Biopharmaceutical Industry-Sponsored Clinical Trials:

Impacting State Economies

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TECONOMY PARTNERS LLC
Innovating Tomorrow's Economic Landscape

For more information on this report please contact TEConomy Partners
1.800.TEC.1296 | info@teconomypartners.com | www.teconomypartners.com

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Executive Summary

Developing a new prescription medicine is a long and complex process, with risk of failure at every step. The research and development (R&D) process in the U.S., from basic science to preclinical and clinical research to approval of new treatments and vaccines for patients, involves a robust R&D ecosystem. The central role of large and small biopharmaceutical companies in the R&D ecosystem is complemented by government, academia, non-profit organizations, patient advocacy groups, health care providers and others who help develop and bring new medical advances to patients.

The U.S. biopharmaceutical industry continues to lead the world in the development of new medicines, harnessing the potential of new scientific and technological advances to expand possibilities for addressing unmet medical needs. At a time when the need for new treatments against some of our most costly and challenging diseases has never been greater, the potential of the R&D pipeline of new drug candidates remains strong.

America's biopharmaceutical companies account for the largest single share of all U.S. industrial R&D investment (17%)[1] and account for half (50%) of all U.S. investments in health and biomedical research and development, including significant spending in clinical research.[2] This report specifically sheds light on the investments and additional economic activity generated by clinical trials site-based activities funded across the country by the biopharmaceutical industry. The analysis provides updated state-level estimates of industry-sponsored clinical research expenditures at trial sites across the country, including the number of trials, the number of trial participants, and the total economic impact derived from industry sponsored clinical trials. The trial records are obtained from www.clinicaltrials.gov, a National Institutes of Health (NIH) database of privately and publicly funded clinical studies conducted in the U.S. and globally. Given that the time for development of a new medicine ranges from 10 to 15 years or more, this report should be viewed as a snapshot of the impact in 2023, the most recent year for which complete data were available.

Each state's economic impact estimate includes the annual direct investments made by companies to establish and operate clinical trial sites in the state, as well as the indirect economic effects that rippled through these local economies as a result of those expenditures in 2023.

This report focuses solely on investments and expenditures at clinical trial sites, which are only a portion of the full economic impact of the R&D enterprise supported by the U.S. biopharmaceutical industry.[3] Beyond the scope of this report are pre-discovery and preclinical research (i.e., prior to testing in humans), as well as activities occurring beyond the operations at clinical trial sites themselves (e.g., clinical trial design, management, coordination, analysis, and related activities). The report also excludes the large nationwide economic impacts associated with non-R&D activities such as manufacturing and distribution, which comprise a substantial portion of industry's overall economic impact in the states.

[1] National Center for Science and Engineering Statistics (NCSES). 2024. Business Enterprise Research and Development: 2022.

[2] Research!America, U.S. Investments in Medical and Health Research and Development: 2016 – 2020, January 2022.

[3] TEConomy Partners, The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates, May 2024, prepared for PhRMA.

Key findings from this report include:

- America's biopharmaceutical companies sponsored nearly 5,300 clinical trials active in 2023, accounting for 78% of all drug, biologic, or genetic trials active during the year.
- These sponsored trials involved more than 906,000 participants, with active trial sites in all 50 states, the District of Columbia, and Puerto Rico.
- The biopharmaceutical industry invested more than $30 billion on site-based clinical trial research across the U.S. in 2023. These resources are in addition to the significant resources invested in clinical trial-related activities occurring outside the individual trial sites, such as trial design, trial management and coordination, and centralized laboratory and data analysis.
- Including the economic ripple effect of expenditures by clinical trial hosts, vendors and contractors, such as clinical research organizations, and spending by industry and vendor employees, biopharmaceutical industry investments at U.S. clinical trial sites generated more than $62 billion in economic activity in communities throughout the U.S. in 2023 (Table ES-1).

Table ES-1. Economic Impact of Industry-Sponsored Clinical Trials in the U.S., 2023

Source of Impact	Economic Impact ($ Billions)
Direct – *Research activities at clinical trial sites around the country*	$30.6
Indirect and Induced – *Vendors and suppliers to trial sites; Consumer purchases by researchers and workers engaged in or supporting the clinical trial process*	$32.0
Total	**$62.6**

Source: TEConomy analysis using state economic impact models from IMPLAN. These data are captured via a summation of the individual results from all 50 states, District of Columbia, and Puerto Rico.

- Population size and the presence of collaborative clinical trial infrastructure helps drive the five states with the highest number of active clinical trials in 2023: California (2,695), Texas (2,508), Florida (2,198), New York (1,932), and Ohio (1,475).
- Because clinical trials occur "in the field" where doctors, trial sites, and volunteer participants are located, sizable investments often occur in states that may not typically be associated with a substantive biopharmaceutical industry presence. For example, Arizona, Georgia, Nebraska, and Tennessee, each generate and support more than $1 billion in total economic impacts.

Introduction

The U.S. biopharmaceutical industry continues to lead the world in the development of new medicines. Due to new scientific and technological advances that are expanding the possibilities for treating disease, the potential of the research and development (R&D) pipeline remains strong. At the same time, the need for new treatments and vaccines against some of our most costly and challenging diseases has also never been greater.

To develop a new treatment or vaccine, researchers and others involved in the R&D process work to piece together the basic causes of disease at the level of genes, proteins, and cells. Out of this understanding emerge "targets," which potential new medicines might be able to affect. Biopharmaceutical companies work to:

- validate these targets,
- discover the right molecule (potential drug) to interact with the target chosen,
- assess these investigational medicines first in the lab and then through clinical trials,
- submit to the FDA for review and approval,
- manufacturer and distribute new medicines, and
- conduct additional studies and monitoring for many years beyond Food and Drug Administration (FDA) approval.

The rigorous and highly controlled clinical trials process is required to ultimately demonstrate a medicine's safety and efficacy for approval by the FDA for use by patients. The potential new medicines in clinical trials today are the therapies, treatments or even cures of tomorrow. These clinical trials represent the most resource intensive part of the R&D process.

The major resource investments required to test these medicines – identifying and securing clinical trial sites; hiring staff and contractors including clinical investigators and laboratories for testing; recruiting, retaining, and treating trial volunteers; and conducting various other clinical trial activities – generate significant economic expenditures within the host local communities across the United States.

This report focuses solely on biopharmaceutical industry-sponsored clinical trials' site-specific expenditures and the economic activity generated by these trials across the nation. Given continued interest in understanding how the conduct of clinical trials generate economic activity in states, this report provides state-level estimates of industry-sponsored clinical trial activity across the country, including the number of trials, the number of trial participants, and the total economic impact.

This report presents a high-level overview of clinical trials as a crucial element of the research and development (R&D) process – diving into the different testing phases that are central to our discussion and shedding light on the numbers of industry-sponsored clinical trials and their participants across various states. Moreover, the report details our innovative approach to cataloging the costs associated with conducting clinical research at local trial sites.

