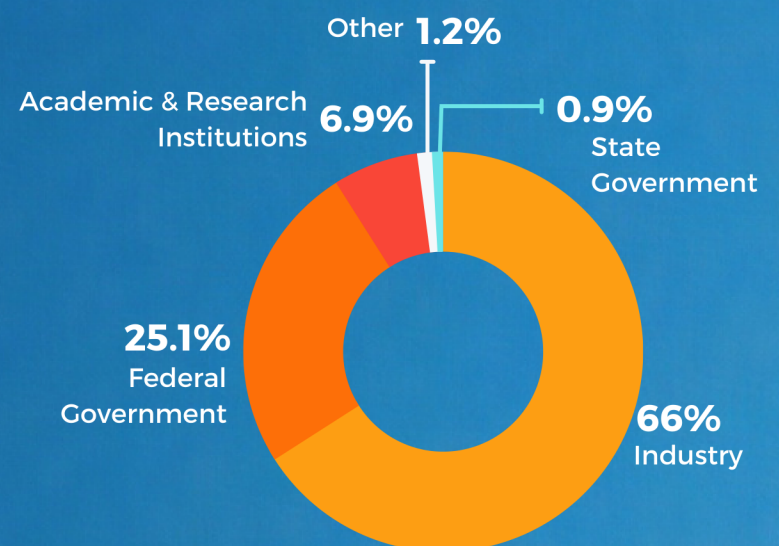


# RESEARCH & DEVELOPMENT PIPELINE

The research and development (R&D) pipeline describes the multi-pronged process that – over time and with many false starts – produces meaningful progress against deadly and debilitating health threats. Patients; federal, state, and local governments; industries spanning pharmaceutical, medical technology, manufacturing, health care, and more, each play a role in combating threats that needlessly rob each of us of health, capacity, and time.

U.S. Medical and Health R&D Investments Shares by Source, 2020



Source: [U.S. Investments in Medical and Health Research and Development 2016-2020](#)

## BASIC RESEARCH

- Basic research answers fundamental questions about living organisms (the what, why, when and how). This new knowledge often provides clues to safeguarding, improving, or restoring health.
- The majority of basic research is conducted at institutions of higher education followed closely by the private sector.

## APPLIED RESEARCH

- Applied research starts with the clues basic research uncovers and assesses potential paths forward to safeguarding, improving, or restoring health.
- The private sector is a crucial leader for conducting applied research.

### The Role of Technology Transfer

Technology transfer is the movement of intellectual property (IP) rights between individuals or organizations. The landmark, bipartisan Bayh-Dole Act, signed into law in 1980, [gives universities the rights to intellectual property \(IP\) generated from federal funding](#). By fostering academic-industry partnerships in the applied, pre-clinical, and clinical research phases of drug development, Bayh-Dole ushered in a new era of cross-sector collaboration and medical progress.

## CLINICAL RESEARCH

- Clinical research comes into play to further refine and assess potential medical advances.
- Clinical research typically involves both patients and healthy volunteers.
- **Phase I trials** examine the safety of the product in a very small group of healthy volunteers. Approximately 70% of drugs make it past Phase I.
- **Phase II trials** assess the efficacy and correct dosing in a larger group of patients. Approximately 33% of drugs make it past this stage.
- **Phase III trials** test the product in a much larger, more diverse population to confirm efficacy, monitor potential side-effects, and develop usage guidelines. Up to 30% of drugs make it past this point.
- **Phase IV**, otherwise known as Post-Market Safety Monitoring, assesses continued safety in the first few months to years after a drug is in use by patients.

## REGULATORY REVIEW AND SCALE-UP

- The Food and Drug Administration ([FDA](#)) is the U.S. government agency that reviews the safety and efficacy of new drugs, determining whether to approve them for sale in the U.S.
- Once a drug is approved, the FDA works with drug companies to develop prescription information for providers and patients.
- After approval, companies begin the process of large-scale manufacturing and marketing the new product.

## IMPLEMENTATION IN HEALTH CARE

- As medical products enter the market, health care providers must determine how to incorporate their use into practice.
- The Agency for Healthcare Research and Quality ([AHRQ](#)) and the National Institutes of Health ([NIH](#)) fund health services research and implementation research, which helps inform health care decision making by providers.

Research!America's "Discovery, Development, Delivery: Understanding the Biomedical Research and Development Pipeline" briefing ([watch the video of the briefing](#)) was supported in part by the Lupus Foundation of America, Lupus and Allied Diseases Association, Inc., Janssen Pharmaceuticals, Horizon Therapeutics, and GlaxoSmithKline. You may also want to read our [Primer on the Pharmaceutical R&D Pipeline](#).

