Investigators hope for FDA approval. A private investor agrees to finance clinical trials of the new vaccine. These trials are necessary to get FDA approval of the vaccine. 3 phases of clinical trials are required:

**Phase I**: Is it safe to use in humans, and if so what doses are appropriate?

**Phase II**: Does it work?

**Phase III**: Does it work on large numbers of people?

A new company called Shield Biotech is formed to develop the vaccine. It is headed up by Dr. Tuohy as chief science officer, and includes a scientific panel of leading cancer experts.

Generous supporters Mort and Iris November give $1 million to establish an endowed chair for Dr. Tuohy at Cleveland Clinic.

Cleveland Plain Dealer, September 17, 2013

The vaccine was found to be both safe and effective.

When do we get the new breast cancer vaccine?

Quick answer: If all goes well, maybe by 2023

Dr. Tuohy publishes a study showing that a single vaccination with a breast-specific protein prevented breast tumors from forming in mice, while also inhibiting the growth of already existing tumors.

Completion of all Phase I testing.

Dr. Tuohy and Cleveland Clinic seek funding for further studies of the vaccine. The cost to produce the vaccine is estimated to exceed $1 million, and the total cost of conducting a trial approved by the Food and Drug Administration is more than $4 million.

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Cleveland Clinic researcher Vincent K. Tuohy, PhD, studies the biology of breast cancer in search of vaccine targets.