The findings reveal significant insights into the economic impact of industry-sponsored research at the site level, underscoring its importance for local economies. Finally, this report not only highlights these findings but also explores their implications for policymakers, emphasizing the need for informed decision-making to support and enhance clinical research in our communities.

Overview of Clinical Trials Role in the R&D Process

According to Citeline's Pharmaprojects analysis there were 11,200 drugs in the pipeline of U.S. biopharmaceutical manufacturers at the end of 2023.[4] Approximately two-thirds of these potential medicines represent novel, first-in-class approaches to addressing disease in such areas as neurology, cancer, diabetes, and immunology.[5] New scientific approaches representing the cutting edge of research are being explored across a range of therapeutic areas in clinical trials across the country, including new cell and gene therapies, small and large molecule drugs and therapeutics, and genetically targeted therapies often referred to as precision medicine.

These potential medicines are all in some stage of clinical testing, that is, controlled trials in participants designed to demonstrate whether they are safe and effective. While the clinical trials process is long, complex and costly, the drug development process begins even earlier, with initial drug discovery (discovering a potential target and then an investigational compound to impact that target), followed by specific pre-clinical testing in the lab to determine if the potential new medicine is safe for human testing. The key elements of the R&D process are described below, with particular attention paid to the clinical testing (or "clinical trials" process). This material is adapted from FDA materials (see https://www.fda.gov/patients/drug-development-process).

Discovery, Development, and Preclinical Research/Testing

Biopharmaceutical companies typically initiate a drug development program when new insights have been gained into a specific disease process, through large scale testing of molecular compounds to find possible beneficial effects, when existing treatments have unanticipated effects, when new technologies allow for improved targeting to specific organs, sites, proteins, or genetics, or when a disease or clinical condition is identified for which, there are no effective treatments.

Promising results that a candidate has a positive therapeutic effect generally leads to further validation and exploratory research to justify further drug development efforts. Researchers generate a hypothesis that the candidate through inhibition or activation of a specific protein or pathway will have a therapeutic effect on a certain disease or condition. Researchers also begin to assess and study, through laboratory testing (including in vitro and in vivo research and testing), how the candidate is absorbed, distributed, metabolized, and excreted, initial understanding of potential benefits and mechanisms of action, parameters around potential dosage and delivery, potential side effects and other adverse events, and whether it is believed that the candidate could affect different groups of people differently (e.g., by gender, race, or ethnicity). Before this stage in the process there may be many potential candidates for development as a medical treatment. After this early testing, however, only a small number of these compounds may look promising enough to warrant further study.

Prior to testing in humans, the candidate compound is in the preclinical (laboratory) testing phase versus the development phase. The focus of preclinical testing is to assess whether the drug development candidate is safe for human volunteers and whether it exhibits significantly robust pharmacological activity to merit further investigation. If the investigational compound meets these criteria, the company files an **investigational new drug (IND)** application with the FDA to pursue clinical

[4] *Pharma R&D Annual Review 2024*, Citeline (Pharmaprojects), March 2024,
[5] *The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development*, The Analysis Group, July 2017.

testing in humans. Within the IND applications drug developers or sponsors must include information and any existing data including that related to any animal studies, toxicity, proposed manufacturing processes, and prior-related human research. Additionally, the submission must include the clinical protocols or plans for clinical studies and information about the principal investigator and study team.[6]

Clinical Testing in Human Volunteers

Potential new drugs must undergo extensive study in human volunteers (referred to as participants in the remainder of this report) to demonstrate safety and efficacy to the FDA. Clinical trials comprise the most lengthy and costly portion of the R&D process. The clinical trials process occurs in several phases, each with increasing levels of complexity in terms of the number of participants, duration, and other requirements. Biopharmaceutical industry-sponsored clinical trials are conducted around the country in a variety of settings, including physician offices, dedicated clinical trial testing centers, and collaborating hospitals and medical centers across the country.

As noted above, while many potential compounds may be investigated in the discovery and pre-clinical phase, very few will eventually become approved medicines—only 10%-20% of compounds entering a Phase 1 clinical trial will ultimately be approved. However, this varies, in part, based upon differences in drug features and targets.[7,8] Drug development consists of several distinct clinical trial phases leading to FDA review and approval as outlined below:

- **Phase 1 clinical trials** typically are conducted with a small number of healthy volunteers, typically fewer than 100, to determine the safety, tolerability, and pharmacokinetics and pharmacodynamics of the potential drug (i.e., researchers assess how the potential drug behaves in the body and relationship between the compound's molecular structure and its effects on volunteers). Phase 1 studies typically last three months or less.
- **Phase 2 clinical trials** begin if the drug successfully passes Phase 1 testing. This phase generally involves between 100 and 500 participants and is focused on assessing the efficacy and dose response of the investigational drug under development, including identification of common, short-term potential side effects. Phase 2 studies typically last several months to two years.
- **Phase 3 clinical trials** are initiated if the potential new medicine is found to be both safe and efficacious through Phases 1 and 2 testing. Phase 3 trials may enroll 1,000 to 5,000 patients or more across numerous clinical trials sites in the United States and around the world. These randomized, controlled trials generate large amounts of data to support submission to the FDA for drug or biologic approval. Phase 3 studies typically last one to four years.
- **FDA regulatory review and approval** involves the submission of the data collected from preclinical studies and the full set of clinical trial data if the trials are successful. The data are submitted to the FDA in the form of a new drug or biologic license application. If the drug is approved, the company may market the drug for its approved indications.

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[6] Companies also generally initiate patent fillings with the U.S. Patent and Trademark Office prior to clinical trials begin.

[7] Yamaguchi S, Kaneko M, Narukawa M., *Approval success rates of drug candidates based on target, action, modality, application, and their combinations.* Clinical Translational Science, May 14, 2021. https://pmc.ncbi.nlm.nih.gov/articles/PMC8212735/

[8] Additionally, many more compounds are eliminated prior to human testing via laboratory and pre-clinical screening.

- **Phase 4 post-approval studies**, which are conducted after a treatment is approved for use by the FDA, provide additional surveillance and information gathering regarding the treatment or drug's risks, benefits, and best use. Phase 4 trials can vary significantly in terms of the duration of the study depending on the scope of the study and the monitoring requirements.

