

The Clinical Research Landscape in Rhode Island

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ABSTRACT

OBJECTIVES: To present an overview of clinical research activity and the state of medical research funding in Rhode Island.

METHODS: We utilized clinicaltrials.gov registry to profile clinical studies between 2011 to 2016. NIH RePORT and other federal databases were used to extract information on levels of federal funding. Previously published hospital financial reports were reviewed for data on hospital-specific total external research funding.

RESULTS: During 2011-2016, 1651 clinical studies were registered in clinicaltrials.gov. Nearly a third of all clinical studies were in oncology (21%) and cardiovascular diseases (10%). Alzheimer's dementia, breast cancer, HIV, and hepatitis C accounted for nearly 17% of all clinical trials. Seventy-five percent (75%) of clinical trials in RI were conducted in hospitals affiliated with Lifespan or Care New England. Financial support for clinical trials largely came from industry (60%) with 23% being supported by the National Institutes of Health (NIH). The rest are funded by nonprofit organizations, charitable foundations, educational institutions, and unlisted concerns.

KEYWORDS: clinical studies, medical research, research funding, NIH funding

INTRODUCTION

Although Rhode Island is the smallest state and seventh to last in terms of population, medical research in Rhode Island is robust. As of 2009, Rhode Island has led the nation in per capita number of active clinical studies (**Figure 1a**).^{1,2} Furthermore, Rhode Island ranks third among states in the union in per capita NIH funding, just behind Massachusetts and Maryland (**Figure 1b**).^{1,3} In the period of 2011-2016, over 1600 trials have been active in the state, encompassing a broad range of medical fields. In the past year alone, federal agencies dispensed \$130 million to support 353 projects (which includes both clinical studies and biomedical research).^{2,3} Given this vast volume of research, this report seeks to give a detailed overview of the clinical research currently conducted in Rhode Island, as well as an overview of the current climate of medical research funding in the state.

Figure 1a. Top ten states by number of clinical studies per 10,000 people in the years 2011 to 2016. Data is obtained from clinicaltrials.gov registry.

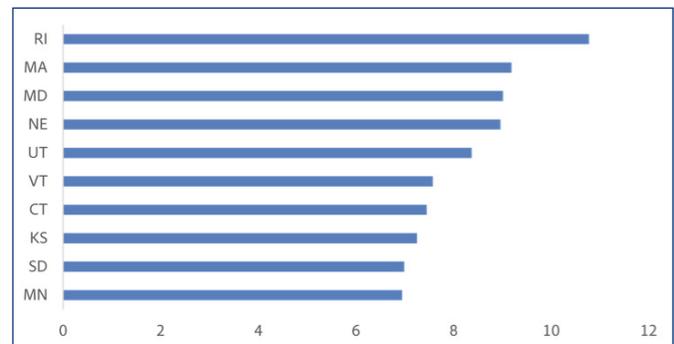
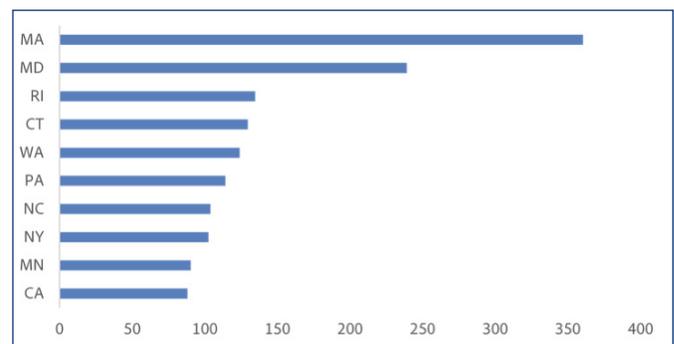


Figure 1b. Top ten states by average annual per-capita NIH funding in dollar amounts between years 2011 to 2015.



