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A Geographic Information System (GIS) Analysis of Cancer Clinical Trial Locations in the State of Georgia by Major Cancer Type

Shaunta Shanell Parker

A GEOGRAPHIC INFORMATION SYSTEM (GIS) ANALYSIS OF CANCER CLINICAL TRIAL LOCATIONS IN THE STATE OF GEORGIA BY MAJOR CANCER TYPE

by

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ABSTRACT

SHAUNTA S. PARKER

A Geographic Information System (GIS) Analysis of Cancer Clinical Trial Locations in the State of Georgia by Major Cancer Type
(Under the direction of Dr. Michael Eriksen, Faculty Member)

Improving cancer care through clinical research is a major public health issue. However, in Georgia, the exact number of cancer clinical trials is unknown, indicating the need for baseline data regarding cancer clinical trial locations and cancer burden. This study provides the first statewide analysis of cancer clinical trial locations using Geographic Information Systems (GIS). This study examines cancer clinical trial locations by county, according to incidence rates, racial patterns and mortality rates of the four major cancer types: breast, colorectal, lung, and prostate. Findings from this study suggest that metro-Atlanta counties have higher densities of cancer clinical trials. This study also found that there were little or no cancer clinical trials available in counties with the highest rates of overall incidence, African American incidence and overall mortality. This research demonstrates the need to increase availability of cancer clinical trials in counties with the highest cancer burden.

INDEX WORDS: Cancer clinical trials, Geographic Information Systems (GIS), cancer burden, racial disparities, availability of cancer clinical trials

Chapter I – Introduction

Cancer is the second leading cause of death in the state of Georgia. Approximately 13,500 Georgians die from cancer each year and an estimated 36,000 Georgia residents are diagnosed annually. The most common forms of cancer in the state include breast, prostate, colorectal, lung cancer, accounting for 58 percent of all cancer diagnosed and 53 percent of all cancer deaths. Cancer is a serious public health issue that can be addressed in a variety of ways including prevention and treatment, particularly in cancer clinical trials (Singh et al. 2005). Cancer is commonly treated by surgery, radiation, chemotherapy, hormones, immunotherapy or a combination of two or more of these methods. Due to the severity of this disease, prevention and treatment of this disease have become increasingly important. Cancer treatment has improved over time due to advancements in clinical research (Ford et al. 2005).

Clinical trials provide an important tool that assists in the advancement of research and cancer treatment, thereby reducing cancer mortality and in some cases morbidity (through prevention trials). Clinical trials are also vital in the determination of effective therapies for cancer treatment and prevention. For many patients, clinical trials provide an opportunity to receive cutting edge treatment (Comis et al. 2003).

Yet, enrollment for cancer clinical trials across the state remains low (Murthy et al. 2004). Researchers have conducted studies revealing reasons that cancer patients do not participate in clinical trials. Recent studies suggest that only 3 percent of cancer

patients participate in clinical trials (Sateren et al. 2002). This is scant compared to the fact that over 60 percent of children with cancer participate in cancer clinical trials. This issue has spurred numerous studies geared to identify barriers associated with cancer clinical trial enrollment. Numerous barriers to cancer clinical trial enrollment have been found, some of which include geography, racial obstacles and physician awareness (NCI 2001). Racial obstacles regarding cancer clinical trial enrollment is a major public health issue due to the disproportionate burden of the disease. In Georgia, African American males are 20 percent more likely to be diagnosed with and 39 percent more likely to die from cancer than their white counterparts. In addition, breast cancer mortality rates for African American women in the state are 33 percent higher that Caucasian women. African American women in Georgia also experience colorectal cancer mortality rates 71 percent higher than their white counterparts (Singh et al. 2005). Yet, African Americans have lower cancer clinical trial participation than whites (Corbie-Smith et al. 2004). It is important to ensure that clinical trial participants reflect the entire population and that cancer clinical trial results are generalizable (Etling et al. 2006).

This issue gives rise to concerns of whether there is sufficient availability of cancer clinical trials for those most affected by the disease. Because there is no centralized cancer clinical trial database and the various cancer clinical trial registries are not linked, obtaining information regarding sufficient availability within the state can be daunting (McCray 2000). There is a national registry for clinical trials (www.clinicaltrials.gov), but it hosts trials for all diseases and may not always include local level details regarding specific locations for oncology practices. There is also a national database for cancer clinical trials, TrialCheck™ (www.trialcheck.org) which

supports the Georgia Cancer Trials database. This makes Georgia unique, as one of the few states in the U.S. with a state-specific cancer clinical trial database. Before the Georgia Cancer Trials database, monitoring and assessing the quantity and distribution of trials in the state was virtually nonexistent. This left Georgia grappling with many other states regarding the issue of whether there is sufficient availability of cancer trials for affected populations.

Purpose of this study

Utilizing data gathered from Georgia's only statewide cancer clinical trial registry, Georgia Cancer Trials, this paper will reveal the geographic distribution of cancer clinical trials in the state and also expose racial disparity patterns in those areas. This thesis will use Geographic Information Systems (GIS) as an analysis tool to graphically display cancer clinical trial locations throughout the state. In an effort to address issues of information asymmetry, this thesis will provide baseline data regarding the geographic distribution of cancer clinical trials in the state, by cancer type, in a format that is consistent with the current cancer incidence reporting mechanism, GIS. This research will also show the racial patterns in those areas to provide information or details regarding the racial disparities in specific locations. The data will be presented at the county level.

Viewing the geographic distribution of cancer clinical trials in Georgia through GIS mapping systems will create data that may assist with the state cancer plan and with potential strategic placement of needed cancer centers and cancer clinical trials across the state. It is hypothesized that many of the cancer clinical trials are located in the heavily

populated metro-Atlanta area, as opposed to rural areas where cancer clinical trial opportunities may be scant. Many times, rural areas of Georgia exhibit a higher cancer incidence rate than the metro-Atlanta areas. Obtaining data to confirm or refute this assumption is necessary in developing a strategic approach to advancing cancer clinical research in the state and determining if there are vast disparities in cancer clinical trial availability in specific areas.

Study Objectives

1) To identify the geographic distribution of cancer clinical trials in Georgia by cancer type.
2) To examine the racial patterns of cancer incidence rates surrounding cancer clinical trial geographic locations.
3) To establish baseline data for cancer clinical trial locations across the state.
4) To make recommendations regarding strategic cancer clinical research improvement.

Research Questions

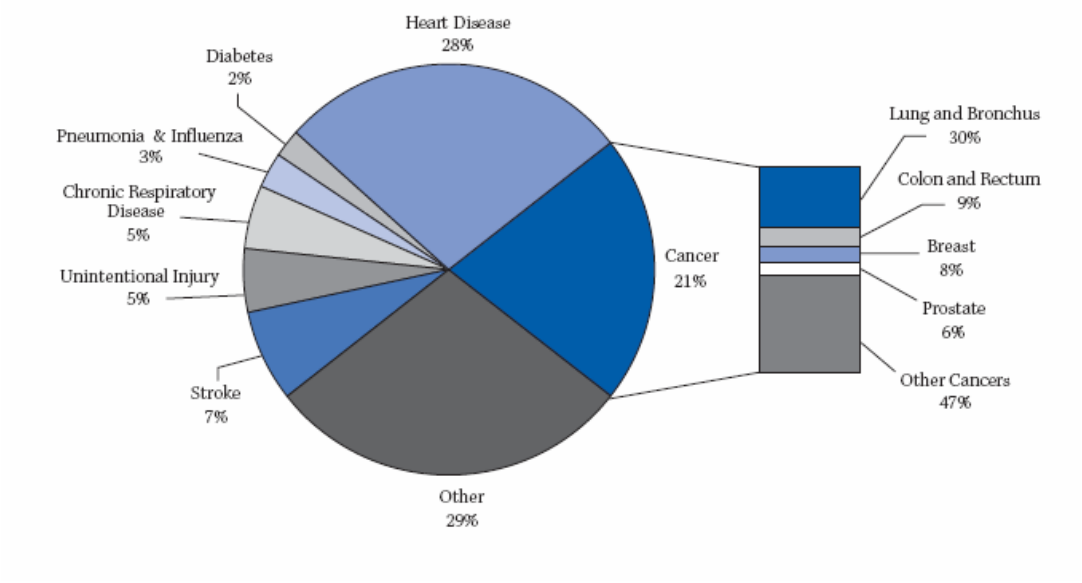
1) What is the geographic distribution of cancer clinical trials in Georgia?
2) Are trials available in counties experiencing the highest burden of the disease?
3) Is there a disparity in cancer clinical trial locations as it relates to racial pattern?

This paper will provide an analysis of cancer clinical trials in Georgia by major cancer type using GIS. The review literature will highlight issues related to cancer clinical trial participation and how GIS can be used in cancer clinical research. Chapter III will detail the methods and procedures used to analyze cancer clinical trials in the Georgia through the GIS ArcMap application based on the Georgia Cancer Trials database, cancer morbidity and mortality data. Chapter IV will reveal results found in this study, providing tables and maps to display where cancer burden is greatest versus where cancer clinical trials are located in the state. The final chapter will discuss details found in this study, answer the previously outlined research questions and make recommendations based on study results.

Chapter II- Review of Literature

Cancer is a major cause of death in Georgia, accounting for 21 percent of all deaths in the state. In Georgia, prostate, breast, lung, and colorectal cancer are among the most common cancer types, accounting for 53 percent of all cancer deaths in the state (Singh et al. 2005), as seen in Figure 2.1.

Figure 2.1 Leading Causes of Death, Georgia, 1998-2002



*****Source: Georgia Cancer Data Report, 2005

There is great concern in the cancer research community regarding the low enrollment of cancer patients in cancer clinical trials. The need for more patients to enroll in trials has spurred the conduction of research to review why patients participate in cancer clinical trials. Many oncologists are concerned about whether there a sufficient

trials available. According to the Georgia Department of Human Resources, Division of Public Health, an estimated 39,520 Georgians were diagnosed with invasive cancer in 2006. Recent studies suggest that burden of disease is higher in rural areas of Georgia, compared to metro areas. According U.S. statistics, males have a 1 in 2 lifetime risk of developing cancer while women have a 1 in 3 lifetime risk. The severity of this disease gives implications for the importance of cancer clinical trials and developing a cure for the disease (Singh et al. 2005).

This review of literature will discuss cancer clinical trial basics and registry issues. In addition, the following topics related to cancer clinical trial participation will also be reviewed: racial/ethnic issues, socioeconomic status and cancer trials, effects of distance and cancer trial locations. It is important to review these topics not only because they are directly related to the research conducted in this paper, but also because they encompass the various reasons why patients enroll in cancer clinical trials.

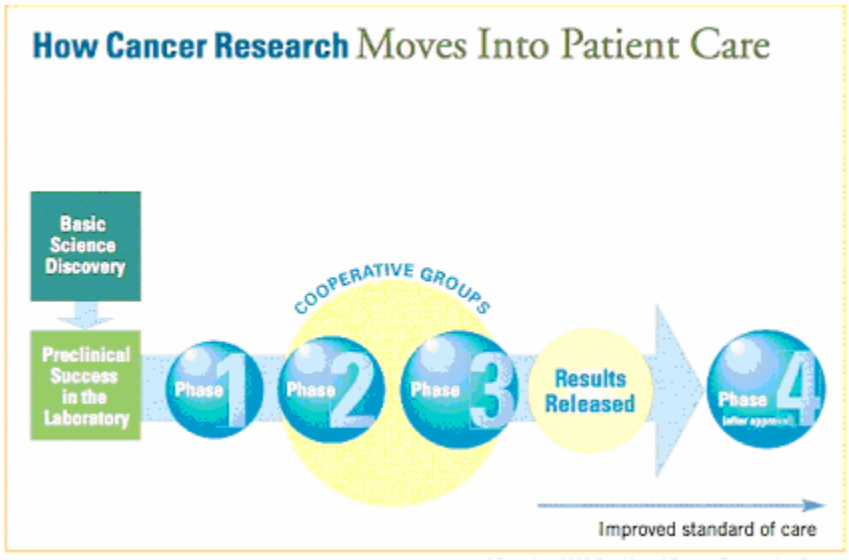
Cancer Clinical Trials Background

Clinical trials represent how advancements in research are made and answer important questions regarding whether a cancer drug is safe and effective. This section will describe the various phases of cancer trials, types of cancer trials, and levels of prevention in cancer trials.

There are 4 phases to cancer clinical trials. Phase I cancer trials evaluate how new drugs should be given, how often they are given, and what dose is safe in humans. Phase II cancer trials test the safety of the new drug, and begin to evaluate how well the new drug works on a particular cancer type. Phase III cancer trials test a new drug, a

combination of drugs, or a new surgical procedure in comparison with the current standard of treatment. Phase IV cancer trials review the long term safety and benefits of a treatment. This phase continues after the study treatment has been approved for use and doctors are able to give it to patients routinely. These trials can be used to gather information on any side effects that may have been missed in the earlier trials (NCI 2001). Figure 2.2 below exhibits how cancer clinical research translates into patient care.

Figure 2.2 How Cancer Research Moves into Patient Care



* Source: Coalition of Cancer Cooperative Groups, 2006

In addition, cancer clinical trials can also be categorized by type of trial, including prevention, treatment, supportive care and other. Prevention studies reveal ways of reducing the risk of getting cancer in one of two ways: by doing something, such as exercise or quitting smoking (Action studies), or by taking something, such as certain medicines, vitamins or minerals (Agent studies). Treatment studies test new treatments such as the following: new cancer drug, new approaches to surgery or radiation therapy,

new combinations of treatments, or new methods such as gene therapy. Supportive care studies work to find better methods for caring for the side effects caused by cancer treatment and the side effects of the cancer itself. Many supportive care studies use drugs to treat the side effects. Supportive care is given to improve the quality of life for patients with serious diseases (NCI 2001).

There are three levels of prevention in cancer clinical trials: primary, secondary, and tertiary prevention. Primary prevention trials are designed to intervene among people with cancer risk profiles; the objective is to eliminate exposure that could trigger mutagenesis or carcinogenesis (i.e., in occupational settings). Secondary prevention trials identify genetic markers, biomarkers, or early diagnosis and clinical manifestation (i.e., breast lump, skin lesion, or persistent cough) to stop the process through drugs prior to serious disease manifestations. Tertiary prevention involves surgical ad adjuvant chemotherapies or natural remedies to rehabilitation to ensure maximal quality of both function and life (NCI 2001).

Cancer Clinical Trial Registries

Because the Georgia Cancer Trials registry is a major data source for this paper, it is important to discuss mandates for cancer clinical trial registries, issues associated with maintenance of cancer clinical trial registries, and patient utilization of cancer clinical trial registries.

There are federal mandates requiring the listing of cancer clinical trials in a database (Hillner 2004). In 1997, a section of the FDA Modernization Act required creation of a clinical trials database:

A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions….which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria of participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public (McCray 2000).

Cancer clinical trials databases in the US include (but are not limited to) the following: NCI, NIH registry, National Coalition for Cancer Cooperative Groups, Oncolink, TrialCheck and Centerwatch (NCI 2001). Though there are federal mandates for clinical trials registration, trials are registered through various databases and oftentimes patients are unaware of cancer clinical trial options (McCray 2000). The Georgia Cancer Trials database is powered by TrialCheck which means that the nationally registered data is filtered into the state-specific database with more details regarding actual locations of oncology practices and contact information. Georgia CORE also adds cancer clinical trials conducted at community practices to the database that may not be captured at the national level. In addition, the information regarding trials in the database is sent to the oncology practices for frequent updates, which ensures that the database is a true representation of oncology clinical research in Georgia. Therefore, the Georgia Cancer Trials database is a more accurate picture of where cancer clinical trials are located in the state.

Dickersin and Rennie (2003) reviewed the importance of clinical trial registration. They highlighted the need to develop a comprehensive cancer clinical trial registry, particularly since it is not currently possible to find information regarding all initiated cancer clinical trials in a central location. This is important because clinical trial registries are used by physicians and patients to identify which studies are open for enrollment (Dickersin and Rennie 2003).

Alexa McCrary (2000) conducted a study to investigate associated with cancer clinical trial registries. McCrary's study found numerous issues with maintaining clinical trial registries, some of which included that they required extensive resources to create and maintain the database; required agreement on standard data elements; required managing data from multiple sources; required regular updates to ensure accuracy; raised proprietary concern; and involved technical challenges. He also found that there were numerous benefits associated with clinical trial registries. For example, they served as resources for patients, physicians and researchers; helped patients find trials for which they might be eligible; assisted in accrual of patients; helped physicians identify treatments under study; and helped in the initiation and design of new trials (McCray 2000).

Wei and colleagues (2004) discussed utilization of an internet-based database to enroll patients in cancer clinical trials. This study highlighted the increasing use of internet for patient resources and information regarding cancer clinical trial availability. Wei and others (2004) reviewed how cancer patients access information regarding clinical trials by surveying patients who enrolled through internet-based database vs. telephone call center enrollment. They found that most registrants (88 percent) accessed

information through the internet. They also found that participants who registered through the internet were significantly younger than those who registered through the call center (Wei et al. 2004).

There are many determining factors of cancer clinical trial participation. The following content will discuss issues associated with patients' decision to participate in cancer clinical trials: cancer clinical trial availability, racial/ethnic issues, socioeconomic status, and effects of proximity to trial locations.

