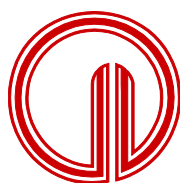


**A Report on the Clinical Research Industry Cluster in
Southeastern North Carolina**



**North Carolina
Biotechnology Center**

Updated December 2016



*The southeastern region's **North Carolina Coast Clinical Research Initiative** is a collaborative, cluster development effort between clinical research companies, healthcare providers, economic developers, University of North Carolina Wilmington, and the North Carolina Biotechnology Center Southeastern Office, who work together to strengthen and grow the clinical research industry cluster in our area. The goals of the **NC Coast Clinical Research Initiative**, an economic development initiative, are to help existing companies grow and to attract additional talent and companies to the region by creating greater cohesiveness between members of the clinical research community, by enhancing the local clinical research workforce, by increasing physician-led clinical research trials in the region, and by promoting the local clinical research cluster in the region and beyond, all for the economic, societal, and health benefit to the southeastern region of North Carolina.*

*The **North Carolina Biotechnology Center** provides long-term economic and societal benefits to North Carolina through support of biotechnology research, business, education and strategic policy statewide. Headquartered in Research Triangle Park, the Center has five regional offices, including the Southeastern Office in Wilmington, focused on regional biotechnology economic development.*

A Report on the Clinical Research Industry Cluster in Southeastern NC

The Clinical Research industry cluster is vital to Southeastern North Carolina, supporting over 3,200 knowledge-sector jobs to strengthen the region's diverse economy. The Wilmington area is home to a wide range of clinical research companies, including small entrepreneurial ventures and large, multinational companies, such as PPD, the third largest clinical research organization (CRO) in the world, headquartered in downtown Wilmington. This industry cluster, along with Wilmington's proximity to the Research Triangle Park, has helped the area attract other major CROs and spawn numerous entrepreneurial startups in clinical research. Of the 31 (up from 25) CROs represented in the region, 4 (up from 3) have Wilmington headquarters.

The multitude of additional companies in Southeastern North Carolina providing specific support to CROs in the area has increased substantially since the last report (more than 60 companies, up from 40 companies). Clinical research support companies provide very specialized services, such as biostatistics, clinical trial data management, laboratory testing services, medical writing, and patient recruitment. The region also experienced an increase in the number of drug, medical device, and testing companies in Wilmington.

The southeastern region is rich with talented professionals in the clinical research industry. In addition to the existing clinical research employee base, educational programs at UNC Wilmington, including the undergraduate and graduate degree programs, enhance the local workforce with highly skilled graduates. Recently, Duke Energy awarded \$390,000, with a significant funding match from UNC Wilmington, for the creation of a clinical research workforce development program to bolster the industry in the region. UNC Wilmington, the NC Biotech Center Southeastern Office, and local industry leaders partnered to design and implement this program, which includes Continuing Education offerings, Curriculum Enhancements, a Fellowship Program, and an industry/academia Collaborative Workspace.

Local healthcare providers already conduct many clinical trials, often managed by CROs, but ample opportunity exists to increase the number of clinical trials conducted locally. A range of issues contributes to the number of clinical trials offered in a community. Currently, more than 22 medical practices and over 45 physicians conduct clinical trials locally. Additionally, several local firms actively recruit patients to participate in clinical trials in a variety of therapeutic areas, including heart disease, COPD, arthritis, and diabetes.

The purpose of this report is to provide an industry snapshot to illustrate the impact of the clinical research industry on the area and to identify ways in which the cluster can grow here. This report specifically addresses a three-county focus area that includes Brunswick, New Hanover, and Pender counties, with broader implications for our expanded rural region. To determine what action steps are needed to enhance the local clinical research cluster, information pertinent to the clinical research industry has been compiled in this report. From this information, general conclusions are made with specific recommendations to increase the number of local clinical trials and to help the local cluster of companies continue to grow.

Open Clinical Trials in Wilmington

As of October 2015, there were 22,445 open clinical studies in the United States, 2,345 or 10.4% of which have an investigative site in North Carolina (*ClinicalTrials.gov*), (down 0.4% from last report). The Wilmington area currently has 115 open clinical trials. Of those studies, 8 are observational registries managed by companies, such as INC Research, located in Wilmington. As seen in *Table 1: Clinical Trial Phases*, the trials conducted in the Wilmington area range from phase 0 to phase IV. The focus areas of the clinical trials in Wilmington vary widely. A large number of trials focus on cancer, diabetes, dermatology, chronic obstructive pulmonary disease (COPD), and cardiovascular disease, as shown in *Table 2: Clinical Trial Focus Areas*. Of the 13 cancer studies being conducted in our area, 10 trials are funded by the National Cancer Institute (NCI).

Table 1: Clinical Trial Phases

Phase	Number of Studies
Phase 0	22
Phase I	6
Phase II	14
Phase III	53
Phase IV	16
Unreported	4
Source: ClinicalTrials.gov	

Table 2: Clinical Trial Focus Areas

Focus	Number of Studies
Cancer	13 (20 in 2014)
Diabetes	12 (15 in 2014)
Dermatology	9 (4 in 2014)
COPD	6 (8 in 2014)
Cardiovascular Disease	7 (7 in 2014)

Number of Clinical Trials Conducted in Areas Similar in Size to Wilmington

Wilmington is well-positioned to increase the number of clinical trials conducted locally. *Table 3: Comparison of Clinical Trials by City* shows that, while the New Hanover County population is only slightly lower than in Buncombe County, the Wilmington area hosts significantly fewer trials than the Asheville area. A range of actions can increase the number of clinical trials conducted locally.

Table 3: Comparison of Clinical Trials by City

City/County	Number of Clinical Trials	2013 County Population	2013 Physicians per 10,000 (County Level)
Durham/Durham	881	286,053	74.5
Chapel Hill/Orange	553	139,694	105.4
Winston-Salem/Forsyth	547	360,471	50.2
Charlotte/Mecklenburg	533	991,867	29.1
Raleigh/Wake	226	964,616	23.8

Table 3: Comparison of Clinical Trials by City (continued)

Asheville/Buncombe	171	248,872	38.1
Greensboro/Guilford	134	507,419	24.2
Greenville/Pitt	120	173,879	46.5
Wilmington, NC/New Hanover	115	213,809	32.3
High Point/Guilford	59	507,419	24.2
Cary/Wake	32	964,616	23.8
Fayetteville/Cumberland	28	332,553	17.5

Source: ClinicalTrials.gov, NC OSBM, and Cecil G. Sheps Center for Health Services Research

Companies Recruiting Patients for Clinical Trials

Several companies in Wilmington are devoted to clinical trial enrollment, including PMG Research and Trial Management Associates. These firms actively recruit patients in the Wilmington area to participate in a variety of observational and interventional clinical trials. PMG Research currently has open enrollment for studies including arthritis, COPD, cardiovascular, and diabetes. These firms have also partnered with medical providers, such as Wilmington Health, with the goal of education, awareness, networking, and making connections to relevant clinical trials in the community.

Physicians, Medical Practices, and Others Participating in Clinical Trials

Over 22 (up from 19) groups in Wilmington have participated in at least 1 clinical trial (see *Appendix 1: Medical Practices Engaging in Clinical Research*). The focus areas of these clinical trials include HIV, Hepatitis C, arthritis, cancer, cardiology, dermatology, gastroenterology, internal medicine, diabetes, neurology, sleep disorders, psychiatry, smoking, and urology. In Wilmington, 60 (up from 45) clinical trials identify the medical groups participating in a particular clinical trial. A list of specific trials and the groups associated with each trial is listed in *Appendix 2: Medical Practices and Other Groups Associated with Specific Clinical Trials*. The list of practices engaging in clinical trials is based upon the most currently available data and is not complete, because many practices and studies choose not to release trial information to the general public.

Health Professional Data

Table 4: Health Professional Data by County lists the number and focus area of doctors practicing in the 3-county focus area, in 2013. An important statistic to note is the number of physicians per 10,000 residents. North Carolina has an average of 22.7 (up from 22.1) physicians per 10,000 residents and a rate of 8.6 (up from 7.8) primary care physicians per 10,000 residents. New Hanover County well exceeds the state average (32.3 per 10,000 residents) and is ranked in the top 10 counties in the state in both areas. *Appendix 3: Health Professional Data for Selected NC Counties* combines the data seen in *Table 3* and *Table 4* to illustrate the connection between

the number of physicians and clinical trials being conducted. Based upon that data seen in *Appendix 3*, the presence of a greater number of physicians per 10,000 residents often results in a greater number of clinical trials. Upon request, additional information regarding the number of specialists in specific areas is available.

Table 4: Health Professional Data by County 2013

	New Hanover County	Brunswick County	Pender County
County Population	213,809	115,716	55,568
Primary Care Physicians <i>(* included in primary care physicians total)</i>	255	58	16
<i>Family Practice*</i>	50	19	8
<i>General Practice*</i>	4	3	0
<i>Internal Medicine*</i>	59	11	3
<i>Obstetrics/Gynecology*</i>	27	4	0
<i>Pediatrics*</i>	41	6	0
Other Specialties	435	59	3
Federal Physicians	11	0	0
Total Physicians	690	117	19
Physicians per 10,000 Population	32.3	10.1	3.4
<i>Physicians: State Rank (1=most physicians)</i>	6	56	90
Primary Care Physicians per 10,000 Population	11.9	5	2.9
<i>Primary Care Physicians: State Rank (1=most physicians)</i>	7	68	87
Pharmacists	280	74	24
Registered Nurses	3,095	550	215
Nurse Practitioners	141	44	13
General Hospital Beds 2012	813	85	25
Hospital Discharges 2012	20,763	12,252	5,700

Source: Cecil G. Sheps Center for Health Services Research

Contract/Clinical Research Organizations

Wilmington is home to a wide range of large and smaller CROs operating in the city and region. Many of these companies continue to grow and develop in the Wilmington area. With recent mergers, acquisitions, and new business growth here, at least 31 CROs (up from 25) are now represented in the region with a total employment of more than 2,700 (up from 2,500).

Additionally, the Wilmington area is home to at least 60 clinical research support companies, employing more than 380 (up from 200) individuals. This industry sector has grown immensely in the last few years with an increase in the number of new support companies in the Southeastern region, now supporting more CROs and helping to bring more jobs and business to the Wilmington area. Clinical research support companies provide very specialized services, such as biostatistics, clinical trial data management, laboratory testing services, medical writing, and patient recruitment. These companies range in size from large, multi-national companies to small entrepreneurial ventures. The region is also home to at least 22 (up from 13) drug, medical device, and testing development companies employing more than 150 (up from 50) individuals.

Below is a list of the CROs and clinical trial support companies that are either headquartered in or have a presence in the Wilmington area, which includes New Hanover, Pender, and Brunswick Counties. *Appendix 5: CRO Contact Information* provides each company's contact information, as well as a synopsis of activities. *Appendix 6: Clinical Research Support Company Contact Information* provides each company's contact information and focus areas. *Appendix 7: Drug, Medical Device, & Testing Development Company Contact Information* lists the companies that develop pharmaceuticals, medical devices, and offer testing services.

Contract Research Organizations

Alcami (HQ)	Metrics
Blitz Research	Modoc (HQ)
Catalent	Novella Clinical—a Quintiles Company
Chiltern International (US HQ)	OrphanReach
Clinipace Worldwide	PAREXEL International
Covance	Pharm-Olam International
The EMMES Corporation	PharPoint Research
Global Pharma Tek	PPD (HQ)
Health Decisions	PRA International
ICON	Premier Research
INC Research	Quintiles
Intrafusion	Sarah Cannon Research Institute
inVentiv Health	SynteractHCR
Jubilant Clinsys	TKL Research
Lexitas	Worldwide Clinical Trials
Medpace OH	

Clinical Trial Collaborators and Support Companies

Biostatistics

Array Biostats (HQ)

Biostudy Solutions (HQ)

Triangle Biostatistics, LLC

Clinical Trials Data Management

Clinical Ink

Dataflex Solutions LLC (HQ)

OptumInsight

SAS

Clinical Trial Insurance

Arthur J. Gallagher Risk Management Services

Aquesta Insurance Services

Consulting Services

Amanda Grim's GCP Audits (HQ)

Argent Rx Solutions (HQ)

A2Z Regulatory Publishing

Biopharmaceutech International (HQ)

Cape Fear Research Consultants (HQ)

Coastal Pharmaceutical Consultants (HQ)

Delozier Consulting Inc. (HQ)

DMS Clinical Research Services (HQ)

Eastwood Pharmaceutical Consulting (HQ)

Hal Price Biotechnology Consulting

Hermes (HQ)

KButler GxP Consulting (HQ)

Leonard Consulting LLC (HQ)

Live Oak Pharmaceuticals Inc.(HQ)

MSS Pharmaceutical Consulting (HQ)

Navigator Life Science Advisory (HQ)

Nuventra Pharma Sciences

Outsourcing Support Services, Inc (HQ)

ProMetrics

Rothermel Clinical Research Consulting (HQ)

Wagoner Consulting (HQ)

HR Support

Babb McGrew (HQ)
The CSI Companies
Green Key Resources
Hawthorne Search (HQ)
Human Capital Solutions (HQ)
Prestige Scientific
Thinkingahead
Trellis HR Outsourcing LLC (HQ)
YS Companies

Information Technology Solutions

Bluewater Technology Partners (HQ)
Clinverse/Bioclinicia
CRA360 Inc. (HQ)
Medidata
UNCW CREST Research Park

Laboratory Testing Services

Eurofins Scientific
Quality Chemical Laboratories (HQ)
Solstas Lab Partners
Wilmington Pathology Associates (HQ)
UNCW-DNA Analysis Core Facility

Marketing

A. Revell Communications (HQ)
Bon's Eye Marketing (HQ)
Inspire Creative (HQ)
Pure Communications Inc.
TGK Marketing

Medical Writing

Nightingale Medical Writing LLC (HQ)
Modoc (HQ)
Regulatory Writing Solutions (HQ)

Patient Recruitment and Logistics

ClinEdge

Endeavour Clinical Solutions

MediciGlobal Inc

Paragon International, Inc.