Furthermore, additional research on the drug or biologic does not end once the therapeutic reaches patients. Post-approval R&D can often include clinical trials related to:

- **New uses or indications.** Medicines for one disease can be determined to work for the treatment of a different medical condition. For example, when a rheumatoid arthritis medicine is subsequently approved for psoriatic arthritis, Crohn's disease or ulcerative colitis.
- **New patient populations.** Medicines originally approved for adults can be tested for children with the same or other conditions, potentially opening the door to helping a wider group of patients. Post-approval research may also lead to a medicine's review and possible approval for patients with different stages of disease.
- **New formulations.** In medicines where the active ingredient is already FDA-approved, a new formulation can be developed for specific populations, e.g., an easier to administer and more palatable formulation for children.
- **New dosage forms.** New dosage forms can improve patient health by helping to increase patient adherence to therapy, ensure a proper dose is taken or improve quality of life for patients who must take their medicines on an ongoing basis. An example is a medicine formerly taken as an injection can now be administered as a nasal powder or orally, which are logistically often easier for patients.

Post-approval research and development advances often require additional clinical research and can necessitate supplemental or new applications to FDA, which are held to the same rigorous standards as the initial approved application. This is an extremely intensive process, particularly when additional patient participation in clinical trials is required.

Estimating and Categorizing Industry-Sponsored Clinical Trials

This study develops estimates of the state-level economic impacts associated with the site-based expenditures in support of biopharmaceutical industry-sponsored clinical trials active for part or all of 2023. These estimates were produced by combining elements from several data sources. As with any estimation methodology, there are limitations to the approach used for this analysis resulting from limitations of the source data. The methodology and potential limitations are summarized below and described in more detail in the Appendix.

ClinicalTrials.gov

The number of industry-sponsored clinical trials was tabulated directly from data available from ClinicalTrials.gov. ClinicalTrials.gov is a registry and resource maintained by the U.S. National Institutes of Health (National Library of Medicine), as required under Food and Drug Administration Modernization Act of 1997, and contains data on publicly and privately supported clinical studies of human participants conducted around the world. While ClinicalTrials.gov is the most comprehensive single source of clinical trials data, it does not contain data for all clinical studies conducted in the United States because not all studies are required by law to be registered. Therefore, it is likely that

ClinicalTrials.gov understates total industry-sponsored clinical trial activity and also likely that economic estimates reported within this study are correspondingly lower.

Active Clinical Trials – Number and Duration

Using ClinicalTrials.gov, complete records were captured for all industry-sponsored (or co-sponsored) biopharmaceutical interventional studies (more commonly referred to as "clinical trials") active for at least one day of calendar year 2023.[9] For each trial record, a calculation was made to determine the number of days in 2023 that the trials were active – ranging from 1 day to 365 days, and the share of the each trial's total expected duration.

According to data captured from the ClinicalTrials.gov web database, **5,288 interventional studies sponsored by one or more biopharmaceutical company were active in the U.S. at some point during 2023**—including trials that were initiated in 2023, completed in 2023, or ran through the entire year.

Using the clinical trial record's total enrollment value, the average enrollment by global site was calculated and then applied to the number of sites for each trial in each state. Using this approach, TEConomy estimates that **these trials included more than 906,000 participants in the U.S.** (including the District of Columbia and Puerto Rico).

Active Clinical Trials – Phases and Disease Areas

As part of each trial record the active trial "phase" is also reported by the trial sponsors. Table 1 provides the breakdown of the 5,288 trials and the estimated total U.S. enrollment by phase.

Table 1. Estimated Number of Industry-Sponsored Active Clinical Trials and Trial Participants by Phase, 2023

Phase	Number of Active Clinical Trials	Estimated Total U.S. Enrollment
Phase 1	1,533	79,871
Phase 2	2,350	215,093
Phase 3	1,135	563,283
Phase 4	270	48,495
Total, All Phases	5,288	906,742

Source: TEConomy estimates based on information obtained from ClinicalTrials.gov.

Phase 2 trials constitute the largest number of trials at 2,350. Phase 3 trials involved the largest estimated number of U.S. trial participants (563,283), accounting for more than 60 percent of all participants in industry-sponsored clinical trials in the data set. Phase 3 trials are typically the most lengthy and costly phase of the clinical trial process.

Trials were categorized into principal disease areas based on information contained within each ClinicalTrial.gov record. This categorization process was enhanced within this current study through the use of NIH National Library of Medicine's Medical Subject Headings (MeSH) terms, a controlled and hierarchically-organized "key terms" vocabulary that is assigned to most clinical trials.[10]

[9] Data were extracted for this analysis from ClinicalTrials.gov in June 2024.

[10] See https://www.nlm.nih.gov/mesh/meshhome.html and the Appendix for more details of this approach.

Summary counts of trials and estimated numbers of U.S. trial participants by selected disease area from the clinical trials site-level dataset are shown in Table 2. As in prior years, Cancer & Neoplastic Diseases account for the largest number of trials (2,278 trials, or 43 percent of biopharmaceutical industry-sponsored trials) while Infections & Infectious Diseases enrolled the largest number of U.S. trial participants (348,942, or 38 percent of U.S. participants). Large enrollment numbers were also seen in the Cancer and Neoplastic Diseases trial category (165,085 participants) and the Cardiovascular Diseases trial category (69,335 participants).

Table 2. Estimated Number of Industry-Sponsored Clinical Trials and U.S. Participants by Disease Area, 2023

Disease Area	Number of Active Clinical Trials	Estimated Total U.S. Enrollment
Cancer & Neoplastic Diseases	2,278	165,085
Cardiovascular Diseases	229	69,335
Congenital & Hereditary Diseases	141	6,880
Digestive System Diseases	221	23,636
Endocrine System Diseases	31	10,250
Eye Diseases	177	26,921
Head & Neck Diseases	23	2,706
Hematologic & Lymphatic Diseases	129	6,112
Immune System Diseases	213	15,920
Infections & Infectious Diseases	378	348,942
Mental, Behavioral, & Chemical-Related Disorders	180	30,998
Musculoskeletal Diseases	60	30,538
Nervous System Diseases	361	40,061
Nutritional & Metabolic Diseases	252	44,134
Pain, Wounds, & Other Pathological Conditions	54	14,644
Respiratory Diseases	145	18,471
Skin & Connective Tissue Diseases	282	33,920
Urogenital Diseases	134	18,189
Total, All Disease Areas	5,288	906,742

Source: TEConomy estimates based on information from ClinicalTrials.gov.
Note: Disease Area titles are TEConomy nomenclature drawing from the highest level MeSH terms.

Active Clinical Trials – Locations and Sites

Additionally, each trial record was tagged according to the number of unique trials and trial sites by state. For example, an active trial with two different locations in Los Angeles and one in San Francisco would be tagged as one California trial and three California sites. Using this approach estimates are then generated for each trial representing the total number of sites. The geographic footprint of individual trials varies greatly, from small trials listing only one site to large multinational trials listing many sites in the U.S. and abroad. For trials with sites both within and outside of the U.S., only the U.S-based sites were included in any estimates and subsequent analysis. Reported totals are unduplicated. That is, trials

with multiple sites in a state are counted only once in that state's total number of trials, and, similarly, trials with sites in multiple states are counted only once in the total number of trials in the U.S.