Cancer Clinical Trial Availability

Registries are important in assisting patients with locating cancer clinical trials; however, an adequate number of trials must be available. Meyer et al. (2006) conducted a study at the Gundersen Lutheran Cancer Center in Wisconsin to evaluate clinical trial accrual among patients, as well as the availability of trials for adult cancer patients with recurrent or progressive cancer treated in the community. They conducted a retrospective analysis of a specific group of patients who received chemotherapy at the Gundersen Lutheran Cancer Center from November 2004 to October 2005. They also collected data regarding the number, sources, and types of cancer clinical trials that were available. They found that 50 trials were offered, with approximately half of the trials being for the following cancer types: lung (14 percent), pancreatic (12 percent), renal (10 percent), head and neck (8 percent), prostate (6 percent), and breast (6 percent). There were no trials offered in the areas of bladder, colorectal, and gastrointestinal cancers. Of all participants, only 69 patients (49.3 percent) had trials appropriate for their cancer type and stage of cancer. Among the patients with available trials, 24 (34.8 percent) were

eligible to participate. Six of the eligible patients were enrolled in trials, bringing the overall accrual rate to 4.3 percent (Meyer et al. 2006).

Meyer et al. (2006) identified 140 patients, with an equal number of males and females and a median age of 66 years at the time of treatment. They concluded that enrollment was low for cancer patients with recurrent or progressive cancer. More than 80 percent of their cancer patients were denied access to a cancer trial due to protocol unavailability and ineligibility. As a result, researchers found that cancer cooperative groups did not provide an adequate number of cancer clinical trials for patients in the community (Meyer et al. 2006).

Lara and colleagues (2001) conducted a study to evaluate accrual patterns of cancer clinical trials and to determine potential barriers associated with trial enrollment. These factors were reviewed because low cancer clinical trial accrual rates may lead to negative impacts that prolong cancer trial duration, force early closure of key studies and delay the analysis of essential results. Based on their survey of physicians, they found that protocol availability was a major factor affecting cancer trial accrual. They also found that of the 62 percent of patients that physicians considered for clinical trials, 47 percent of them had no available protocols at the time of the survey. Lara and colleagues (2001) also found that physicians who refrained from informing patients about cancer clinical trials cited that the perception that there were no available protocols appropriate for the patient's specific tumor site and stage was the most common reason for doing so. This is an important concept that leads back the unequal gradient of information or information asymmetry. Because physicians perceived that there were no trials available,

based on their lack of information, many patients were not offered cancer clinical trials as treatment option (Lara et al. 2001).

A study on barriers to cancer trial accrual was conducted by Baggestrom and colleagues (2006) and presented at the 2006 American Society of Clinical Oncology (ASCO) meeting. In this study, Baggestrom et al. (2006) reviewed outpatient charts for all patients with thoracic malignancies that were referred by the thoracic medical oncology group from their institution, including non-small cell lung cancer (NSCLC), esophageal cancer, and small cell lung cancer. They found that the most common reasons for nonparticipation included protocol ineligibility and geographic issues. Baggestrom and colleagues (2006) also found that 35 percent of patients were not enrolled in cancer clinical trials because there was a lack of available appropriate trials during the initial consultation period. (Baggstrom et al. 2006). It is important to address issues associated with availability of cancer clinical trials, particularly since a survey conducted by Comis and colleagues (2003) found that 92 percent of respondents felt that cancer clinical trials would benefit themselves and others (Comis et al. 2003). It is imperative that appropriate trials be available to those who desire to participate in research studies.

The number of available cancer clinical trials depends heavily on physician participation. Somkin and colleagues (2005) identified barriers to physician participation in cancer clinical trials. Their study found that 63 percent of oncologists agreed that cancer clinical trials were their treatment choice if available. In addition, nearly 90 percent of the oncologists established that clinical trials provide high quality care. Somkin et al. (2005) also noted the following barriers to physician involvement in cancer clinical trials: lack of support staff, lack of information about trials, effort and time for

informed consent, inadequate money from sponsors, and reduced time for other patients (Somkin et al. 2005).

It is important to note that at large medical centers like NCI designated cancer centers, physicians are expected to participate in cancer clinical research in the quest for a cancer cure and better cancer treatments. Conduction of clinical research by physicians in community practices is vital in order to increase the availability of cancer clinical trials (Albrecht et al. 1999). This need was identified by NCI and they developed the Community Clinical Oncology Program (CCOP) in 1983, in an effort to increase clinical trial accrual and clinical research involvement. This NCI program allows community oncologists the opportunity to compete for funding to support their cancer clinical trials program through a recognized research base, such as the Eastern Cooperative Oncology Group (ECOG), Southwest Oncology Group (SWOG), Cancer and Leukemia Group B (CALGB), etc. This program is limited to physicians who are associated with hospitals that have the capacity to maneuver through the grant process (Cohen 2003).

Racial/Ethnic Issues Associated with Cancer Clinical Trial Participation

Cancer clinical trial participation is low among minority populations. In fact, the proportion of African American participation has declined over the years (Murthy et al. 2004). Advani and colleagues (2003) conducted a study to understand barriers associated with cancer trial enrollment in the African American community. This study surveyed 218 cancer patients (72 African American and 146 white patients) from the Duke Cancer Center and the Duke Oncology Outreach Clinics. They found that more African American patients than white reported that transportation and cost posed problems with

access to the clinic. They also noted that the under representation of African Americans in cancer trials has three major impacts: 1) research findings cannot be generalized to the entire population when there is questionable applicability to groups of ethnic decent; 2) certain types of malignancies occur more frequently in various racial/ethnic groups; and 3) many reports have called attention to the power of survival among African American and Hispanic patients, compared with white patients (Advani et al. 2003).

Baquet and colleagues (2006) investigated predictors of cancer clinical trial participation in Maryland residents in underserved geographic areas. They found that among patients recruited to cancer trials, African Americans were significantly less likely to participate. They also found that childcare and transportation were determining factors in cancer clinical trial participation, specifically in African American women (Baquet et al. 2006).

Baquet et al. (2006) also noted several reasons for disparities in clinical trial participation including the following: availability of trials primarily in academic and non-community settings, patient, community, and health professional barrier; historical factors such as the Tuskegee Syphilis Study and other examples of unethical and exploitative research; reimbursement issues and concerns and study design issues such as use of randomization for group assignment, blinding and placebos (Baquet et al. 2006).

These findings were particularly important because in many states, minority and rural communities suffer distinct disadvantages in accessing quality health care services and health professionals for cancer prevention, screening, early detection, treatment, palliative care, and pain management. Generally, African Americans, other minority populations, rural communities, and uninsured populations have participated in cancer

clinical trials less than other groups. Due to these disparities in research participation, the benefits of standardized quality care in clinical trials and advances in the research are not equally distributed to all communities (Petereit et al. 2005).

Adams-Campbell and colleagues (2004) studied factors associated with enrollment of African Americans onto cancer clinical trials at Howard University over a two year period. They found that thirteen cancer treatment trials were approved and opened during the course of the study. They also found that there was an eligibility rate of 8.5 percent, with a conditional enrollment rate of 60 percent. Adams-Campbell et al. (2004) also found that there were no appropriate trials available for 24.2 percent of the patient population. Co-morbidity of disease caused 17.1 percent of the patients ineligibility for the studies (Adams-Campbell et al. 2004). This is important because many African American patients suffer from co-morbidity of diseases that may exclude them from enrolling in cancer clinical trials.

Brown and colleagues (2000) conducted a study to investigate issues associated with enrollment of cancer clinical trials among minority women. In this study, they interviewed newly diagnosed breast cancer patients of the Harper Hospital in Detroit, Michigan to identify barriers to participation in cancer clinical trials. They also assessed eligibility of trials and documentation of cancer clinical trial participation. Barriers identified by African American women included lack of information, fear and perceived interference with personal responsibilities (Brown et al. 2000).

Fouad and colleagues (2000) held a conference in Tuskegee, Alabama to understand factors involved in minority recruitment in cancer clinical trials. This meeting engaged a workgroup of healthcare professional to identify barriers to minority recruitment to

cancer clinical trials. In this study, physicians in the workgroup noted the following barriers to minority enrollment in cancer trials: lack of knowledge of available resources, poor communication between patients and physicians, and lack of appreciation of the need for clinical trial. Fouad et al. (2000) also found that awareness of the Tuskegee Syphilis Experiment did not affect cancer clinical trial participation. However, this finding is not consistent with previous studies that have cited minorities' distrust of scientific investigators, government and academic institutions based on the inappropriate conduct regarding the Tuskegee Syphilis Experiment (Fouad et al. 2000).

There is a substantial need to address issues related to minority participation in cancer clinical trials. Because decreasing minority cancer clinical trial participation is a major issue, barriers such as: fear, mistrust, inadequate access to trials, protocol ineligibility, cultural myths, and transportation costs must be addressed in a calculated manner (Newman et al. 2006). This is particularly important because more minorities are needed to participate in cancer clinical trials. This not only helps to increase the generalizability of cancer clinical trial results (Moinpour et al. 2000), but it also helps determine if there are genetic or cultural differences which impact cancer outcomes (VanEenwyk et al. 2002).

Low-income populations deal with socioeconomic issues that may prevent them from participating in cancer clinical trials (Abou-Jawde et al. 2006). The next section will discuss socioeconomic issues associated with cancer clinical trial participation.

Socioeconomic Status and Cancer Clinical Trial Participation

Socioeconomic status (SES) also plays a role in cancer clinical trial participation. Sateren and colleagues (2002) conducted a study to examine the influence of SES on accrual of patients to NCI-sponsored cancer treatment clinical trials. They assessed how cancer patients accrued to these trials using a range of socioeconomic, geographic, and demographic variables as indicators. They also estimated the geographic and demographic US cancer burden using Census data and NCI Surveillance, Epidemiology, and End Results (SEER) incidence data, since there is no national cancer reporting mechanism. By combining census and cancer incidence data, researchers developed a sketch of the demographic and geographic patterns of cancer in the U.S. Sateren and colleagues (2002) then calculated the expected number of cancer patients accrued to trials, by geographic level. They studied the number accrued by age, sex, health insurance status, geographic location, SES, average income on county level, and county education level (Sateren et al. 2002).

Sateren et al. (2002) found that the highest percent of adult patients accrued to trials was between 40 and 55 years of age. The majority of patients enrolled were female (56 percent). They compared this with SEER data, which indicated that 47 percent of newly diagnosed patients were female and 53 percent were male. They also found that there were 119 trials open with women sex-specific cancers and 27 trials open with men sex-specific cancers. Additionally, the percentage of white patients enrolled in cancer clinical trials was parallel to the overall population statistics. The percentage of African American men with cancer and were between 30 and 59 years of age and accrued to a

clinical trial was lower than the percentage of white men with cancer in the same age group (Sateren et al. 2002).

Sateren and colleagues (2002) used several measures to determine SES, including mean county education level, mean county income level, mean county poverty level and mean state employment rate. Including all measures, areas with higher socioeconomic levels had significantly higher levels of clinical trial accrual. Also, urban areas with the largest county incomes had the highest rates of observed clinical trial accrual rates. They also found that each percentage increase in unemployment was associated with a drop in observed accrual of almost 37 patients per state, whereas each additional approved cancer program increased accrual by more than nine patients per state. Also, there were 36.5 fewer patients per 1 percent increase in state unemployment. This study was limited to enrollees over a 12-month period and data for approximately 24,000 patients. Also, researchers were limited to data regarding NCI-sponsored cancer clinical trials. In addition, the study did not include patients accrued from pharmaceutical trials (Sateren et al. 2002).

SES is an essential predictor of access to cancer care. It is important to understand how this factor relates to age and race disparities in cancer clinical research. Gross and colleaugues (2004) conducted a cross-sectional analysis of patients enrolled in NCI sponsored lung, colorectal, prostate, and breast cancer clinical trials. For each of the four cancer types, researchers selected 10 cooperative group trials that enrolled the most patients during the study period. They focused primarily on older women; therefore, trials with fewer than 5 percent of elderly patients (aged 65 or less) were not included. As a proxy for SES, researchers used each patient’s zip code to link to the 2000 US Census

data and derived the proportion of participants living in areas below poverty level. Gross and colleagues (2004) utilized a stepwise approach to identify discrete recruitment centers in the Clinical Trial Evaluation Program database. To ensure accuracy, research assistants used several data sources, including the internet and direct telephone contact (Gross et al. 2004).

Gross and colleagues (2004) found that low SES was significantly associated with clinical trial enrollment, even after adjusting for variables such as age, race, and proximity to the nearby cancer research center. Results from this study also suggest that African Americans with Medicaid were generally less likely to participate in cancer research trials than whites. They also found that that white patients were significantly less likely to reside in areas of high poverty (Gross et al. 2004).

According to Giuliano and colleagues (2000), there are three major reasons why individuals with lower SES do not participate in cancer clinical trials. First, having lower SES may result in lower rates of screening and prevention and a higher dependence on public hospitals where physicians are less likely to be involved in cancer clinical research. Second, patients with lower SES may have insurance issues, mainly because they may be more reliant on Medicaid and Medicare insurance. This is unfortunate because reimbursement with participation in a clinical trial is inconsistent and often denied by Medicaid and Medicare. Third, concerns with financial survival may take precedence over health and well-being. Oftentimes, patients with low SES are discouraged from engaging in cancer prevention and screening activities (Giuliano et al. 2000).

Presence or absence of managed care is also an important factor in cancer clinical trial participation, particularly regarding a physician's decision to inform patients about cancer clinical trials (Grunfeld et al. 2002). As indicated by Gross and Krumholz (2005), managed care plays a substantial role in physicians' behavior regarding cancer clinical trial enrollment. Enrolling patients to cancer clinical trials requires a significant investment of time and money. Clinician-investigators and their staff expend an estimated 150-450 hours enrolling patients to cancer clinical trials, with costs ranging from $1300 to $3900. While resources are scarce and reimbursement structures are static, increasing demands of clinical trial enrollment are an additional strain. Decreases in clinical revenues associated with managed care organizations have made many physicians less reluctant to devote additional resources for cancer clinical trial enrollment (Gross and Krumholz 2005).

SES is also related to a patient's ability to travel to oncology practices. Because travel distance may provide another barrier, it is important to discuss how proximity to the research facility effects the patient's decision to enroll in a clinical trial. The next section will provide a review of this issue.

Effects of Proximity to Trial Locations

It is important to understand how travel distance to cancer facilities effect cancer clinical trial participation (Athas et al. 2000). Gross and colleagues (2004) analyzed the effect of travel distance on enrollment of elderly patients to cancer trials. They found that the geographic location of trial participants was important in 2 ways. Both travel distance from the trial recruitment center and underlying age distribution of the population were

related to recruitment of older persons. They also found that participants who lived within 7 miles of a recruitment centers were significantly more likely to be elderly. This is consistent with other research suggesting that travel time is a frequent reason for declining to enroll in a clinical trial (Gross et al. 2004).

This is important because enrolling onto a study may often entail undergoing treatment and clinical assessments in facilities that are further away from the patients' home than they would otherwise use (Nattinger et al. 2000). Elderly persons may have more barriers to travel due to impairments in mobility or cognition (Gross et al. 2004).

A study conducted by Lamont and colleagues (2003) suggests that patients who travel farther to enroll in a study have better survival (Lamont et al. 2003). Considered with findings from the Gross et al. study, it is likely that not only are older persons less likely to travel longer distances to enroll in cancer clinical trials, but those who do may be a healthier subset of the elderly. Therefore, facilitating travel by addressing logistic barriers for older persons may improve not only the number of older persons enrolled in clinical trials but also the generalizability of the results by enabling patients with a broad spectrum of health status to enroll (Gross et al. 2004).

It is important to have a general understanding of how far patients travel to participate in cancer clinical trials. Wright and colleagues (2004) conducted a study to identify the independent predictors of patients' decisions to enter phase III clinical trials. A single institution observational cohort study design was employed, using a series of questionnaires developed to capture trials-related opinions of patients, their physicians, and clinical research associates. They found that mean reported travel distance to the cancer center was 38km, ranging from 1- 166km (Wright et al. 2004).

Gross and Krumholz (2005) conducted an investigation to determine the relationship between managed care patients and cancer clinical trial enrollment. They collected data from NCI Cancer Trials Evaluation Program for participation in NCI-sponsored cooperative group breast, lung, prostate, and colon cancer trials. Trial participants were assigned to counties according to zip code of their residence. Geographic Information System (GIS) data were used to estimate distance, in linear miles, between the center of each county and the nearest county that had an NCI research center. County SES was related to trial enrollment. Counties with higher proportions of their population living below poverty level had substantially lower median enrollment rates, decreasing from 19.1 in counties with less than 9.1% below poverty to 14.0 in counties with the highest poverty level. Counties with NCI research centers had a median rate of 21.7, while counties more than 36.5 miles from the nearest center had a median rate of 15.5 (Gross and Krumholz 2005).

In Gross and Krumholz's study, counties with the highest enrollment fraction were less likely to have 2 or more hospitals with oncology services and tended to be non-urban. In this study, the presence of teaching programs and hospitals was unrelated to trial enrollment. Urban counties at increasing distance from a research center and with a higher proportion of the population uninsured or below poverty also tended to have lower enrollment rates in the multivariate analysis (Gross and Krumholz 2005).