PMG Research

Trial Management Associates (HQ)

Pharmaceutical Sales Training

Proficient Learning (HQ)

Drug, Medical Device, & Testing Development**Drug Development**

Alvogen

CardioPharma (HQ)

Cygnus Technologies Inc. (HQ)

Krka USA LLC

MARBIONC Development Group (HQ)

Osmotica Pharmaceutical (N.A. HQ)

Wilmington Pharmaceuticals (HQ)

Medical Device Development & Testing

Biocomposites

Cortech Solutions (HQ)

MicroSolv Technology Corp. (HQ)

OrthoKinetic Technologies (HQ)

Surgilum (HQ)

Testing Development & Manufacturing

A1 BioChem Labs LLC (HQ)

AccuGenomics (HQ)

Flow Sciences Inc. (HQ)

IKA Works

MicroGuard Consulting (HQ)

Tri-Tech Forensics (HQ)

Strengthening the Workforce for the Local Clinical Research Industry

Recently, in partnership with the N.C. Biotechnology Center Southeastern Office and local clinical research company leaders, UNCW College of Health and Human Services was awarded a \$390,000 grant from Duke Energy to design and implement a workforce development program for the local clinical research industry that will add to the educational and networking opportunities already offered in the area. The program will create new opportunities to support the best-prepared clinical research workforce in the country, with continuing education, curriculum enhancements, a highly selective fellowship program, and a collaborative workspace. The general objectives of this program are as follows:

Continuing Education Program: Enhancing Our Existing Workforce

- Develop continuing education opportunities for industry employees, selected with feedback from local employers, in biostatistics, statistical programming, and clinical operations.
 - Workshops and seminars driven by demand and industry needs.
 - Short courses designed to fill common skill gaps and cover new developments in methodology and/or FDA guidance, especially as industry trends emerge and industry needs evolve.
 - Formal certificate programs in skill areas of need, as determined by industry, including required courses that employees must currently travel elsewhere to take to maintain employment eligibility.

Curriculum Enhancements: Educating the Next Generation of Talent

- Generate enhancements for students in UNCW's exceptional undergraduate and graduate degree programs that prepare them for employment in the clinical research industry.
 - Continuous improvement of current degree programs to provide coursework, technology, and field work directly related to job skills, as industry needs evolve.

Industry Fellowship Program: Preparing Students for the Workplace

- Increase opportunities for in-depth industry experience for students.
 - In addition to the existing internship program, the best-performing students will be eligible to apply to and participate in a fellowship program to provide support for advanced applied learning projects in the field with industry partners.

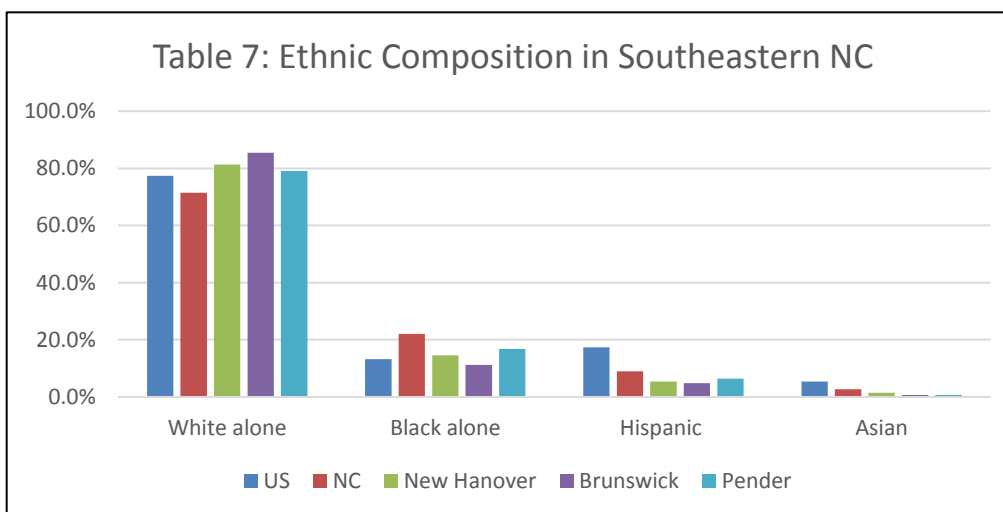
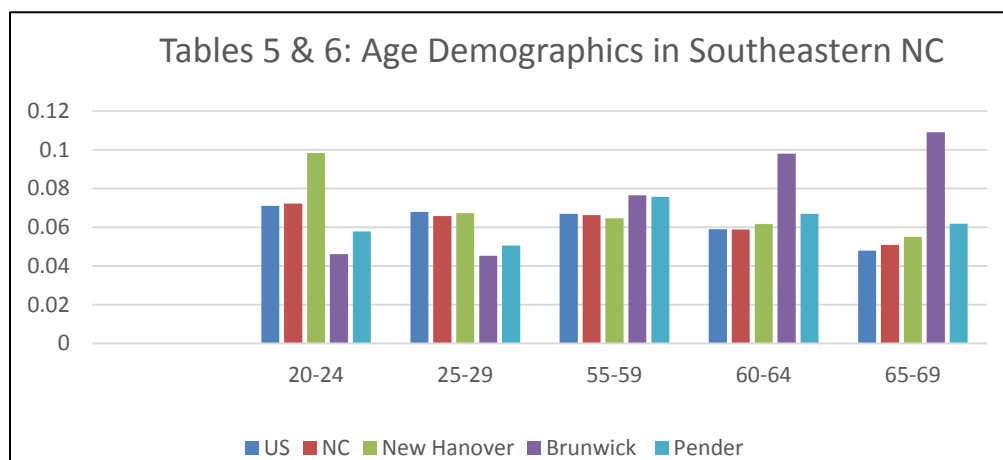
Collaborative Workspace: Building Connections between Academia and Industry

- Initiate a collaborative workspace at the UNCW Center for Innovation and Entrepreneurship.
 - Focal point for collaboration between local industry partners, UNCW faculty and students, and other local entities.
 - Formal support programs to serve, in a more targeted way, the specialized needs of local industry partners, in collaboration with UNCW faculty and students, and other local entities.

Regional Demographics

One important inclusion criteria considered in the clinical trials industry is age. In general, the age distribution within the three-county focus area mimics national and state trends. However, New Hanover County has a larger-than-usual population of individuals ranging in age from 20-24 years old (see *Table 5: Percentage of Young Adults in Southeastern NC*). Brunswick County exhibits a similar trend among individuals over the age of 60 (see *Table 6: Percentage of 60+ in Southeastern NC*).

Race and ethnicity may also be considered an inclusion factor in many clinical trials. North Carolina has a higher percentage of Blacks and a lower percentage of Whites, Hispanics, and Asians compared to the US composition (see Table 7). New Hanover County has similar race and ethnicity demographics to the United States (see *Table 7: Ethnic Composition*). None of the counties in the focus area have a racial composition that is similar to the state of North Carolina.



Source for both tables: NC County Health Data Book, NCDHHS, US Census

Regional Health Data

Health data can be useful when evaluating where to locate investigational sites. Areas with a higher prevalence of certain types of medical conditions are ideal for clinical trials aimed at treating those conditions. The higher rate can help to ensure that a larger number of potential participants for a study that meet the inclusion criteria are available.

Appendix 4: Regional Health Statistics includes a number of health statistics from across Southeastern North Carolina. A broader regional approach to collecting this data was taken for several reasons. One consideration is that patients may already travel to Wilmington to receive treatment for certain healthcare issues and could easily participate in clinical trials being offered in the focus area. Another reason for including regional health statistics is that New Hanover Regional Medical Center has locations throughout the area. Additionally, doctors who have offices in both Wilmington and the rural counties could identify candidates from those areas, as well.

Some highlights identified in *Appendix 4: Regional Health Statistics* include the large percentages of the population with diabetes living in the region. Of the 12 counties included in this data set, only Onslow and Brunswick counties have diabetes occurrence rates lower than the state average. (Update: 9 counties now have lower diabetes rates than state average, see Appendix 4)

Additionally, a relatively large number of individuals are classified as being obese. 9 of the 12 counties have a higher percentage of individuals who are considered obese (defined as body mass index [BMI] greater than or equal to 30) than the state average. Most notable are the obesity rates in Duplin and Robeson counties where 40% of the population is considered obese. It is important to note that obesity is linked to a range of other health issues, according to the Centers of Disease Control (CDC). These issues include heart disease, stroke, type 2 diabetes, cancers, hypertension, high cholesterol, liver disease, gallbladder disease, sleep apnea, respiratory problems, and osteoarthritis. (Update: only 2 counties are below the state average for obesity, with Robeson County now at 40.5% obese, see Appendix 4). *Note: Data methods/calculation changed as “Health Explorer” data was not available for exact data comparisons; therefore, the CDC and County Health Rankings data were used instead.

Cardiovascular disease is another prominent medical condition in the region. From 2003 to 2007, Columbus, Robeson, Sampson and Scotland counties have had a larger proportion of residents hospitalized for medical conditions related to cardiovascular diseases, when compared to the state average. One of the most striking features related to cardiovascular medical conditions is the 5-year hospitalization rates for strokes in 8 of the 12 counties, which are above the state average. (Update: 10 out of 13 counties are now above the state average for 2011-2013 hospitalization rates due to heart disease, and 10 out of 13 counties are now above the state average for three year 2011-2013 hospitalization rates due to strokes. See Appendix 4). *Note: The “Start with your Heart” task force has not updated this data. Current data was used from CDC for Heart Disease and Stroke Hospitalization rates for 2011-2013.

In general, the region appears to have average incidence rates in terms of the number of cancer cases. However, there are some counties with cancer rates that are above average. For example, Onslow County has a substantially higher rate of individuals with lung cancer. (Update: Onslow County and Scotland County have higher-than-average cancer rates than the state, specifically in Lung Cancer, see Appendix 4)

The region also has a large number of hospitalizations due to septicemia, which may make the area a prime location to test new medical advances aimed at treating the illness. (Update: Sampson has the highest rates of discharge for septicemia from 2011-2013. See Appendix 4.

*Note: This data is based on rate of discharge due to septicemia compared to percentages of hospital stays due to septicemia in previous report). *Update: The “Health Explorer” data was not updated for HIV; therefore, the County Health Rankings data was used to show the HIV prevalence for counties examined. See Appendix 4.

Recommendations

Building Community Cohesion: The North Carolina Coast Clinical Research Initiative (NCCCRI) should continue working with CROs, UNCW, healthcare providers, clinical trial patient recruitment companies, other support companies, and other local business and community leaders to host networking opportunities and educational programs that strengthen the existing local cluster of companies (Current activity includes the *Leadership Networking Series*, the *Lunch-and-Learn Series*, and the *Dinner Talk* events, in addition to other targeted educational events and focus groups). Additionally, the NCCCRI should continue working with companies and education leaders to create educational programs, including internships, which develop the clinical research industry workforce.

Promoting the Local Clinical Research Industry Cluster: The NCCCRI should continue to work with CR companies, economic developers, and others to raise awareness about and promote the local CR industry cluster in the region and beyond. In addition to local promotions, the NCCCRI should develop and implement a large-scale marketing campaign to attract additional talent, companies, and clinical trials to the area, as well as to increase public participation in clinical trials. One component of this strategy is to represent the local CR industry cluster at events, such as the annual BIO International Conference, and to target specific companies for recruitment.

Enhancing the Local Clinical Research Workforce: The NCCCRI should continue partnering with UNCW College of Health and Human Services, UNCW Math and Stats, other UNCW departments, industry leaders, and others to implement the Duke Energy-supported workforce development program for the local clinical research industry. The program will result in a more knowledgeable and better prepared community of clinical research professionals, help local companies retain and attract highly skilled talent, and attract additional companies to the area.

Increasing Local Clinical Trials: The NCCCRI should continue working with healthcare providers, clinical trial patient recruitment companies, and CROs to attract additional clinical trials to the area. When the health data is considered, along with the focus area and number of clinical trials, Wilmington could feasibly support additional clinical trials. *Table 3: Comparison of Clinical Trials by City* illustrates that areas slightly larger than New Hanover County, such as Buncombe County, support many more clinical trials than Wilmington. The number of trials supported by a region is related more to the total number of available investigators than the size of its population. For instance, Asheville/Buncombe County's medical centers include a greater number of physicians involved in research. The age of the population is another factor more important than the total population when considering a region's capacity to host clinical trials.