Estimating Site-Based Clinical Trial Costs

To assess the state-specific economic impacts stemming from of these biopharmaceutical industry-sponsored trials, an estimate of the site-based expenditures associated with each unique trial must be developed. For these estimates the data on the number of clinical trial participants, as summarized above, were combined with estimates of the average cost per trial participant by disease area and phase described in this section.

There are many costs and expenditures involved in initiating and operating a clinical trial. Some costs are specific to the trial sites where clinical trial participants are engaged, while other costs are related to more centralized functions, typically located at a biopharmaceutical company facility or at a contract research organization working in partnership with these companies. **The costs included in this analysis are only those related to activities occurring at the trial sites themselves** and are not intended to capture all costs related to the overall clinical trial process.

The resources required to conduct site-based clinical research can vary significantly at the trial level. Costs naturally vary due to the number of volunteer trial participants enrolled at a site, but they can also vary considerably due to a number of other factors including the number and type of staff required to staff and conduct clinical trials, the complexity of the condition being studied, the requirements of the particular clinical trial protocol, and ultimately the disease area and phase of the clinical trial.

The cost data used in this analysis provide insight into the types of activities that must occur at a clinical trial site to effectively conduct a trial including:

- **Investigator, physician, and other site-specific labor costs:** including site-related overhead, investigator honoraria and fees, site-related institutional review board, and ethics reviews
- **Participant enrollment:** Recruitment costs (advertising, travel stipend, etc.), screening, office visits (equipment, diagnostics, etc.), retention costs
- **Clinical procedures:** Initial and ongoing physical exams, vital signs, detailed medical history, test sample collection
- **Materials:** Drug supply, comparator drug, other equipment, shipping, etc.
- **Efficacy assessments:** Blood work, MRIs, CT scans, other diagnostic tests, etc.
- **Laboratory:** Local lab fees, storage, shipping of samples, etc.
- **Site-based IT/data management:** Trial master file, electronic data capture and records, source data verification, interactive voice/web response systems, etc.
- **Other site-specific expenses:** Monitoring, randomization, biostatistics, travel, meetings, etc.

To develop estimates of clinical trial site costs we used a combination of trial total costs developed by Norstella/Citeline using their proprietary clinical trials database, Trialtrove, for this effort. These data were then adjusted and extended using key data and parameters developed by the Eastern Research

Group, Inc. (ERG) for a project submitted to U.S. Department of Health and Human Services, Assistant Secretary of Planning and Evaluation (ASPE).[11]

Table 3 provides the final list of disease areas summary of the per-participant site costs across the final set of disease areas and phase used in this analysis. While Phase 3 (and at times Phase 4) trials are typically the most expensive overall, the substantially larger total participant enrollment of these trials often reduces the "per participant" costs of these trials as site-specific fixed costs are spread over a much larger number of individual participants.

Table 3. Per Participant Site Cost of Industry-Sponsored Clinical Trials by Phase and Selected Disease Area, 2023

Disease Area	Average Per Participant Trial Site Cost by Phase			
	Phase 1	Phase 2	Phase 3	Phase 4
Cancer & Neoplastic Diseases	$163,121	$159,762	$188,736	$201,131
Cardiovascular Diseases	$152,825	$182,226	$181,789	$152,133
Congenital & Hereditary Diseases	$170,887	$234,779	$244,891	$221,999
Digestive System Diseases	$142,817	$148,989	$146,695	$101,273
Endocrine System Diseases	$136,980	$152,575	$162,426	$147,243
Eye Diseases	$139,320	$147,409	$130,102	$47,614
Head & Neck Diseases	$143,625	$154,929	$154,470	$122,385
Hematologic & Lymphatic Diseases	$179,514	$197,020	$266,364	$205,163
Immune System Diseases	$164,276	$167,952	$174,436	$103,669
Infections & Infectious Diseases	$131,181	$134,330	$87,625	$24,227
Mental, Behavioral, & Chemical-Related Disorders	$146,930	$149,056	$171,483	$79,947
Musculoskeletal Diseases	$162,590	$191,724	$185,894	$137,372
Nervous System Diseases	$143,853	$191,563	$148,355	$58,545
Nutritional & Metabolic Diseases	$144,039	$219,450	$185,292	$167,971
Pain, Wounds, & Other Pathological Conditions	$139,877	$164,731	$162,474	$65,468
Respiratory Diseases	$141,814	$152,640	$151,555	$282,494
Skin & Connective Tissue Diseases	$153,190	$170,035	$180,056	$211,652
Urogenital Diseases	$138,434	$144,825	$150,761	$30,160

Source: TEConomy estimates.
Note: Disease Area titles are TEConomy nomenclature drawing from the highest level MeSH terms.

Estimating the Economic Impact of Industry-Sponsored Clinical Trial Site-Based Research Expenditures – States and U.S.

Combining state-level ClinicalTrials.gov location and enrollment data with the estimated average site-based costs per trial participant produces state-level estimates of the total industry clinical trial investments at clinical trial sites in each state. The summation of these state level impacts generates the

[11] Eastern Research Group, Inc., *Examination of Clinical Trial Costs and Barriers for Drug Development*, Final Report to U.S. Department of Health and Human Services, Assistant Secretary of Planning and Evaluation (ASPE), July 25, 2014.

overall U.S. economic impact. The Appendix provides a detailed description of the methodology for this calculation.

Economic Impact of Industry-Sponsored Site-based Clinical Trials in the U.S.

The biopharmaceutical industry's investment in clinical trials activities across the nation has an impact on state and local economies that goes beyond the amounts spent simply conducting the trials. Using standard input-output (I-O) analysis for each state, the District of Columbia, and Puerto Rico combines to generate an estimate that the **more than $30 billion is spent by industry at clinical trial sites across the U.S. and Puerto Rico and these investments generated and supported a total of more than $62 billion after including the economic ripple-effects created in the communities where trial sites are located** (Table 6)**.** These ripple effects include the flow of funds to vendor companies that supply or support clinical trial sites in some way (i.e., indirect impact), as well as dollars that are re-circulated into the local economy through purchases from the wages provided to clinical trial workers and suppliers (induced impact).

Table 6. Economic Impact of Industry-Sponsored Clinical Trial Activities at U.S. Trial Sites, 2023

Impact Type	Economic Impact ($ billions)
Direct – *Research activities at clinical trial sites around the country*	$30.6
Indirect and Induced – *Vendors and suppliers to trial sites; Consumer purchases of personal incomes by researchers and workers engaged in or supporting the clinical trial process*	$32.0
Total	**$62.6**

Source: TEConomy analysis using state economic impact models from IMPLAN. These data are captured via a summation of the individual results from all 50 states, District of Columbia, and Puerto Rico.