Celaya and colleagues (2006) studied whether proximity to a radiation treatment facility (RTF) played a role in the treatment choice of women with early-stage breast cancer. They hypothesized that proximity of the treatment facility to patients' residence may play a role in cancer treatment, particularly in rural populations. Their study

identified all radiation treatment facilities in the New Hampshire, Maine, Massachusetts, and Vermont over 4 years. Celaya et al. (2006) geocoded the addresses of each facility and each patient's address using Geographic Data Technology (GDT) to an exact street address or zip code. They also estimated the shortest straight-line distance to a facility (Celaya et al. 2006).

Celaya and colleagues (2006) found that the average distance between patients' residence and the nearest RTF was 15.1 miles (ranging from 0.1-89.9 miles; median 13.9). Nearly 25 percent of patients lived greater than 20 miles way from the nearest RTF. In a multivariate analysis, they also found that women were less likely to have treatment (breast conserving surgery) with increasing distance from the their residence to the RTF (Celaya et al. 2006). Issues associated with travel distance are extremely important in rural areas in which patients may be required to drive farther distances for a cancer clinical trial.

Paskett and colleagues (2002) conducted a study to investigate cancer clinical trial enrollment factors in rural patients living in North and South Carolina. In this study, access to the clinical trial center and transportation as barriers as factors for participation in cancer clinical trials (Paskett et al. 2002). This study also found that cost and unfamiliarity of physician were also factors that affected clinical trial participation rates in rural cancer patients. There are also geographic differences in cancer clinical trial accrual.

In a study conducted by Sateren and colleagues (2002), geographic differences in clinical trial accrual were found. Specific states and regions of the US had significantly lower or higher accrual to clinical trials than the national accrual figures. Northern states

such as Delaware, Iowa, Minnesota, New Hampshire, and North Dakota had the highest clinical trial accrual rates per number of cancer incidence cases, whereas southern states such as Alabama, Arkansas, Florida, West Virginia, Kentucky and Georgia had the lowest accrual rates per number of cancer incidence. Generally, researchers observed higher clinical trial accrual rates in suburban areas (Sateren et al. 2002).

Geographic Information Systems (GIS)

GIS combines computer hardware, software, databases, and personnel to manage, display, map, and analyze information related to spatial phenomena. The term "geographic information systems" was first used in the 1960s to refer to a computer system for asking questions of maps showing current and potential land use in Canada (Richards et al. 1999). GIS technology provides public health researchers and officials with numerous new types of data. GIS can be used to analyze geographic patterns of disease. The software displays spatial and temporal patterns of health outcomes (Cromley 2003). GIS information must be compatible with the other software used for analysis; therefore, geocoding is performed to create geographic points from data that may not have otherwise been analyzed by this software (Rushton 2003).

Geocoding is a calculation of spatial locations from street addresses. Geocoding in ArcView GIS is a process that creates a layer of visual information based on locational data in tabular form and a reference feature theme. Compared with tools and charts, maps developed using GIS technology can be an extremely effective tool to assist stakeholders and decision makers in visualizing and comprehending public health problems. However,

the use of GIS for community health planning and various public health applications remain a relatively underdeveloped marketplace niche (Rushton et al. 2006).

Basic uses for GIS mapping when visualizing cancer data have been studied by C.A. Brewer (2006). This study identified various mapping methods and discussed how each method helps researchers visualize cancer data. Mapping methods included: chloropleth mapping, color symbols, classing, and proportional symbols (Brewer 2006). GIS can be used to examine inference. According to Geoffrey Jacquez (2004), strong inference begins with a set of hypothesis regarding observed phenomena. Researchers then design a series of critical experiments to systematically test each hypothesis. Spatial systems typically are large and the spatial phenomena of interest in public health (i.e., cancer mortality rates, risky behaviors, demographic changes, and experimental exposures) are difficult to observe directly and/or change slowly through time. This makes it difficult, if not impossible, to conduct designed experiments and in any event there are substantial ethical consideration with experimentation on human population (Jacquez 2004).

Spatial health researchers must often work with encountered data that have been collected for some purposes other that her specific study. In many instances, the data are sampled in a systematic way from a spatially distributed population. However in some instances spatial analysis plays a critical role in identifying spatial and temporal relationship in population level data, giving rise to hypothesis that can be evaluated on additional data to be collected from the same system or on data from analogous spatial systems (Jacquez 2004).

The spatial analyst toolbox includes techniques for quantifying spatial patterns, modeling risk surfaces, and assessing relationships between cancer outcomes and potential exposures. These techniques allows researchers to determine whether observed spatial patterns are statistically significant, to identify the locations of clusters, hot spots and cool spots, to construct maps, showing excess and deficits relative to a risk model, and to quantify association between 2 spatial variables (Jacquez 2004).

Recently, GIS has been used to show spatial patterns of cancer morbidity and mortality trends (Boscoe et al. 2004). This is important for this paper because this GIS analysis of cancer clinical trials in Georgia joins various data sets to determine if cancer clinical trials are offered in areas with the highest rates of cancer incidence and mortality. Spatial patterns will display the relationship between where clinical trials are located and where disease burden is greatest.

Theoretical Approach in this Study

Disparities in cancer treatment are apparent and researchers agree that it should be addressed in a strategic manner. However, there is uncertainty regarding the state of cancer clinical trials and whether there is sufficient availability of cancer clinical trials in needed areas. This has led many to question whether clinical trials are available for vulnerable populations. The literature suggests that this type of analysis has not been graphed on a statewide basis; however, there are few studies conducted at research centers that address the problem for their particular cancer center. This may lead to information asymmetry.

Information asymmetry is a theory that is commonly used in economics to explain market failure (Smith 2005). For the purposes of this paper, information asymmetry is defined as the disproportionate gradient between those with knowledge regarding cancer clinical trials in the state and those who lack the information. In this case, Georgia CORE would be the information holders and physicians, public health officials, patients, and advocates that aren't equipped with the data are at the opposing end of the gradient.

Generally, GIS has been particularly useful in examining cancer incidence and mortality rates in the U.S. Furthermore, these methods can be used to investigate a number of geospatially-related questions. While there is no survey associated with this thesis study, research results from this study will provide baseline details that address barriers found through previous studies: geographic locations and racial patterns.

What is unknown

There is currently no statewide analysis of cancer clinical trials for Georgia. In addition, there is no report with baseline data regarding the number of cancer clinical trials offered in the state by cancer type and cancer clinical trial location. Consequently, there is no consensus on whether an adequate number of clinical trials are being offered throughout the state, particularly for underserved populations. Therefore, this thesis will identify baseline data regarding cancer clinical trial locations across the state by major cancer type (i.e., breast, colorectal, prostate, and lung). This paper will also explore racial patterns surrounding areas with cancer clinical trials as an indicator for appropriate access to trials in the state. GIS will be utilize to address this information asymmetry and provide a more precise measure for assessing this problem in a manner that is consistent

with current cancer morbidity reporting mechanisms. The next section will describe the methods and procedures used to identify, collect, and analyze data in this study.

Chapter III- Methods and Procedures

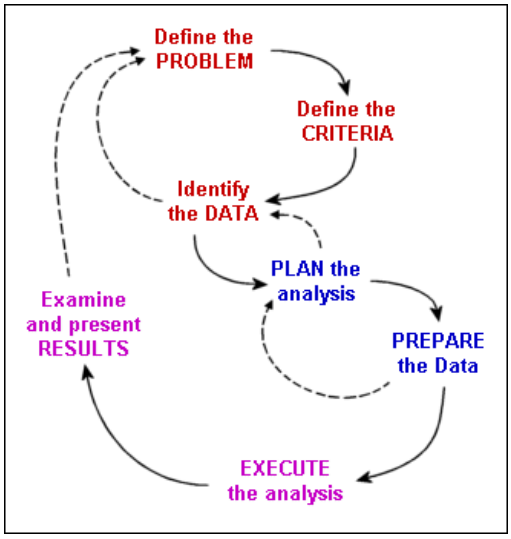
Availability and access to cancer clinical trials are important in securing the quality of cancer care, access to promising therapies and enrollment of cancer patients to trials. Because cancer clinical trials rely heavily on volunteer participation, it is crucial that there are appropriate numbers of trials available to needed populations. An adequate number of trials must be present in order for patients who qualify for the study to enroll. The exact number of cancer clinical trials is currently unknown across the state. Many oncologists and health officials are left to guess regarding the number of cancer clinical trials are in Georgia and their locations. The state-specific, Georgia Cancer Trials database provides a link to the information asymmetry occurring regarding the clinical trial availability. The database is provided through the Georgia Center for Oncology Research and Education, Inc. (Georgia CORE). It is made available through a partnership between Georgia CORE and the Coalition of Cancer Cooperative Groups.

This study was granted exempt-review from the Georgia State University Institutional Review Board, protocol number H07279: approval letter number 17718. Dr. Michael Eriksen was listed as the Principal Investigator and Shaunta Parker as the Student Principal Investigator.

This study was conducted to understand where cancer clinical trials are located by major cancer type and determine if cancer clinical trials in Georgia were offered in counties with highest disease burden, using GIS. Also, geographic racial patterns regarding cancer incidence rates were taken into account in order to determine if

adequate trials were offered in disparate populations where the disease burden may be greater. Generally, GIS analysis takes a stepwise approach, from defining the problem to examining and displaying the results, as seen in Figure 3.1.

Figure 3.1 GIS Analysis Process Map



*Source: ESRI, 2007

The process map displayed in figure 3.1 outlines the method of analysis used in this study. In this study, the problem is defined as the lack of information regarding where cancer clinical trials are located in Georgia and whether trials are offered in counties most affected by the disease.

The next step, using the GIS process map as a guide, defined the criteria for this study. The following factors were included in this study: open active adult cancer clinical trials and their corresponding oncology practices in Georgia. The study did not include childhood cancer clinical trials. The dependent variable of this study includes the quantity of cancer clinical trials. Factors evaluated in this study include counties with trials, cancer incidence and mortality rates by major cancer type and African American cancer

incidence rates. The design of this study called for the listing of all cancer clinical trials along with their corresponding addresses for mapping purposes. In order to view trial locations in the ArcView GIS application, each cancer clinical trial listing required geocoding.

The next step, based on the process map in figure 3.1, identified the data required for this study. Cancer clinical trial location information was collected from the Georgia Cancer Trials database; GIS county shapefile data was collected from the Office of Health Information and Policy's website; and cancer morbidity and mortality data was collected from the Georgia Comprehensive Cancer Registry. Initial data collected from the Georgia Cancer Trials database included the total number of cancer clinical protocols and the total number of trial listings offered to adult cancer patients in the state. Data was collected on all adult cancer trials to obtain a total number of cancer clinical trials in Georgia. The first set of data regarding cancer trial information was collected in October 2006. A report was requested from the national TrialCheck database for all of adult cancer clinical trials listed in the Georgia Cancer Trials database. Upon receipt of the report, the information was entered into a Microsoft excel spreadsheet. Clinical trials were characterized by the following: protocol identification number, Cancer Therapy Evaluation Program identification number (CTEP ID), oncology practice name, cancer type, trial type (i.e., treatment, prevention, supportive care, or other), and address. Official protocol identification numbers were used to verify each protocol to ensure that there were no duplicates. It is important to note the difference between what is described as a protocol versus a cancer clinical trial listing in this study. Protocols refer to the description of rules of how the study is to be carried out and the study purpose. Each

study has a definitive protocol number that is unique to that specific trial. The number of protocols is different from the number of cancer clinical trial listings because the listings include the various locations in which protocols are offered. For example, if protocol A is offered at 12 sites across the state then the protocol has 12 listings that should be included when reviewing the number of trials.

Some oncology practices had numerous CTEP IDs, depending on how the trials were initially entered by the research personnel at the practice. Therefore, oncology practices with numerous CTEP IDs were grouped under one identification number to avoid duplication. Addresses for the clinical trial locations were linked to oncology practices and verified by Georgia Cancer Trials database, Georgia CORE portal, site locations, and/ or the oncology practices' official website. Addresses gathered in the study reflect the physical street addresses for clinical trial locations, because P.O. boxes cannot be geocoded. Suite numbers were also included in the point data.

In an effort to ensure accuracy, a report was sent to cancer clinical trials locations in January 2007 to verify that their sites were accurately reflected in the database report. Upon the dissemination of this report, the clinical trial information was updated for each responding location. As a part of the update, studies from the Accelerated Community Oncology Research Network (ACORN) were also added to the cancer clinical trial listings. Before the update, approximately 50 percent of the ACORN studies were not found in the Georgia Cancer Trials database. These trials were then added to Georgia Cancer Trials, as a result of this study. It is important to note that the Georgia Cancer includes approximately 95% of all cancer clinical trials in the state.

A second data collection and verification process was conducted from March 8, 2007 to March 19, 2007. During this process, trials were updated from an additional report requested from the national TrialCheck database. Trials from this data collection period were added to the initial Microsoft excel spreadsheet that was compiled in January. Duplicates and other internal listing problems involving oncology practices were identified in this stage and can be found in the limitations section of the discussion chapter.

The next step involved planning the analysis for the study. In order to view the number of cancer clinical trials in Georgia, the information had to be changed to a format acceptable by the ArcMap application in ArcGIS. After all corrections regarding duplication of oncology practice were made, the excel spreadsheet was sent to the Office of Health Information and Policy (under the Georgia DHR, Division of Public Health) to be geocoded. The plan for analysis also consisted of collecting data in various formats to create five sets of maps: 1) a general map of the number of cancer trials offered by county, 2) a map of the number of trials by county and the incidence rates by major cancer type, 3) a map of the ratios of cancer trials available to the number of new cancer patients, 4) a map of the number of trials by county and the incidence rates of African American patients by major cancer type, and 5) a map of the number of trials by county and the mortality rates by major cancer type.

It is important to distinguish that there are two common models used to represent geographic data: the vector data model and the raster data model. This study used the vector data model. Objects in this study are represented by either a point or a polygon

feature with well-defined boundaries, as a feature class. A feature class consists of a collection of geographic entities with the same geometry type (such as point, line, or polygon), the same attributes, and the same spatial reference. Feature classes can either stand alone within a geodatabase or be contained within shapefiles, coverages, or other feature datasets. Feature classes also allow homogeneous features to be grouped into a single unit for data storage purposes. Feature boundaries are defined by x,y coordinate pairs. X, Y coordinates are a pair of values that represents the distance from an origin (0,0) along two axes, a horizontal axis (x) representing east-west, and a vertical axis (y) representing north-south. On a map, x,y coordinates are used to represent features at the location they are found on the earth's spherical surface. Points are generally defined by a single x,y coordinate pair while polygons are defined by lines that close to form polygon boundaries (Rushton 2006). The geocoded listing of Georgia cancer clinical trials included these coordinates as point data.

Preparation of Additional Spreadsheets for Data Analysis

The next step was to prepare the geocoded data into spreadsheets that would later be joined with the GIS county shapefile. Much of the preparation was done in the initial spreadsheet. However, that data required further manipulation upon receipt in order to tailor the information for the various types of maps. In order for the information to translate into a readable file, the information needed to be saved as a delimited text file. In addition, the data had to be joined with the existing shapefile or a new shapefile had to be created. In this study, data was both joined to the Georgia shapefile map and

additional shapefiles were created to view data. This required the creation of numerous spreadsheets. A general spreadsheet listing the 159 counties in Georgia were compiled with the heading “County Name” in order to match the one-to-one relationship needed to join the same information with the county shapefile, which was also listed by county name. Then, the number of trials in each county was paired with the corresponding county name. An additional spreadsheet was created to list the number of trials in each county by major cancer type: breast, colorectal, lung and prostate. Data retrieved for this spreadsheet included: county name, number of trials, and major cancer type. The spreadsheet was saved as a delimited text file to ensure readability in the ArcMap application.

Next, two spreadsheets were combined. The first spreadsheet consisted of a listing of cancer clinical trial locations across Georgia with the name of the institution, county, and number of trials offered. Counties were labeled and identified for each cancer clinical trial listing using the zip codes in the address of the institutions where clinical trials were located. The county information was paired with the corresponding trial location and verified using the U.S. Census website. Then, the second spreadsheet was created so that the point data (all cancer clinical trial listings in the state) could be joined. In order to do the second spreadsheet, the attribute table for the county shape file was referenced. Each county was listed in the second spreadsheet in the same format used in the attribute table.

Additional spreadsheets were created utilizing cancer incidence and mortality rates provided by the Georgia Comprehensive Cancer Registry. Each spreadsheet contained information regarding county name and the corresponding incidence rates for

each of the major cancer types. This was also done for African American cancer incidence by major cancer type as well as mortality rates for the entire Georgia population. After these spreadsheets were created, the data was saved as a delimited text file, in preparation for joining with the county shapefile data.

Conversion of point data into a shapefile

Because the information in this study was collected and geocoded as point data, the information had to be converted into a shapefile of the trial locations in order to view over patterns of incidence and mortality rates. A shapefile consists of vector data storage in a format for storing the location, shape, and attributes of geographic features. A shapefile is stored in a set of related files and contains one feature class. A single shapefile generally contains at least three main files, and as many as eight.

