



BioNJ Economic Impact Study of Clinical Trials Activity in New Jersey

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To the New Jersey Life Sciences Community,

We are delighted to release this research brief highlighting clinical trials activity in BioNovation, New Jersey's life sciences innovation ecosystem. BioNovation has a wealth of clinical and commercial development expertise, marked by a robust infrastructure of innovator companies, clinical research organizations, academic and health centers and related operations, as well as the thousands of tireless researchers, medical personnel and staff who work directly with Patients. Translating technologies into drugs and products and bringing meaningful advances to Patients requires the full complement of clinical expertise to fully realize the medical and healthcare value of these products and — just as importantly — to provide the hope that often only experimental therapeutics can provide.

It is the first study of its kind in New Jersey and serves as a call for efforts to increase clinical trials capacity and resources and for the education of Patients as to the need for trials and their participation and the opportunity to do so right here at home in New Jersey.

In this study, we describe the extent of this clinical infrastructure with a focus on the clinical trials activity in New Jersey and its economic impact. The report is based on the ongoing efforts of the BioNJ Clinical Trials Committee which is charged with developing and promoting clinical activity in New Jersey. BioNJ partnered with Rutgers Business School and Rutgers Bloustein School of Planning and Public Policy to provide an in-depth analysis of clinical trials conducted through the State and to assess their economic impact.

We are very thankful to the BioNJ Clinical Trials Committee, co-chaired by BioNJ Board Member Spiro Rombotis, President and CEO, Cyclacel Pharmaceuticals; and Dr. Ulo Palm, SVP and Head of Global Brands Drug Development Operations, Allergan, and our staff liaison to the Committee Thomas Richardson Ph.D., Vice President, Strategic Initiatives. The Committee is comprised of representatives from Allergan, Berkley Life Sciences, Biologics Consulting Group, Cancer Genetics, Cyclacel Pharmaceuticals, D3 Medicine, Genewiz, Helsinn Therapeutics, Novartis, Precision for Medicine, Reed Smith, Rowan University, Rutgers University Cell and DNA Repository/Infinite Biologics, the Cancer Institute of New Jersey and Virtua Medical Group. We are indebted for their guidance.

We are especially grateful to Berkley Life Sciences for underwriting this report and to the BioNJ Board of Trustees and BioNJ Team for their tireless support for BioNovation and for Patients.

We hope you find this report to be informative and look forward to working with our Members and Partners and Friends to make a difference for our ecosystem.

Because Patients Can't WaitSM,

A handwritten signature in black ink, appearing to read "Debbie Hart", with a long horizontal flourish extending to the right.

Debbie Hart
President and CEO, BioNJ

Executive Summary

New Jersey's Clinical Trials Activity and its Economic Impact: An Introductory Study by BioNJ, Rutgers Business School and Rutgers Bloustein School of Planning and Public Policy

BioNovation, New Jersey's life sciences innovation ecosystem, has well known and well regarded clinical and commercial development expertise. A central activity of translating scientific discoveries and developing technologies into products is evaluation of the innovations via clinical trials¹, which represent a significant cost of developing drugs and products in the healthcare industry. Conduct of a trial typically assesses safety and efficacy in a relevant population and this assessment underpins regulatory filings with the Food and Drug Administration for product approval. It is, therefore, both a critical step in delivering healthcare advances to Patients and a technically rigorous process requiring skilled labor and significant investment.

To understand BioNovation's clinical trials activity and enable meaningful initiatives for long-term strategic investments, we developed and analyzed some key metrics that provide insights for stakeholders looking to grow and support clinical trials. The results of this effort provide a mosaic comprising clinical trials activity, patient participation and economic impact that collectively provide important baseline information on the ecosystem. This study is thus not an exhaustive analysis of one particular area or another but lays important groundwork. It establishes a baseline for future benchmarking and progress measurement and provides insight into the participation of New Jersey Patients in clinical trials.

To perform this study, BioNJ worked in collaboration with Rutgers Business School and

Rutgers Bloustein School of Planning and Public Policy. We specifically quantified the number of clinical sites in the State, assessed the number of New Jersey participants involved in clinical trials and determined investments associated with conducting these trials to calculate the resulting economic impact. Further, we quantified the distribution of clinical trials across key indication areas.