METHODS

We chose clinical study data registered with the US clinical trial registry at clinicaltrials.gov as the source data for quantifying clinical research activity. All studies with either initiation or completion dates falling between 1/1/2011 and 9/12/2016 were selected for analysis. We utilized NIH RePORT, and other federal databases available from the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), and the Department of Defense (DoD) as the source of data on federal funding for medical research. Included in the category of medical research for purposes of funding analysis are clinical trials as well as translational and basic biomedical science research. We utilized publically accessible financial statements (2011–2015) released by Lifespan and Care New England for data on external research funding received by their respective hospitals.

CLINICAL RESEARCH ACTIVITY

Clinical trials in oncology, followed by cardiology, neurology, psychiatry, infectious diseases, gastroenterology, and pulmonology comprise the bulk of the clinical research in Rhode Island (Figures 2 and 3). The majority of clinical trials are conducted in medical centers (64%), with the remainder in private medical offices and research facilities. Approximately 60% of studies are either solely or partially industry sponsored, and 22% are federally funded (primarily via NIH), with the rest funded by a combination of different sources, which may include private foundations, nonprofit groups and other public sources (Figure 4). Most major pharmaceutical companies sponsor clinical trials in RI, with Pfizer, Roche, and Novartis (78, 66, 54 trials respectively) having the largest presence, corresponding to their size in the overall industry. Phase 3 trials are the most common studies (44%), followed by phase 2, and observational studies (Figure 5).

The majority of investigational therapies are pharmaceuticals, which is followed by behavioral interventions, biologics, medical devices, and lastly, procedures (Figure 6).

Mirroring the major causes of mortality in Rhode Island, cancer and cardiovascular diseases are the most actively researched areas, accounting for one-third of the clinical trials conducted in the state.⁴ The incidence of cancer in RI is above the national average (479 vs. 448 per 100,000 individuals),⁵ and is also the number one killer in the state (number two if all cardiovascular diseases were considered in one category). Most of these are large national multicenter trials of chemotherapy with significant cooperation/support from industry. Within oncology, the largest portion of research (~20%) is devoted to breast cancer, followed by lung cancer, hematologic cancers, and ovarian cancer (Figure 3). Compared to Rhode Island's epidemiologic data of cancer rates, there is a relative paucity of clinical investigational

Figure 2. Clinical studies by research category.

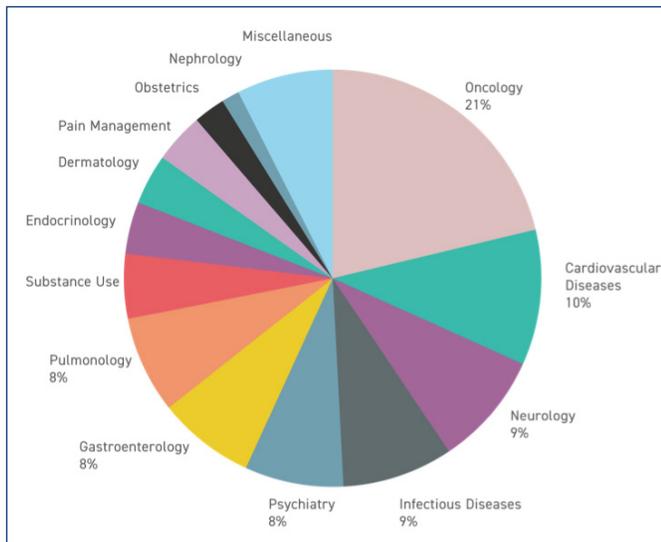


Figure 4. Sources of clinical study funding by number of clinical trials.