An additional spreadsheet was required to layer the number of trials over maps containing cancer incidence rates for each major cancer type. This was done using the geocoded version of the master spreadsheet containing cancer clinical trial listings. The data was filtered and sorted by major cancer type and the new spreadsheets were created containing information needed to plot trials for each major cancer type. The master cancer clinical trial spreadsheet contained a total listing of cancer clinical trials across the state; therefore, the data needed to be sorted by major cancer type. Once the data was sorted, the information was copied into a separate spreadsheet and labeled as the geocoded version by major cancer type (i.e., Breast_Cancer_Clinical_Trials_Geocoded). After further analysis, the file had to be reduced to one location in each county in order to have one point representing the number of trials per county because there were numerous

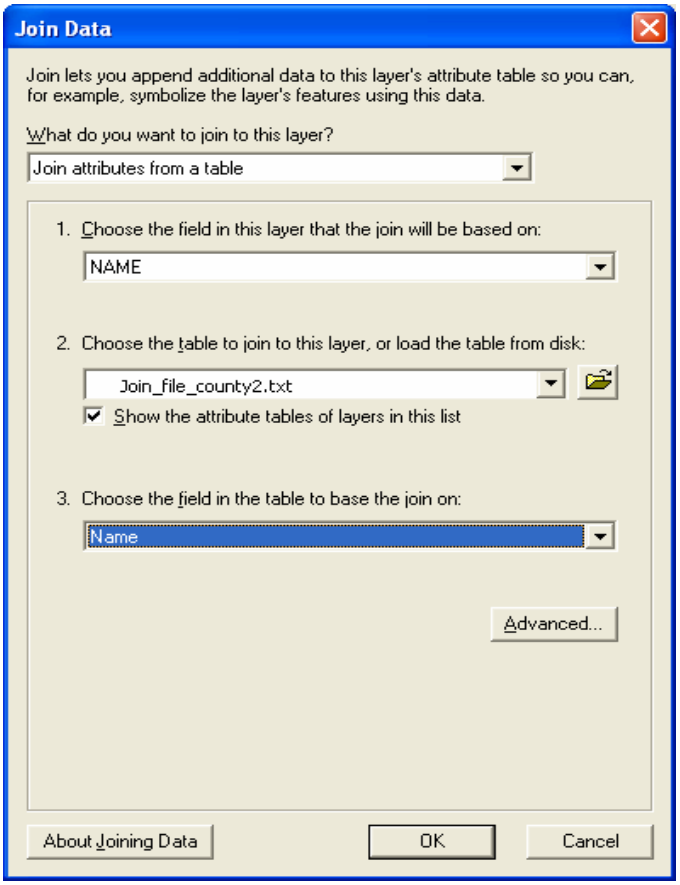
points in counties with multiple locations. Leaving this issue unaddressed would have produced an inaccurate reflection regarding the density of trials. This data was used along with the previously described spreadsheets in order to create maps that reflected cancer incidence and mortality rates as a base map with the quantities of trials plotted over the incidence rates. In an effort to increase accuracy, statistics regarding the frequency of trials by county and major cancer type were analyzed in Statistical Package for the Social Sciences (SPSS).

Constructing Maps

The analysis was executed by joining the information gathered in this study to the ArcMap application in ArcGIS. A preliminary map showing the point locations was performed through the following steps. First, the downloaded county shapefile was added to the ArcMap application. Next, the delimited text file containing geocoded Georgia cancer clinical trial listing was added as a layer to the Georgia county map file. The file appeared as Georgia_Cancer_Clinical_Trial-Listing_4_2_07_Geocoded1.txt in the application.

A join file was created to link the information gathered on the number of trials to the ArcMap application. In order to create a join file, the information has to be listed in the same sequence as the file in which it will be joined, as seen in figure 3.2. Once the tables are joined, the quantities can be displayed.

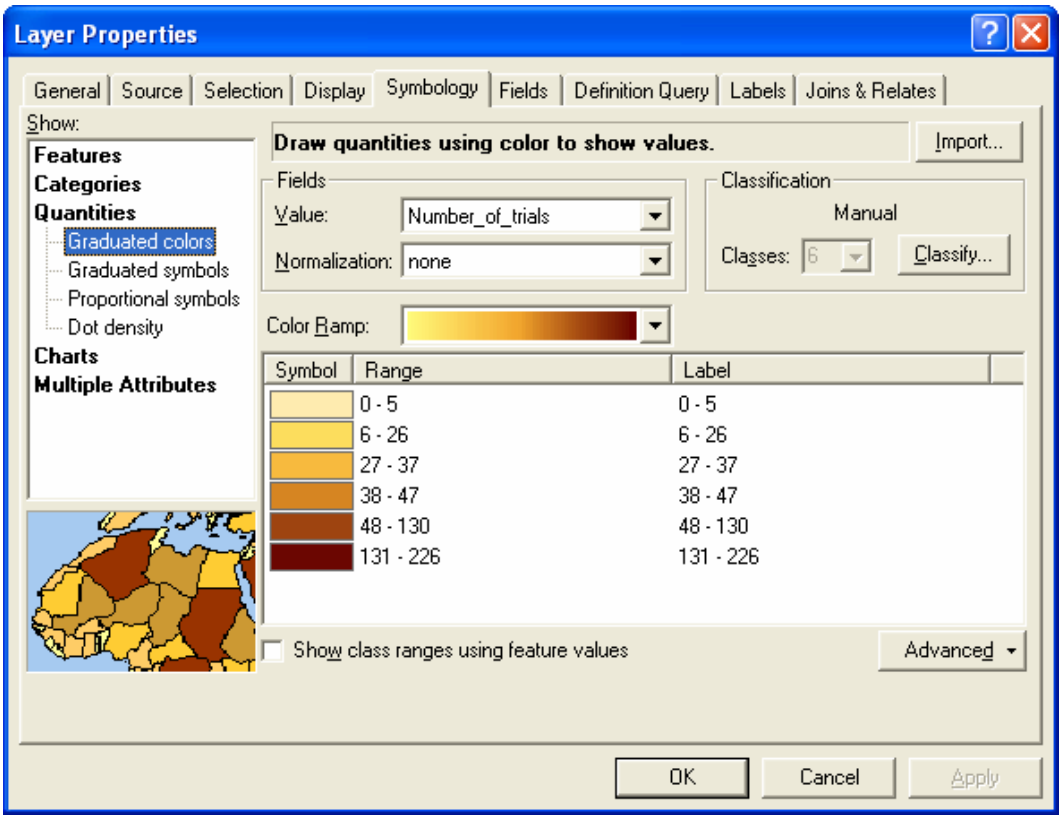
Figure 3.2 Joining Data in ArcView



Next, the ArcMap application was used to create a shape file for the number of trials. The county information was linked to the shapefile by joining the two tables. Next, the symbology screen was access through layer properties and the quantity field was accessed through layer properties to view the quantity of trials by graduated color. The value field selected was “number_of_trials”, in order to view the number of trials by

county. Class breaks were selected with the colors graduating from yellow to orange, as seen in figure 3.3.

Figure 3.3 Layer Properties Displaying Graduated Colors



Additional maps were done in 4 series. The first series was a basic map showing county cancer clinical trial listings by major cancer type. This map was constructed through the following steps. First the county shape file was added into ArcGIS. Next, the data was joined to the spreadsheet join_file2. Then, the layer properties were changed by creating quantity stratification and colors for the newly joined data. This was done in the

quantities field. The cancer type was selected as the variable and the default setting was selected for the number of natural breaks.

The next series of maps were created to show the cancer incidence as the base data with the number of trials displayed as point data with density of cancer trial locations shown by graduated symbol. This was done by conducting the following steps. First the base map of the county shape file was joined to the delimited text major cancer incidence file, previously described. Then, the layer properties were changed to reflect the quantities of cancer incidence joined to the county shape file. The color range was chosen and 5-6 natural breaks were selected (depending on the cancer type and pattern). Next, the data file containing the limited geocoded cancer clinical trial information by major cancer type was added. The X, Y data was displayed and the data was exported into a shapefile. The data was then added as a separate layer on top of the base map with incidence rate. The newly added data was then joined with the delimited text file containing the number of trials by county and major cancer type. As previously noted, this information only contained the county names listed with the number of trials in each county by major cancer type. Next, the layer properties were changed to display the quantities of trials by county. Graduated symbols were used to identify the quantity of trials available. A separate map was constructed for each of the four major cancer types using these steps.

The next series of maps were constructed to show the distribution of cancer trials as it relates to patterns of cancer incidence rates among African American patients in the state by major cancer type. This process was similar to the previously described map construction. First, the county shapefile was added and joined with the cancer incidence

rate join file. Then the geocoded limited file for the major cancer type was added. This file was then converted into a new shapefile and layer. Next, the quantity distribution colors were developed in the layer properties.

The final series of maps displayed the number of trials by mortality rates to reveal if trials were available in counties with the highest rates of death. The mortality data retrieved from the Georgia Comprehensive Cancer Registry was joined with the county shapefile in ArcMap. The number of trials was mapped over the chlorepleth map using graduated symbols. The next section will examine and present results found in the GIS analysis of cancer clinical trial locations in Georgia.

Chapter IV- Results

This study found that there are 321 cancer clinical trials (see Appendix A) currently enrolling in Georgia. Protocols for the four major cancer types accounted for 42.1 percent of all protocols (see figure 4.1). This study also found that there are 961 listings of cancer clinical trials in Georgia. The listings of trials include the locations where protocols are offered. This study also found that 53 percent of the cancer clinical trials offered in Georgia were in the four major cancer types: 23% breast, 10% colorectal, 14% lung, and 6% prostate (see figure 4.2). This finding was interesting since the "big four" cancers account for 58 percent of all cancer diagnosed and 53 percent of all cancer deaths. This study found that cancer clinical trials in the four major cancer types did not make up half of the cancer trials offered in the state.

Figure 4.1 Cancer Clinical Trial Protocols in Georgia by Major Cancer Type

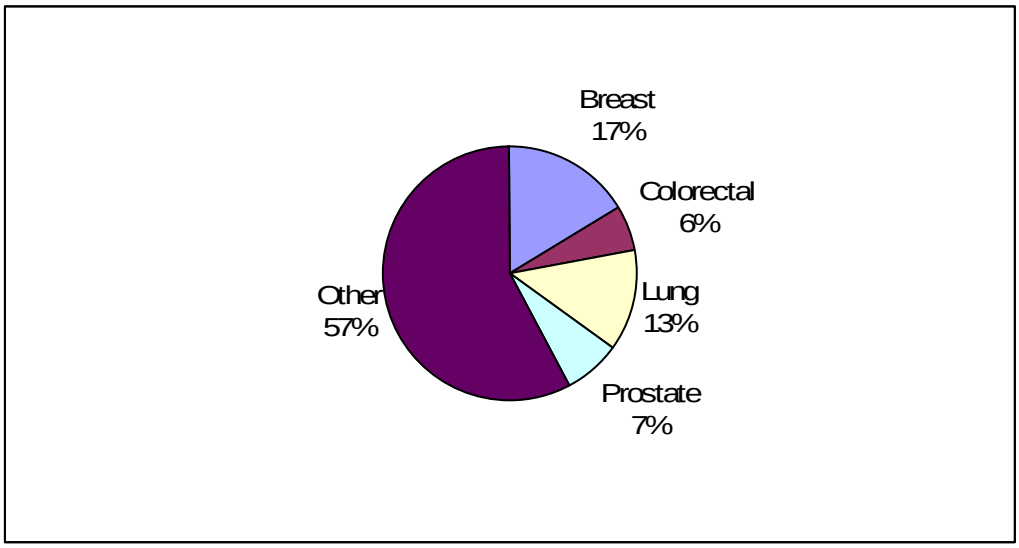
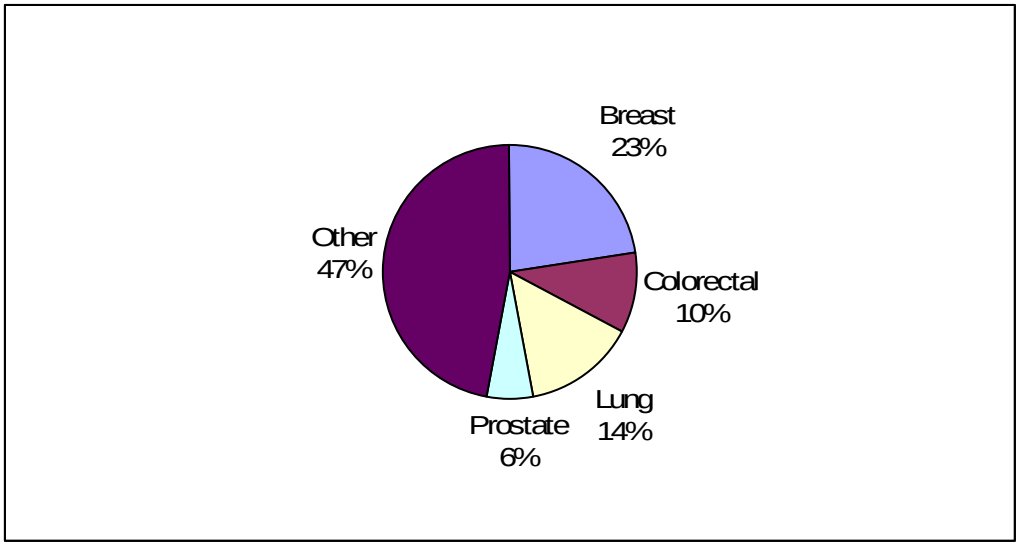


Figure 4.2 Cancer Clinical Trial Listings in Georgia by Major Cancer Type



Results from this study suggest that nearly 80 percent of the trials were treatment trials, see table 4.1.

Table 4.1 Types of Cancer Clinical Trial in Georgia

Type of Trial	Number of Trials	Percent
Treatment	767	79.8
Supportive care	46	4.8
Prevention	24	2.5
Other	124	12.9
Total	961	100.0

Of the 321 protocols found in this study, there were 961 total cancer clinical trials offered in the state. It is important to point out that there is a total of 321 cancer trials offered in Georgia at approximately 46 sites. The cancer clinical trial listing of 961

reflects where the 321 cancer trials are offered. Therefore, the reference to cancer clinical trial listings includes the actual locations where trials are being offered, not simply the overall number of protocols. Table 4.2 shows the number of cancer clinical trial listings by cancer type. Breast cancer trials are the leading type of cancer trial in Georgia, with 22.8 percent of the 961 listing of total trials; followed by lung (13.7 percent), colorectal (13.1 percent), lymphoma (6.7 percent) and prostate (6.2 percent).

Table 4.2 Number of Cancer Clinical Trial Listings by Cancer Type

	Cancer Type	Frequency	Percent
	Billiary Tract	1	.1
	Bladder	3	.3
	blood	5	.5
	Blood	23	2.4
	Bone and soft tissue	3	.3
	Brain	20	2.1
	Breast	219	22.8
	Cervix	10	1.0
	Colorectal	97	10.1
	Esophageal	13	1.4
	Gallbladder	8	.8
	Gastrointestinal	23	2.4
	Genitourinary	4	.4
	Gynecologic	6	.6
	Head and Neck	38	4.0
	Kidney	18	1.9
	Leukemia	57	5.9
	Liver	3	.3
	Lung	132	13.7
	Lymphoma	64	6.7
	Melanoma	35	3.6
	Multiple Myeloma	9	.9
	Myeloma	24	2.5
	other	28	2.9
	Other	2	.2
	Ovarian	25	2.6
	Pancreas	9	.9
	Prostate	60	6.2
	skin (non-melanoma)	9	.9
	Uterine	12	1.2
	Vagina	1	.1
	Total	961	100.0

Cancer clinical trials were found in 15 counties across 24 cities. A complete listing of cancer clinical trial listings by county can be found in table 4.3.

Table 4.3 Cancer Clinical Trial Listing by County

County	Number of Cancer Trials	Percent
Bibb	44	4.6
Chatham	121	12.6
Clarke	17	1.8
Clayton	37	3.9
Cobb	96	10.0
DeKalb	227	23.6
Dougherty	24	2.5
Floyd	7	.7
Fulton	131	13.6
Gwinnett	42	4.4
Hall	47	4.9
Lowndes	26	2.7
Muscogee	33	3.4
Richmond	105	10.9
Spalding	4	.4
Total	961	100.0

In this study, trials were found at 46 sites across the state (see Appendix B). This study also found that the majority of cancer clinical trials in Georgia were located in metro-Atlanta counties. Table 4.3 shows that nearly 24 percent of all cancer trial listings were found in DeKalb County. The number of trials varied outside of the metro-Atlanta counties from 7 to 121 trials. There were also a greater number of trials in counties with

medical schools. This study found that 55.8 percent of all cancer clinical trial listings were located in metro Atlanta counties.

Table 4.4 Number of Cancer Clinical Trials by Major Cancer Type and County

County	Breast trials	Colorectal trials	Lung trials	Prostate trials
Bibb	11	2	6	1
Chatham	21	16	17	6
Clarke	6	2	4	1
Clayton	9	2	4	1
Cobb	28	10	17	2
DeKalb	32	24	25	15
Dougherty	5	3	2	1
Floyd	1	0	3	0
Fulton	33	12	18	11
Gwinnett	10	5	9	1
Hall	15	2	5	6
Lowndes	5	3	5	1
Muscogee	10	5	3	2
Richmond	31	6	13	12
Spalding	2	1	0	0

Findings from this study show that the majority of cancer clinical trials were located in Fulton, Richmond, Cobb, Chatham and DeKalb counties. It is interesting that the metro Atlanta counties and counties with University medical centers have the majority of the trials in the state. Fulton, DeKalb, and Cobb counties are located in metro Atlanta. Richmond and Chatham counties have University medical centers, Medical College of Georgia and Mercer University School of Medicine, respectively. As seen in table 4.4, these counties also tend to lead the state in the most trials in the major cancer types.