Site-Based Economic Impact of Industry-Sponsored Clinical Research by State

The state-level estimates of site-based clinical trial activity provide a perspective on the distribution of industry-sponsored clinical trials across the country and how this level of industry clinical trial expenditures impacts state economies. Combining the developed clinical trials site-level dataset and the estimated per-participant costs by disease area and phase data we estimate a total cost and geographic distribution of these costs by trial. The generated values are then summed across all trials to yield an estimate of the site-based investment made by biopharmaceutical industry-related clinical trials in each state, the District of Columbia, and Puerto Rico (52 regions).

Table 4 shows the eighteen states with $1 billion or more in total economic impact from industry-sponsored clinical trials in 2023, with the active trial number ranging from 445 in Nebraska to 2,695 in California. Twelve of these states had more than 1,000 clinical trials underway at some point during 2023, with three states, California, Texas, and Florida exceeding 2,000 distinct trials active in 2023.

While California ranks first in terms of number of clinical trials active in the state, it is estimated that Texas, followed by Florida, generate the most trial participation with estimated participants numbers reaching 102,462 and 102,016, respectively and California reaching 96,885. In total, ten states exceed

25,000 or more participants involved in industry-sponsored clinical trials in 2023, including seven additional states: New York, Ohio, Pennsylvania, Massachusetts, North Carolina, Georgia, and Arizona.

Table 4. States with $1 Billion+ Total Industry-Sponsored Clinical Trial-related Economic Impacts, 2023

State	Industry Clinical Trial Activity in 2023			
	Number of Trials Active in State	Estimated Total Trial Enrollment	Estimated Total Site-Based Trial Investments ($ millions)	Total Economic Impact ($ millions)
Florida	2,198	102,016	$3,747.5	$8,296.3
Texas	2,508	102,462	$3,493.2	$7,689.1
California	2,695	96,885	$3,426.6	$7,155.8
New York	1,932	48,242	$1,641.0	$3,147.1
Ohio	1,475	36,317	$1,140.5	$2,350.5
Massachusetts	1,175	33,014	$1,060.3	$2,128.3
Pennsylvania	1,315	34,314	$958.8	$1,949.2
Arizona	1,041	25,438	$887.9	$1,932.8
North Carolina	1,226	32,554	$902.1	$1,838.2
Georgia	1,106	25,590	$832.7	$1,780.9
Utah	640	19,411	$823.8	$1,722.4
Illinois	1,125	21,084	$721.9	$1,513.4
Tennessee	1,116	22,076	$664.9	$1,354.5
Maryland	936	18,053	$658.3	$1,239.2
Nebraska	445	17,405	$640.4	$1,190.3
Missouri	969	17,650	$576.2	$1,129.3
Michigan	1,052	16,469	$514.2	$1,055.3
Virginia	896	19,466	$538.7	$1,041.5

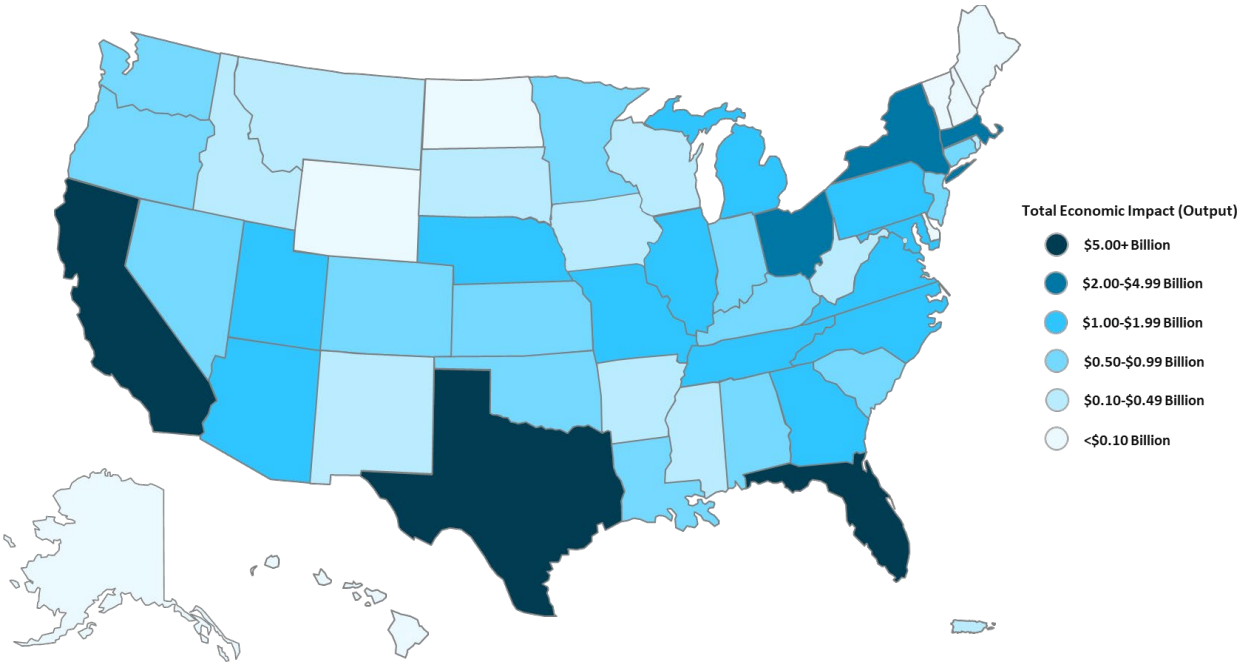
Source: TEConomy analysis using state economic impact models from IMPLAN.

This level of industry-sponsored clinical trial activity generates a substantial direct, indirect, and induced economic effect on the site-based locations. In terms of estimated direct clinical trial site-based investment, six states are the recipients of more than $1 billion from industry: Florida, Texas, California, New York, Ohio, and Massachusetts. Of the eighteen states exceeding $1 billion in generated and supported economic activity (output) from these trial efforts, Florida, Texas, and California again rise to the top with all three exceeding $7 billion in total economic impacts and three more states, New York, Ohio, and Massachusetts exceeding $2 billion.

It should be noted, and is illustrated by the map in Figure 1, industry-sponsored site-based clinical trial investments are found throughout all 50 states generating economic activity and impacts across the nation. These clinical trials occur “in the field” where doctors, trial centers and hospitals, and volunteer participants are located. It is interesting to note, some states not typically associated with a large biopharmaceutical industry presence, such as Arizona, Georgia, Nebraska, and Tennessee, generate and

support more than $1 billion in total economic impacts from industry-sponsored site-based clinical trials.

Figure 1. Estimate of Total Economic Impact of Industry-Sponsored Clinical Trials Activity Across the U.S., 2023



Source: TEConomy analysis using state economic impact models from IMPLAN.

