

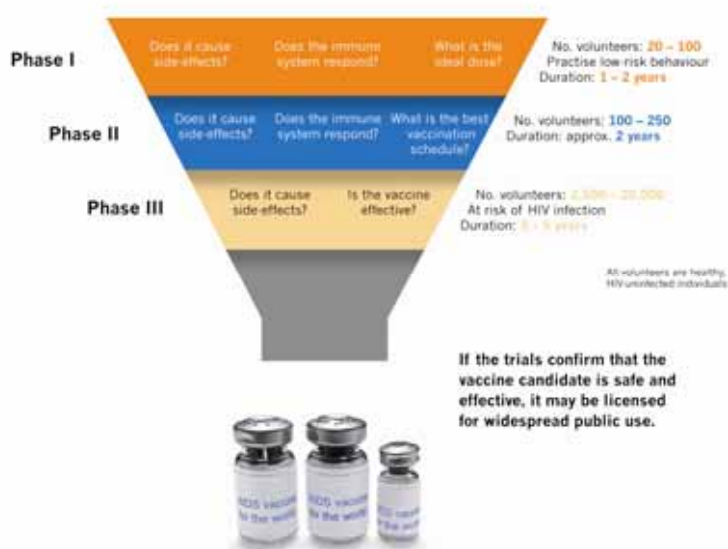
## AIDS vaccine research

Developing a vaccine to prevent HIV/AIDS is particularly challenging. HIV is one of the most complicated viruses ever identified, and the traditional vaccine development approach – utilizing a killed or weakened version of a virus as a vaccine to prompt a protective immune response against the real virus – has not been feasible. Scientists use their extensive knowledge of HIV, vaccines and the immune system to develop candidate vaccines in laboratories. Most AIDS vaccines being developed are preventive vaccines.

Vaccines that show promise need to be tested in human trials to demonstrate whether they are safe and effective (this is true for any vaccine or indeed any medical product). There are three phases of clinical trials. In these trials, the vaccine candidates are tested in humans for their safety, ability to cause immune responses and, ultimately, the ability to protect against HIV infection or slow the progression of disease.

For an AIDS vaccine specifically, Phase I involves a relatively small number of healthy HIV-negative adult volunteers at low risk of HIV infection. Phase I tests primarily if the vaccine is safe and well tolerated. Phase II trials involve a few hundred healthy HIV-negative adult volunteers, some of whom are at higher risk of HIV infection. Phase II tests for safety, an immune system response, as well as early information on required dose and route of administration of the vaccine. Phase III trials involve several thousand adult volunteers at high risk of HIV infection to assess the efficacy of the vaccine in preventing HIV infection and AIDS.

### Three phases of clinical trials



Source: *Developing AIDS vaccines for the world: the role of Europe*, IAVI, 2006.

Development of any new vaccine is normally a long and complicated scientific research process. Generally it takes 10 to 15 years to develop and fully test each vaccine candidate. There are currently two vaccines in advanced clinical trials and information about their effectiveness will become available over the coming years. These data will provide considerable insight into the promise of other vaccine candidates currently in early stages of clinical development. Today, there are more than 30 clinical trials running in 24 countries across five continents. In 2006, 13 new AIDS vaccine trials were initiated, including in Africa (Kenya, Tanzania, Uganda, Zambia), the United States, Peru, Sweden, the United Kingdom and the Russian Federation.

### 30 clinical trials worldwide in 24 countries



Source: IAVI, 2007

More details on clinical trials worldwide can be found at:

[http://www.iavireport.org/vax/english/VAX\\_Jan07\\_Table.pdf](http://www.iavireport.org/vax/english/VAX_Jan07_Table.pdf)