One potential way to increase the number of clinical trials in the Wilmington area is to establish a greater focus on clinical research at the regional medical center. For example, Mission Hospital in Asheville has established a Research Institute to attract and host clinical trials. Similarly, East Carolina University's Brody School of Medicine in Greenville has established a clinical trials working group. While New Hanover Regional Medical Center (NHRMC), Wilmington's primary hospital facility, does offer clinical trials through the Zimmer Cancer Center in conjunction with the University of North Carolina at Chapel Hill, NHRMC does not appear to offer clinical trials in any other therapeutic areas currently.

The Association of Clinical Research Organizations, says the top 5 therapeutic areas for CRO activity are: oncology, central nervous system, infectious disease, metabolic disorders and cardiovascular disease. Vaccine development is another growing area of research for CROs. More focus on these areas of testing could result in more trials in our area.

Additional clinical trials should be targeted to match the specific medical conditions in the region in which there is higher prevalence, to increase the likelihood of obtaining the optimal number of patients. These medical conditions include the following: diabetes, obesity, alcohol and drug addiction, dermatology, septicemia, heart disease, and stroke. NCCCRI should target doctors who work in those specialty areas to gauge their interest in participating in clinical trials. The data from this report should be used to validate why doctors in those specific fields are being targeted to conduct trials and why ample opportunity exists to increase clinical trial enrollments.

Clinical trials that have inclusion criteria related to requiring participation from patients aged 20-24 or aged 60 and over should also be targeted. As *Tables 5* indicates, New Hanover County has a significantly higher percentage of 20-24 year olds, most likely due to the UNCW location. *Table 6*, displays the advantages Brunswick County offers in terms of being able to produce clinical trial candidates over the age of 60. An additional benefit of the region is that the racial and ethnic composition mirrors the United States. Patient recruitment companies, such as PMG Research and Trial Management Associates, should be directly involved with attracting additional studies and recruiting additional physicians to participate in the trials, as well. (Update: NC has a higher percentage of Blacks and a lower percentage of Whites, Hispanics and Asians compared to the US composition, see Table 7).

Conclusion

The Southeastern Region is home to a strong and growing cluster of companies working in and supporting the clinical research industry with a full range of services, as well as educational support from UNCW and promotional support from local economic development leaders. The increased number of CROs and support companies adds to the importance of the industry's impact on our local economy. An anticipated increase in residents and a diverse, maturing clinical research industry locally can result in further increases in talent attraction and companies choosing to join the clinical research community in southeastern North Carolina.

Despite this world-class clinical research cluster, the Wilmington area lags in the number of clinical trials being conducted locally. This report has outlined several strategies to increase the number of clinical trials conducted in the southeastern region, including targeting trials that focus on specific health issues that are prevalent in the greater Wilmington area. The NCCCRI should continue its work to increase the awareness and number of clinical trials in the area, to host events that connect the members of the clinical research community, and to work with key partners in a variety of other ways to strengthen the impressive clinical research cluster in the southeastern region.

Data Sources and Methodology

Data used in this report were gathered from variety of sources, including governmental and educational institutions, companies, and social media. Information related to the number and types of clinical trials being conducted in the area was gathered from ClinicalTrials.gov. Data regarding the medical practices engaged in clinical trials and the trials being conducted at each practice were compiled from CenterWatch.com and ClinicalTrials.gov. The Cecil G. Sheps Center for Health Services Research, supported by UNC – Chapel Hill, served as the source for the number of health professionals, hospital beds, and discharges. Demographic information was acquired from the 5-Year American Community Survey, conducted by the US Census Bureau, and the NC Office of State Budget and Management. Information and statistics related to the number and types of companies and employment in the area was gathered from a variety of sources, including LinkedIn and similar sources, through surveys of each company’s website, and direct communication with companies, including human resource departments.

Report Rationale

In many cases the *North American Industry Classification System* (NAICS) can be used to estimate the impact a particular industry has on a local economy. However, the local clinical research cluster is multi-disciplinary, and NAICS codes do not accurately capture the industry cluster’s impact locally. The most commonly used *NAICS code for clinical research* is 541711 - research and development in biotechnology. While NAICS 541711 captures many employees of the clinical research industry, it does not include important components such as health services, biostatistics, and patient recruitment. NAICS codes also exclude personnel who work locally for a company that is headquartered outside of the Wilmington area. The purpose of this Report is to examine local employment data in a deeper, more comprehensive way to provide a more accurate illustration of the local industry cluster, in a way that NAICS codes do not allow.

Average Salary Calculation

In 2012, the US Bureau of Labor Statistics Quarterly Census of Employment and Wages estimated 1,895 individuals in the Wilmington area were classified as NAICS 541711 employees and combined to earn an average salary of \$82,578. This salary average is specific to the CRO industry and has not been updated as of the 2016 report. There is data available at a more general level but would not be an accurate portrayal of the current local CRO industry here in Wilmington, so it was not included.

Acknowledgement

Thank you to Kate Mullis and Emmit Owens for their significant contributions to the creation and update of this report. Thanks, also, to Julie Orr (Modoc), Jim Blum (UNCW), Jared Kerr (UNCW), Jim Lyon (UNCW), Chris Matheus (Lexitas), and Susan Sinclair (UNCW) for reviewing and contributing to this update.

Appendix 1: Medical Groups Engaged in Clinical Research

Medical Practice Name	Address	City	State	Zip Code	Phone Number
New Hanover Regional Medical Center - Zimmer Cancer Center	2131 S. 17th St.	Wilmington	NC	28403	(910) 343-7000
New Hanover Regional Medical Center - Betty Cameron Women & Children's Hospital	2131 S. 17th St.	Wilmington	NC	28403	(910) 343-7000
Wilmington Gastroenterology Associates	5115 Oleander Dr.	Wilmington	NC	28403	(910) 362-1011
Coastal Carolina Neonatology	2212 S. 17th St.	Wilmington	NC	28401	(910)667-2970
Coastal Carolina Radiation Oncology	1988 S. 16th St.	Wilmington	NC	28401	(910) 251-1839
Carolina Arthritis Associates	1710 S. 17th St.	Wilmington	NC	28401	(910) 762-1182
UNC Wilmington, Department of Psychology	600 S. College Rd.	Wilmington	NC	28403	(910) 962-3000
Dermatology Associates, P.A.	6781 Parker Farm Road, Suite 300	Wilmington	NC	28405	(910) 763-1555
Coastal Urology, PLLC	1099 Medical Center Dr., Ste 101	Wilmington	NC	28401	(910) 254-9995
Coastal Surgery Specialists	1411 Physicians Dr.	Wilmington	NC	28401	(910) 343-0811
INC Research (call centers)	1011 Ashes Dr.	Wilmington	NC	28405	(910) 341-3300
Trial Management Associates	1302 Medical Center Dr.	Wilmington	NC	28401	(910) 338-1555
Wilmington Dermatology Center	710 Military Cutoff Rd. #320	Wilmington	NC	28403	(910) 256-4350
PMG Research	1907 Tradd Ct.	Wilmington	NC	28401	(910) 799-5500
Cape Fear Cancer Specialist	1520 Physicians Dr.	Wilmington	NC	28401	(910) 343-0447
PPD, INC	929 North Front Street	Wilmington	NC	28401	(910) 251-0081
Derm One	1099 Medical Center Dr.	Wilmington	NC	28401	(910) 251-9944
Cape Fear Retina	1104 Medical Center Dr.	Wilmington	NC	28401	(910) 332-3560
Antiretroviral Pregnancy Registry	1011 Ashes Dr.	Wilmington	NC	28405	(800) 258-4263
South East Area Health Education Center (SEAHEC)	2507 Delaney Ave.	Wilmington	NC	28403	(910) 772-9202
INC Research	1011 Ashes Dr.	Wilmington	NC	28405	(910) 509-4700

Note: Registries were not included unless local address was listed. Source: CenterWatch and ClinicalTrials.gov

Appendix 2: Medical Practices and Other Groups Associated with Specific Clinical Trials

Specific Study	Focus	Phases	Medical Practice
Effects of Abatacept in Patients With Early Rheumatoid Arthritis	Rheumatoid Arthritis	Phase 3	Carolina Arthritis Associates
A Long Term Study To Evaluate The Safety And Tolerability Of CP-690,550 For Patients With Moderate To Severe Chronic Plaque Psoriasis	Psoriasis	Phase 3	Dermatology Associates
Simulines Non-Inferiority Pivotal Study	Skin Laxity	N/A	Wilmington Dermatology Center
Mesalamine 4 g Sachet for the Induction of Remission in Active, Mild to Moderate Ulcerative Colitis (UC)	Ulcerative Colitis	Phase 3	Wilmington Gastroenterology Associates
A 26-week Extension of the ZRHR-ERS-09-US Study Evaluating Biological and Functional Changes in Healthy Smokers After Switching to THS 2.2	Smoking	N/A	PMG Research of Wilmington, LLC
"Six-week Study of the Safety and Efficacy of JZP-110 in the Treatment of Excessive Sleepiness in OSA"	Obstructive Sleep Apnea	Phase 3	PMG Research of Wilmington, LLC
A Study of Arformoterol Tartrate Inhalation Solution and Tiotropium Bromide on Re-hospitalization in Chronic Obstructive Pulmonary Disease (COPD) Subjects	Chronic Obstructive Pulmonary Disease (COPD)	Phase 4	PMG Research of Wilmington, LLC
A Study of LY3337641 in Moderate to Severe Rheumatoid Arthritis	Rheumatoid Arthritis	Phase 2	PMG Research of Wilmington, LLC
A Study of Dulaglutide (LY2189265) in Participants With Type 2 Diabetes Mellitus	Type 2 Diabetes Mellitus	Phase 3	PMG Research of Wilmington, LLC
Dose-Ranging Study to Evaluate the Glycemic Effects, Safety, and Tolerability of Metformin Delayed Release in Subjects With T2DM	Type 2 Diabetes Mellitus	Phase 2	PMG Research of Wilmington, LLC
The Evaluation of Bococizumab (PF-04950615; RN316) in Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects	Cardiovascular Disease	Phase 3	PMG Research of Wilmington, LLC
Randomized Clinical Trial of Bococizumab (PF-04950615; RN316) in Subjects With Hyperlipidemia or Mixed Dyslipidemia at Risk of Cardiovascular Events	Hyperlipidemia	Phase 3	PMG Research of Wilmington, LLC

A Prospective, Randomized, Double-Blind Multicenter Study Comparing Continuous Diffusion of Oxygen (CDO) Therapy to Standard Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Ulcers	Diabetic Foot Ulcer	N/A	PMG Research of Wilmington, LLC
Smoking Cessation Study In Healthy Adolescent Smokers	Smoking Cessation	Phase 4	PMG Research of Wilmington, LLC
An Evaluation of Neurofeedback Efficacy in Adults With ADHD	ADHD	N/A	Department of Psychology, UNC Wilmington
S1505: Combination Chemotherapy or Gemcitabine Hydrochloride and Paclitaxel Albumin-Stabilized Nanoparticle Formulation Before Surgery in Treating Patients With Pancreatic Cancer That Can Be Removed by Surgery	Pancreatic Adenocarcinoma, Resectable Pancreatic Cancer	Phase 2	Cape Fear Cancer Specialists, New Hanover Regional Medical Center/Zimmer Cancer Center
Standard Versus Intensity-Modulated Pelvic Radiation Therapy in Treating Patients With Endometrial or Cervical Cancer	Cervical Cancer, Endometrial Cancer	Phase 3	Coastal Carolina Radiation Oncology, New Hanover Regional Medical Center
Cosmetic Evaluation of Lumpectomy Versus Oncolytic Mammoplasty With Bilateral Breast Reduction for Early Stage Breast Cancer	Breast Carcinoma	N/A	Coastal Carolina Radiation Oncology, Zimmer Cancer Center
Tamoxifen Citrate, Letrozole, Anastrozole, or Exemestane With or Without Chemotherapy in Treating Patients With Invasive RxPONDER Breast Cancer	Breast Cancer	Phase 3	Cape Fear Cancer Specialists, New Hanover Regional Medical Center/Zimmer Cancer Center
Long Term Safety Study of Plecanatide	Irritable Bowel Syndrome	Phase 3	Synergy Pharmaceuticals Inc.
Tradipitant in Treatment-resistant Pruritus Associated With Atopic Dermatitis	Atopic Dermatitis, Eczema, Chronic Pruritus	Phase 2	Wilmington Dermatology Center
A Long-term Active Treatment Study of Mongersen (GED-0301) in Subjects With Crohn's Disease	Crohn's Disease	Phase 3	Trial Management Associates LLC
Safety of 4CMenB Exposure During Pregnancy	Pregnancy Outcome	N/A	PPD, Inc.
Efficacy and Safety Study of Mongersen (GED-0301) for the Treatment of Subjects With Active Crohn's Disease	Crohn's Disease	Phase 3	Trial Management Associates LLC

ELUVIA [®] , [®] Drug-eluting Stent Versus Zilver [®] PTX [®] Stent	Atherosclerosis of Native Arteries of the Extremities	Phase 3	Coastal Surgery Specialists, David Weatherford, MD
Evaluate the Effect of ALLN-177 in Reducing Urinary Oxalate in Patients With Secondary Hyperoxaluria and Kidney Stones Over 28 Days	Secondary Hyperoxaluria, Nephrolithiasis, Kidney Stones, Hyperoxaluria, Dietary Hyperoxaluria	Phase 2	Coastal Urology, Victor Abraham, MD
Safety of Furosemide in Premature Infants at Risk of Bronchopulmonary Dysplasia (BPD)	Bronchopulmonary Dysplasia	Phase 2	New Hanover Regional Medical Center, Fernando Moya, MD
Mesalamine 2 g Sachet for the Maintenance of Clinical and Endoscopic Remission in Ulcerative Colitis (UC)	Ulcerative Colitis	Phase 3	Trial Management Associates, LLC
Safety and Efficacy Study of the Draeger Babylog VN500 Device in HFOV Mode in VLBW Neonates	Respiratory Distress Syndrome In Premature Infants	N/A	New Hanover Regional Medical Center, Fernando Moya, MD
PROMComplete for Determination of Rupture of Fetal Membranes	Fetal Membranes, Premature Rupture	N/A	New Hanover Regional Med Center
A Randomized, Double-blind, Study to Explore the Effect of GED-0301 in Subjects With Active Crohn's Disease	Crohn's Disease	Phase 1	The Management Associates
Memantine Hydrochloride and Whole-Brain Radiotherapy With or Without Hippocampal Avoidance in Reducing Neurocognitive Decline in Patients With Brain Metastases	Cognitive Impairment, Metastatic Malignant Neoplasm in the Brain, Solid Neoplasm	Phase 3	Coastal Carolina Radiation Oncology
A Prospective Longitudinal Breast Cancer Study	Breast Cancer		New Hanover Regional Medical Center, Kenneth Kotz, MD
Flucelvax Pregnancy Registry	Pregnant Women, Influenza	N/A	PPD, Inc.
Longitudinal Pancreatic Cancer Study	Pancreatic Cancer	N/A	New Hanover Regional Medical Center, John Anagnost, MD
Meningococcal Quadrivalent CRM-197 Conjugate Vaccine Pregnancy Registry	Pregnancy, Meningococcal Disease	N/A	PPD, Inc.