New Jersey Numbers at a Glance:

- As of 2013, the State of New Jersey had 244 sites conducting clinical trials.
- New Jersey residents are willing to participate as Patients in clinical trials, comprising 6.8% of enrollees in clinical trials nationally. (New Jersey represents 2.8% of total U.S. population.)
- Clinical trials activity is above the national average in oncology, and infection and inflammatory diseases.
- Total annual investments in clinical trials by corporate and NIH sponsors totaled \$263.3 million and resulted in \$779 million in economic output in 2013.
- Clinical trials investment supports 3,750 jobs on an annual basis.
- GDP impact is \$337 million.
- Direct wages total \$142 million.
- Per \$1 million invested in clinical trials, 15 jobs are created; \$1.37 million is added to GDP.

Introduction

The value of clinical trials activity can be measured in several ways. First, investments in clinical trials and research confer economic benefits to the job market, to the sites conducting the trials and to the economy as a whole. Second, access to highest quality medical care contributed by trial sponsors saves the State considerable expenditures by offering world-class standard of care and access to cutting edge technologies and treatments. Third, and most importantly to the participants in these trials and to their families, is hope. Many Patients have no other choice. Many have exhausted currently available treatments and through their heroic participation in evaluating experimental therapies, they may have the chance to find cures and treatments to their ailments and offer avenues to others who do not have such access. The total value of clinical trials to society is measured in more than just dollars. This study is an attempt to provide some benchmarks of the economic impact of these trials in New Jersey.

Methodology and resources

To assess the clinical trials infrastructure in New Jersey and its economic impact, we used data sets from publicly available sources and published reports from other organizations. We then applied a New Jersey-specific economic model to quantify relevant factors, which are listed below. First, we determined the number of clinical trials performed in the State and calculated the number of New Jersey participants involved in clinical trials. Second, we determined investments associated with conducting these trials, and calculated the

resulting economic impact. These complementary data were used to gauge the extent and impact of clinical trials conducted in New Jersey.

Clinical trial sites

Sites were determined from internal research and include university and academic medical centers, hospitals and health networks, private practices and individual investigators.

Clinicaltrials.gov

Clinical trials information is maintained at clinicaltrials.gov, a “registry and results database of publicly and privately supported clinical studies of human participants conducted around the world².” It is among the most comprehensive listings of clinical trials available. The U.S. National Library of Medicine and the National Institutes of Health maintain the site and clinical investigators provide content. Upon registration, each trial is assigned an identifier and linked to a record that includes information on proposed site locations, enrollment, dates, sponsors and phases as well as a description of the trial. These data were aggregated and analyzed for New Jersey by a consulting team comprised of MBA students at the Rutgers Business School. The Rutgers team parsed the clinical trials data to tabulate the number of trial sites in New Jersey. A trial site, for purposes of this report, is a specific site linked to a unique trial. If a site is conducting more than one trial, each trial is counted separately; similarly, if one trial is being conducted at more than one site, each site is counted. These data are summarized in **Table 1**.

Table 1: Total Trial Sites from ClinicalTrials.gov

Distribution of Sites	NJ Trial Sites	U.S. Trial Sites
	6,152	197,326
As a % of sites in U.S.	3.12%	

The vast majority of clinical trials in New Jersey are in several general categories of indications shown in **Table 2**.

Table 2: Indications

	New Jersey	U.S.
Oncology	58%	41%
Heart, Lung, Blood	13%	12%
Infection, Inflammatory Disease	11%	8.3%
Neurology and CNS	10%	14%
Diabetes, Digestive, Kidney Diseases	6.0%	5.7%

Current estimates of clinical trials activity in New Jersey

There are no known studies that estimate clinical trials activity specifically in New Jersey, though some related published reports are available. The Pharmaceutical Research and Manufacturers of America (PhRMA) sponsored a national study, published in 2015, that captures the economic impact of biopharma-funded clinical trials activity in the U.S.³ This study focused on industry-sponsored clinical trials and provides a state-by-state analysis. It does not, however, include sponsorship from federal sources, such as the National Institutes of Health. Another study, commissioned by the Cancer Institute of New Jersey, captured the impact of the operations of the Institute only⁴. While some data in these studies are relevant to this report and analysis, they do not sufficiently capture the broader investments across the clinical trials infrastructure in the State nor do they include the fuller complement of public and private institutions sponsoring clinical trials. Therefore, where applicable, we use aggregated data for our analysis.

Participation in clinical trials by New Jersey residents

While New Jersey is the 11th most populous state

in the U.S., according to the PhRMA study, it ranks 18th by the number of active clinical trials. To assess the participation of New Jersey residents in clinical trials and gain additional insights, the Rutgers Business School Team combined trial site data with enrollee data to estimate that enrollees from New Jersey represent 6.8% of all enrollees in clinical trials nationally.

