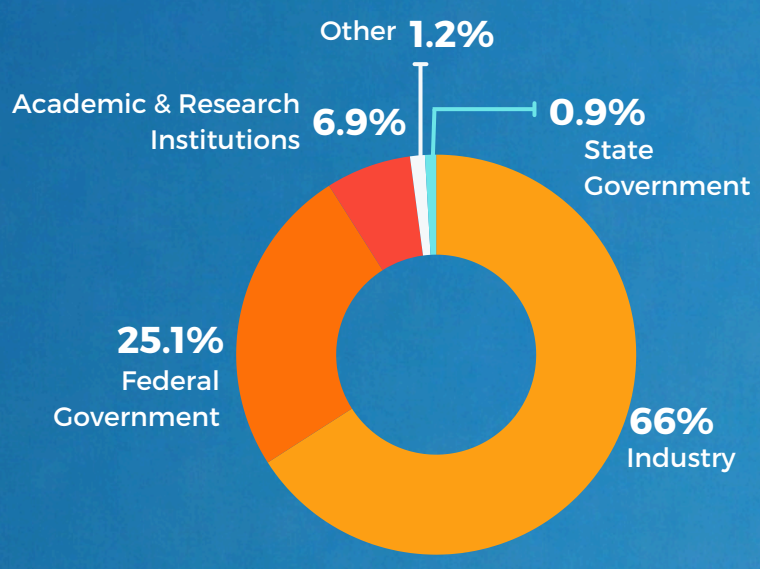
RESEARCH & DEVELOPMENT PIPELINE

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 academic institutions and independent research institutes across the United States.

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 and supporting applied and clinical 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., Jansson Pharmaceuticals, Horizon Therapeutics, and GlaxoSmithKline. You may also want to read our Primer on the Pharmaceutical R&D Pipeline.