

# HIV VACCINES FACILITATOR'S MANUAL

MASIKHULISANE, SAAVI COMMUNITY INVOLVEMENT PROGRAMME

## HIV Vaccines Facilitator's Manual

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### Disclaimer

This Manual aims to provide users with information to better understand the process of HIV vaccine research and development and related ethical, legal and human rights and community involvement issues. It is not provided as medical or professional advice or intended to be used to diagnose, treat, cure or prevent any disease. Persons who have, or suspect that they have, a health related problem should consult a suitable health care provider.

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## ACKNOWLEDGEMENTS

*Masikhulisane* warmly thanks all the authors and contributors who gave of their time and experience to make this *Facilitator's Manual* possible (please see our alphabetical list of authors on page iv, and our list of contributors on page x).

We also thank our funders for their support which made it possible to write, edit, design and print this Manual. Our funders include:

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Grateful thanks also go to the Centre for the Study of AIDS (CSA) at the University of Pretoria, who first began development of this Manual as a partner with the MRC and the AIDS Legal Network (ALN) in the EC-funded project, SA HIVAC (see below). Former CSA staff who co-ordinated the original development of the Manual include Brenton Maart and Gloria Malala.

### Who is Masikhulisane?

*Masikhulisane*, is SAAVI's Community Involvement Programme, our name meaning 'Let's grow together'. *Masikhulisane* was formed in 2004 following a second successful grant application to the European Commission (EC), and evaluation of the South African HIV Vaccine Action Campaign (SA HIVAC). The SA HIVAC project was established as a result of a first contract with the European Commission (EC), which began in 2000.

Currently our Vision is to see: A South African society working in a mutually beneficial and meaningful partnership with researchers in a vibrant human and legal rights environment.

Our Mission is therefore to create a sustainable, accountable learning organisation founded on a human rights ethos, to ensure an informed and educated South African society with strengthened, active and sustained community involvement in the HIV vaccine-development process (this includes research, development and testing of HIV vaccines).

To achieve our mission, we focus on the following activities: awareness raising and education about HIV vaccines in different sectors of the South African society; providing a toll-free HIV Vaccine Info-Line; and, research and capacity development in community involvement, and human rights, legal and ethical issues related to HIV vaccines. We are also involved in facilitating collaborative activities to encourage knowledge exchange between national, regional and international role-players involved in the HIV vaccine-development process.

*Masikhulisane* sees community involvement as an ongoing, long-term engagement with communities through consultation and dialogue about all parts of the HIV vaccine-development process. Here community involvement includes 'Community preparedness' which is seen as the preparation of a community around a trial site where an HIV vaccine will be tested.

Currently *Masikhulisane* is headed by a Programme Manager, who manages a team of staff including a Programme Administrator, several Vaccine Educators across the Western Cape, KwaZulu-Natal and Gauteng, a Materials Developer, and a Human Rights, Legal and Ethics Advisor. *Masikhulisane* is SAAVI's Community Involvement programme, and is located and is part of the South African Medical Research Council (MRC).

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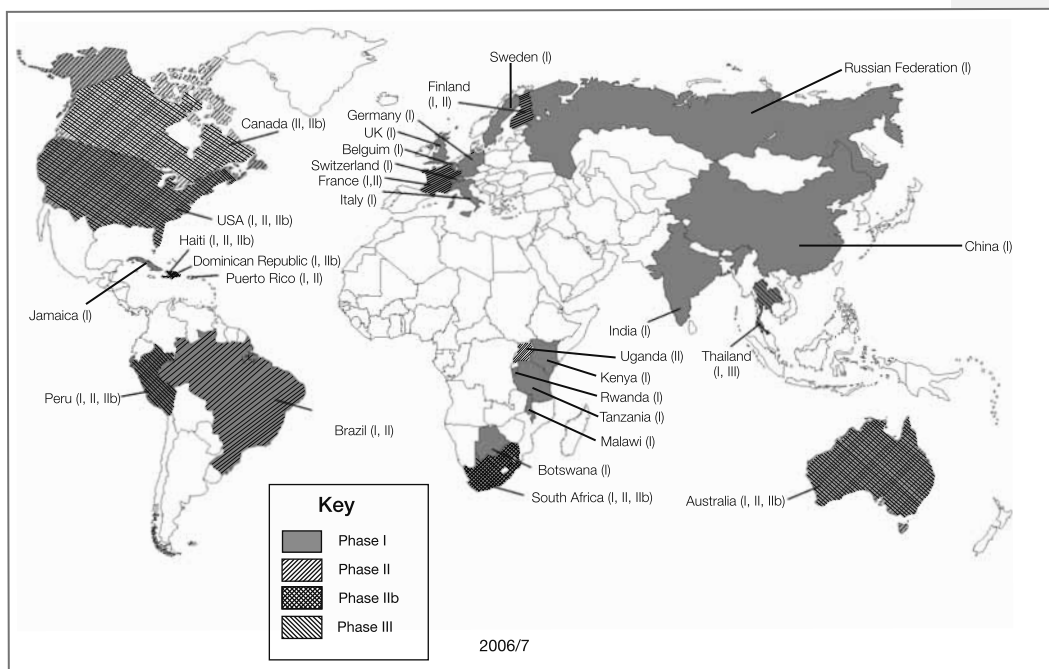
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## ABOUT THE HIV VACCINES FACILITATOR'S MANUAL