Table 5 expands upon the Table 4 estimates of site-based clinical trial activity and the related economic impacts for all 50 states, the District of Columbia and Puerto Rico. Only seven states had fewer than 100 biopharmaceutical industry-sponsored clinical trials active in 2023.

Table 5. Industry-Sponsored Clinical Trial Activity and Related Economic Impacts at Trial Sites by State, 2023

State	Industry Clinical Trial Activity in 2023 ($ Millions)			
	Number of Trials Active in State	Estimated Total Trial Enrollment	Estimated Total Site-Based Trial Investments	Total Economic Impact
Alabama	659	15,843	$474.7	$875.4
Alaska	29	174	$3.7	$6.2
Arizona	1,041	25,438	$887.9	$1,932.8
Arkansas	376	6,104	$204.2	$377.5
California	2,695	96,885	$3,426.6	$7,155.8
Colorado	860	12,255	$420.9	$891.9
Connecticut	512	8,109	$324.5	$632.5
Delaware	56	371	$13.4	$23.7
District of Columbia	312	4,287	$124.2	$177.0
Florida	2,198	102,016	$3,747.5	$8,296.3
Georgia	1,106	25,590	$832.7	$1,780.9
Hawaii	75	1,119	$29.2	$55.2
Idaho	218	5,444	$176.5	$334.7
Illinois	1,125	21,084	$721.9	$1,513.4
Indiana	649	9,882	$412.0	$790.8
Iowa	316	5,313	$147.0	$259.1
Kansas	563	12,098	$482.2	$891.7
Kentucky	529	9,351	$353.2	$663.3
Louisiana	528	15,719	$477.9	$892.6
Maine	65	864	$23.8	$46.5
Maryland	936	18,053	$658.3	$1,239.2
Massachusetts	1,175	33,014	$1,060.3	$2,128.3
Michigan	1,052	16,469	$514.2	$1,055.3
Minnesota	695	8,525	$362.1	$758.5
Mississippi	215	4,803	$134.2	$236.7
Missouri	969	17,650	$576.2	$1,129.3
Montana	109	2,430	$68.1	$125.4
Nebraska	445	17,405	$640.4	$1,190.3
Nevada	420	8,792	$296.1	$575.2
New Hampshire	115	919	$29.0	$55.1
New Jersey	820	13,186	$465.7	$927.0
New Mexico	204	4,111	$105.1	$181.8
New York	1,932	48,242	$1,641.0	$3,147.1
North Carolina	1,226	32,554	$902.1	$1,838.2
North Dakota	87	1,577	$52.5	$88.0
Ohio	1,475	36,317	$1,140.5	$2,350.5
Oklahoma	513	10,336	$322.3	$619.2
Oregon	624	9,221	$359.3	$696.7
Pennsylvania	1,315	34,314	$958.8	$1,949.2
Puerto Rico	188	4,193	$127.5	$231.4

Rhode Island	173	4,046	$194.8	$368.4
South Carolina	627	16,253	$500.6	$966.0
South Dakota	144	1,894	$56.5	$101.1
Tennessee	1,116	22,076	$664.9	$1,354.5
Texas	2,508	102,462	$3,493.2	$7,689.1
Utah	640	19,411	$823.8	$1,722.4
Vermont	51	374	$11.3	$20.8
Virginia	896	19,466	$538.7	$1,041.5
Washington	838	13,459	$369.0	$715.4
West Virginia	108	1,807	$59.9	$102.0
Wisconsin	463	5,389	$214.0	$418.8
Wyoming	4	46	$2.6	$4.1
U.S. Totals	5,288	906,742	$30,626.7	$62,623.8

Source: TEConomy analysis using state economic impact models from IMPLAN. Note: U.S. Totals for Number of Trials Active is non-duplicative so column will not sum.

Conclusion

This report identifies and estimates the significant investments biopharmaceutical companies make every year in supporting clinical trial site-based activities across the U.S. These expenditures are critical to bringing new medicines to patients that will improve their health and quality of life.

An important "side effect" of this clinical trial activity are the economic benefits to states in terms of the economic impact generated through trial-related activities such as the selection of clinical trial sites; the implementation of trials including the recruitment of physicians and other health care providers and various vendors; the manufacture of small batches for testing; services to patients, including clinical procedures and lab tests and ongoing health monitoring; and the collection and management of the enormous amount of data generated by clinical trial sites. These clinical trial activities require significant expenditures by biopharmaceutical companies and their suppliers, vendors, and contractors.

Using conservative data sources and assumptions, this analysis identified more than 5,200 industry-sponsored clinical trials involving more than an estimated 906,000 volunteer trial participants in 2023. Biopharmaceutical companies invested over $30 billion at these trial sites, with an economic impact of more than $62 billion across the communities where the trials were located. Clinical trial sites were operated in all 50 states, the District of Columbia, and Puerto Rico, reflecting the broad geographic reach of this aspect of the biopharmaceutical industry. These estimates describe the multifaceted life sciences ecosystem, one that not only produces biopharmaceutical innovations that improve lives, but which also delivers important economic benefits to states and to the nation. Maintaining the viability of this ecosystem requires a long-term view, with policies and regulatory structures that are consistent, predictable, and focused on meeting the needs of patients.

APPENDIX: Methodological Approach—Details and Considerations

Because detailed state-level data on total biopharmaceutical industry-sponsored clinical trial spending do not publicly exist, estimates were produced by combining several data sources. The following table provides the core data sources used in this effort. The number of industry-sponsored clinical trials was tabulated directly from the data available in ClinicalTrials.gov (a website of the U.S. government and the National Institutes of Health). These data were supplemented by clinical trial cost data obtained from Norstella/Citeline and additional cost parameters from Eastern Research Group.

Table A-1: Data Sources Used

Data Source	Information or Data Component
ClinicalTrials.gov (a website of the U.S. government and the National Institutes of Health)	Data records of 5,288 industry-sponsored trials including: • Phase of each trial • Title/Abstract/MeSH Terms to Classify the Trial • Information Regarding the U.S. and Global Number of Sites and Specific Locations
Norstella/Citeline	Average Total Clinical Trial Costs per Participant by Disease Area (MeSH "C" Structure) and Phase (Phases 1, 2, and 3)
Eastern Research Group (2014)	Estimates of Site-based Share of Total Clinical Trial Costs by Phase (Phases 1, 2, 3, and 4)
	Relationship between Phase 1, 2, and 3, costs to average Phase 4 costs by key therapeutic areas

The number of trial participants in each state was estimated based on total reported (actual or expected) enrollment per trial, apportioned to each state (including the District of Columbia and Puerto Rico) based upon the number of sites in each state listed within the ClinicalTrials.gov record, and with each site assigned the same number of participants. Total site-based trial costs were estimated by applying derived estimates of average per-participant costs by phase and disease area to the state-level enrollment estimates. Total state-level economic impacts were then estimated using standard input-output analysis, reflecting the economic multiplier effect in the states in which the clinical trials were located. The sections below describe each of these steps and the data used in more detail.