The following map contains a geographic representation of cancer clinical trials in the state by listing.

Figure 4.3
Total Number of Cancer Clinical Trial Listings in Georgia by County

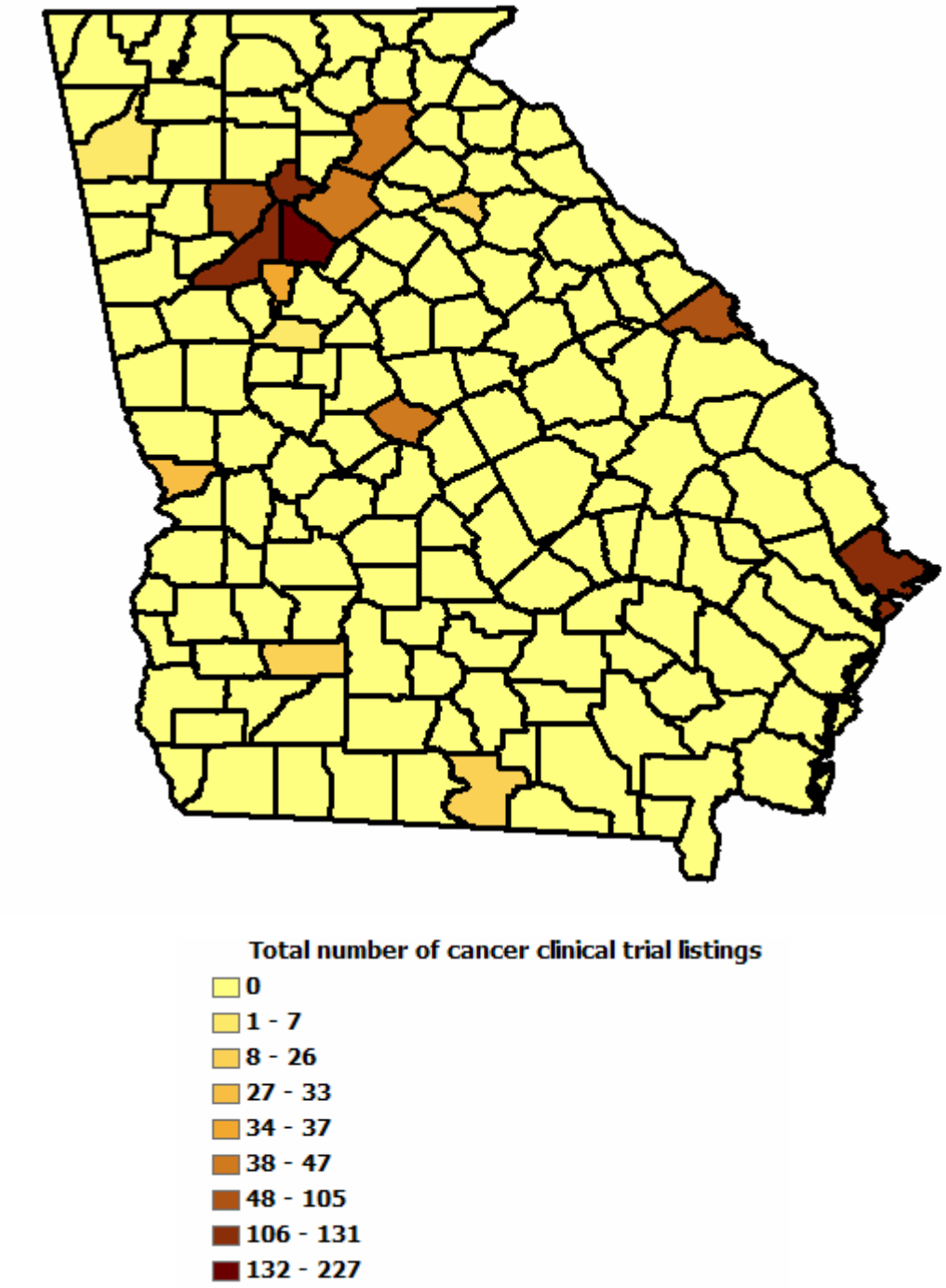
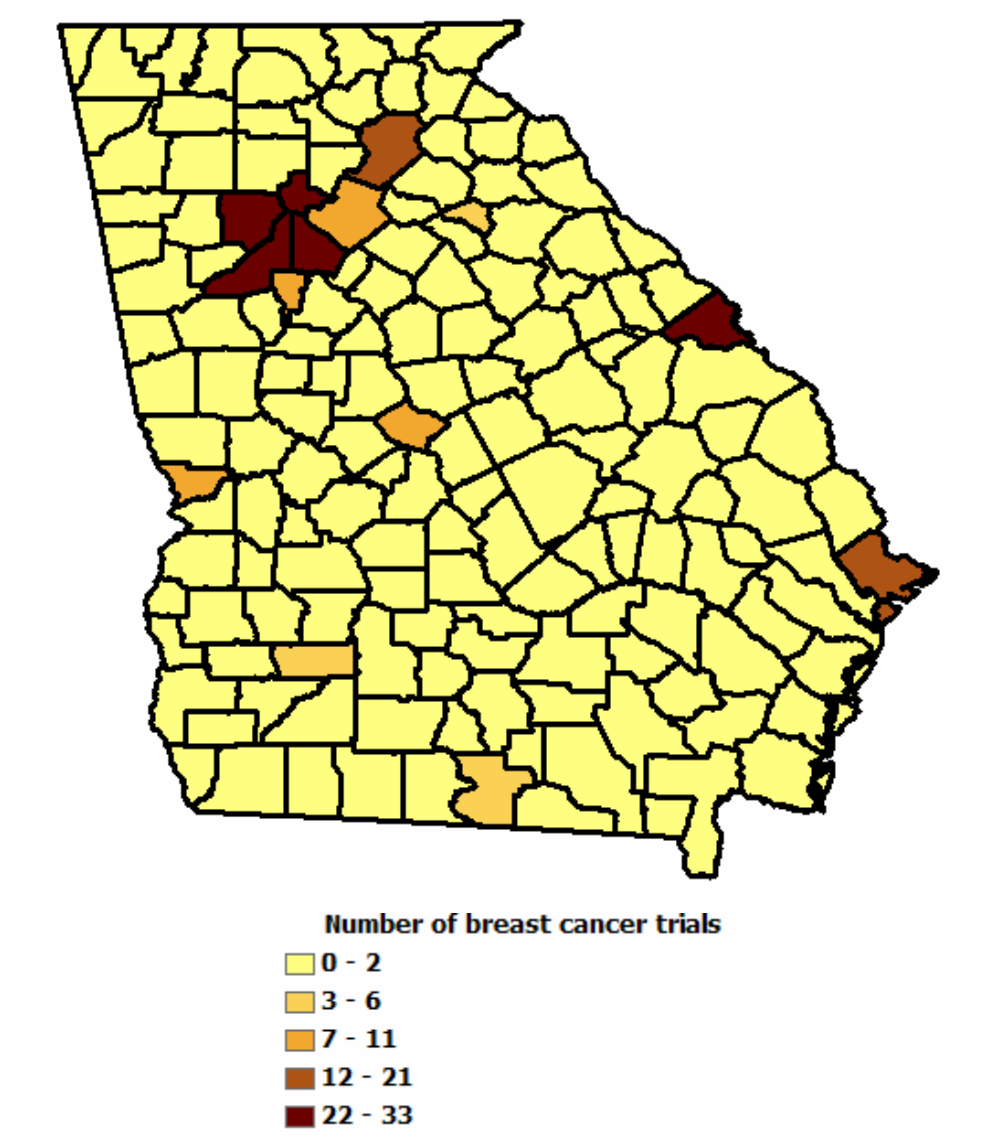


Figure 4.3 exhibits the nature of cancer clinical trial distribution across the state. Generally, color-coded distribution is only utilized to show rates or ratios; however, for illustration purposes, this distribution is shown to give a basic view of trial quantity distribution throughout the state. DeKalb County has the largest density of cancer clinical trials, followed by Fulton, Chatham and Richmond counties. The following map shows the distribution of breast cancer clinical trials in the state. The highest densities of trials are offered in metro Atlanta counties.

Figure 4.4
Breast Cancer Trial Listings in Georgia, by County



The following map, Figure 4.5, shows the distribution of colorectal cancer clinical trials in the state. Most of the colorectal cancer trials offered in Georgia are also in metro Atlanta. DeKalb County has the largest density of colorectal cancer trials of any county in the state. This is partly due to the Winship Cancer Institute at Emory University.

Figure 4.5
Colorectal Cancer Clinical Trial Listings in Georgia, by County

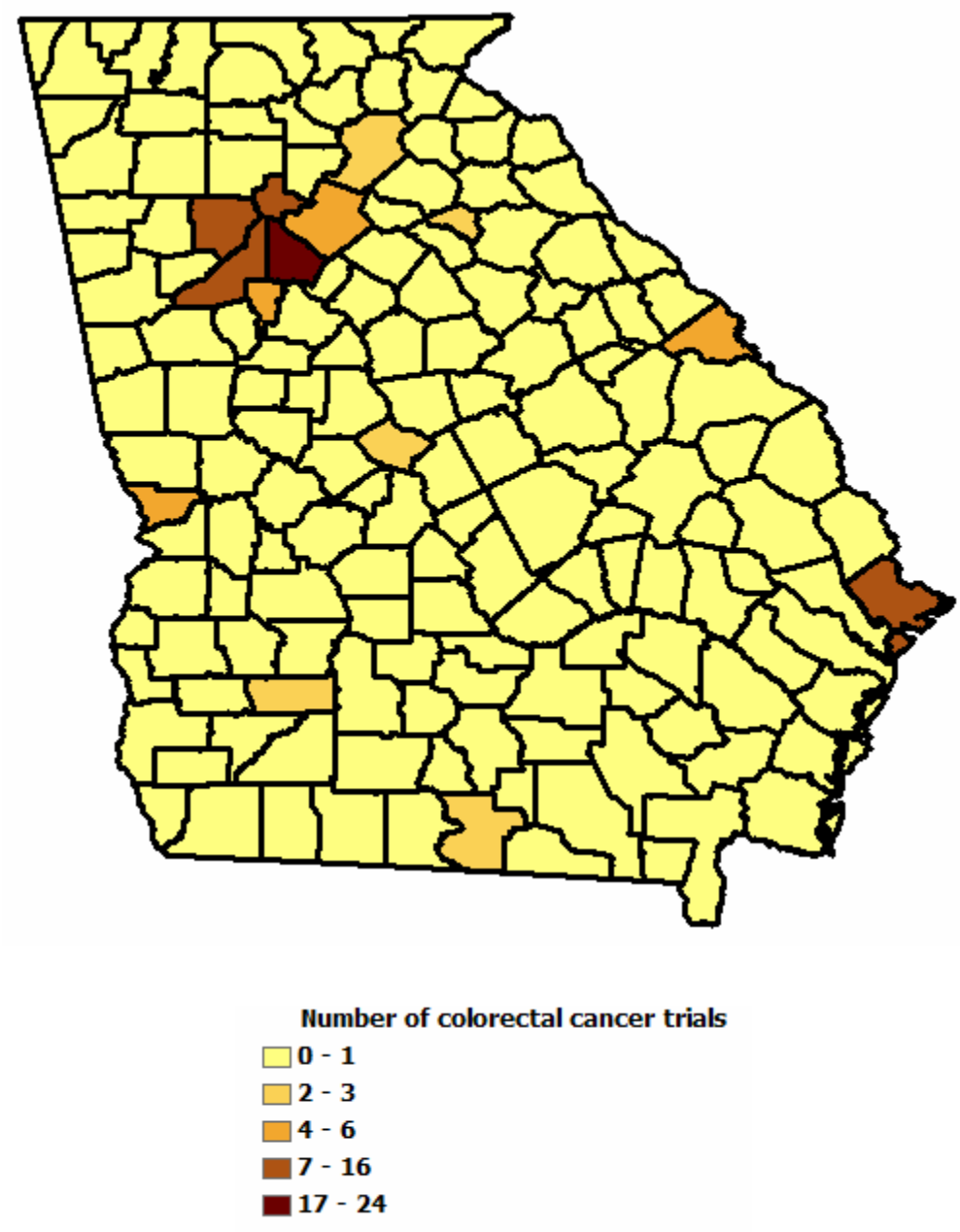


Figure 4.6
Lung Cancer Clinical Trial Listings in Georgia, by County

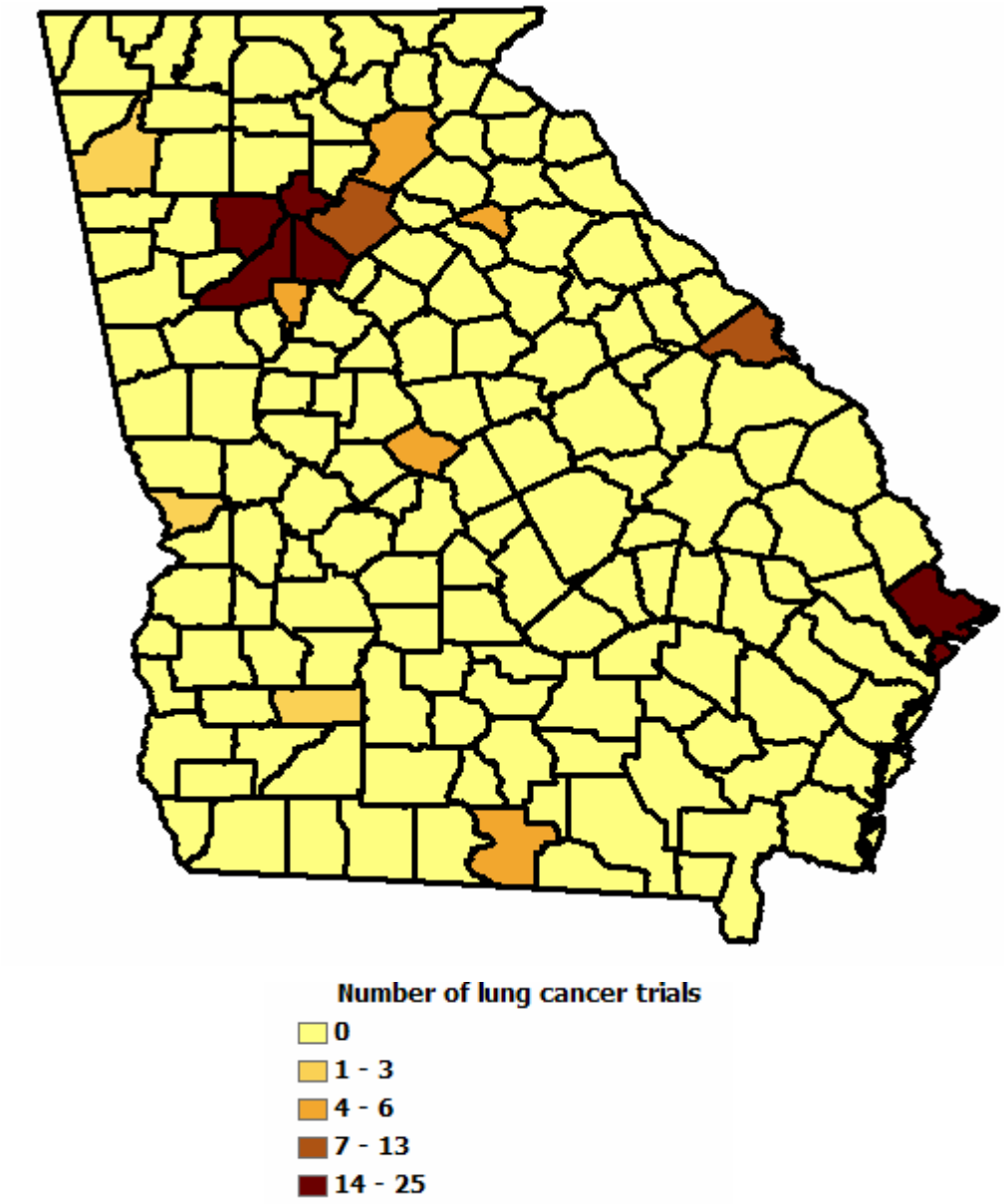
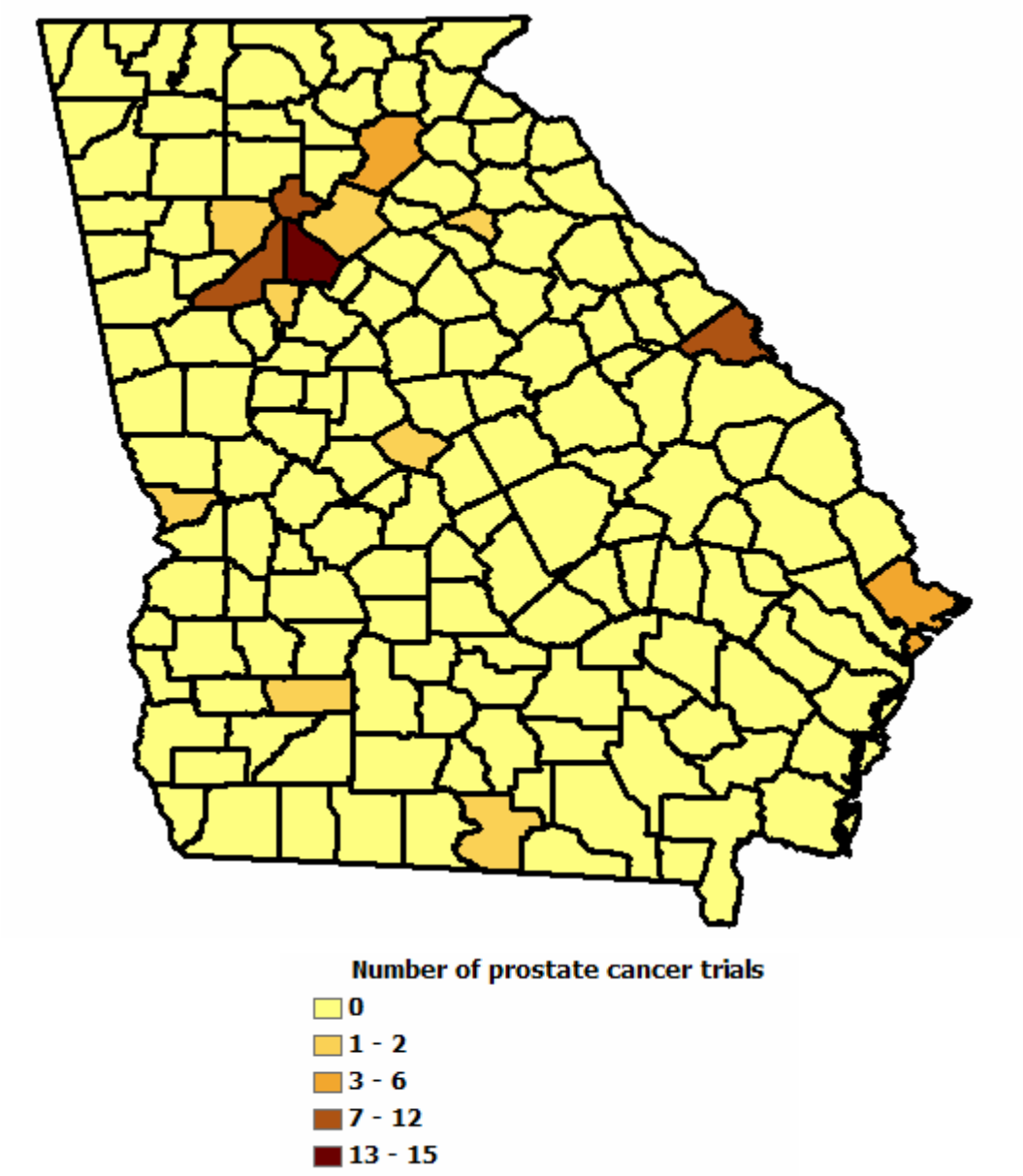