The search for an effective HIV vaccine is underway. Throughout the world different communities are involved in different ways and in different stages and phases of the HIV vaccine research and development process. In South Africa too there are HIV vaccine trials happening in various provinces, and sites such as Soweto, Cape Town, Durban, Klerksdorp etc.



In the next few years more and more people will want to know about HIV vaccine trials, and may want to volunteer to participate in them. They will need information, knowledge and understanding about how the test HIV vaccines work and the processes that are followed in HIV vaccine clinical trials. People will need to be trained to give this information and to facilitate this understanding.

### Who is this Manual for?

This Manual is for trainers who will facilitate workshops and awareness raising for different organisations, parties, agencies and people about the HIV vaccine research and development process. It was written to give people the most accurate information possible, to standardise the messages that we all are giving about HIV vaccines, and to give these messages in the most active and participatory way possible.

### How is the Manual structured?

There are seven modules in the Manual, each of which covers a different area about HIV vaccine research and development. Module 1 is slightly different to the rest of the modules because it is written for workshop facilitators and gives guidelines on how to run participatory workshops and other awareness-raising events.

Modules 2-7 contain the main information that should be covered in these workshops. Each of these modules is divided into two main sections:

**Section 1:** includes the background information that facilitators need to understand the topics covered in the module.

**Section 2:** includes activities that help facilitators present this information to others in a participatory way.

### **What are some features in each module?**

#### ***Section 1: Background information that facilitators need to know***

- Each module starts on page 1. This is so that it will be easy for us to constantly update information without having to reprint the whole Manual.
- Page 1 of each module lists outcomes, i.e. what you should know or be able to do by the end of working through the module.
- The outcomes in the Manual are designed to meet unit standards submitted via the Ancillary Healthcare SGB (Standards Generating Body) to SAQA (South African Qualifications Authority) for registration on the NQF (National Qualifications Framework). These are awaiting approval.
- Throughout the Section there are questions for you to think about or to discuss with others. These are called, *Take 5 minutes ...* and are aimed to help you become a more active reader, to consolidate what you are learning, and to prepare to ask these questions to the workshop participants to encourage discussion about a particular topic.
- Boxes called, *Key words* define technical or unfamiliar words used, when they first appear in the Manual. These words are also highlighted in bold on the page. It is important to understand what these words mean as they may be used by trial site staff and researchers.
- The *Did you know?* boxes contain additional interesting information about a topic.
- Where relevant, you are referred to other modules for more information about a topic.
- Each Section 1 ends with a summary of the main messages covered.
- Usually there is also a list of references or information sources that were used in the module to which you can refer to for further information.

#### ***Section 2: Activities to help you present the information covered in the module to others***

- Each Section 2 begins by listing the overall outcomes of all the activities – what workshop participants should know or be able to do by the end of working through the activities.
- Each activity also lists the specific outcomes of that activity; the materials you will need; suggested timing for the activity; what preparation you should do; and a suggested process of how to take workshop participants through the activity.
- Some modules contain handouts to use with workshop participants – these are referred to in the relevant modules.
- Some modules include an Appendix with relevant documents that you will need to use or refer to.

- Once you are more familiar with presenting workshops on HIV vaccines, you might want to adapt or use other exercises to achieve the outcomes listed under each activity.

We encourage you to gather and use other relevant resources in your workshops, including relevant sections of the *HIV Vaccines Learner's Handbook*. This handbook is specially written for workshop participants, who attend sessions on all the modules in the Manual, to use and take away with them.

### **What topics are covered in each module?**

*Module 1: Facilitator's guidelines*, discusses how adults learn and how we can best facilitate their learning. The module provides general suggestions on how to run participatory workshops on the HIV vaccine research and development process.

