

**Strategy 1.4.2:** Strengthen the Nation’s capability to provide technical support, training, and assistance to new developers of vaccines.

**Strategy 1.4.3:** Expand the Nation’s capability to conduct research monitoring functions, including data audits of pivotal clinical trials submitted with vaccine Product License Applications.

**Objective 1.5 Promote the Improvement of Existing Vaccines and Development of New Vaccines and Vaccine-Related Technologies for Diseases of Importance in Developing Countries**

**Strategy 1.5.1:** Support basic and applied research to develop, evaluate, and introduce (1) improved vaccines and vaccine technologies that are affordable in developing countries and (2) new vaccines and technologies for diseases of particular importance in developing countries.

**Strategy 1.5.2:** Strengthen vaccine field evaluation sites in developing countries.

**GOAL 2 ENSURE THE OPTIMAL SAFETY AND EFFECTIVENESS OF VACCINES AND IMMUNIZATION**

There are five objectives for this goal:

**Objective 2.1 Enhance the Capability to Evaluate the Safety and Effectiveness of Vaccines**

**Strategy 2.1.1:** Ensure the capability of Federal agencies to fulfill legislative mandates to evaluate new vaccines, to conduct prompt reviews of vaccine applications, investigational new drug and Product License Applications, and to provide for the continuous monitoring of licensed vaccines.

**Strategy 2.1.2:** Develop improved methods for preclinical and clinical evaluation of vaccines under development.

**Strategy 2.1.3:** Establish appropriate standards and specifications for new vaccines prior to their approval and/or release.

**Strategy 2.1.4:** Investigate mechanisms of adverse events following vaccination.

**Strategy 2.1.5:** Expand the capacity to conduct bioresearch monitoring functions.

**Strategy 2.1.6:** Establish procedures for evaluating vaccines to be used in response to national vaccine emergencies resulting from vaccine shortages or national defense needs.

**Objective 2.2 Improve the Surveillance and Evaluation of Adverse Events Following Vaccination**

**Strategy 2.2.1:** Continue to evaluate and improve the existing Vaccine Adverse Event Reporting System (VAERS) to collect and analyze accurate and complete information for those patients with reported serious adverse events following vaccination.

**Strategy 2.2.2:** Maintain and expand collection of information on immunization and medical events by linkage of vaccine records and medical records in large, linked data bases (LLDBs).

**Strategy 2.2.3:** Explore the need for alternative methods to collect and analyze reports of adverse events.