Figure 4.6 shows the basic distribution of lung cancer clinical trials in the state. The largest number of trials appears mainly in metro Atlanta counties, with the exception of Chatham County.

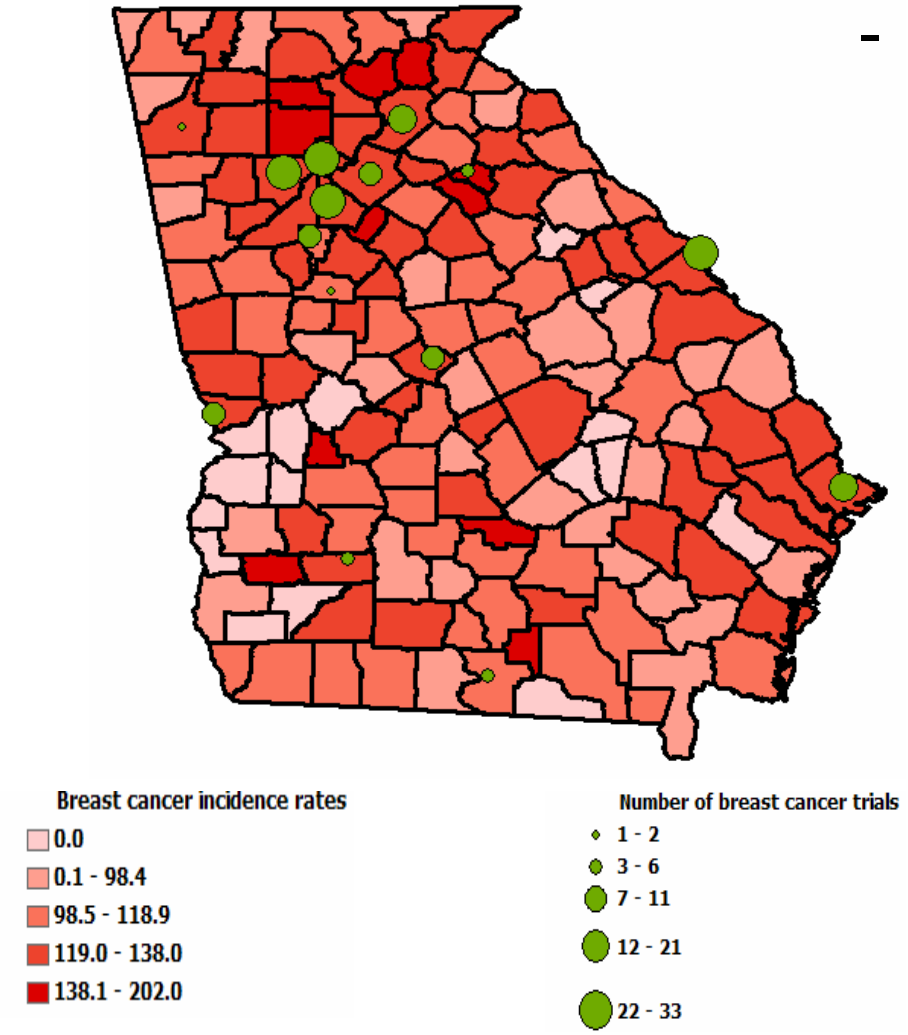
Figure 4.7
Prostate Cancer Clinical Trials in Georgia by County



A basic distribution analysis of the prostate cancer clinical trials in the state shows that the largest quantity of trials in DeKalb County, followed by Fulton and Richmond

counties. The next series of maps will display cancer incidence rates by major cancer types and the number of trials by county.

Figure 4.8
Breast Cancer Incidence Rates (1999-2003), Number of Breast Cancer Trials in Georgia by County



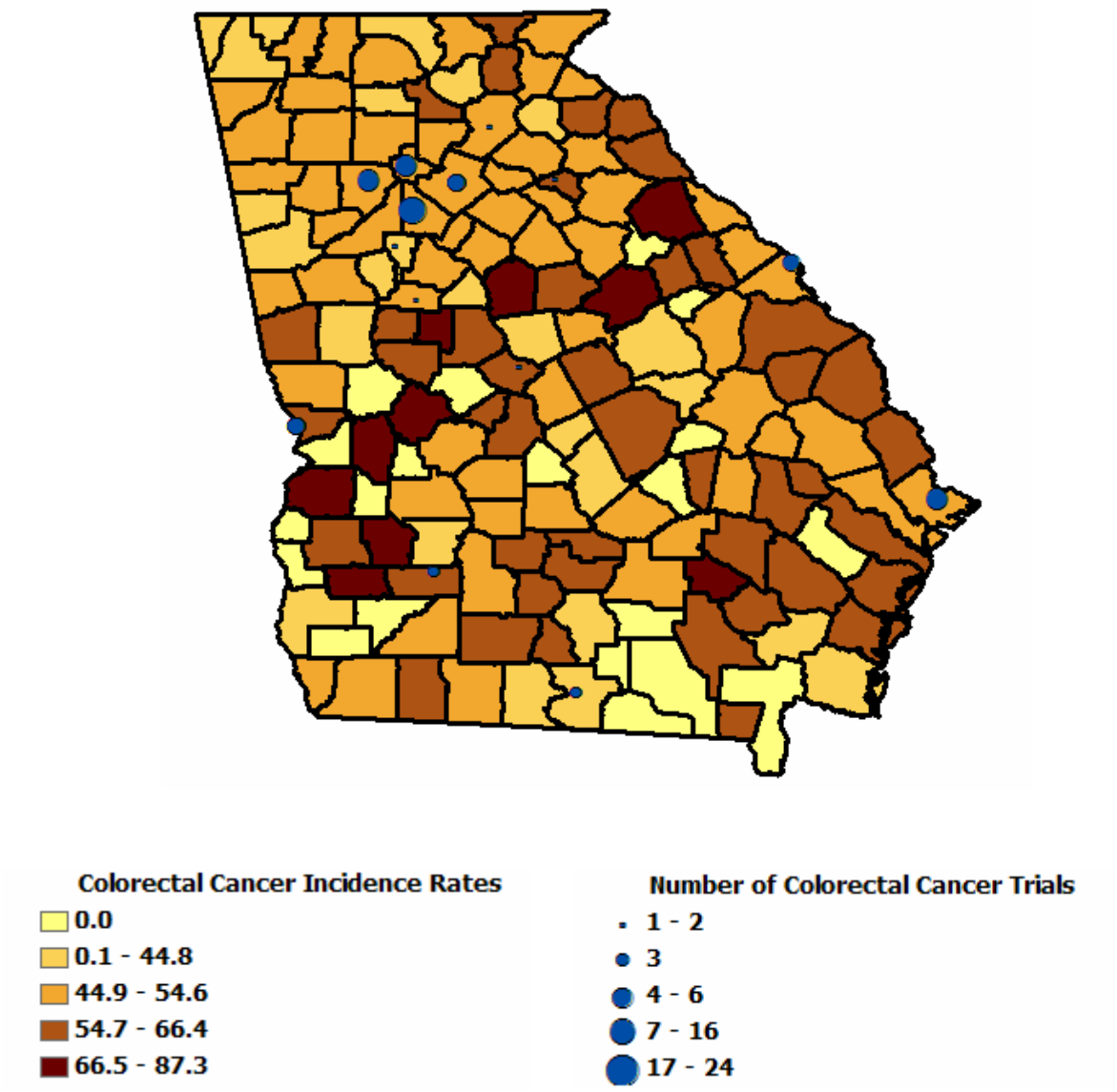
The map above shows the distribution of breast cancer incidence rates in the state as the base map. In addition, the numbers of breast cancer clinical trials are plotted over

the incidence rates to view where the breast cancer trials are in relation to the rates of new breast cancer cases. The darker pink color indicates a higher breast cancer incidence rate while larger densities of trials are indicated by graduated circular symbols. This study found that of the 11 counties with the highest rates of breast cancer incidence, only one had cancer clinical trials available: Clarke county (see table 4.5)

Table 4.5. Presence of Cancer Trials in Georgia Counties with Highest Level Breast Cancer Incidence

County	Breast Cancer Incidence Rate	Presence of Breast Cancer Clinical Trials
Schley	202.0	No
Ben Hill	158.3	No
Pickens	156.1	No
Calhoun	151.5	No
White	148.3	No
Lumpkin	147.5	No
Cherokee	144.3	No
Oconee	143.2	No
Clarke	142.6	Yes
Lanier	141.1	No
Rockdale	140.7	No

Figure 4.9
Colorectal Cancer Incidence Rates (1999-2003), Number of Colorectal Cancer Trials in Georgia by County



This study found that 13 counties in Georgia have colorectal cancer clinical trials available. The largest quantity of trials is indicated by a larger circle in figure 4.9. This figure reveals the number of colorectal trials available in each county layered over the

colorectal cancer incidence rates. The findings suggest that the counties with the highest incidence rates of colorectal cancer have no cancer trials available in those counties. A large number of the colorectal trials are located in the metro Atlanta counties where the colorectal cancer incidence rates are lower.

Table 4.6 Presence of Cancer Trials in Georgia Counties with Highest Level Colorectal Cancer Incidence

County	Colorectal Cancer Incidence Rate	Presence of Colorectal Cancer Clinical Trials
Jasper	87.3	No
Terrell	86.6	No
Marion	77.8	No
Taylor	77.8	No
Hancock	76.1	No
Calhoun	73.3	No
Bacon	71.0	No
Lamar	70.9	No
Wilkes	69.6	No
Stewart	68.6	No

Calhoun and Lanier counties both have the highest incidence rates of breast and colorectal cancer and neither have trials available. In addition, there are limited trials in proximity to these counties.

Figure 4.10 shows the lung cancer incidence rates in Georgia with the number of trials. Findings were similar to the disparities found in the figure 4.9. Counties with the largest rates of new lung cancer cases have no lung cancer trials available.

Figure 4.10 Lung Cancer Incidence Rates (1999-2003), Number of Lung Cancer Trials in Georgia by County

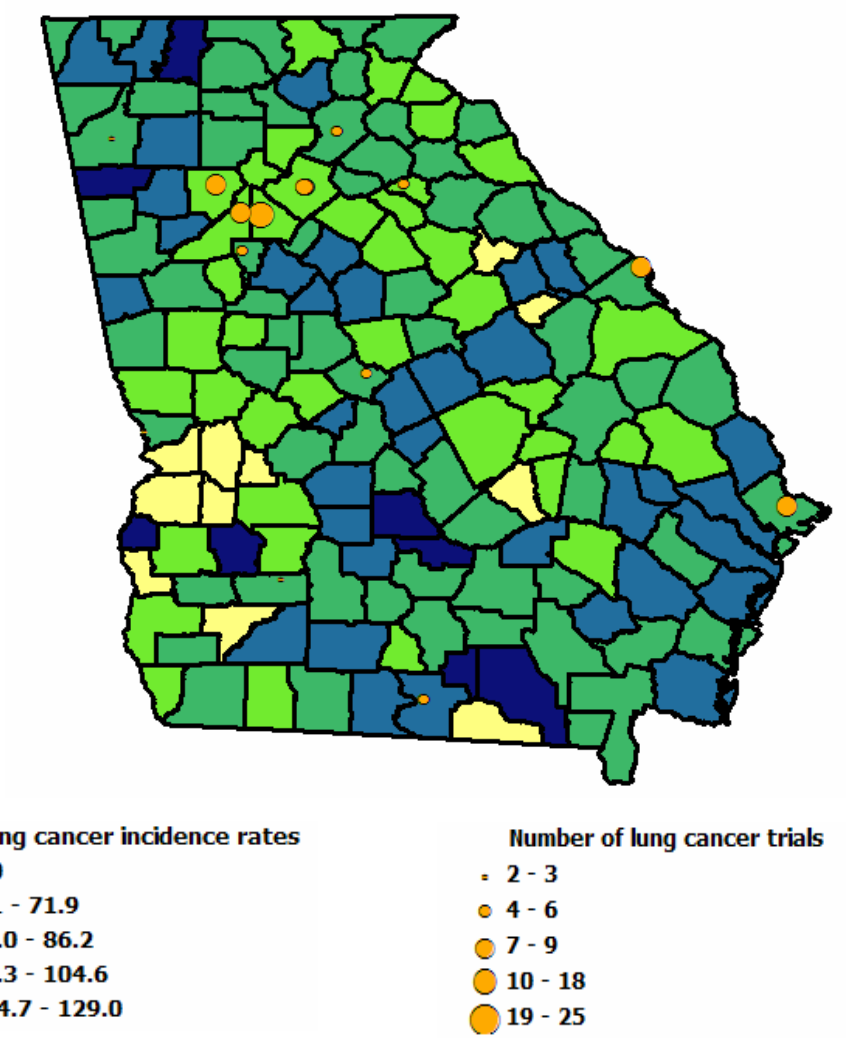


Table 4.7 Presence of Cancer Trials in Georgia Counties with Highest Level Lung Cancer Incidence

County	Lung Cancer Incidence Rate	Presence of Lung Cancer Clinical Trials
Lanier	129.0	No
Quitman	122.9	No
Ben Hill	122.7	No
Murray	116.1	No
Terrell	113.2	No
Clinch	111.7	No
Polk	109.6	No
Wilcox	107.3	No

Lanier County appears again as one of the counties with the highest levels of lung cancer incidence and yet they have no cancer clinical trials available. Appendix C shows the map with Georgia counties labeled.

An analysis of the number of prostate cancer clinical trials by incidence rates revealed that 13 of the 159 counties in Georgia offer prostate cancer trials, as seen in figure 4.11. Counties with the highest burden of prostate cancer had no prostate cancer trials available. Consequently, trials available in neighboring counties were scant. This study also found that the number of prostate cancer trials available across the state was substantially lower compared to the number of breast, colorectal, and lung cancer trials.