Long Term Safety and Efficacy Study of Calcitriol 3 mcg/g Ointment in Pediatric Subjects With Plaque Psoriasis	Psoriasis Vulgaris	Phase 4	DermOne of North Carolina
Oropharyngeal Administration of Mother's Colostrum for Premature Infants	Infection, Enterocolitis, Necrotizing, Ventilator-associated Pneumonia	N/A	Betty Cameron Women & Children's Hospital, Fernando Moya, MD
Safety Study Of Tofacitinib Versus Tumor Necrosis Factor (TNF) Inhibitor In Subjects With Rheumatoid Arthritis	Arthritis, Rheumatoid	Phase 4	Carolina Arthritis Associates
Ocriplasmin Research to Better Inform Treatment (ORBIT)	Symptomatic Vitreomacular Adhesion		Cape Fear Retina, Leon Charkoudian, MD
Antibiotic Safety (SCAMP)	Complicated Intra-abdominal Infections	Phase 2, Phase 3	New Hanover Regional Medical Center, Fernando Moya, MD
Efficacy and Safety of Alpha1-Proteinase Inhibitor (Human), Modified Process (Alpha-1 MP) in Subjects With Pulmonary Emphysema Due to Alpha1 Antitrypsin Deficiency (AATD)	Pulmonary Emphysema in Alpha-1 PI Deficiency	Phase 3	PMG Research, Mitchell D Lee, MD
Standard or Comprehensive Radiation Therapy in Treating Patients With Early-Stage Breast Cancer Previously Treated With Chemotherapy and Surgery	Stage IB Breast Cancer, Stage II Breast Cancer	Phase 3	Coastal Carolina Radiation Oncology
A Prospective, Observational Study of Pregnancy Outcomes Among Women Exposed to Truvada for PrEP Indication	HIV Infection		Antiretroviral Pregnancy Registry
Prospective Trial Comparing Two Different Polypropylene Meshes for Inguinal Hernias	Hernia, Inguinal	N/A	New Hanover Regional Medical Center, William W Hope, MD
A Trial to Reduce Adhesions Following a Primary Cesarean Section	Tissue Adhesions	N/A	New Hanover Regional Medical Center, Henry A Easley, MD
HCV-TARGET- Hepatitis C Therapeutic Registry and Research Network	Hepatitis C	N/A	Trial Management Associates (TMA)
Observational Study of the Use of KRYSTEXXA® in Refractory Chronic Gout	Chronic Gout	N/A	Carolina Arthritis Associates, PA
Cisplatin and Radiation Therapy With or Without Carboplatin and Paclitaxel in Patients With Locally Advanced Cervical Cancer	Cancer	Phase 3	New Hanover Regional Medical Center/Zimmer Cancer Center

Androgen-Deprivation Therapy and Radiation Therapy in Treating Patients With Prostate Cancer	Prostate Cancer	Phase 3	Coastal Carolina Radiation Oncology Center
Early Surgery or Standard Palliative Therapy in Treating Patients With Stage IV Breast Cancer	Breast Cancer	Phase 3	New Hanover Regional Medical Center/Zimmer Cancer Center, Cyrus A. Kotwall, MD
Oxaliplatin, Leucovorin Calcium, and Fluorouracil With or Without Celecoxib in Treating Patients With Stage III Colon Cancer Previously Treated With Surgery	Colorectal Cancer	Phase 3	New Hanover Regional Medical Center, Cyrus A. Kotwall, MD
The Savella Pregnancy Registry	Fibromyalgia	N/A	INC Research
Diet and Physical Activity Change or Usual Care in Improving Progression-Free Survival in Patients With Previously Treated Stage II, III, or IV Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Cancer	Phase 3	New Hanover Regional Medical Center/Zimmer Cancer Center
International Hernia Mesh Registry	Hernia		South East Area Health Education Center (SEAHEC)
Ribavirin Pregnancy Registry	Birth Defects, Pregnancy Complications, Hepatitis C	Phase 4	INC Research, LLC
An Efficacy And Safety Study Evaluating Tofacitinib With And Without Methotrexate Compared To Adalimumab With Methotrexate	Rheumatoid Arthritis	Phase 4	PMG Research of Wilmington, LLC

Source: ClinicalTrials.gov and CenterWatch

Appendix 3: Health Professional Data for Selected NC Counties

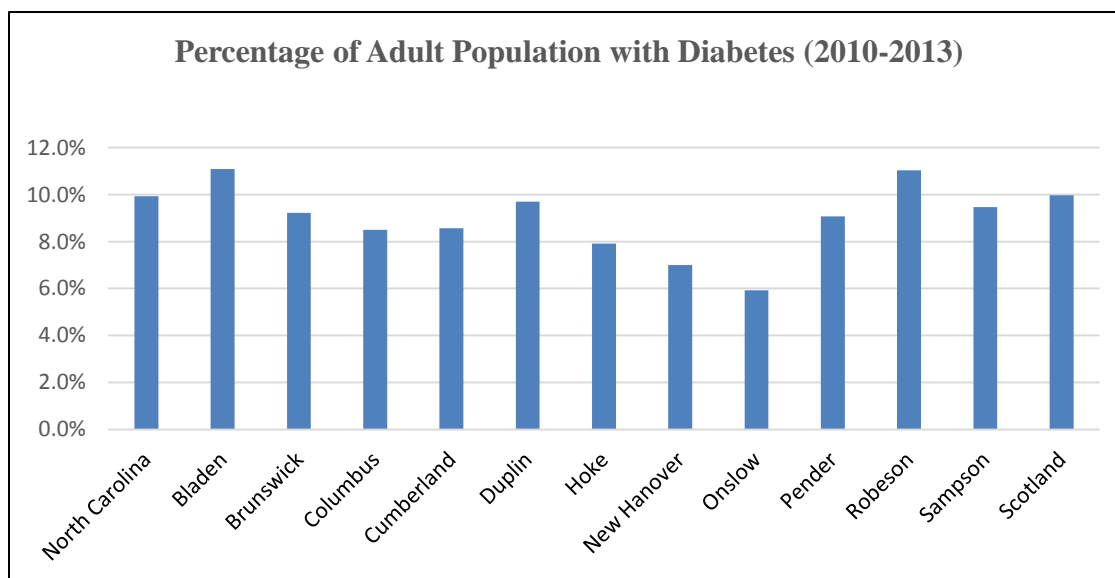
Appendix 3: Health Professional Data for Selected NC Counties* 2013	New Hanover County	Durham County	Orange County	Forsyth County	Mecklenburg County	Wake County	Buncombe County	Guilford County	Pitt County	Cabarrus County	Cumberland County
Number of Clinical Trials	115	881	553	547	533	226	171	134	120	44	28
Largest Cities	Wilmington	Durham	Chapel Hill	Winston-Salem	Charlotte	Raleigh	Asheville	Greensboro	Greenville	Concord	Fayetteville
2013 County Populations	213,809	286,053	139,694	360,471	991,867	964,616	248,872	507,419	173,879	186,457	332,553
Primary Care Physicians	255	525	348	533	1,033	900	362	473	257	185	247
<i>Family Practice*</i>	50	65	65	103	201	203	122	114	52	47	59
<i>General Practice*</i>	4	5	6	7	7	16	6	3	3	-	6
<i>Internal Medicine*</i>	59	156	86	158	297	217	69	126	66	41	50
<i>Obstetrics/Gyn*</i>	27	34	27	37	108	87	31	49	23	15	28
<i>Pediatrics*</i>	41	124	83	96	215	221	42	92	53	36	49
Other Specialties	435	1,606	1,125	1,276	1,850	1,394	586	753	551	244	336
Total Non Federal Physicians	690	2,131	1,473	1,809	2,883	2,294	948	1,226	808	429	583
Federal Physicians	11	159	10	31	28	17	85	3	16	1	197
Physicians per 10,000 Population	32.3	74.5	105.4	50.2	29.1	23.8	38.1	24.2	46.5	23.0	17.5
<i>Number of Physicians: State Rank (1=most physicians) 2011 Rank</i>	6	2	1	3	8	13	5	12	4	16	28
<i>Rank in 2011</i>	6	2	8	1	3	13	12	5	4	32	6

Primary Care Physicians per 10,000 Population	11.9	18.4	24.9	14.8	10.4	9.3	14.5	9.3	14.8	9.9	7.4
<i>Number of Primary Care Physicians: State Rank (1=most physicians)</i>	7	2	1	3	11	17	5	18	4	12	38
<i>Rank in 2011</i>	9	2	12	1	5	18	19	7	3	49	9
Pharmacists	280	738	341	582	1,138	1,272	377	499	235	197	285
Registered Nurses	3,095	6,851	3,659	6,935	11,493	10,363	4,473	6,052	3,762	1,914	3,008
Nurse Practitioners	141	409	220	313	527	514	203	265	161	76	123
General Hospital Beds	813	1,434	724	1,878	2,215	1,445	730	1,476	731	457	594
Hospital Discharges	20,763	24,266	9,196	40,817	78,850	69,145	23,281	50,713	18,238	17,816	32,041

Note: Chart sorted by number of clinical trials. Source: US Census, ClinicalTrials.gov, and Cecil G. Sheps Center for Health Services Research

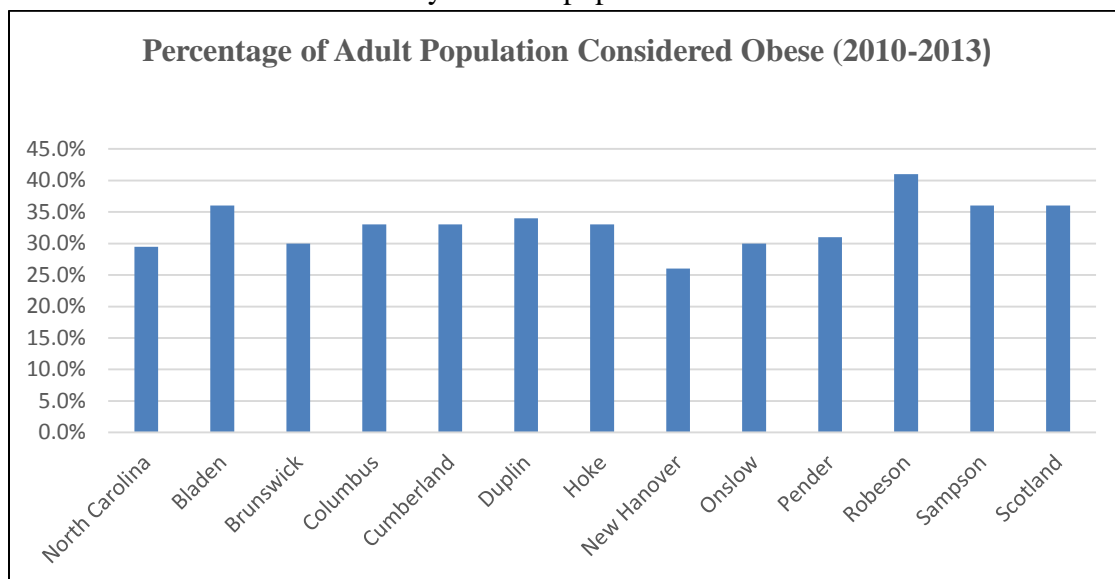
Appendix 4: Regional Health Statistics

The health data used in this appendix was gathered from a variety of sources listed below each chart. Additionally, a short explanation of the data is provided beneath each chart.



