptable commendations commendations commendations of Participants ected Guidance and Regulations on the Use of Placebos in ical Research rnative Trial Designs in lieu of Individually Randomized Controlled Trials luding Placebo-Controlled Trials) Vaccine Trials in Thailand MS (2002) International Ethical Guidelines for Biomedical Research trol Vaccines umococcal Vaccine Trial in Bangladesh avirus Vaccine Trials in India

Acknowledgments

The Expert Consultation on the Use of Placebos in Vaccine Trials was convened by the World Health Organization (WHO) in Annecy, France on 17–18 January 2013 under the overall guidance of Rüdiger Krech, WHO Director of the Department of Ethics and Social Determinants, and Marie-Paule Kieny, Assistant Director-General, Health Systems and Innovation. WHO is grateful to the panel of experts who contributed to this Report (see Annex 1).

Special thanks go to James Colgrove and Annette Rid for acting as rapporteurs, and to James Colgrove for developing the first draft of this report.

The following experts' contributions to the case studies described in the document are also acknowledged: Ames Dhai, Pieter Neels, Punnee Pitisuttithum, Michael Selgelid and Mark Sheehan.

The input of Patricia Loh, working as an intern with the WHO Department of Ethics and Social Determinants, is particularly appreciated for her dedication to ensuring that all the comments and recommendations of the experts are included and that the document is consistent and concise.

Finally, gratitude is expressed to the following WHO staff members for their valuable comments and support: Marie-Charlotte Bouesseau, Sergio Nishioka, Vaseeharan Sathiyamoorthy, and Abha Saxena.

Abbreviations

CIOMS	Council for International Organizations of Medical Sciences
HIC	high-income country
HIV/AIDS	human immunodeficiency virus / acquired immunodeficiency syndrome
ICH	International Conference on Harmonisation of Technical Requirements
	for Registration of Pharmaceuticals for Human Use
LMIC	low- and middle-income countries
REC	research ethics committee
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization
WMA	World Medical Association

预览已结束, 完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5_28214