Figure 4.11
Prostate Cancer Incidence Rates (1999-2003), Number of Prostate Cancer Trials in Georgia by County

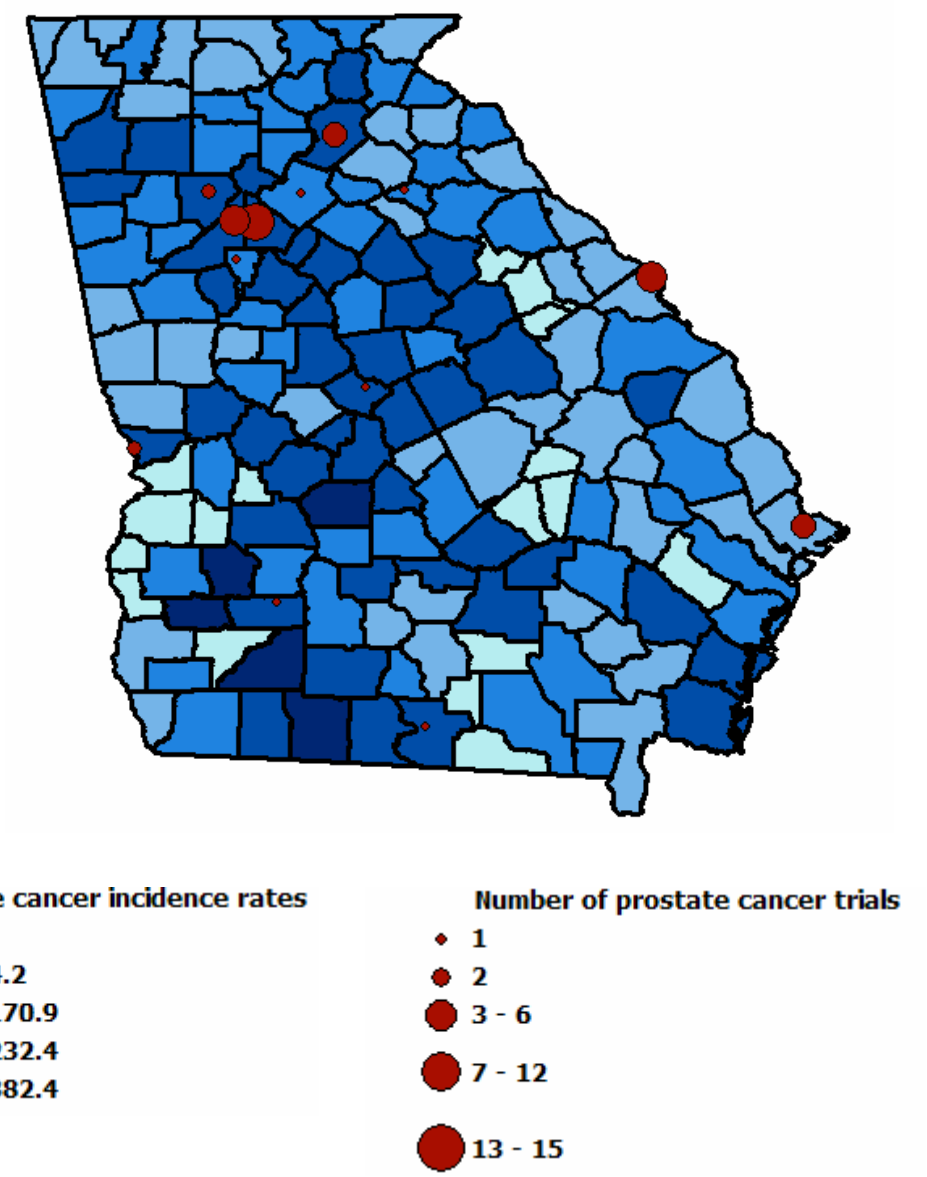


Table 4.8 Presence of Cancer Trials in Georgia Counties with Highest Level Prostate Cancer Incidence

County	Prostate Cancer Incidence Rate	Presence of Prostate Cancer Clinical Trials
Calhoun	382.4	No
Thomas	261.8	No
Terrell	254.6	No
Mitchell	249.0	No
Dooly	247.9	No

It is interesting to note that the highest rates of new prostate cancer cases are largely comprised in South Georgia. Yet, these counties have no prostate cancer trials available. Table 4.8 displays the five counties with the highest rates of prostate cancer incidence. These findings indicate a serious public health issue, particularly since there is only a combined five prostate cancer trials in the entire southwest corner of the state. This also leads to a question regarding why there are no more than 15 trials found in one county, compared to the number of trials available for breast, colorectal and lung cancers.

Figure 4.12
Breast Cancer Incidence Rates in African Americans (1999-2003), Number of Breast Cancer Trials in Georgia by County

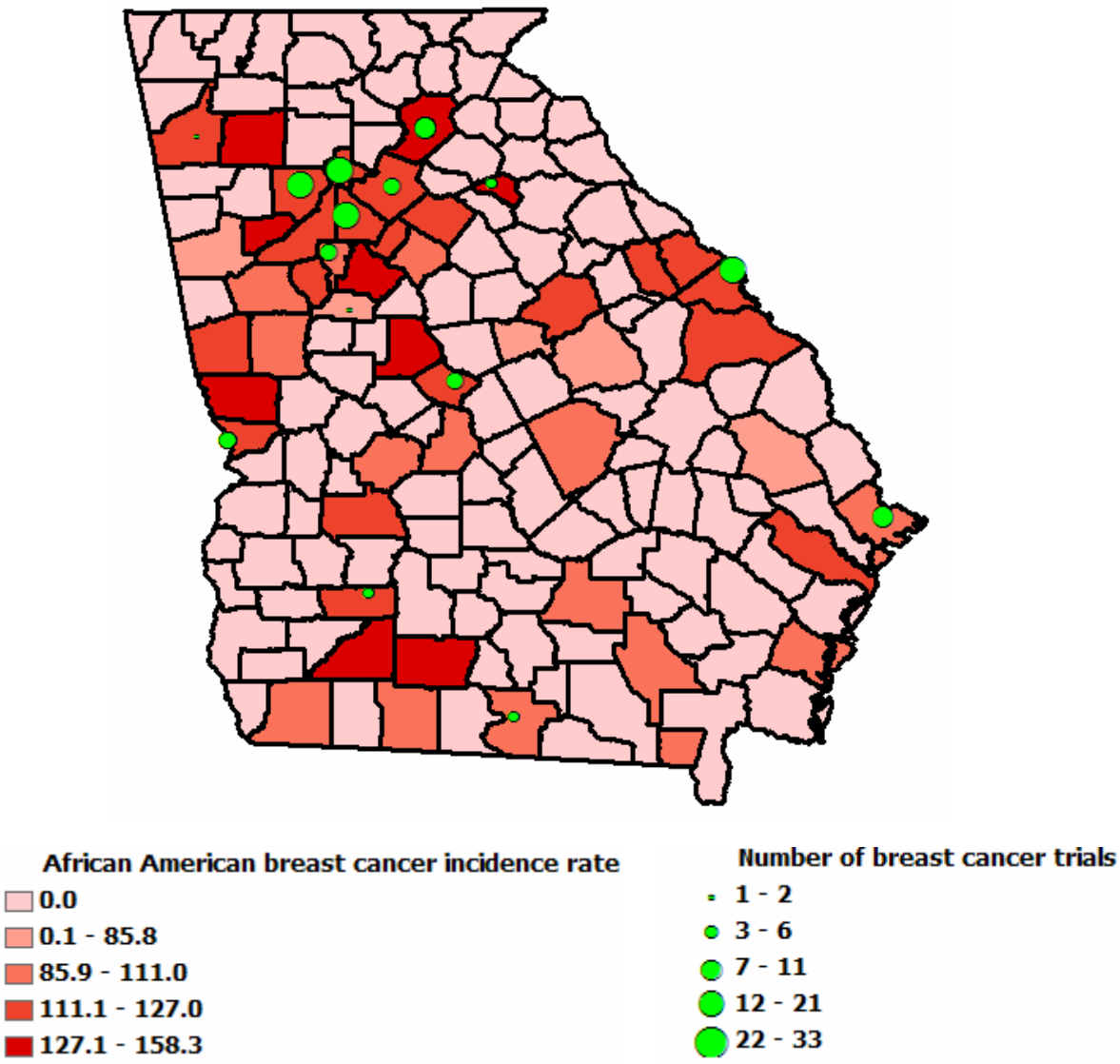


Figure 4.12 shows the rates of new breast cancer cases in African American women in the state. This analysis revealed that 2 of the 9 counties with the highest breast

cancer incidence rates for African American women had breast cancer trials, Clarke and Hall counties. The largest quantities of trials were found in Fulton, DeKalb, Cobb, and Richmond.

Figure 4.13
Colorectal Cancer Incidence Rates in African Americans (1999-2003), Number of Colorectal Cancer Trials in Georgia by County

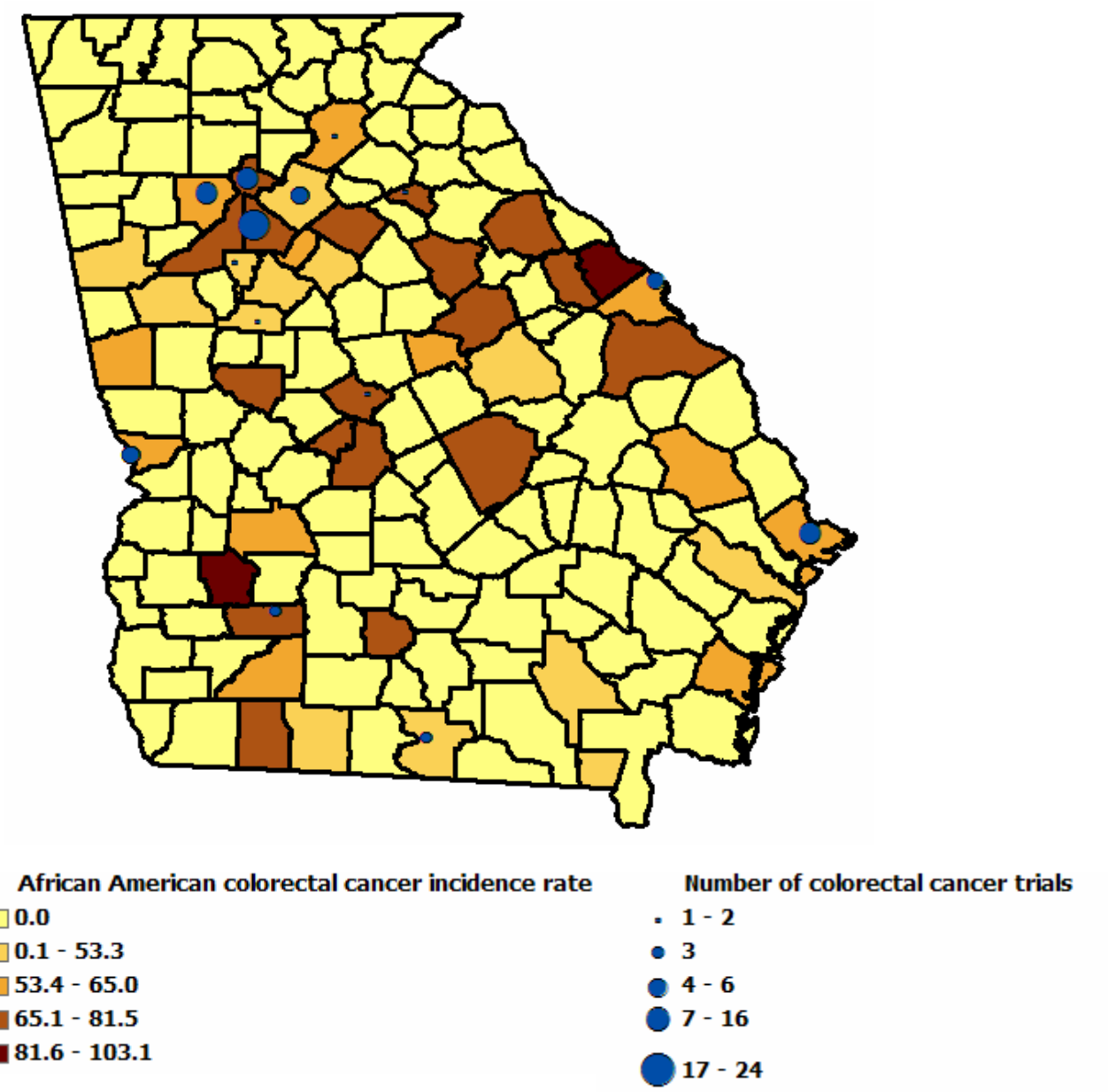


Figure 4.13 shows the colorectal cancer incidence in the African American population by county and the number of trials available. Counties with the highest rates of colorectal cancer incidence in African Americans, there were no trials present. However, in counties with moderately high colorectal cancer incidence rates for this population, trials were available in 5 out of 17 counties.

An analysis of lung cancer incidence rates in African Americans and lung trials available to them found no trials available in the counties with the highest incidence rates, as seen in figure 4.14. In addition, no more than six trials were available in counties with the second highest level of lung cancer incidence in the African American population. Furthermore, the highest quantities of trials were found in counties with moderate lung cancer incidence rates. Two-thirds of the counties with the largest quantities of trials were located in metro Atlanta.

Figure 4.14
Lung Cancer Incidence Rates in African Americans (1999-2003), Number of Lung Cancer Trials in Georgia by County

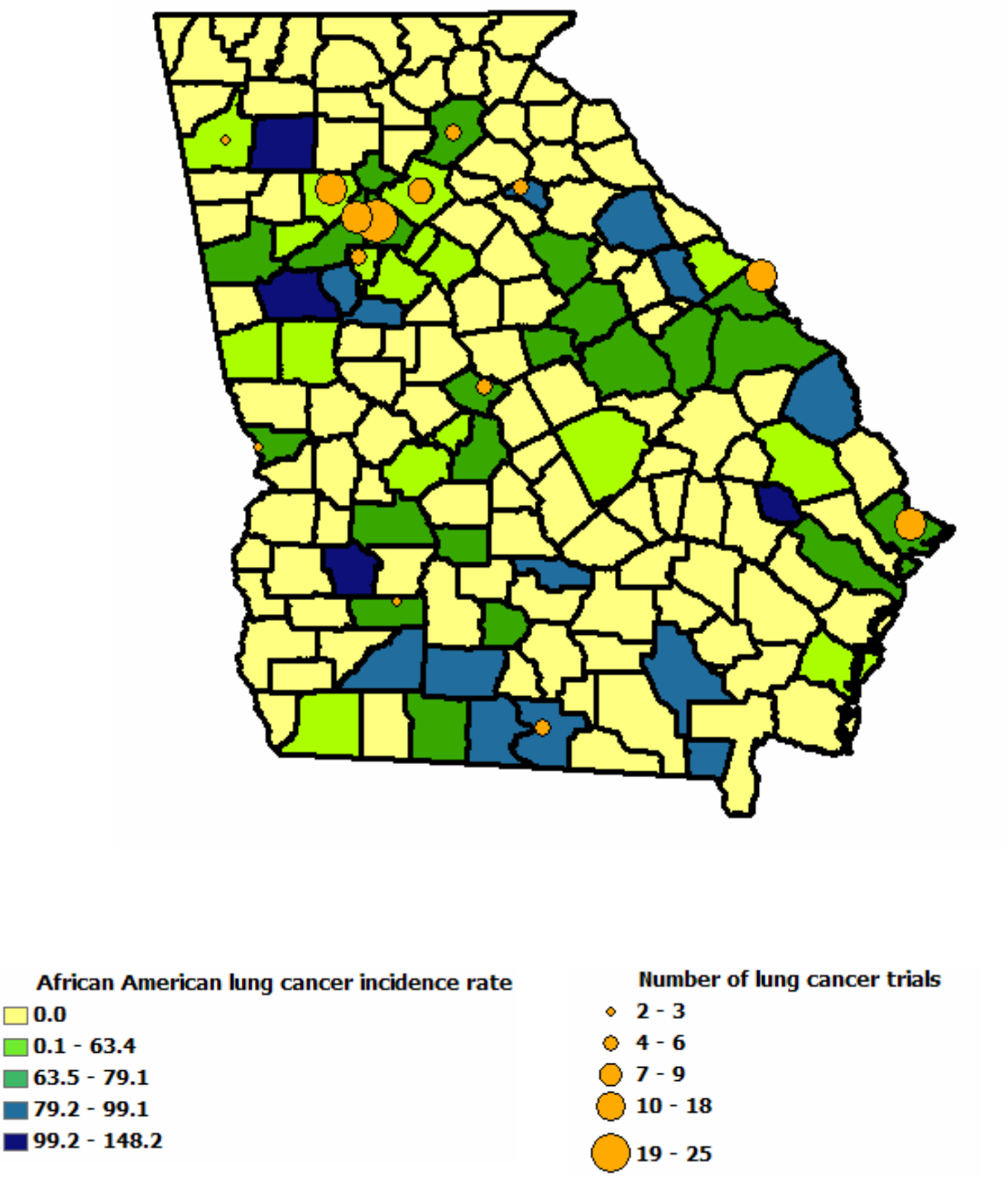
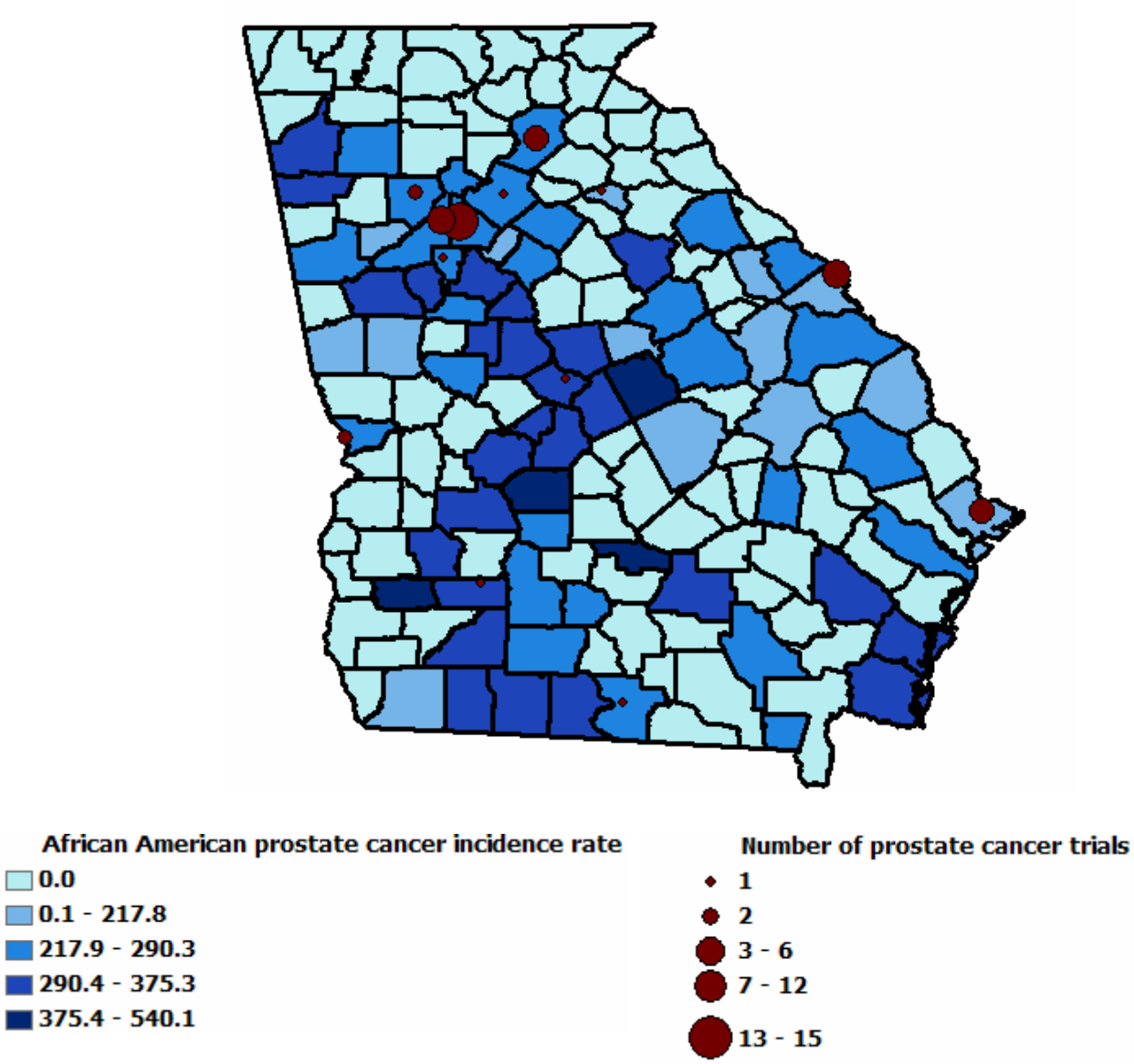