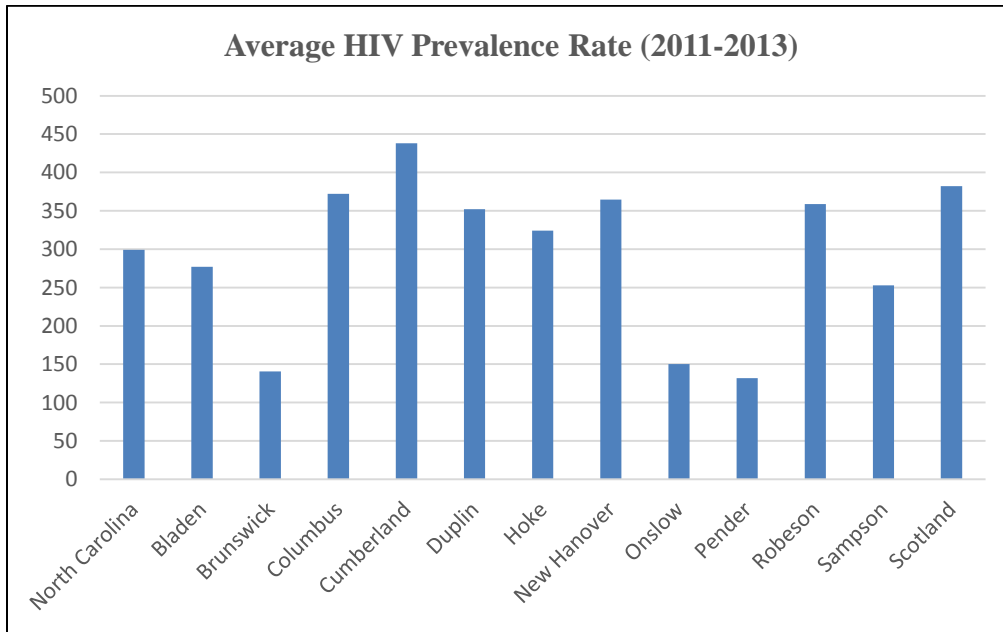
Source: US Census, Centers for Disease Control

The percentage of the adult population with diabetes is calculated by dividing the estimated number of adults with diabetes by the total population.

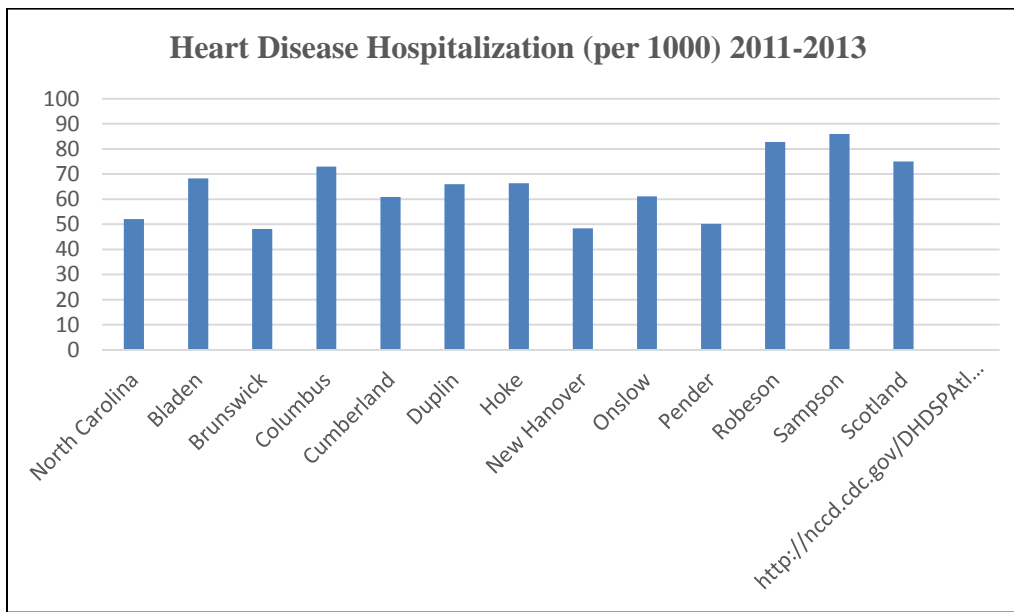


Note: Defined as BMI greater than or equal to 30. Source: County Health Rankings, CDC

The percentage of the adult population considered obese is calculated by dividing the estimated number of adults considered obese by the total population.

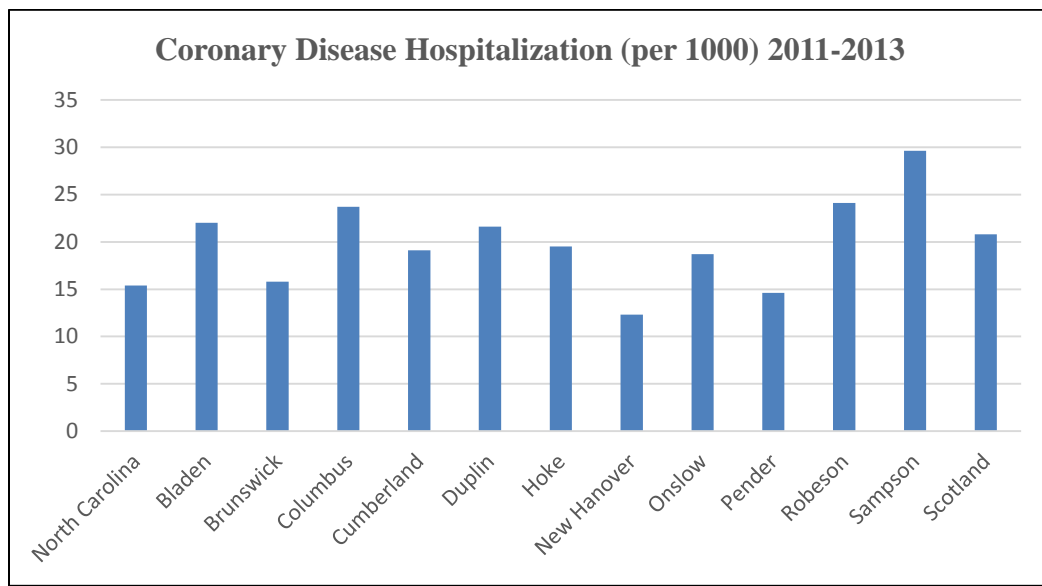


Source: County Health Rankings



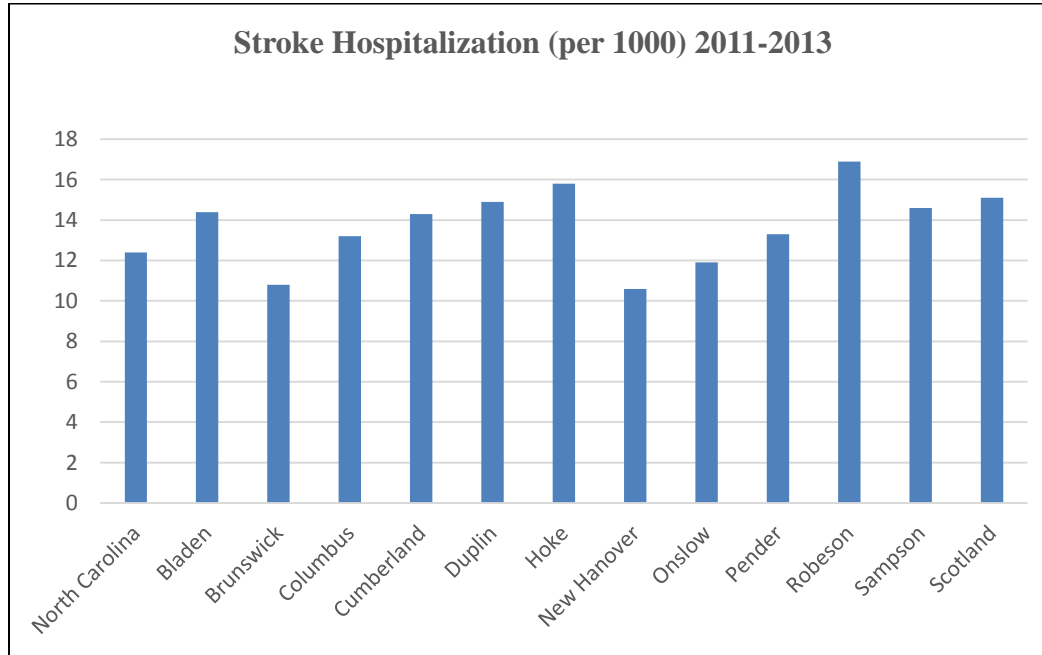
Source: CDC

Heart disease is limited to diseases of the heart.



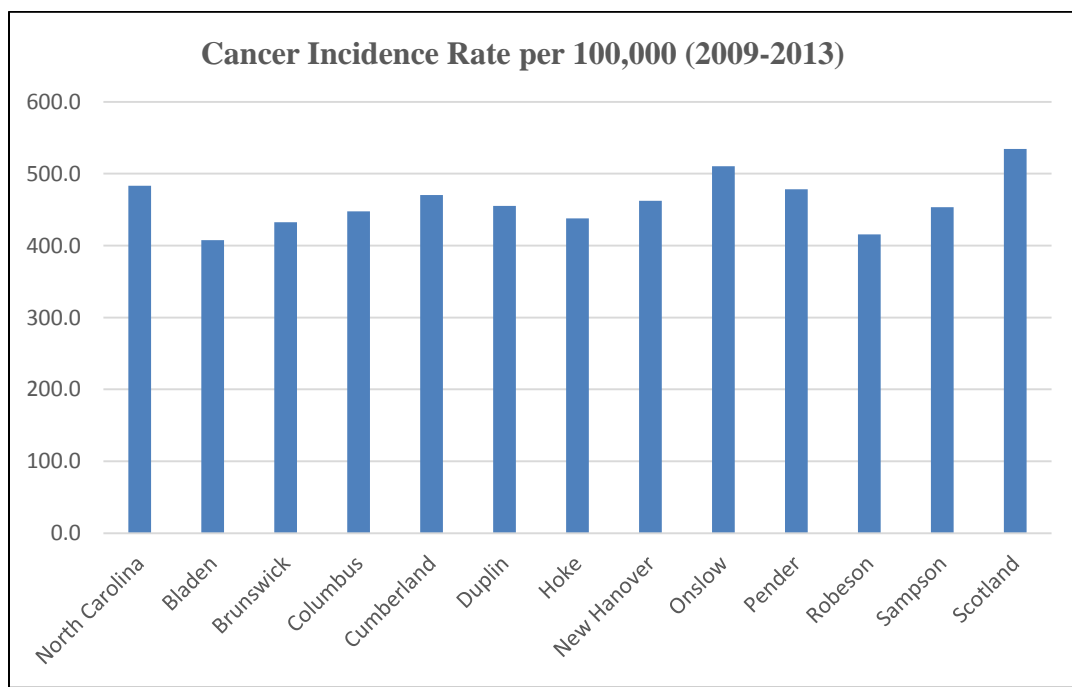
Source: CDC

Coronary heart disease is due to the narrowing of blood vessels that supply blood to the heart.



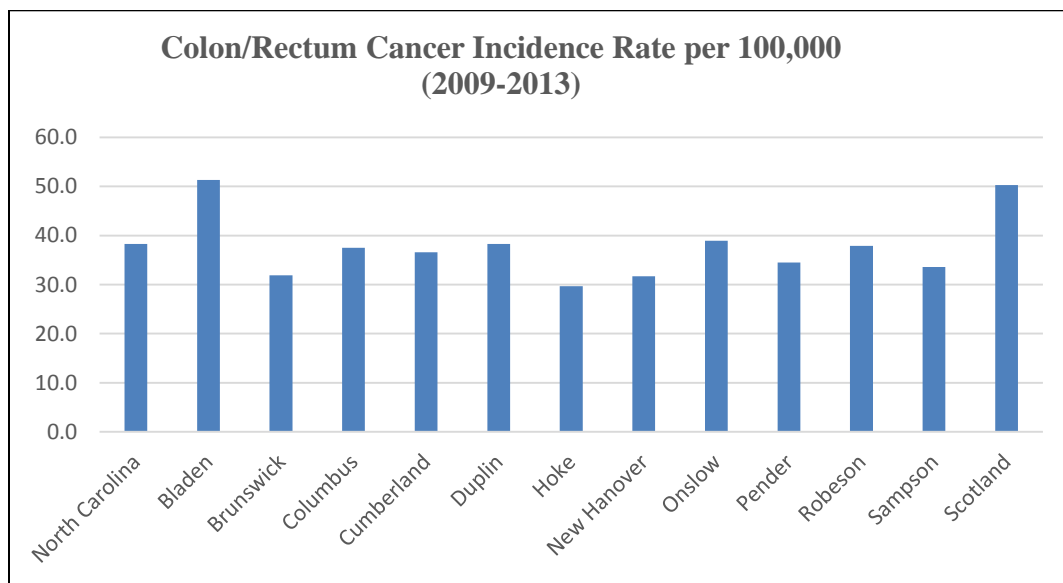
Source: CDC

Stroke is the sudden loss of consciousness due to a rupture or occlusion of blood vessels that lead to the brain.