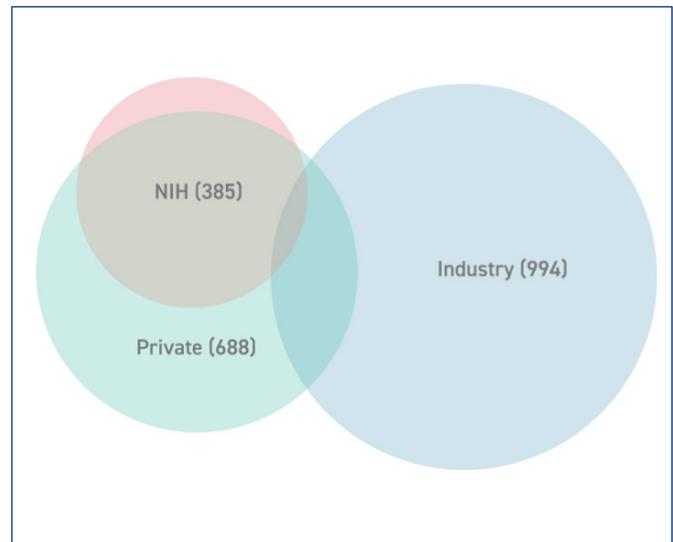


Figure 3. Clinical studies in oncology.

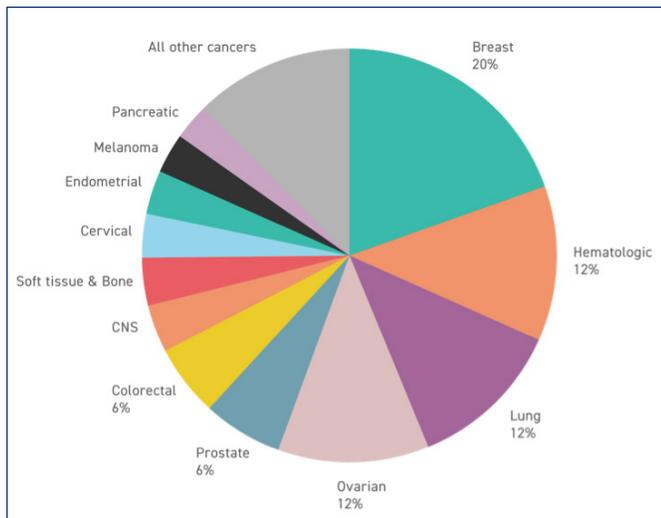


Figure 5. Clinical study by type.

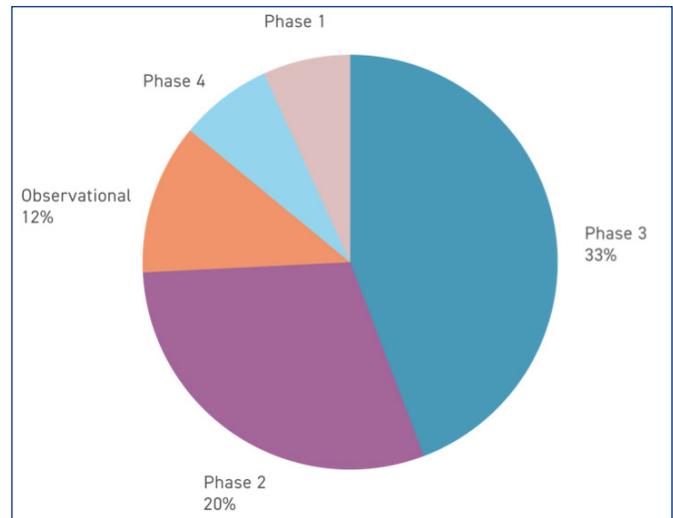


Figure 6. Clinical trials by type of intervention studied.

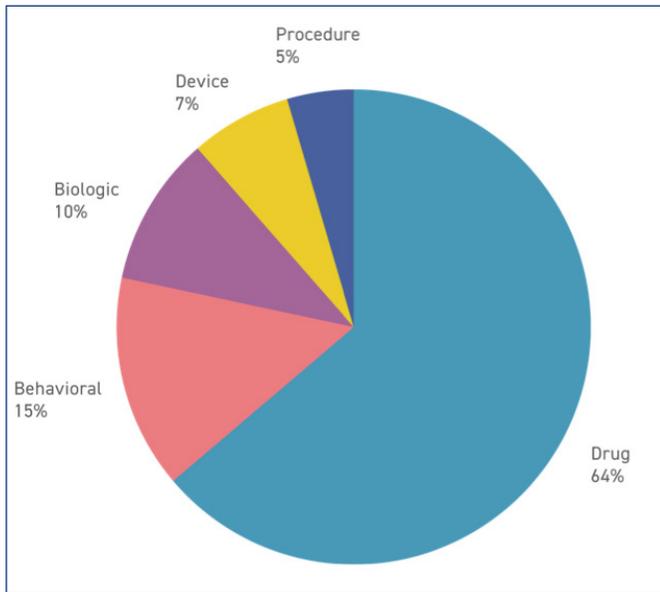


Figure 7. Top causes of death in Rhode Island compared to top researched clinical categories. Values are expressed as percentage of total for both metrics.

