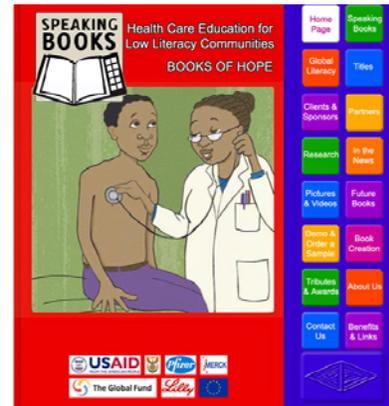


## Understanding Clinical Trials with a “Speaking Book”

For Pfizer and other companies in the health care industry, ensuring the objectives of clinical trials are clear and easy to understand is among the necessary, ethical prerequisites to obtaining informed consent from trial participants. Pfizer created a “speaking book” about clinical trials in locations with low literacy. The speaking book is an audio book that helps patients and their relatives understand their role, rights and responsibilities as participants in a clinical trial.



### Local Experts, Global Partners

In many parts of the world, patients and their relatives do not read and write well enough to understand health information, including typical “informed consent” information that would be provided to them, by the investigator, when the potential trial participant is deciding to enroll in a study or not.

“Extremely low literacy rates are concentrated in three regions, South and West Asia, Sub-Saharan Africa, and the Arab states, where one-third of the men and half of the women are illiterate. Africa, as a whole continent, has less than a 60% literacy rate.”<sup>1</sup>

To address this challenge, Pfizer partnered with Books of Hope, as well as the World Medical Association, the Steve Biko Centre for Bioethics, and the South African Medical Association. Each organization had an important role to play. The World Medical Association (WMA) developer of the *Declaration of Helsinki* (the international standard for Ethical Principles for Medical Research Involving Human Subjects), was consulted early in the process to ensure the text of the book matched the latest revisions to the Declaration. The Steve Biko Centre for Bioethics and the South African Medical Association served as experts in reviewing the words and images used in the book, so cultural as well as cognitive understanding would be appropriate. Books of Hope was responsible for adapting the written text to the “speaking book” format – an expertise they have perfected via their many other speaking books on other health topics. The Clinical Trial Speaking book was launched at the World Medical Association General Assembly in Seoul, Korea, October 17, 2008 supported by a WMA press release talking about the necessity and value of the book. Dr. Edward Hill, Chair of Council, World Medical Association, noted the books facilitate “more

<sup>1</sup> <http://www.booksofhope.com/openbook/index.php?/global-literacy.html>

attention to the poorer communities of this world instead of abandoning them or just ignoring their needs." Jack Watters, Vice President, Pfizer added that "It is absolutely crucial that all people involved in clinical research - whether a health professional, an ethics committee member or a patient - have the necessary knowledge and skills to play their role."<sup>2</sup>

## Speaking Books: A World Changing Idea

The speaking books were first created by Books of Hope for the South African Depression and Anxiety group (SADAG) to help patients and health care providers communicate about mental health issues. Books of Hope is a non-governmental organization (NGO) also based in South Africa.

Speaking books use cartoons or pictures in addition to text that is spoken when the corresponding button is pushed for that page. Speaking books in general have many advantages including:<sup>3</sup>

1. Visual messages accompanied by sound are much more effective at conveying accurate messages.
2. The recorded text serves as a script and provides quality assurance in places where health volunteers may only receive only brief training and cannot be readily supervised.
3. Contrary to radio and television, the Speaking Book does not depend on access to electricity or proximity (e.g. to telephone or radio reception).
4. Speaking Books are user-driven: the audience can play and re-play the message at any time, at their own pace.
5. Each copy of a Speaking Book has the potential to reach hundreds of people. Each copy of a Speaking Book can be heard simultaneously by several listeners, between 2 and 10 depending on the setting and the background noise. Each copy can be played between 50 and 60 times for the lower model, and between 120 and 500 times for an upgraded model.