Obtaining Clinical Trial Records from ClinicalTrials.gov

Detailed records of clinical trials are available to the public through the U.S. National Institutes of Health and include information on funding sources, trial sites, and numbers of participants. Using the ClinicalTrials.gov website search interface to access trial records, a query was used to identify the records of **all interventional clinical trials sponsored by biopharmaceutical-related industry sources.**

Among the information directly provided for each clinical trial listed in the ClinicalTrials.gov database include:

- Title, description, and design of the study
- Sponsors and collaborators in the study
- Recruitment status and enrollment (anticipated or actual)
- Phase
- Disease or condition

- Intervention (for example, the medical product, behavior, or procedure being studied).
- Requirements for participation (eligibility criteria) and description of study participants
- Key trial and administrative dates – start date; primary completion date; completion date; and date of latest record update

Each clinical trial record also contains text fields containing additional trial information and protocol details. While this information is visible when using the ClinicalTrials.gov site, these extended records are only available in downloadable form as part of the API files from ClinicalTrials.gov and not available through the basic ClinicalTrials.gov download. These additional API fields include tags that identify parts of the individual trial records corresponding to text information including the locations of trial sites and keyword-based descriptive information in the form of Medical Subject Headings (MeSH) terms, the National Library of Medicine's controlled vocabulary thesaurus used for indexing and cataloging biomedical literature, clinical trials, and often research awards.

Records for all biopharmaceutical-related industry clinical trials active for at least one day in 2023 were obtained through various queries of ClinialTrial.gov. For each of the 5,288 records, the state locations of all U.S. trial sites (a single trial often has many participant sites in different states) were identified and tabulated using this method to create a database of total number of trial sites per state for each clinical trial.

Mapping Clinical Trials to Key Disease Areas

Using textual information related to condition being addressed, the trial title and abstract, and primarily the related MeSH keyword terms allowed TEConomy to assign a “disease area” to each of the 5,288 trials. Beyond the MeSH terms TEConomy used the additional textual information to determine the most appropriate disease area depending on the nature of the trial. It should be noted that in general, cancer-related trials were classified into the Cancer & Neoplastic Diseases area versus the anatomical “system” where the cancer might be located.

Establishing Trial Phase for Calculation Purposes

Certain valid trials are included in the ClinicalTrials.gov database with a multi-phase designation (e.g., Phase 1/Phase 2 or Phase 2/Phase 3. Given the broader, more comprehensive nature of these trials they are treated as the later phase for calculation purposes.

Estimating the Number of Industry-Sponsored Clinical Trials and Trial Sites by State

Beyond the core information regarding each clinical trial’s purpose, each trial listed in the ClinicalTrials.gov database contains information in the form of free-text entries listing the addresses of the active clinical trial sites. The size of trials varies greatly, from small, Phase 1 trials listing only one site to large multinational Phase 3 trials listing many sites in the U.S. and abroad. For trials with sites both within and outside of the U.S., only the U.S-based sites were included.

Totals were generated for each state representing the number of trials and trial sites that were active for at least one day of calendar year 2023.

Estimating the Number of Participants Enrolled in Industry-Sponsored Clinical Trials by State

Conceptually, the number of trial participants in each state was estimated based on total reported enrollment per trial in ClinicalTrials.gov, apportioned by state based on the number of trial sites listed for each state compared to the number of global trial sites for each trial.

Most records within ClinicalTrials.gov have a sponsor-provided "enrollment" value (either expected or actual), with trials increasingly likely to report actual enrollment numbers once trial recruitment is completed. For some trials providing estimated enrollment values, the final number of enrollees does not reach this level, while other trials may exceed it, especially if recruitment reveals the need for an expanded study protocol. For the distinct purposes of this economic impact study, TEConomy used the enrollment values from ClinicalTrials.gov as representative of the overall clinical trial enrollment activity. Using the site and location information parsed out of the ClinicalTrials.gov API records, TEConomy developed a total count of the number of sites found in the U.S. and abroad and within the U.S. by state. If a state had more than one location where patients could be enrolled in the trial, the number of distinct locations was captured. The total enrollment value was divided by the total number of global sites to yield an "expected per-site enrollment" value.

To estimate U.S. trial impact only, locations and per-site enrollment values for non-U.S. sites were removed from subsequent data and calculations. For each specific U.S.-based trial-state pair, a value equal to the average per-site enrollment multiplied by the number of sites within that state was calculated. For example, if a trial within ClinicalTrials.gov shows expected enrollment of 1,000 participants and 10 trial sites includes 5 sites in Canada, 3 sites in Massachusetts, and 2 sites in North Carolina, the trial-specific records would include one field with 300 enrollees for Massachusetts (3/10 times 1,000) and one field with 200 enrollees for North Carolina (2/10 times 1,000) and the remaining 500 enrollees assigned to Canada would be removed from subsequent data and calculations of U.S. site-based activities.

Estimating "Annual" Trial Duration

Most records within ClinicalTrials.gov have a sponsor provided "start date" and "primary completion date" indicating the expected duration of the clinical trial, with significant variability in duration depending on the trial phase. These dates include the full extent of the trial's activities, not just the core period where ongoing participant or patient involvement is occurring. For example, if the trial requires six months to recruit a suitable participant group, these six months are also included in the trial duration. Start dates for active clinical trials can begin many months prior to the date the clinical trial records were captured. Additionally, completion dates for active clinical trials can be months or years in the future from when the records were captured.

To provide a controlled, single year measure of economic impact, a specific 12-month active "window" was used to filter all the trials' durations; For this study's purposes 2023 is used. This "active in 2023" filter was applied to the timeframe established by each trial's start and completion dates. Only trials that were active for at least one day in 2023 are included in the analysis. The number of active days in 2023 is then applied to the total number of days covered and/or expected from Start Date to Primary Completion Date, to estimate what share of each trial's specific timeframe occurred within 2023. Of the

5,288 “active in 2023” trials, the 2023 “trial share actually active in 2023” ranges from 0.04% to 100.00% (the latter share typically a Phase I trial that begins and ends all in 2023).

For example, if a Phase 1 trial started October 1, 2023, and was completed on December 31, 2023, all three months of this trial falls within the “active in 2023” window, and hence, 100% of the trial’s impact is captured as part of the analysis. If a Phase 3 trial started on October 1, 2021, and will complete on September 30, 2025, only 12 months of the total 48 months of the trial fall within the “active in 2023” window, and hence, 25% of the trial’s total impacts are captured as part of the analysis.

Estimating Site-Based Costs – Norstella/Citeline Data

For this current effort, TEConomy and PhRMA agreed that an improved/expanded approach to estimating per participant, site-based costs would be ideal, since a similar 2017 study performed by TEConomy used the NIH’s Biomedical Research & Development Price Index (BRDPI) to inflation adjust data on clinical trials costs for activities that occurred in 2012 or earlier.