R/ECON methodology

R/ECON is an economic input-output model developed and maintained by the Center for Urban Policy Research at Rutgers University's Edward J. Bloustein School of Planning and Public Policy⁵. It is used to estimate the economic impacts of various types of expenditures or investments, in terms of employment, state gross domestic product, compensation (e.g., income) and tax revenues. It adapts national level input-output tables, last published by the Bureau of Economic Analysis in 2007 and updated for 2012 price levels, to the New Jersey economy. The model categorizes the New Jersey economy into 384 individual sectors, and measures the effect of expenditures in one industry on economic activity in all other industries, with a focus on employment, wages and compensation and proprietor's income. Accordingly, the model uses direct spending and multiplier effects to

generate indirect and induced output, and thus enables R/ECON to estimate the cumulative impact on New Jersey's overall economy. Through historical analysis, the model also embeds estimates of the share of demand for labor and capital that can be met from within the State with the key input being investment.

Costs of clinical trials

To deploy the R/ECON economic models, inputs for clinical trials expenditures were needed.

Clinical trials expenditures continue to rise and recent estimates for the total cost of developing a new drug approach \$2.6 billion, according to the Tufts Center for the Study of Drug Development⁶. As clinical trials represent the major cost associated with developing and evaluating a new drug, the price per participant is also increasing, with an annual growth rate of 7.5% (1989-2011; **Table 3**)⁷. This value greatly exceeds the U.S. inflation rate, averaging about 2.5% over the same time period.

Table 3: Grant Cost per Patient Source: U.S. Bureau of Labor Statistics, 2014

Year	Mean	Median	Standard Deviation	N*
All Years	\$6,191.80	\$4,195.07	\$6,860.91	216,076
1989	3,772.59	2,779.43	2,921.34	1,370
1990	4,385.77	3,147.77	4,016.57	3,443
1991	3,774.43	2,774.83	4,186.06	92,088
1992	3,493.63	2,399.00	6,129.31	14,126
1993	3,664.58	2,325.45	4,254.28	15,733
1994	3,911.39	2,882.35	3,925.46	16,625
1995	4,183.00	3,203.85	3,941.90	15,670
1996	4,884.89	3,748.77	4,708.14	14,442
1997	4,549.12	3,200.00	4,422.39	13,321
1998	5,393.70	3,948.38	5,445.89	14,370
1999	5,501.08	4,361.94	4,874.07	13,943
2000	6,220.42	4,682.79	6,243.02	18,761
2001	6,078.96	4,777.00	5,150.11	16,864
2002	6,567.58	4,744.10	5,984.32	12,201
2003	8,174.90	6,765.00	6,866.55	6,515
2004	10,264.00	8,582.72	7,758.22	3,216
2005	11,412.77	9,682.02	7,828.89	2,693
2006	12,364.68	10,900.00	7,460.17	4,012
2007	13,001.19	10,738.47	8,863.90	4,764
2008	14,834.64	12,720.94	10,328.42	3,216
2009	16,518.28	13,965.42	12,550.80	4,591
2010	15,099.19	12,581.93	10,860.27	4,814
2011	16,566.55	13,222.14	13,556.92	2,188

*N = number of observations on investigator grants

We used as an input for R/ECON, \$263 million as the aggregated investment of clinical trials sponsorship in New Jersey, comprising both

industry- and NIH-supported trials. A summary of the direct and indirect impacts based on the R/ECON model is provided in **Table 4**.

Table 4: R/ECON Model Outputs

Summary	Direct	Indirect/Induced	Total
Output (in \$000's)	263,280	515,756	779,036
Employment (#)	1,890	1,863	3,753
Earnings (in \$000's)	142,594	119,570	262,164
GDP (in \$000's)	163,744	173,128	336,873

Summary	Per \$1mm	Total
Jobs created (#)	15	3,753
Wages/Earnings (\$)	1,066,140	262,163,764
State tax revenue (\$)	59,773	14,698,184
Local tax revenue (\$)	88,676	21,805,537
GDP (\$)	1,369,958	336,873,659

Thus, the estimated \$263 million spent on clinical trials in the State results in \$516 million in economic output from indirect and induced effects, for \$779 million in total output. Approximately 3,750 jobs are created from that annual spending. Ultimately, in-state spending on clinical trials is estimated to add \$337 million to New Jersey's GDP.