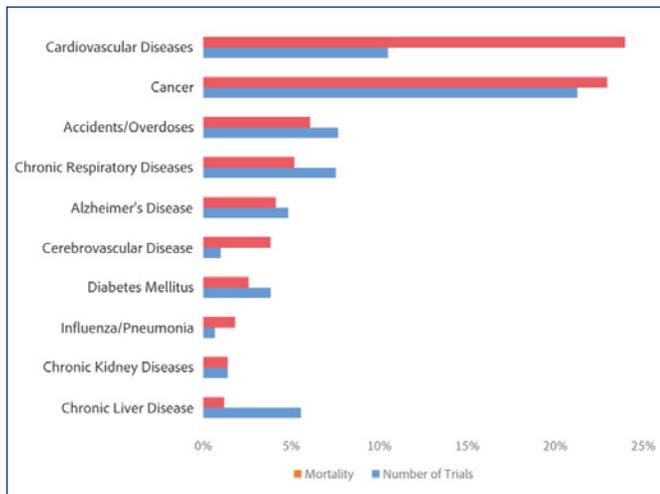
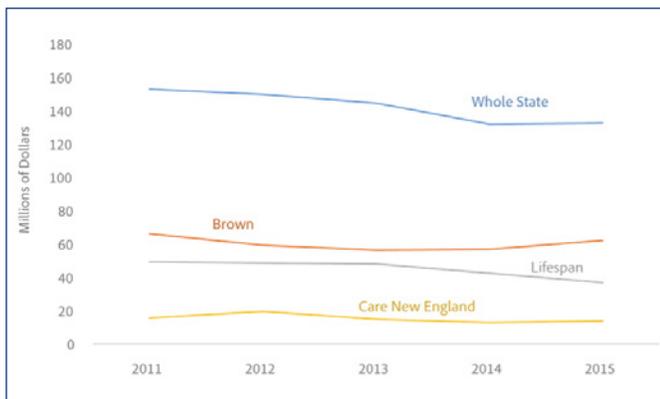


Figure 8. NIH funding for state of Rhode Island.



therapies in colorectal, prostate, bladder, and liver cancer, while there is a relative abundance of trials in hematologic cancers and ovarian cancer. Cardiovascular diseases, which include conditions affecting the heart and the peripheral vasculature, when taken as a whole, are the leading causes of mortality in Rhode Island, with heart disease accounting for the majority of deaths (Figure 7). Correspondingly, clinical trials in ischemic heart disease and related acute coronary syndromes make up the bulk portion of clinical cardiovascular research, followed by preventative cardiology (lifestyle changes, blood pressure and cholesterol management), arrhythmias, and peripheral arterial disease.

Outside the fields of oncology and cardiovascular disease, there are a significant number of trials devoted to dementia and hepatitis C. Alzheimer's disease afflicts 23,000 Rhode Islanders⁶ and is the most researched singular disease entity, with 73 clinical trials investigating novel therapies as well as diagnostic/screening tools, primarily at Rhode Island Mood and Memory Institute and Butler Hospital's Department of Memory and Aging. Clinical research in hepatitis C, particularly in the realm of antivirals (65 studies), account for a significant fraction of both gastrointestinal and infectious disease research. Similarly, trials of antivirals in HIV-1 therapy have also received special attention with 63 studies conducted over the past 5 years. Other conditions with high number of clinical trials include diabetes, depression, asthma, COPD, pain management, and substance addiction. Furthermore, research in pulmonary hypertension deserves special attention, as the number of clinical trials (n=20) is relatively high given the condition's rarity.