Due to the extreme difficulty in finding publicly available data suitable for these purposes, PhRMA contracted with Norstella and their Citeline suite of market intelligence offerings. Using the data captured and estimated in their Trialtrove database for each specific clinical trial, Citeline consultants were able to create a database that provided an estimate of per participant, total clinical trial costs and collaborated with TEConomy to summarize and provide these estimates across the MeSH terms “C” level terminology for Phase 1, 2, and 3 clinical trials.[12]

The unique nature and requirements of this economic impact assessment of site-based expenditures required an additional data step, as the Citeline/Trialtrove data captured all (total) clinical trials costs on a per participant basis. To eliminate from each “per-participant cost” value, the value of centralized clinical trial development, support, and laboratory functions, TEConomy used data from the groundbreaking Eastern Research Group (ERG) study to estimate, by trial-Phase, the share of the total costs that are site-based costs. These shares were then used to downward adjust the Citeline/Trialtrove per-participant cost data.[13]

Estimating Phase 4 Activities (using ERG data)

One other issue that required additional data estimation was the lack of any Phase 4 data within the Citeline/Trialtrove database, as the standard usage and clients for the Trialtrove data do not typically require Phase 4 information.

Once again, TEConomy turned to the ERG study to generate an estimate of overall Phase 4 per-participant costs. The ERG study includes cost data across all four Phases for a number of disease/therapeutic areas, with all of them reflected in MeSH-based structure used for classifying “active in 2023” trials. TEConomy used these data to establish a proportional relationship between Phase 1, 2, and 3 costs and Phase 4 costs and then applied this same relationship to the adjusted per-participant costs obtained from Citeline/Trialtrove.

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[12] These data are seen as much more reflective of current trial protocols and costs, compared to the prior approach where historical costs were inflation adjusted using the Biomedical Research and Development Price Index (BRDPI) collaboratively developed by NIH and U.S. Bureau of Economic Analysis (BEA).

[13] Eastern Research Group, Inc., *Examination of Clinical Trial Costs and Barriers for Drug Development*, Final Report to U.S. Department of Health and Human Services, Assistant Secretary of Planning and Evaluation (ASPE), July 25, 2014.

Estimating Total Economic Impact of Site-based Industry-Sponsored Clinical Trials Expenditures by State

Economic impact broadly consist of three types of effects: ***direct effects*** (the impact of the actual "first round" spending by the biopharmaceutical companies for clinical trial service providers to conduct trials at each site), ***indirect effects*** (the impact of expenditures by suppliers to these clinical trial service providers), and ***induced effects*** (the additional economic impact of the spending of clinical trial service provider employees and suppliers' employees in the overall economy that can be attributed to the actual "first round" expenditures). Taken together, these three effects combine to form the ***total impact***.

Economic impacts are measured using the well-established regional economic analysis technique of input-output analysis (I-O) which tracks the revenues of a sector and the related economic activity of suppliers to the sector and its personnel through the earning of wages and spending of those wages throughout the economy. Output, sometimes referred to as business volume, is defined as the dollar value of sales, goods, and services produced in an economy. Output represents the typical measure expressed as the ***economic impact*** in a standard economic impact study.

To estimate the site-based economic impacts of the biopharmaceutical-related clinical trials activities on overall output in the U.S. and state economies, the analysis in this report employed separate, customized IMPLAN I-O models for the U.S. and each state for 2022, the most recent models available. Economic values for 2023 activities were entered into the model as current dollars.

Industry-sponsored or industry-collaborative clinical trials site-based activities occur in Physician Offices, Outpatient Centers and Hospitals. For the purposes of this study, we used an aggregation of these three IMPLAN sectors (e.g., IMPLAN sectors: 483 – Offices of physicians; 486 – Outpatient care centers; 490 – Hospitals) in which to model the state-level data used in this effort.

The industry clinical trials estimated site-based spending within each region is used as the "direct" economic impact to drive the I-O analysis. The model then estimates the impact and "ripple effect" of this spending on the U.S. and each state level economy, leading to a total economic impact metric (i.e., total output impacts) for the U.S., each state, the District of Columbia, and Puerto Rico.

Limitations of the Estimation Methodology

As with any estimation methodology, there are limitations to the approach used for this analysis resulting from limitations of the source data and the simplifying assumptions required to generate estimates at the level of detail reported here.

First, the ClinicalTrials.gov database likely understates the number of industry-supported clinical trials active in the U.S. in 2023, because not all studies are required by law to be registered, especially many types of Phase 1 trials. The estimates of the number of trials and spending by state for this first phase research are therefore likely to be somewhat conservative.

Second, data to estimate the share of a trial's participants in each state are limited. The data records within ClinicalTrials.gov provide target participation only at the trial level (actual participation is often reported if recruitment is completed and the clinical trial record is updated). However, specific site or

state level participation is not provided, so the number of participants are distributed equally across all trial sites provided (including non-U.S. locations) for estimation purposes.

However, evidence suggests that some sites over-enroll while others under-enroll. For example, the University of North Carolina at Chapel Hill found historically that:[14]

- 15-20% of sites never enroll a single patient
- 30% of sites under-perform (i.e., enroll 5% of evaluable patients)
- 20% of sites are average performers (i.e., enroll 25% of evaluable patients)
- 30% of sites are high performers (i.e., enroll 70% of evaluable patients)

To the extent that some clinical trial sites are less or more successful than others, the state-level estimates will overstate or understate enrollment, respectively. Also, in cases where the trials fail to achieve overall target enrollment, our estimates will have overstated enrollment and hence, participant and other site-specific costs. Mitigating this source of bias, to some degree, is the fact that many sites that underperform must bear similar costs of study start-up, regulatory management, and study closure as sites that accrue well. Thus, actual costs may not vary to the same degree as enrollment.

Third, the analysis relies on the use of average site-based clinical trial costs per participant by disease area to estimate total clinical trial spending, even though the cost of a clinical trial may vary significantly from trial to trial within a single area. Drivers of variable and increased costs can include challenges of recruiting patients across multiple sites; certain disease areas or therapeutic protocols with unique recruitment and operational challenges, such as rare diseases; increasingly complex clinical trial protocol development; increased use of new technologies and testing; and costs related to compliance regulations. To the extent the actual cost per participant for a given clinical trial are above or below the average cost, total trial costs will be over or understated. However, we do not believe this introduces significant bias to the aggregate cost estimates at the regional level.

The estimates in this report provide a useful snapshot of the site-based economic impact of industry-sponsored clinical trials in the U.S. in 2023.

[14] *Budgeting at the Investigative Site*, University of North Carolina at Chapel Hill, Office of Clinical Trials Newsletter. July/August 2006.