In *Module 2: Understanding the background to HIV vaccines*, we examine the HIV and or AIDS pandemic and the impact it has had on the world and sub-Saharan Africa, especially South Africa. We explain what HIV and AIDS are, how the immune system works, and how HIV impacts on it. This helps us to understand how vaccines work and why finding an effective HIV vaccine is one of the biggest hopes for controlling the pandemic in the future. We also introduce the history and concepts of vaccines in general.

*Module 3: Science and research* looks generally at how science helps us answer questions about the world around us, including questions about health and disease in humans. We discuss steps in the modern scientific method; the four stages involved in developing a new drug or vaccine; and the four phases of clinical trials in humans. We look at the parties that are involved in approving, running and quality assuring this research. We also look at the development of the research protocol, and the guidelines and laws that researchers must follow in doing this

In *Module 4, HIV vaccine research and development*, we apply the general information covered in Module 3 to the research and development of an HIV vaccine. We explain the difference between preventative and therapeutic HIV vaccines; what is a successful HIV vaccine; the stages and phases involved in the research and development of an HIV vaccine; the different parties that are involved in clinical trials; where these trials are happening in the world and how trial sites are chosen; and the guidelines, laws and regulations that apply to development of the HIV vaccine clinical trial protocols.

*Module 5: Ethical issues*, examines what ethical principles should guide our research with humans and how these principles need to be balanced. We identify different key requirements for ethical research, and we explore how these principles and standards are put into practice in HIV vaccine trials. The module ends by exploring a controversial ethical issue in the HIV vaccine research and development process.

### **NOTE**

For copies of the *HIV Vaccines Learner's Handbook* or overheads for the Activities, please contact *Masikhulisane* who will send you an electronic copy of the document. You can use the document to print the pages that you need as this may be easier and less costly than photocopying notes from Section 1 of the Manual.

In *Module 6, Legal and human rights*, we discuss which legal and human rights are important to HIV vaccine trial participants and communities and why these are important. We focus on how to ensure that these rights are respected, protected, promoted and fulfilled, and how the draft *SAAVI Preventive HIV vaccine Trial Participant Charter of Rights* can be used to raise awareness of these rights.

The final module, *Module 7: Community involvement and participation*, reminds us that at the heart of the HIV vaccine research and development process are communities and people. We discuss the importance of community involvement and participation and how we can facilitate this. We outline the different steps involved in participating in an HIV vaccine trial.

### **How to use the modules**

The manual is designed in such a way that you can use Modules 2-7 in their current order in a comprehensive and progressive programme for the same group of participants. Each module will build on the knowledge presented in the previous module.

However, you can also choose to use only specific modules with specific groups; or even certain sections from specific modules for short inputs.

No matter how you choose to work with these modules please remember the following:

- You, as the facilitator, should read through all the modules so that you have a comprehensive understanding of the HIV vaccine research and development process. This will help you to present specific information in the most accurate way possible and to answer workshop participant's questions in an informed way.
- Only by reading through the entire Manual will you know which sections are most relevant for which group of participants; and how best to combine sections or modules so that they fit together logically.
- The suggested activities in Section 2 of each module are just that – suggestions. You can use them as is, or adapt or change them to meet the needs of your workshop participants, or, you can develop your own activities – as long as you ensure that you can cover the outcomes given in the module.

### **A note about South African information**

This Manual was developed primarily for South African audiences and so most examples, case studies, statistics, and legal sections are specific to the South African context. However, these can be adapted or substituted if you are using the Manual in a different context. You will need to research which laws, documents, regulations, statistics, etc. are relevant to your situation.

### **A note about language**

The Manual is written in plain, easy-to-read language. However, this is sometimes challenging when you are talking about complex and technical information, like medical, scientific and legal processes.

In your own workshops, try to watch the language you use to educate and inform people.

- Use words that are most familiar to your workshop participants.
- Use concrete, real examples that people can relate to, rather than abstract concepts.
- Explain scientific, medical or legal terms or avoid them if possible.
- Translate words if necessary to ensure that everyone understands.
- Watch out that you do not stereotype communities and that your language and examples are bias free and are gender sensitive.

We hope that you will find this Manual useful. It is a work in progress and will grow and develop as it is used by facilitators with their workshop participants. We welcome your input and comments and will try to include them in future editions. Please send your suggestions to the Materials Developer at *Masikhulisane*, the SAAVI Community Involvement Programme. See the *Masikhulisane* contact details on page iii.

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## ABOUT THE CONTRIBUTORS

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### Acknowledgements

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