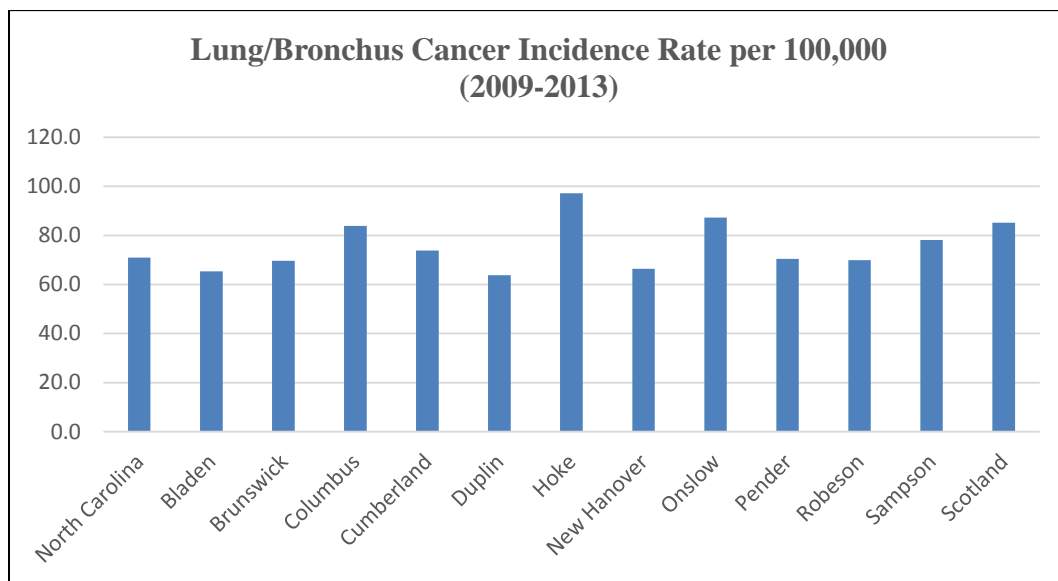
Source: North Carolina State Center for Health Statistics

The cancer incident rate includes each case of cancer regardless of site. The cases are aggregated and calculated on a per 100,000 person basis.



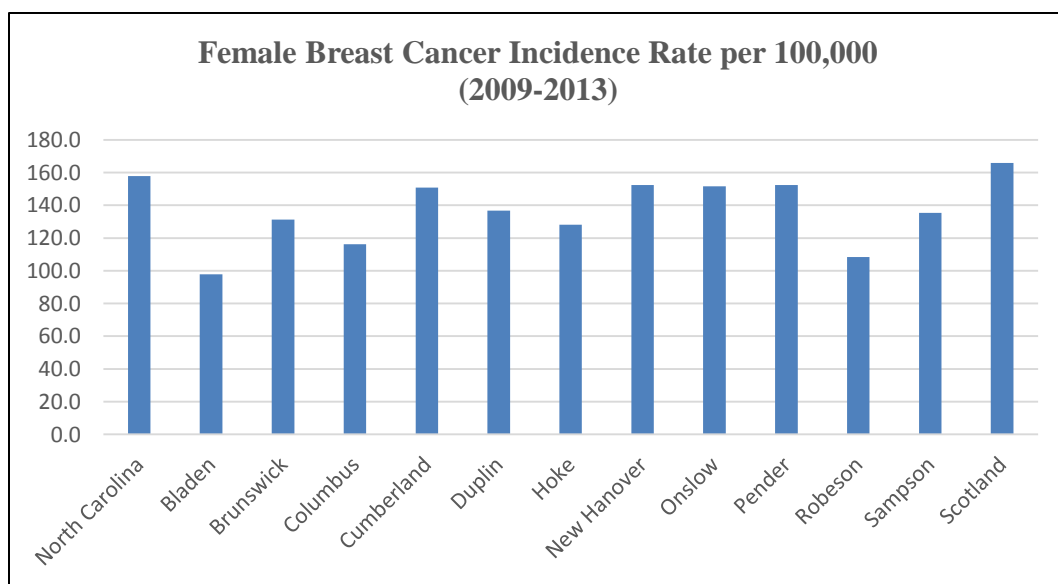
Source: North Carolina State Center for Health Statistics

The colon/rectum cancer incidence rate is limited to cancers located in the colon and rectum. The cases are aggregated and calculated on a per 100,000 person basis.



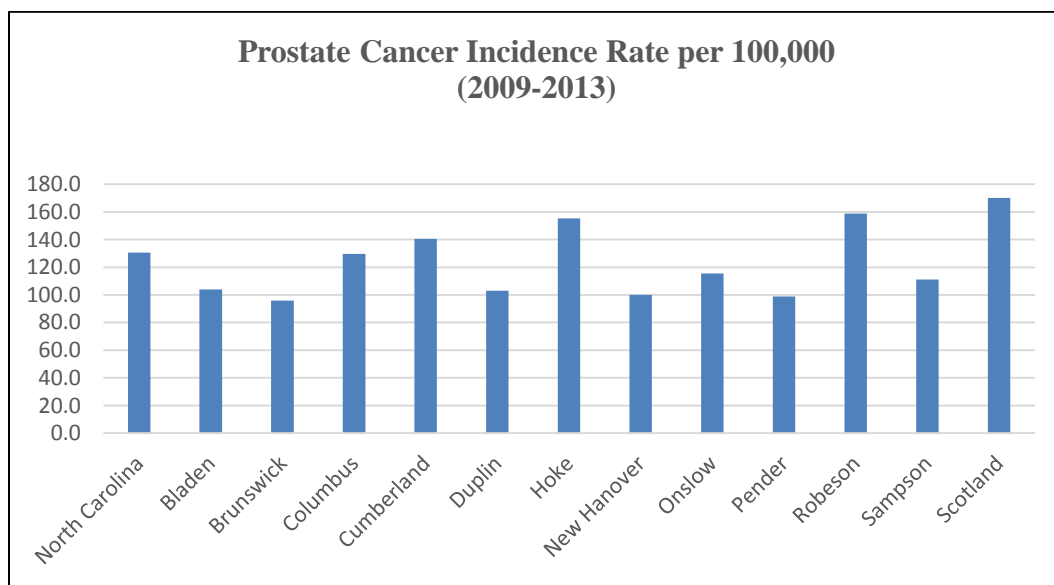
Source: North Carolina State Center for Health Statistics

The lung/bronchus cancer incidence rate is limited to cancers located in the lungs and bronchi. The cases are aggregated and calculated on a per 100,000 person basis.



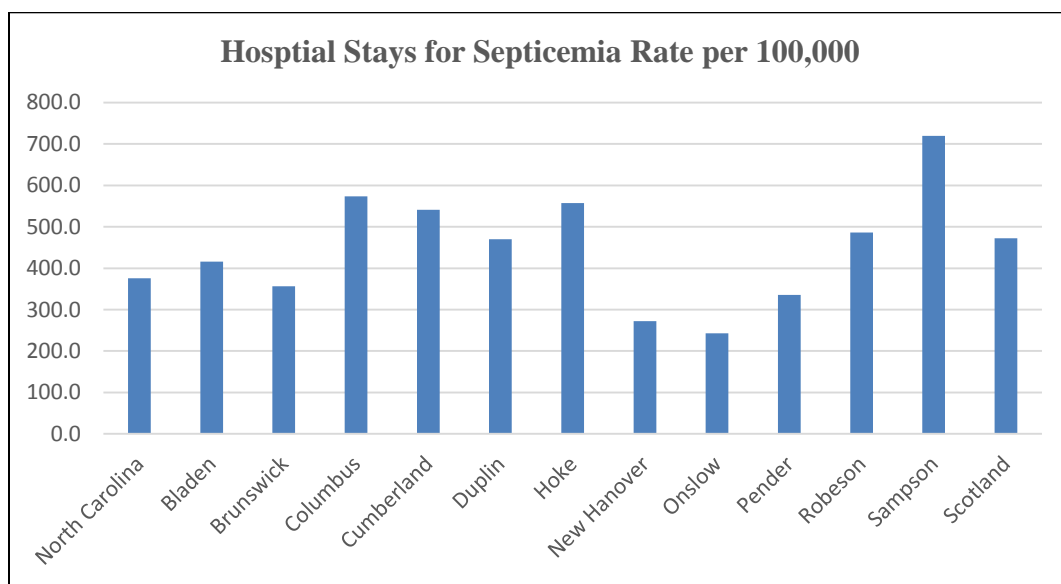
Source: North Carolina State Center for Health Statistics

The female breast cancer incidence rate is limited to cancers located in female breast. The cases are aggregated and calculated on a per 100,000 person basis.



Source: North Carolina State Center for Health Statistics

The prostate cancer incidence rate is limited to cancers located in prostate. The cases are aggregated and calculated on a per 100,000 person basis.



Source: Department of Health and Human Services

Appendix 5: CRO Contact Information

Alcami

www.alcaminow.com
(910) 254-7000 Fax: (910) 815-2300
2320 Scientific Park Drive
Wilmington, NC 28405-1800

Alcami offers individualized pharmaceutical development and manufacturing services that can be integrated for a less fragmented and faster pathway for products.

Blitz Research

www.blitzresearch.com
(910) 332-4000
5512 Business Drive
Wilmington, NC 28405

Blitz Research offers a wide range of services including pharmacovigilance, patient recruitment, and market analysis.

Catalent

www.catalent.com
(919) 481-4855 Fax: (919) 481-4908
P.O. Box 13341
Research Triangle Park, NC 27709

Catalent is a full-service CRO focusing in the development, delivery and supply of pharmaceuticals.

Chiltern International

www.chiltern.com
(910) 338-4760 Fax: (910) 799-1467
2528 Independence Blvd., Suite 101
Wilmington, NC 28412

Chiltern is a leading, full service, global Contract Research Organization with extensive experience in the management of Phase I-IV clinical trials across a broad range of therapeutic areas and contract staffing solutions.

Clinipace Worldwide Inc.

www.clinipace.com
(919) 224-8800 Fax: (919) 321-2322
3800 Paramount Pkwy, Suite 100
Morrisville, NC 27560

Clinipace is a clinical research software company that provides a single, integrated data capture and study management platform for post-approval research and registries.

Covance

www.covance.com
(888) 268-2623 Fax: +86 10 6569 4119
210 Carnegie Center
Princeton, NJ 08540

Covance provides comprehensive drug development services with focuses in nonclinical development, clinical development, and periapproval and market access.



The EMMES Corporation

www.emmes.com

301-251-1161

401 N. Washington St., Suite 700

Rockville, MD 20850

EMMES offers services as a professional partner to clinicians, scientists, and program leaders. EMMES provides the full range of Contract Research Organization expertise necessary to conduct clinical research with a firm scientific basis that is fully compliant with national and international regulatory guidelines.

Global Pharma Tek

www.globalpharmatek.com

(732) 543-7155

15 Corporate Pl S #345

Piscataway Township, NJ 08854

Global Pharma Tek is a fast-growing premier global pharmaceutical company that provides end-to-end services in pharmaceutical industry round the globe.

Health Decisions

www.healthdec.com

(919) 967-2399

2510 Meridian Pkwy

Durham, NC 27713

Health Decisions is a full-service specialty CRO and more – that is why we are a CRO+. We are the clinical development partner of choice for forward-looking biopharma, diagnostics, precision medicine and medical device companies worldwide.

ICON Clinical Research

www.iconclinical.com

(919) 294-2200 Fax: (919) 294-2360

79 TW Alexander Drive, 4501 Research

Commons, Suite 300

Durham, NC 27709

ICON provides drug development and clinical services, from compound selection to Phase I-IV clinical studies, in areas including oncology, cardiovascular and biosimilars.

INC Research (Wilmington)

www.incresearch.com

(910) 509-4700 Fax: (910) 509-4701

1011 Ashes Drive

Wilmington, NC 28405

INC Research specializes in providing clinical trials services to support global Phase I - Phase IV studies, and we offer deep therapeutic clinical trial expertise across a wide variety of indications, as well as for special populations, such as women and pediatrics.

Intrafusion

www.intrafusion.com

(713) 861-7676

1920 N Memorial Way

Houston, TX 77007

intraFUSION has since built on our success with infusion therapy management and now provides clinical research management through clinical trials and drug studies as well complete revenue cycle management through practice billing.



intraFUSION is actively involved in clinical trials management for a multitude of practices and several different studies.

inVentiv Health

www.inventivhealth.com
800-416-0555
1 Van de Graaff Drive
Burlington, MA 01803

InVentiv offers a full suite of services that support Phase I (first-in-human) through Phase IV (post-launch) clinical trials.

Jubilant Clinsys

www.clinsys.com
(919) 518-8888 Fax: (919) 848-8461
8540 Colonnade Center Drive, Suite 407
Raleigh, NC 27615

Jubilant Clinsys is a scientifically focused contract research organization that provides pharmaceutical, biotechnology and medical device companies with a full range of services in support of Phase I – IV drug and device development

Lexitas Pharma

www.lexitaspharma.com
(919) 205-0012
313 Foster St.
Durham, NC 27701

Lexitas provides clinical trial services and advice to pharma and biotech companies in the ophthalmology therapeutic area

Medpace

www.medpace.com
1.800.730.5779
5375 Medpace Way
Cincinnati, Ohio 45227

A global leader in research-based drug and medical device development, Medpace builds strong strategic partnerships with select Sponsors to advance the most efficient and cost-effective path to approval

Metrics Research

hwww.mrcro.com
(+92-21) 35880781-2
Plot # 23-C, 3rd Floor, Old Sunset
Boulevard, DHA, Phase I
Karachi, Pakistan 75500

Metrics Research (Pvt.) Ltd. (MR) is Pakistan's pioneer and leading Contract Research and Site Management Organization (CRO & SMO). MR offers comprehensive clinical research and site management related services for pharmaceutical and biotechnology companies, device manufacturers, global CROs and research institutions worldwide.

