



Common Questions about **Vaccine Research and Development**

Who sponsors the research and development of new vaccines?

Vaccine research is sponsored by the National Institutes of Health (NIH) and other agencies of the U.S. Department of Health and Human Services, the Department of Defense, pharmaceutical and biotechnology companies, and medical foundations.

The National Institute of Allergy and Infectious Disease (NIAID), one of the Institutes of the NIH provides the majority of federal grants for the development of new childhood vaccines. Scientists at universities, medical centers, hospitals, and private research firms compete against each other for federal funding by demonstrating that their proposed studies are well-designed and scientifically sound. The NIH also conducts research on vaccines in its own laboratories.

Since 1981, the regularly updated report known as *The Jordan Report* has provided an overview of current vaccine research. The *Jordan Report 2000* includes information about the current vaccines in development. The most recent version can be obtained on the Internet at the NIAID Web site (<http://www.niaid.nih.gov/publications/pdf/jordan.pdf>).

Most grant-related information (investigator name and institution, project title, abstract) is considered public information. Brief descriptions of federally funded biomedical research projects may be found on the Internet in the CRISP database (www-commons.cit.nih.gov/crisp/). In addition, the NIH encourages grantees to make the results of their vaccine studies available to other scientists and the public. Usually they do this by presenting their data at scientific meetings and publishing their findings in medical journals.¹

In sum, researchers in both the public and private sectors generate high-quality research, and the rigorous Food and Drug Administration approval process ensures that only safe and effective vaccines are released for use in children and adults.

Is enough research conducted before vaccines are licensed by the Food and Drug Administration?

Vaccine research and development is a lengthy and thorough process. Before vaccines are even tested in infants and young children, they are studied in adults and older children to ensure that they are effective and safe. And before they are licensed, they are tested extensively in the specific population (e.g., infants) in which they will be used. Many vaccine candidates drop out during the research and development process. Vaccine candidates that emerge at the end of the long development process are then scrutinized by the government's regulatory process with input from the FDA's independent Vaccines and Related Biological Products Advisory Committee and government scientists.

This committee determines when a sufficient amount of research has been conducted to recommend licensure of the vaccine. If additional studies are needed to determine whether the vaccine is safe and effective, the committee will request additional research before the vaccine is considered for licensure. When a new vaccine is developed and tested, the sponsor must show that its benefits outweigh any risks.

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Does the research process end when a vaccine is licensed by the Food and Drug Administration?

Although careful attention is placed to ensuring vaccine safety and effectiveness before the FDA licenses a vaccine, some extremely rare events may not be identified in the pre-licensure research studies. For example, if a vaccine has an adverse side effect that occurs only once in 500,000 immunizations, it is unlikely to be found until the vaccine is administered to millions of children. Therefore, the FDA and CDC carefully monitor vaccines for safety after they are approved by the FDA and recommended to the general public. This monitoring continues for as long as the vaccine is in use and possibly longer.

Several different vaccine-monitoring programs are in place. For example, the FDA and Centers for Disease Control and Prevention (CDC) monitor adverse events associated with the use of vaccines. The federal government monitors reports to the Vaccine Adverse Event Reporting System (VAERS) and actively reviews the data. If questions about the vaccine's safety arise, the federal government can recommend that the vaccine be withdrawn from the market until additional studies are performed.

The Vaccine Safety Datalink (VSD), established by the CDC in 1990, links the large databases of four large health maintenance organizations in Oregon, Washington, and California. Because this system actively finds cases and systematically reviews medical records from a population of known size, the VSD captures more complete data on adverse events associated with vaccination. The VSD makes it possible to do large epidemiological studies of vaccine adverse events, captures information on less commonly occurring types of adverse events, and helps determine whether an event is linked with a vaccine or with some other cause.

In addition, other types of vaccine studies are conducted by FDA to improve the safety of vaccines. For example, FDA researchers might try to improve tests of vaccine purity by adopting newly developed laboratory methods. Or, FDA researchers might explore methods of modifying components of a vaccine to make it safer without diminishing its effectiveness.

Do any of the people who serve on federal advisory committees receive research support from pharmaceutical companies?

Yes, some of these experts may conduct research on vaccines with support from a number of sources. These may include the government, pharmaceutical companies, private foundations and other sources. The FDA's recommendation and approval process involves the best scientists, clinical researchers and statisticians from universities, the government, and private industry. The recommendation process is open and public, however, and all voting members are subject to conflict-of-interest laws (described in detail below).

Members of the FDA's Vaccines and Related Biological Products Advisory Committee include: representatives of the FDA's Center for Biologics Evaluation and Research, a representative of the Centers for Disease Control and Prevention, professors and researchers from leading U.S. universities, and representatives of other organizations. The names and affiliations of the members of the Vaccines and Related Biological Products Advisory Committee are listed on the FDA's Web site (www.fda.gov/cber/advisory/vaccine.htm).

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Voting members of the advisory committee “are subject to the conflict of interest laws and regulations either as special government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service” (Code of Federal Regulations, Title 21, Volume 1, Part 14, Subpart E, Section 14.80).² According to federal code 18 U.S.C. 208(a), advisory committee members are excluded from voting if they have a financial interest in the vaccine under review. Exclusion is noted for the public record. The FDA is strict about compliance with its conflict-of-interest policy. At the beginning of the meeting, advisory committee members publicly report any financial interests that would present a conflict of interest or the appearance of a conflict of interest. Transcripts of FDA advisory committee meetings are available on the FDA’s Web site (www.fda.gov). In addition, waiver statements made by advisory committee members are available by written request under the Freedom of Information Act.

Sources:

- 1 National Institutes of Health. NIH Grants Policy Statement—Part II: Terms and Conditions of NIH Grant Awards. Available on the Internet at grants.nih.gov/grants/policy.
- 2 Code of Federal Regulations. The Code of Federal Regulations may be accessed on the Internet at www.access.gpo.gov/nara/cfr/index.html#page1.

Recommended books and Web sites on this topic:

Humiston SG and Good C. Vaccinating your child: Questions & answers for the concerned parent. Atlanta: Peachtree Publishers; 2000.

Offit PA and Bell LM. Vaccines: What every parent should know, revised edition. New York: IDG Books; 1999.

FDA Web site (www.fda.gov/fdac/features/095_vacc.html).

National Institute of Allergy and Infectious Diseases Web site (www.niaid.nih.gov).