Rotavirus infection produces a serious health burden in the United States, causing an estimated > 100,000 hospitalizations and >100 deaths annually. This health burden is comparable to that for measles, pertussis, mumps, and varicella before vaccines for these diseases were routinely given to children. Rotavirus vaccines have the potential to significantly reduce a serious public health problem in the United States. However, while development and licensure of vaccines is a major breakthrough, it represents only the first step in disease prevention.

Vaccines must be recommended by major immunization advisory committees, financed in both the public and private sectors, and successfully integrated into the existing vaccination schedule. Vaccines must reach all targeted children, and monitoring systems must be established or adapted to better determine vaccine safety and disease impact. Reevaluation of disease prevention strategies must be ongoing and fueled by new information on safety and disease reduction.
Phase 1:
Drug or treatment is given to a small group of people (20-80) to evaluate its safety and identify side effects and safe dosage range.

Phase 2:
Drug or treatment is given to a medium group of people (100-300) for further evaluation.

Phase 3:
Drug or treatment is given to a larger group of people (1,000-3,000) to evaluate its safety.

Phase 4:
Post-marketing studies delineate additional information including the drug risk, benefits and optimal use.