Modoc

www.modocresearch.com
(910) 777-2671 Fax: (910) 777-2676
1410 Commonwealth Dr, Ste 201
Wilmington, NC 28403

Modoc works with biotechnology and pharmaceutical companies to develop and conduct Proof of concept (POC) and Phase I-II clinical trials. They offer a full range of



clinical operational support and medical writing services.

Novella Clinical—a Quintiles Company (Wilmington)

www.novellaclinical.com
(910) 791-8438 Fax: (910) 791-8317
1985 Eastwood Road, Suite 100
Wilmington, NC 28403

Novella Clinical is a full service clinical research organization dedicated to clients in the oncology, medical device and biopharmaceutical industries.

OrphanReach

www.orphan-reach.com
856 952-5999
Audubon, New Jersey 08106

OrphanReach is the first of its kind Global Service Alliance dedicated to Orphan and Rare Disease Drug Development offering the full spectrum of clinical development services.

PAREXEL International Corp.

www.parexel.com
(919) 544-3170 Fax: (919) 544-3410
2520 Meridian Parkway, Suite 200
Durham, NC 27713

Parexel provides drug-development and launch services, including clinical development, integrated advanced technologies, regulatory affairs consulting and commercialization services.

Pharm-Olam International

www.pharm-olam.com
(919) 237-4300 Fax: (919) 237-4301
P.O. Box 14089

Research Triangle Park, NC 27709
Pharm-Olam provides Phase I-IV clinical research services with focuses on data services and pharmacovigilance.

PharPoint Research (Wilmington)

www.pharpoint.com
(910) 790-0482 Fax: (866) 589-4865
1985 Eastwood Road, Suite 100

Wilmington, NC 28403
PharPoint Research provides contract clinical management, programming, and biostatistics consulting and operational services. The company's biostatistics practice is based in its Wilmington office

PPD

www.ppdi.com
(910) 251-0081 Fax: (910) 762-5820
929 N. Front St.
Wilmington, NC 28401

PPD, a global contract research organization, provides drug discovery, development and lifecycle management services to pharmaceutical, biotechnology, medical device, academic and government organizations.

PRA Health Sciences International

www.prahs.com

(919) 786-8200 Fax: (919) 786-8201

4130 Park Lake Ave., Suite 400

Raleigh, NC 27612

PRA International, a global CRO, provides services across all phases of pharmaceutical and biotech drug development by combining therapeutic and operational expertise with local knowledge.

Premier Research

www.premier-research.com

919 627 9100

One Park Drive, STE 150

Box 13608

Research Triangle Park, NC 27709

Premier Research is a global contract research organization (CRO) serving biotech, pharmaceutical, and medical device corporations. Its services include clinical research and regulatory outsourcing in the areas of analgesia; neurology; infectious, cardiovascular, and respiratory disease; dermatology; and oncology.

Quintiles

www.quintiles.com

(919) 998-2000 Fax: (919) 998-2003

4820 Emperor Blvd.

Durham, NC 27703

Quintiles is a contract research organization that provides clinical- and product-development services for pharmaceuticals, biosimilars and medical devices.

Sarah Cannon Research Institute

www.sarahcannonresearch.com

(877) 691-7274

3322 West End Ave., Suite 900

Nashville TN 37203

Sarah Cannon Research Institute works with sponsors at all levels on study design, data analysis, interpretation, protocol development, and clinical study reports.

SynteractHCR

www.synteracthcr.com

(760) 268-8200 Fax: (760) 929-1419

5759 Fleet Street, Suite 100

Carlsbad, CA 92008

SynteractHCR is a full-service CRO with more than two decades of success delivering customized Phase I-IV clinical trial solutions, contributing to numerous product approvals across multiple therapeutic areas.

TKL Research

www.tklresearch.com

201-587-0500

Barclay Commons

2520 Independence Blvd, Suite 202

Wilmington, NC

TKL Research strives to be a leading CRO, providing clinical trial management services and facilities while delivering to our clients a competitive edge with accelerated enrollment.



Worldwide Clinical Trials

www.wwctrials.com

(310) 786-9100 Fax: (310) 786-9102

401 N. Maple Drive

Beverly Hills, CA 90210

Worldwide Clinical Trials is a global CRO that provides full-service drug development services to the pharmaceutical and biotechnology industries.

Appendix 6: Clinical Research Support Company Contact Information

Biostatistics

Array Biostats

www.arraybiostat.com

847-868-2947

PO Box 16391

Wilmington NC 28408-6391

Array Biostatistics LLC offers customized statistical support to the pharmaceutical, medical device, and biotechnology industry.

Biostudy Solutions

www.biostudysolutions.com

910-795-0379

228 N. Front Street, Suite 302 A,

Wilmington, NC 28401

Biostudy Solutions provides pharmacokinetic and statistical services and study design related to BA/BE testing.

Triangle Biostatistics

www.trianglebiostatistics.com

(888) 316-3544 Fax: (888) 316-8753

4039 Masonboro Loop Road, Suite 1-E

Wilmington, NC 28409

Triangle Biostatistics has experience in regulatory submissions worldwide and provides a variety of Statistical consulting and programming services.

Clinical Trials Data Management

Clinical Ink

www.clinicalink.com

800-301-5033

525 Vine Street, Suite 130

Winston-Salem, NC 27101

Clinical Ink offers electronic source documents-providing the first true Electronic Source Record (ESR) in the clinical trials market.

Dataflex Solutions (HQ)

www.edcwithease.com

(910) 399-6946

2214-B Wrightsville Ave.

Wilmington, NC 28403

DataFlex Solutions of Wilmington, North Carolina, provides an alternative service to the often inflexible, overpriced, and bureaucratic contract research organizations in the pharmaceutical industry.

OptumInsight

www.optuminsight.com

(888) 445-8745 Fax: (952) 833-7201

11000 Optum Circle,

Eden Prairie, MN 55344

OptumInsight specializes in improving the performance of the health system by providing analytics, technology and consulting services that enable better decisions and results.



SAS Institute

www.sas.com

(919) 677-8000 Fax: (919) 677-4444

100 SAS Campus Drive

Cary, NC 27513-2414

SAS software accelerates knowledge discovery in biomedical product development.

Clinical Trial Insurance

Arthur J. Gallagher Risk Management Services

www.ajg.com

(910) 509-9000 Fax: (910) 509-9006

1430 Commonwealth Drive, Suite 302

Wilmington, NC 28403

Walker Taylor Agency/Arthur J. Gallagher Risk Management Services serves the pharmaceutical and life sciences industries for property, casualty insurance, professional liability and executive liability protection.

Aquesta Insurance Services

(Glasgow Hicks Insurance Agency)

www.aquesta.com

(910) 794-6100

700 Military Cutoff Rd #104

Wilmington, NC 28405

Glasgow Hicks Insurance Agency provides insurance for the life science and clinical trial industries.

Human Resources Support

Babb McGrew

www.babbmcgrew.com

(910) 791-8570 Fax: (910) 791-8579

2618 Columbia Ave

Wilmington, NC 28403

Babb McGrew is a full service life science executive search firm serving pharmaceutical, biotechnology, healthcare and marketing companies.

The CSI Companies

www.thecsi.companies.com

(800) 582-0828

9995 Gate Pkwy N #100

Jacksonville, FL 32246

The CSI Companies offer flexible, targeted solutions to staffing needs, from temporary staffing to direct hire to long-term consulting, to project based staffing.

Green Resources

www.greeneresources.com

(910) 251-0505

5036 New Centre Dr

Wilmington, NC 28403

Greene Resources is an employment solutions company headquartered in Raleigh, North Carolina that helps companies locate, land and develop the talent critical to the success of their organizations

**Hawthorne Search**

www.hawthornesearch.com

(910) 798-1800 Fax: (910) 798-2811

1319 Military Cutoff Road, Suite CC #147
Wilmington, NC 28405

Hawthorne Search is a recruitment firm with specialization in recruiting for the pharmaceutical and biotechnology industries.

Human Capital Solutions

www.humancs.com

(910) 338-2790 Fax: (910) 509-9833

2018 Eastwood Rd.
Wilmington, NC 28403

HCS is a business consulting firm specializing in executive search, human resources consulting, leadership, learning and employee development, business strategy, lean manufacturing and quality systems and personal coaching.

Prestige Scientific

www.prestigescientific.com

866-900-7372

414 Chestnut St. Suite 303
Wilmington, NC 28401

Prestige Scientific is an executive search firm that advises our clients on recruiting impactful leaders with proven abilities to increase revenue, decrease expenses, and mitigate business risk in the drug development process.

ThinkingAhead Executive Search

www.thinkingahead.com

(910) 509-3831 Fax: (910) 509-3832

700 Military Cutoff Rd, Suite 305
Wilmington, NC 28405

ThinkingAhead is an executive recruiting firm with offices in the United States and Europe. The Wilmington Office focuses on Pharmaceutical and Medical Device recruitment.

Trellis HR Outsourcing (HQ)

www.trellis-hr.com

910-547-5228

3404 Sparrow Hawk Court
Wilmington, NC 28406

Trellis offers full-scope HR operations for emerging biotech and medical device companies through a combination of on-site and remote services, providing a cost-effective alternative to in-house staffing.

YS Companies

www.ystalent.com

910-799-0103

2517 Delaney Ave
Wilmington, NC 28403

Since 1991 YS Companies has utilized state of the art technology to attract top talent in order to fulfill our client's employment needs.



Consulting Services

Amanda Grim's GCP Audits

www.gcpaudits.org

(919) 349-4798

403A Harper Ave.

Carolina Beach, NC 28428

Amanda Grim's GCP Audits offers GCP audits and training.

Argent Rx Solutions

www.argentrx.com

(910) 547-3355

1925 Hallmark Lane

Wilmington, NC

Argent Rx Solutions provides customized market and financial consulting for pharmaceutical companies.

A2Z Regulatory Publishing

www.A2Zregulatorypublishing.com

910-795-0105

Wilmington, NC

A2Z Regulatory Publishing services include appendices compilation, document level publishing, clinical study report publishing, and consulting/training.

BioClin Consulting

www.bioclinconsulting.com

(910) 398-7769

6603 Wheatfields Court

Wilmington, NC 27411

BioClin Consulting provides clinical trial management services.

Biopharmaceutech International

[linkedin.com/pub/david-johnston/1/633/1aa](https://www.linkedin.com/pub/david-johnston/1/633/1aa)

david.johnstonphd@att.net

A biotechnology and pharmaceutical consultancy specializing in helping growing companies with strategic advice.

Cape Fear Research Consultants

www.capefearresearch.com

(910) 399-2220

4217 Pine Hollow Road

Wilmington, NC 28412

Cape Fear Research Consultants provides clinical trials services including report writing, auditing, site selection and monitoring, training and education.

Coastal Pharmaceutical Consultants

(910) 259-8877

7950 Old River Road

Burgaw, NC 28425

Coastal Pharmaceutical Consultants provides regulatory and quality consulting services, including assistance with product development regulatory strategies, consulting on GMP and GCP issues, and assessment of QC and QA functions.

Delozier Consulting (HQ)

www.delozierconsulting.net

910-352-4951

746 Sailor Court

Kure Beach, NC 28449

Delozier provides clinical trial development consulting, monitoring and auditing.

**DMS Clinical Research Services**

2330 Cedar Hill Road
Leland, NC 28451

DMS Clinical Research Services has expertise in conducting, monitoring, and managing clinical trials.

Eastwood Pharmaceutical Consulting

www.epcpharma.com
(910) 794-1826
100-A Eastwood Center, Suite 118
Wilmington, NC 28403

EPC is a global biotech consulting and product development organization focused on developing therapeutic medicines, from ANDAs through biologics, with further expertise in devices, diagnostics and other health-related technologies.

Hal Price Biotechnology Consulting

(910) 256-6624
1955 Prestwick Lane
Wilmington, NC 28405

Hal Price Biotechnology Consulting Service provides biotechnology manufacturing advisory services.

Hermes

www.hermesllc.com
(910) 375-5454
331 Cape Fear Blvd.
Wilmington, NC 28401

Hermes designs, develops and implements research projects, as well as provides technical assistance and training services.

KButler GxP Consulting

113 Wyndham Way
Wilmington, NC 28411

KButler GxP Consulting provides QA compliance expertise to pharmaceutical companies.

Live Oak Pharmaceuticals (HQ)

(910) 231-0250
6117 Clairidge Road
Wilmington, NC 28409

Live Oak Pharmaceutical Consulting Inc. provides Chemistry, Manufacturing, and Control (CMC) and non-clinical consulting services to the pharmaceutical industry.

MSS Pharmaceutical Consulting

2017 Woodwind Drive
Leland, NC 28451

MSS Pharmaceutical Consulting provides expertise in clinical monitoring, CRA resourcing, and CRA management.

Navigator Life Science Advisory

www.navigatorlsa.com
(910) 233-5037

Navigator Life Science Advisory is a consulting firm that specializes in drug discovery and development, drug safety, preclinical and clinical, FDA and EU regulatory affairs.