SOURCES OF RESEARCH FUNDING

While several federal agencies (DoD, AHRQ, PCORI, Veteran's Administration, Centers for Disease Control, Food and Drug Administration) and the RI Department of Health all contribute to funding of medical research in Rhode Island, the NIH and its constituent organizations represent the lion's share of public research funding (\$132 million from NIH to ~\$10 million from non-NIH government agencies in 2015). However, NIH funding has decreased from \$152 million in 2011 to \$132 million in 2015 (Figure 8).³ While NIH grants tend to support traditional laboratory, translational and clinical research, other organizations such as AHRQ and PCORI support research in measuring population healthcare outcomes. Furthermore, the VA funds all types of medical research activity from basic sciences to healthcare delivery. While the VA does not publish research expenditures by state publically, the VA budgeted \$500 million nationally in medical and prosthetics research in 2015.^{7,8} The VA Medical Center in Providence is a designated Center of Innovation, with 7 active projects⁹ as well as possessing a dedicated research facility, the Ocean State Research Institute. Historical data from Brown University's Alpert Medical School shows that the VA spent between \$20-23 million annually on internal

medicine related projects between 2009 and 2013.¹⁰ Furthermore, the VA supports orthopedic research projects at Brown, and in 2012, jointly funded The Center for Neurorestoration and Neurotechnology with local area institutions.¹¹

In addition to national charities, the Rhode Island Foundation, which pools financial resources of 19 local charitable funds that actively donate to medical research, supports 10-12 grants up to \$25,000.¹² Higher educational institutions in Rhode Island such as Brown and URI contribute to research funding within the state; however, out-of-state universities such as Yale and Columbia Universities have provided funding to active in-state research as well.¹³ The majority of clinical trials, in particular chemotherapeutic trials, are funded in whole or in part by pharmaceutical firms.²

RESEARCH FUNDING LANDSCAPE

Lifespan hospitals (RIH, Miriam, Bradley) in conjunction with Brown University, the institution for which the former serve as affiliated teaching hospitals, account for just over half of the state’s clinical research activity.² Other significant centers of research activity include the Care New England hospital system (Butler, Women & Infants, Memorial Hospital of RI, Kent Hospital); CharterCARE Health Partners (Roger Williams and Fatima Hospital), and the Providence VA Medical Center (Figure 9). In the past five years, while overall federal support for medical research in RI has declined by 15%, research funding for Brown University has remained fairly consistent at around \$50-\$60 million per year annually. Furthermore, while Lifespan hospitals have seen cuts in federal research support, the annual external research funding has remained stable, between \$70—\$80 million, with the majority (~\$50 million) going to Rhode Island Hospital (Figure 10a,b).¹⁴ This indicates an increase from private sources of funding at the same time that public funding has decreased.³

For Lifespan, in the period between 2011 and 2015, federal support for research funding has declined from \$49 million annually to \$37 million (Figure 8). In the same period, federal research funding for Care New England hospitals have fluctuated from a high of \$19 million in 2012 to \$14 million in 2015. The vast majority of federal funding came from NIH grants, and the rest from DoD, CDC, and AHRQ. Between 2011 and 2016, there were 550 ongoing clinical trials, with 45% of trials funded by NIH, and a third of trials funded by industry, with significant overlap between the two. However, a majority of the clinical studies are neither supported by public funds nor the for-profit private sector, but instead come from grants by nonprofit organizations and educational institutions. The second largest contributor to clinical research in the state, Care New England, had an annual total research funding of \$23 million in 2015, and \$25 million in 2014.¹⁵ Between 2011 to 2016, Care New England hospitals were the site of 349 clinical trials, with 60% of trials funded by the NIH and 17% funded by industry.^{2,3}

Figure 9. Clinical study by location. Not included in the figure are ~400 studies conducted industry research facilities and individual medical offices. Not labeled in the last three slices of the figure are Fatima, South County, and Landmark hospitals.