The Rutgers Business School team further identified the specific sub-sectors involved in various clinical trials activities and quantified the expected costs attributed to each. Clinical trials activities are conducted unevenly among the four major sectors specified in R/ECON; therefore, the Rutgers Business School team used individual weightings of these sectors in conjunction with total spending to estimate the effects of each on the New Jersey economy.

The clinical trial-specific activities for these were used for additional estimates on the impact on job creation. For every \$1 million spent in the State in each of these categories:

- **Medical and diagnostic labs** create 12 direct jobs and over \$830,000 in wages, contribute \$1.17 million to the State's GDP, and generate \$120,000 in tax revenues.
- **Hospitals** create 14 direct jobs and over \$915,000 in wages, contribute \$1.21 million to GDP, and generate \$130,000 in tax revenues.
- **Physicians' offices** create 15 direct jobs and over \$1.23 million in wages, contribute \$1.37 million to GDP, and generate \$165,000 in tax revenues.
- **Outpatient care centers** create 14 direct jobs and \$935,000 in wages, contribute \$1.28 million to the State's GDP, and generate tax revenues of \$130,000.

Conclusions

BioNovation maintains an active infrastructure for clinical trials activity that provides benefits both to the economy and to Patients by providing access to cutting edge therapies. Data indicate that clinical trials conducted at institutions in New Jersey and in the immediate region enroll a larger proportion of New Jersey residents than would be predicted from simple demographic data.

When compared nationally, New Jersey has significant clinical trials activity in oncology, infection and inflammatory disease, reflecting historical strength in the region in this arena.

This study implores a series of considerations and questions for stakeholders and opinion leaders in the State to consider:

- Given the high per capita Patient participation in trials, strategies should be developed to conduct more trials and increase investments in the State.
- An assessment should be made of the types of treatments Patients are seeking at regional centers beyond our borders. How many among the New Jersey Patient population are participating in clinical trials at New York and Philadelphia institutions? How can we attract them to New Jersey institutions?

- An assessment should be made of the economic value and cost savings to the State from the high quality of care to Patients in trials sponsored by companies and institutions.
- In light of New Jersey's industry leading clinical and commercial workforce, are we supporting this knowledgeable talent sufficiently to maintain our long held position as "The Medicine Chest of the World?"
- How have per-Patient costs impacted clinical trials activity?
- How can stakeholders communicate more effectively the value of clinical trials — from economics and jobs to therapies, cures and hope — to offset misunderstanding among the public about these critical activities?

BioNJ, in collaboration with academic institutions, clinical care centers, life sciences companies and other stakeholders in the State, must continue to work with legislative leaders to address these questions. One key goal is to ensure a full understanding of clinical trials activity in order to promote investment and meaningful policies to grow and support this segment of the life sciences industry.

It is imperative that Patients have access to the highest quality of care, life-saving therapies and hope for more tomorrows.

Because, Patients Can't WaitSM.

Appendix

1. Clinical Trials overview; CenterWatch: <http://www.centerwatch.com/clinical-trials/overview.aspx>
2. ClinicalTrials.gov; U.S. National Institutes of Health: <https://clinicaltrials.gov/>
3. Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies; Battelle Technology Partnership Practice, Pharmaceutical Research and Manufacturers of America (2015)
4. The Economic Impact of Rutgers Cancer Institute of New Jersey; TrippUmbach, Rutgers Cancer Institute of New Jersey (2014)
5. Revising Domestication Techniques, the Notion of Re-exports and Some Comments on Regional Accounting; Michael L. Lahr, Economic Systems Research, Vol.13, #2, 2001 (2000)
6. Tufts Center for the Study of Drug Development: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study
7. Price indexes for clinical trials research: a feasibility study; Bureau of Labor Statistics: <http://www.bls.gov/opub/mlr/2014/article/price-indexes-for-clinical-trial-research-a-feasibility-study.htm> (2014)

About BioNJ

BioNJ, The Gateway to Health, is a network of more than 400 Members representing research-based life sciences companies and stakeholders dedicated to propelling a vibrant ecosystem where Science is Supported, Companies are Created, Drugs are Developed and Patients are Paramount. Because Patients Can't WaitSM, BioNJ supports its Members in the discovery, development and commercialization of therapies and cures that save and improve lives and lessen the burden of illness and disease to society by driving capital formation, fostering entrepreneurship, advocating for public policies that advance medical innovation, providing access to talent and education and offering a cost-saving array of critical commercial resources. For more information about BioNJ, please visit www.BioNJ.org.

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