**Nuventra Pharma Sciences (PK/PD)**

www.nuventra.com

(919) 627-4694

1 Stone Street, Suite A

Wrightsville Beach, NC 28480

Nuventra helps pharmaceutical and biotechnology companies understand how drugs interact with the body and how the body interacts with drugs.

Outsourcing Support Services

www.outsource-support.com

(317) 408-0286

Outsourcing Support Services offers services in outsource management, QA facility audits, and preclinical study monitoring.

ProMetrics

www.prometrics.com

610-265-6344

2116 Capital Drive , Ste 100

Wilmington, NC 28405

ProMetrics aggregates, integrates, analyzes, and reports data across the specialty brand's distribution network including Specialty Pharmacies, Specialty Distributors, 3PLs, Hubs, GPOs and more.

Rothermel Clinical Research Consulting

(910) 579-5263

631 Eastwood Park Road

Sunset Beach, NC 28468

Rothermel Clinical Research Consulting provides contract medical writing and

consulting, specializing in oncology clinical research.

Wagoner Consulting

www.wagonerconsultingllc.com

910-386-9019

PO Box 15729

Wilmington, NC 28408

Wagoner Consulting provides cost-effective professional regulatory and quality assurance consulting services in the areas of medical devices, biologic products, pharmaceuticals, and consumer products.

Information Technology**Bluewater Technology Partners**

www.bluewatertechnc.com

109 Braxlo Ln.

Wilmington, NC 28409

Bluewater Technology Partners is an innovative consultancy focused on information technologies for life sciences, pharmaceuticals, biotechnology and bioanalytical as well as general information technology initiatives.

Clinverse/Bioclinica

www.clinverse.com

(877) 325-1122

4505 Emperor Blvd #130

Durham, NC 27703

Clinverse, Inc., recently acquired by Bioclinica as part of its eHealth Solutions segment, manages the global automation and financial management of clinical trials.

CRA360 Inc.

www.cra360.com
(910) 612-8283
803 South College Rd.
Wilmington, NC 28405

CRA360 is a specialized platform for CROs to enhance the hiring, management and deployment of CRA resources.

MEDIDATA

www.mdsol.com
877 511 4200
350 Hudson Street, 9th Floor
New York, NY 10014

Industry-leading technology and analytics for better, faster development decisions.

Laboratory Testing Services**Eurofins Scientific**

www.eurofins.com
(866) 324-8691
14100 Park Meadow Drive, suite 110
Chantilly, Virginia 20151

Eurofins operates one of the industry's leading central laboratories worldwide, supporting clinical trials in more than 50 countries across six continents.

Quality Chemical Laboratories

www.qualitychemlabs.com
(910) 796-3441 Fax: (910) 796-3425
3400 Enterprise Drive
Wilmington, NC 28405

Quality Chemical Laboratories offers contract analytical and microbiological testing services to pharmaceutical companies, including raw-material and finished-product testing, stability testing, method development and validation.

Solstas Lab Partners

www.nextwavelabs.com
(910) 202-2400 Fax: (910) 202-2499
1915 S. 17 St., Suite 100
Wilmington, NC 28401

Solstas Lab Partners provides medical laboratory testing services to hospitals, nursing homes, home health, clinics, urgent-care facilities and other businesses.

Wilmington Pathology Associates

www.wilmingtonpathology.com
(910) 362-9511 Fax: (910) 362-9512
1915 S. 17 St., Suite 100
Wilmington, NC 28401

Wilmington Pathology Associates offers surgical pathology and cytopathology diagnostic services.

**University of North Carolina Wilmington
- CMS DNA Analysis Core Facility**

www.uncw.edu/cms
910-962-2330
5600 Marvin K. Moss Lane
Wilmington, NC 28409

The CMS DNA Analysis Core Facility provides UNCW faculty, students and researchers with the state-of-the-art



infrastructure and expertise needed to generate and analyze DNA data for research and education.

Marketing

A.Revell Communications

www.arevell.com

(919) 909-1097

11 Church Street

Wilmington, NC 28401

A.Revell public relations, events and creative marketing services helps you refine your message and proclaim your position to the market.

Bon's Eye Marketing

www.bonseyeonline.com

(910) 399-2700 Fax: (866) 830-3270

228 N. Front Street, Suite 302 B

Wilmington, NC 28401

Bon's Eye Marketing provides a full range of services specifically tailored to CROs including: Media and PR, Online Marketing, Brand Building, and Market Messaging.

Inspire Creative

www.inspirecreativestudios.com

(910) 395-0200

720 N. Third St. Ste. 101

Wilmington, NC 28401

Inspire is a full service advertising agency and creative content development firm based in Wilmington, NC. We devise brand-building integrated marketing solutions using a dynamic mix of research, strategy,

inspiring ideas, and the most effective and efficient media.

Pure Communications

www.purecommunicationsinc.com

(910) 509-3970

1838 Sir Tyler Drive, Suite 204

Wilmington, NC 28405

Pure Communications, Inc. is a leading strategic communications consultancy focused on the healthcare industry.

TGK Marketing

www.tg-k.com

(800) 620-8480

221 N 2nd St

Wilmington, NC 28401

Tayloe Gray Kristof (TGK) is a full-service digital marketing and creative services agency located in Wilmington, NC.

Medical Writing

Regulatory Writing Solutions

www.sites.google.com/site/regulatorywritingolutions/our-company

(910) 794-5283

Regulatory Writing Solutions provides professional regulatory medical writing and consulting services to the pharmaceutical, biotechnology, and CRO industries



Modoc

www.modocresearch.com
(910) 777-2671 Fax: (910) 777-2676
1410 Commonwealth Dr., Ste. 201
Wilmington, NC 28403

Modoc works with biotechnology and pharmaceutical companies to develop and conduct Proof of concept (POC) and Phase I-II clinical trials. They offer a full range of support services.

Nightingale Medical Writing LLC

www.nightingalewriting.com
(910) 279-5294
805 Albatross Way
Hampstead, NC 28443

Supporting clients to create the documents needed for new product approvals, completing projects according to the highest quality and ethical standards, helping clients streamline document generation processes with quality results, and sharing knowledge.

Patient Recruitment

ClinEdge

www.clin-edge.com
(857)496-0054
137A Lewis Wharf
Boston, MA 02110

ClinEdge provides a range of marketing and patient recruitment services as well as a range of clinical operations services.

Endeavour Clinical Solutions

www.endeavour-clinical.com
127 E. 4th Street
Corning, NY 14830

Endeavour provides consultative services for global clinical development and health outcomes intended to transform clinical research participation from study planning and feasibility through patient enrollment, retention, and improved health outcomes.

MediciGlobal

www.mediciglobal.com
(484) 674-6800
800 Adams Ave.
Audubon PA, 19403

MediciGlobal is a specialty patient recruitment-retention firm serving the clinical trials industry.

Paragon International, Inc.

www.paragonmeetings.com
(910) 772-1599
5725 Oleander Drive, Suite D4
Wilmington, NC 28403

Paragon International provides customized non-clinical logistical support for clinical trial patients - arranging and coordinating transportation and lodging support as well as expense management for the Pharma/Biotech industry.

**Trial Management Associates**

www.trialmgt.com

(910) 833-1954 Fax: 910-338-3137

2460 Delaney Avenue

Wilmington, NC 28403

Trial Management Associates is a clinical research management company that manages and executes Phase II-IV industry-sponsored clinical research studies.

PMG Research of Wilmington

www.pmg-research.com/wilmington

(910) 799-5500 Fax: (910) 799-1002

1907 Tradd Court

Wilmington, NC 28401

PMG Research of Wilmington conducts Phase II, III and IV clinical trials in a wide range of therapeutic areas.

Pharmaceutical Sales Training**Proficient Learning**

www.proficientlearning.com

(910) 509-0104 Fax: (910) 509-9105

1508 Military Cutoff Road, Suite 304

Wilmington, NC 28403

Proficient Learning offers sales training in medical devices, oncology pharmaceuticals and offers fully customizable training.

Appendix 7: Drug, Medical Device, & Testing Development Contact Information Drug Development

Alvogen

www.alvogen.com
(973) 796-3400
10 Bloomfield Avenue
Pine Brook, NJ 07058

Alvogen is an international, privately-owned specialty pharmaceutical company focused on the development, manufacturing and marketing of generic pharmaceuticals, biosimilar products and OTC (over-the-counter medicines).

CardioPharma

www.cardio-pharma.com
(910) 791-1361 Fax: (910) 794-1829
100-A Eastwood Center Drive, Suite 117
Wilmington, NC 28403

CardioPharma develops combinatorial products to treat cardiovascular disease.

Cygnus Technologies Inc

www.cygnustechnologies.com
(910) 454-9442
4332 Southport-Supply Rd SE
Southport, NC 28461

Cygnus Technologies Inc. is focused on supplying highly specialized analytical products to the pharmaceutical and biotechnology industry for use in process development and quality control.

Krka USA LLC

www.krka.biz
(910) 313-0008
4216 Cravens Point Road
Wilmington, NC 28409

Krka's basic line of business is the production and sale of prescription pharmaceuticals, non-prescription products and animal health products.

Leonard Consulting, LLC

(910) 232-3281
2201 S. Live Oak Pkwy
Wilmington, NC 28403

Leonard Consulting provides consulting services focused on development of novel NDA products and 505(b)(2)/Abridged Hybrid products in the US and EU.

MARBIONC Development Group

www.marbionc.org
(910) 962-2330 Fax: (910) 962-2410
5600 Marvin K. Moss Lane
Wilmington, NC 28409

MARBIONC Development Group is a not-for-profit organization that develops and markets new products and technologies derived from marine and aquatic organisms.

**Osmotica Pharmaceutical Corp.**

www.osmotica.com

(910) 509-0114 Fax: (910) 509-0115

1205 Culbreth Drive, Suite 200

Wilmington, NC 28405

Osmotica Pharmaceutical specializes in drug-delivery technologies and neurology-based therapies, including a treatment for Parkinson's disease.

Wilmington Pharmaceuticals

www.wilmingtonpharma.com

(910) 509-0097 Fax: (888) 482-8024

1904 Eastwood Road, Suite 305

Wilmington, North Carolina 28403

Wilmington Pharmaceuticals patient-friendly, fast-dissolving formulations for established medicines with an unmet patient need for simpler, more reliable dosage forms.

Medical Device Development & Testing**Biocomposites**

www.biocomposites.com

(910) 350-8015

700 Military Cutoff Rd # 320

Wilmington, NC 28405

At Biocomposites, we are pioneering calcium compound devices to regenerate and repair bone and soft tissue.

Cortech Solutions

www.cortechsolutions.com

(910) 362-1143 Fax: (910) 362-1147

1409 Audubon Blvd., Unit B1

Wilmington, NC 28403

Cortech Solutions is the source for sales and support for all the tools a neuroscientist needs for advanced brain research.

MicroSolv Technology Corp.

www.mtc-usa.com

(732) 380-8900

9158 Industrial Blvd NE

Leland, NC 28451

A privately held company in the USA that acquires, develops and manufactures technologies and other tools for separation sciences.

Surgilum

www.surgilum.com/

910-202-2202

1717 Shipyard Blvd, Suite 140

Wilmington, NC 28403

An ophthalmic surgical device company dedicated to bringing innovative instruments to Ophthalmologists conducting cataract surgery.

OrthoKinetic Technologies

www.orthokintech.com

(910) 253-9883 Fax: (910) 253-9884

2790 Creekbridge Court

Southport, NC 28461



OrthoKinetic Technologies is a consulting and testing company who guides orthopedic and neurosurgical medical device companies in the areas of regulatory and preclinical strategies for FDA submissions.

Testing Development and Manufacturing

A1 BioChem Labs

www.a1biochemlabs.com

(315) 299-4775

UNCW CREST Research Park –
MARBIONC, Suite# 2022
Wilmington, NC 28406

ABCL offers custom synthesis, catalog compound, and worldwide chemical sourcing services to large pharmaceutical and agrochemical companies, biotechs, universities, and research institutes.

AccuGenomics

www.accugenomics.com

(910) 332-6522 Fax: (910) 679-4263

1410 Commonwealth Drive, Suite 105
Wilmington, NC 28403

Accugenomics develops gene expression tests to diagnose/monitor cancer treatment.

IKA Works

www.ikausa.com

(910) 452-7059

2635 Northchase Pkwy SE
Wilmington, NC 28405

A German-based world leader in processing equipment and technology.

Flow Sciences

www.flowsciences.com

(910) 763-1717

2025 Mercantile Dr NE
Leland, NC 28451

Flow Sciences' mission is to provide containment systems for laboratory, pilot plant and manufacturing areas. The products are designed to protect operators from exposure to hazardous particulates and vapors while performing delicate operations.

MicroGuard Consulting

www.microguardconsulting.com

(910) 616-0066

4837 Wedgefield Drive
Wilmington, NC 28409

MicroGuard Consulting provides microbiology consulting services to pharmaceutical and biotechnology companies.

Tri-Tech Forensics

www.tritechforensics.com

(800) 438-7884

4019 Executive Park Blvd., SE
Southport, NC 28461-8026

Tri-Tech Forensics provides evidence collection and crime scene investigation products to crime laboratories and crime scene investigators throughout the world.