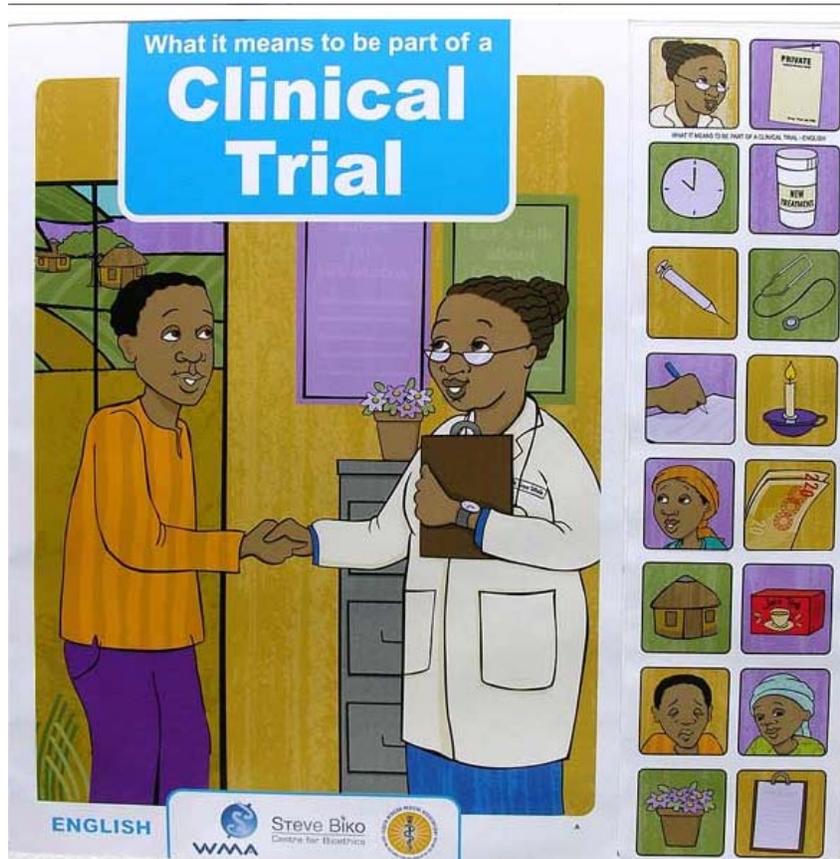
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<sup>2</sup> World Medical Association press release, "New speaking book on clinical trials aimed at African populations with low literacy levels," 17 October 2008. <http://www.wma.net>

<sup>3</sup> For all 10 advantages see: <http://booksofhope.com/openbook/index.php?/benefits-a-links.html>

## "What it Means To Be Part of a Clinical Trial"

Pfizer's first speaking book is titled, "*What it Means To Be Part of a Clinical Trial.*" The book is 18 pages long, and takes approximately seven minutes to listen to or "read."<sup>4</sup> The book explains several issues related to trials including:



- What research is and why it is done
- Rights and responsibilities of participants, including confidentiality
- Benefits, risk and the possibility of side effects
- Costs of participation and processes
- Concept of informed consent
- Encouraging participants to ask questions

The South African language soundtrack was recorded by a local television celebrity, as using a voice recognized across the country helps increase cultural comprehension.

Pfizer is distributing 4,500 copies of the book in South Africa mostly in urban medical clinics, and three other sub-Saharan African countries. The hope is to have the book translated into several African languages that can be used by patients, social workers and community-based health workers involved in clinical trials.

<sup>4</sup> To view the speaking book, go to YouTube at:

[http://www.youtube.com/watch?v=uckmgymTWcE&url=http://www.booksofhope.com/open\\_book/youtube/titles/youtube\\_16.html](http://www.youtube.com/watch?v=uckmgymTWcE&url=http://www.booksofhope.com/open_book/youtube/titles/youtube_16.html)

Several groups in other parts of Africa have already expressed interest in using the book as a learning tool. Among them are the Association of Good Clinical Practice in Nigeria, and AIDS support groups in Kenya and Uganda.

### **Pfizer's International Clinical Trials Initiative**

The initiative supports Pfizer's efforts in building capacity and knowledge about conducting clinical trials in developing countries. Pfizer is now supporting the development of a similar speaking book to be used in India. Working with Books of Hope and the World Medical Association, Pfizer hopes to launch an English and a Hindi version (the second most used language in India) at the WMA General Assembly meeting in Mumbai, India in October 2009 in collaboration with the Indian Medical Association.

## Discussion Questions

1. What experts, or organizations, should be involved in the development of speaking books related to health care? Related to clinical trials?
2. Should ethics committees make their own "Speaking Books" or should they be made for certain trials, rather than trying to focus on typical clinical trial issues?
3. Is it likely that a "Speaking Book" will make a major difference in being able to obtain informed consent with an illiterate population?
4. Should patients who cannot read or write be solicited or encouraged to participate in clinical trials, even though they may have great difficulties understanding the risks of participation?
5. Why is it important to have a discussion with the investigator and/or study staff in addition to the "Speaking Book"?
6. What role, if any, should sponsors play in preparing materials for use in the informed consent process?