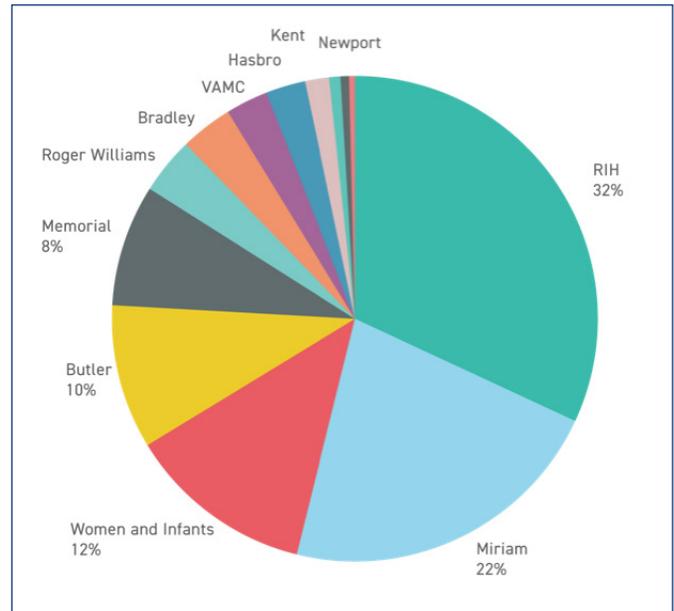


Figure 10a. Total external research funding and NIH funding for Lifespan hospitals.

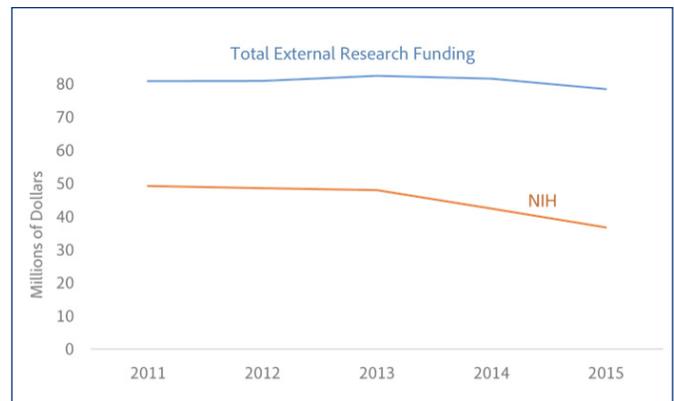
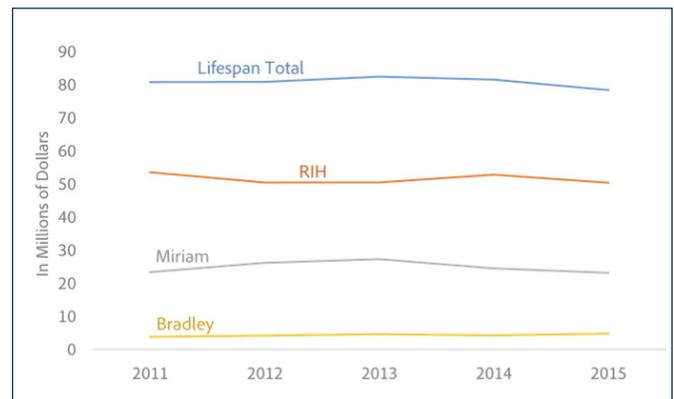


Figure 10b. Research funding at Lifespan constituent hospitals.



CONCLUSION

Rhode Island remains a robust contributor to medical research, and the research landscape is dominated by oncology, cardiovascular, neuropsychiatric, and infectious diseases. Brown University and affiliated hospitals (Lifespan and Care New England healthcare systems) account for the majority of research activity and funding in the state. While overall research funding at Brown and Lifespan hospitals has remained stable, the proportion of federal funding for medical research has declined, with the gap made up for by private sources of funding as well as the hospitals themselves. This therefore highlights the need for investigators to have access to outside sources of funding and initiatives that promote increased inter-institutional collaboration if medical research is to remain unaffected by the current federal budgets cuts.

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