INFOGRAPHIC //

Experimental Deficit

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First it was call centers and computer operations. Now U.S. pharmaceutical companies are sending clinical trials offshore to cope with the shortfall of willing subjects at home. Here, a look at the effects of outsourcing, for both good and ill.

THE OUTSOURCING EQUATION

INCREASED DEMAND...

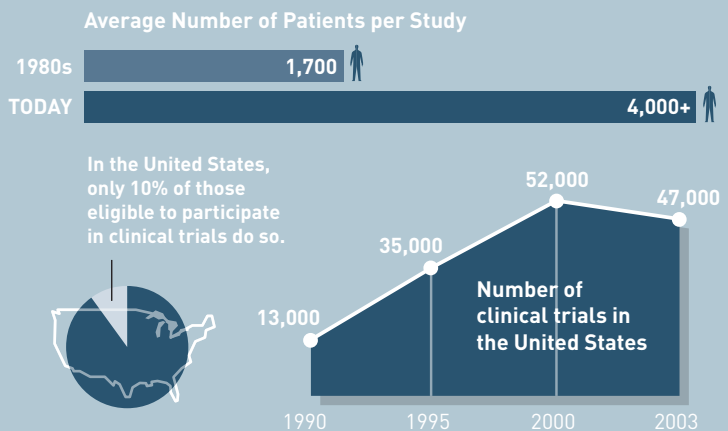
In the United States, demand for research volunteers has grown because of increased drug development and because many trials require more subjects than ever. A larger sample size helps uncover rare side effects and shows a new drug's small improvement over an existing one.

...PLUS DIMINISHED SUPPLY...

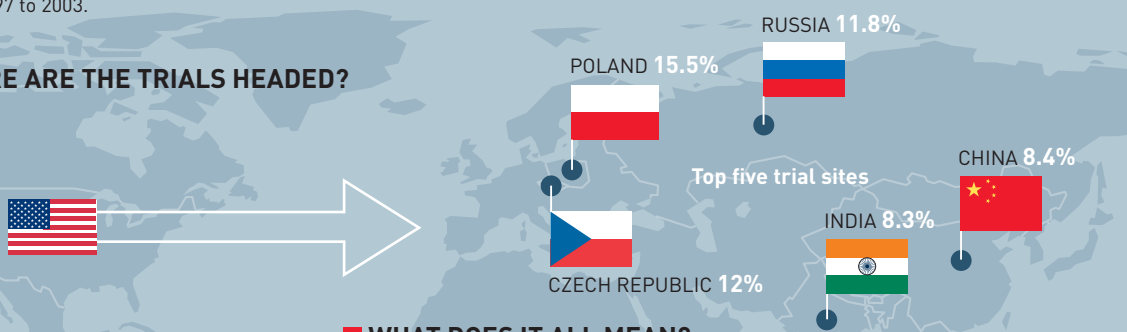
The estimated number of clinical trials going on during any one year varies wildly—from **8,000** to **80,000**—and as a result, so does the estimate of trial subjects needed. Regardless, recruitment is difficult: It consumes **40%** of the approximately **$450 million** required to conduct a trial for a new drug.

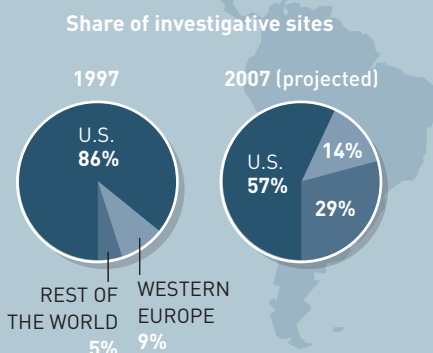
...EQUALS TRIAL DELAYS

- Only **6%** of trials finish on time.
- The number of U.S. trials running on schedule decreased by **12%** from 1997 to 2003.
- The number of U.S. trials that were delayed longer than one month increased by **12%** from 1997 to 2003.



WHERE ARE THE TRIALS HEADED?





WHAT DOES IT ALL MEAN?

PROS

- Pharmaceutical firms can recruit large numbers of research volunteers relatively quickly.
- Trials are much less expensive, saving pharmas **40%–60%** per research participant.
- Study participants in poor countries get medicine they might not otherwise receive.
- In some countries, the local government requires that the host population receive early access to the drug being tested.
- Subjects tend not to be on other drugs, reducing drug interactions that could skew results.

CONS

- Although foreign data must ultimately measure up to FDA standards, the trial process is not monitored as closely as in the United States.
- Foreign institutional review boards may not always uphold ethical or scientific standards.
- The outcome of studies done with one racial group may not always apply to other groups.
- Unsophisticated subjects could unwittingly be put at risk because they may not understand the consent process or even the treatment they're being given.

SOURCES: CENTER FOR INFORMATION AND STUDY ON CLINICAL RESEARCH PARTICIPATION; TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT; FORTUNE; BCC RESEARCH; MCKINSEY CONSULTING