Figure 4.15 displays the number of prostate cancer trials available by county and prostate cancer incidence rates in the African American population. This study found that there were no trials available in counties with the highest prostate cancer incidence rates. In addition, the counties with the second highest levels of prostate cancer incidence rates in this population had a single trial in 1 out of 26 counties.

Figure 4.15
Prostate Cancer Incidence Rates in African Americans (1999-2003), Number of Prostate Cancer Trials in Georgia by County



The next series of maps will display cancer mortality rates by major cancer type and the number of trials by county.

Figure 4.16
Breast Cancer Mortality Rates (1999-2003), Number of Breast Cancer Trials by County in Georgia by County

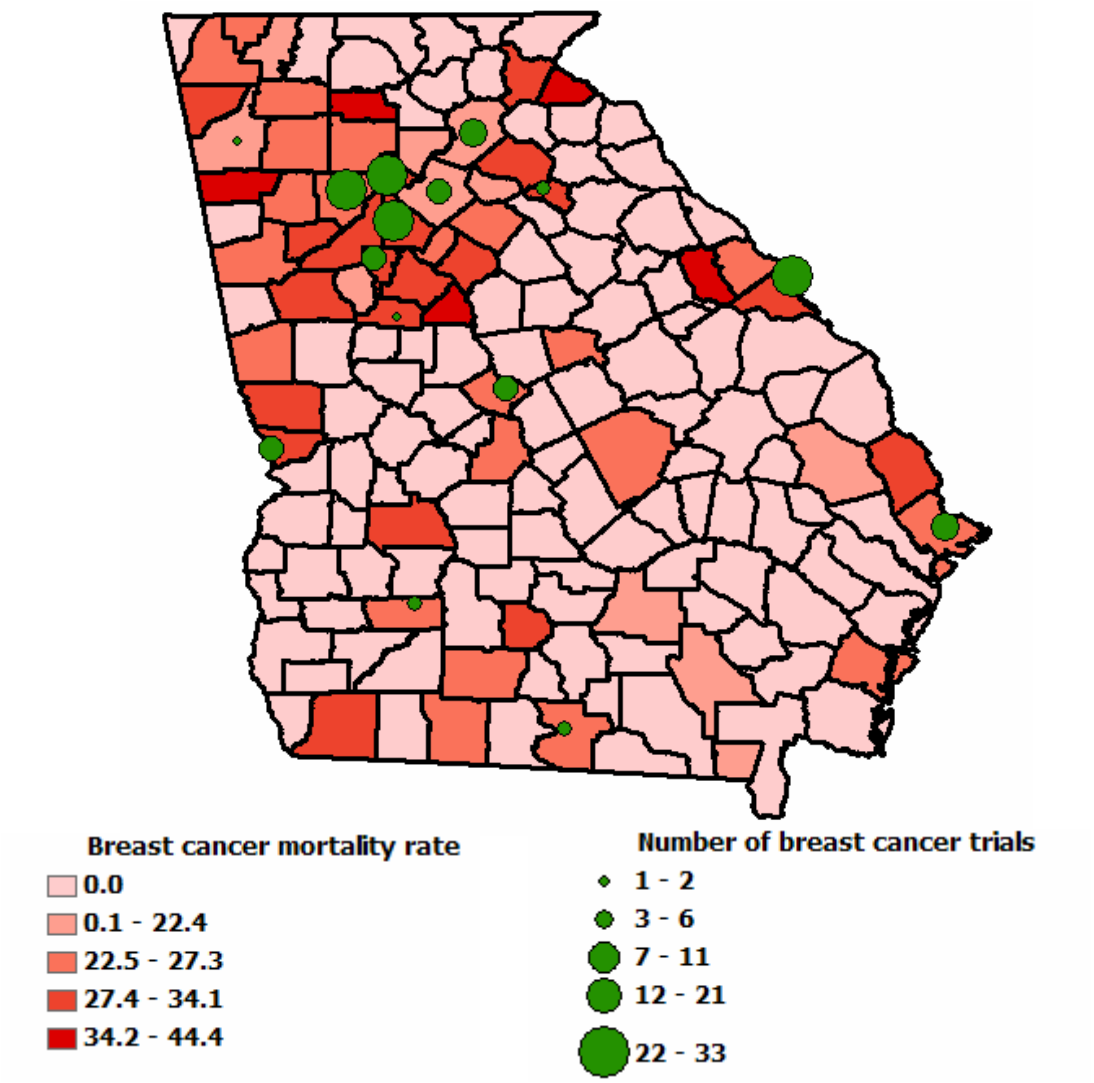


Figure 4.16 depicts the number of breast cancer trials by mortality rates of the disease. There were no trials found in counties with the highest rates of breast cancer

deaths. However, of the counties offering breast cancer trials, the largest number of trials was found in counties with the second highest mortality rates.

Table 4.9 Presence of Cancer Trials in Georgia Counties with Highest Level Breast Cancer Mortality Rates

County	Breast Cancer Incidence Rate	Presence of Breast Cancer Clinical Trials
Butts	44.4	No
Stephens	43.2	No
Pickens	39.5	No
Polk	36.1	No
McDuffie	35.2	No

This study also analyzed the number of colorectal cancer trials by the rates of colorectal cancer deaths, as seen in figure 4.17. Results show that there were no trials available in counties with the highest mortality rates. In addition, there were no colorectal cancer trials found in counties with the second highest rates of colorectal cancer deaths.

Figure 4.17
Colorectal Cancer Mortality Rates (1999-2003), Number of Colorectal Cancer Trials in Georgia by County

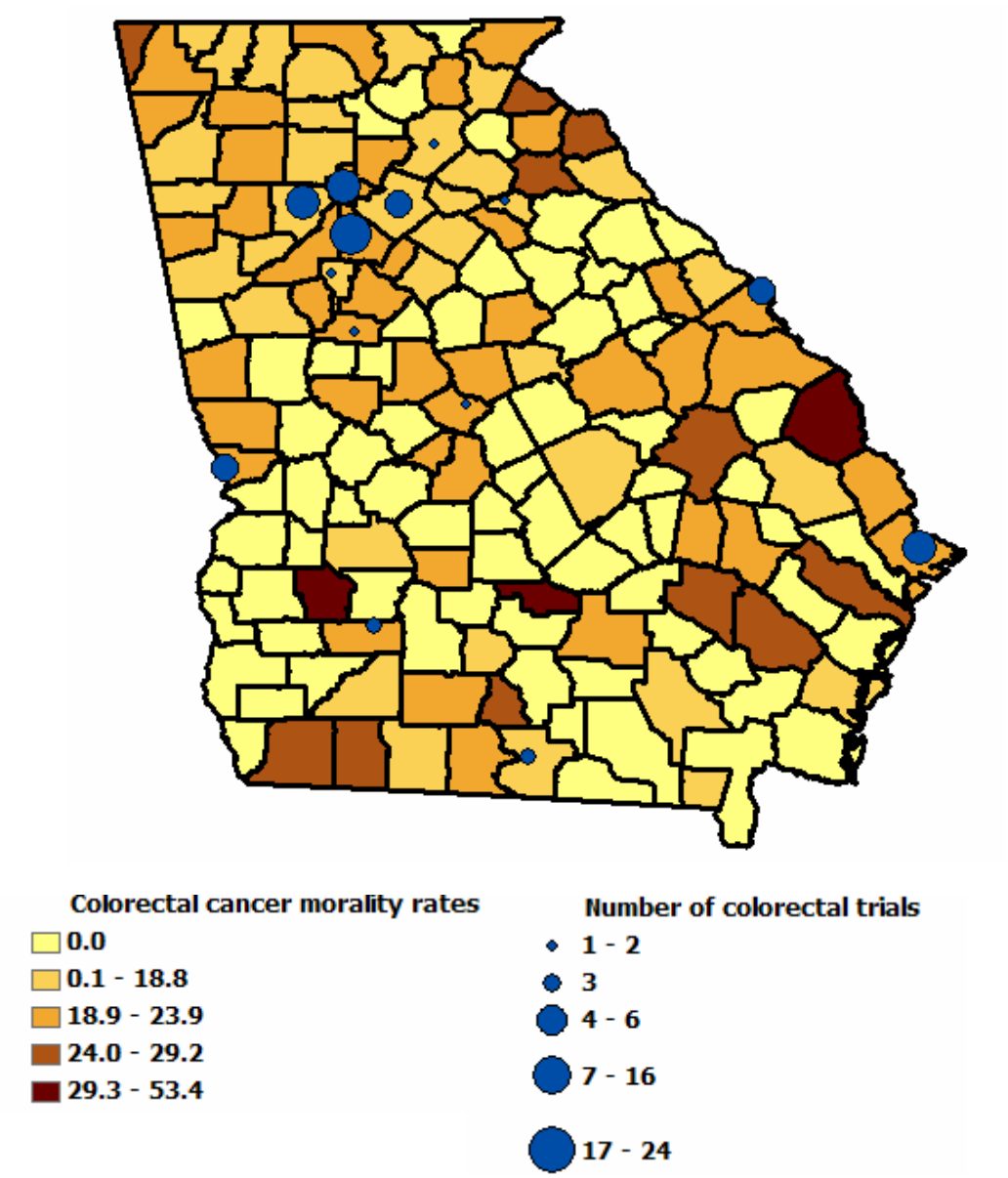


Table 4.10 Presence of Cancer Trials in Georgia Counties with Highest Level Colorectal Cancer Mortality Rates

County	Colorectal Cancer Mortality Rate	Presence of Colorectal Cancer Clinical Trials
Terrell	53.4	No
Screven	34.2	No
Ben Hill	32.1	No

Table 4.10 shows that there were no colorectal cancer clinical trials available in counties with the highest rates of mortality for the disease. Terrell, Screven and Ben Hill counties were the top three counties with the highest colorectal cancer mortality rates in Georgia.

Figure 4.18
Lung Cancer Mortality Rates (1999-2003), Number of Lung Cancer Trials in Georgia by County

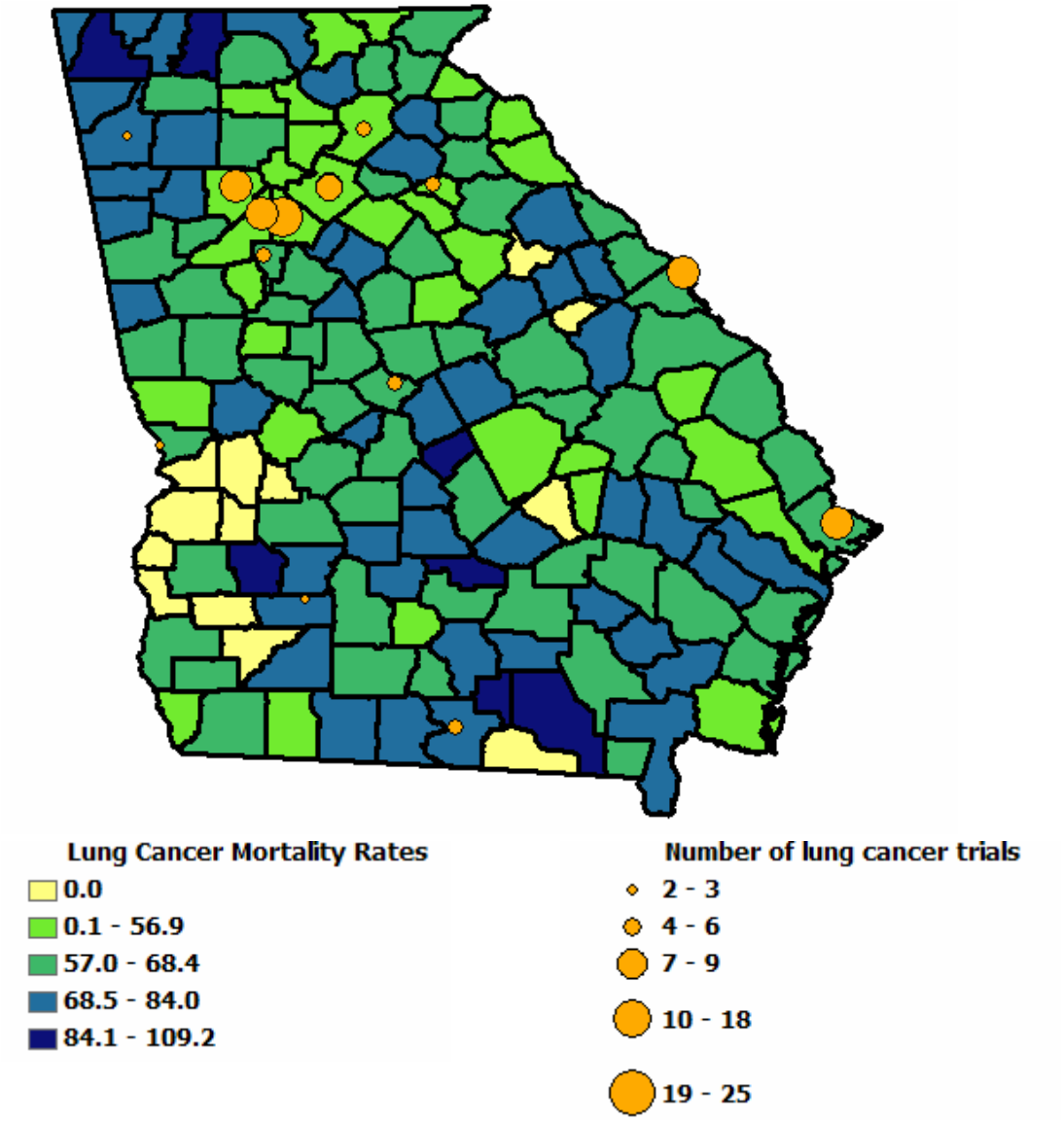


Figure 4.18 shows the number of lung cancer trials and mortality rates of lung cancer by county. Results reveal that the counties with the highest rates of mortality have no cancer clinical trials. Also, the counties with the second highest levels of lung cancer

mortality have trials available in 0 out of the 35 counties with mortality rates between 84.1 and 109.2 per 100,000, as seen in table 4.11.

Table 4.11 Presence of Cancer Trials in Georgia Counties with Highest Level Lung Cancer Mortality Rates

County	Lung Cancer Mortality Rate	Presence of Lung Cancer Clinical Trials
Murray	109.2	No
Ben Hill	108.8	No
Terrell	102.1	No
Clinch	97.4	No
Bleckley	96.3	No
Walker	88.6	No
Lanier	88.2	No

The next map displays the number of prostate cancer clinical trials in the state by prostate cancer mortality rates, see figure 4.19. There were no trials found in counties with the highest death rates from prostate cancer. However, a substantial number of trials were found in counties with the second largest prostate cancer mortality rates.

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Figure 4.19
Prostate Cancer Mortality Rates (1999-2003), Number of Prostate Cancer Trials in Georgia by County

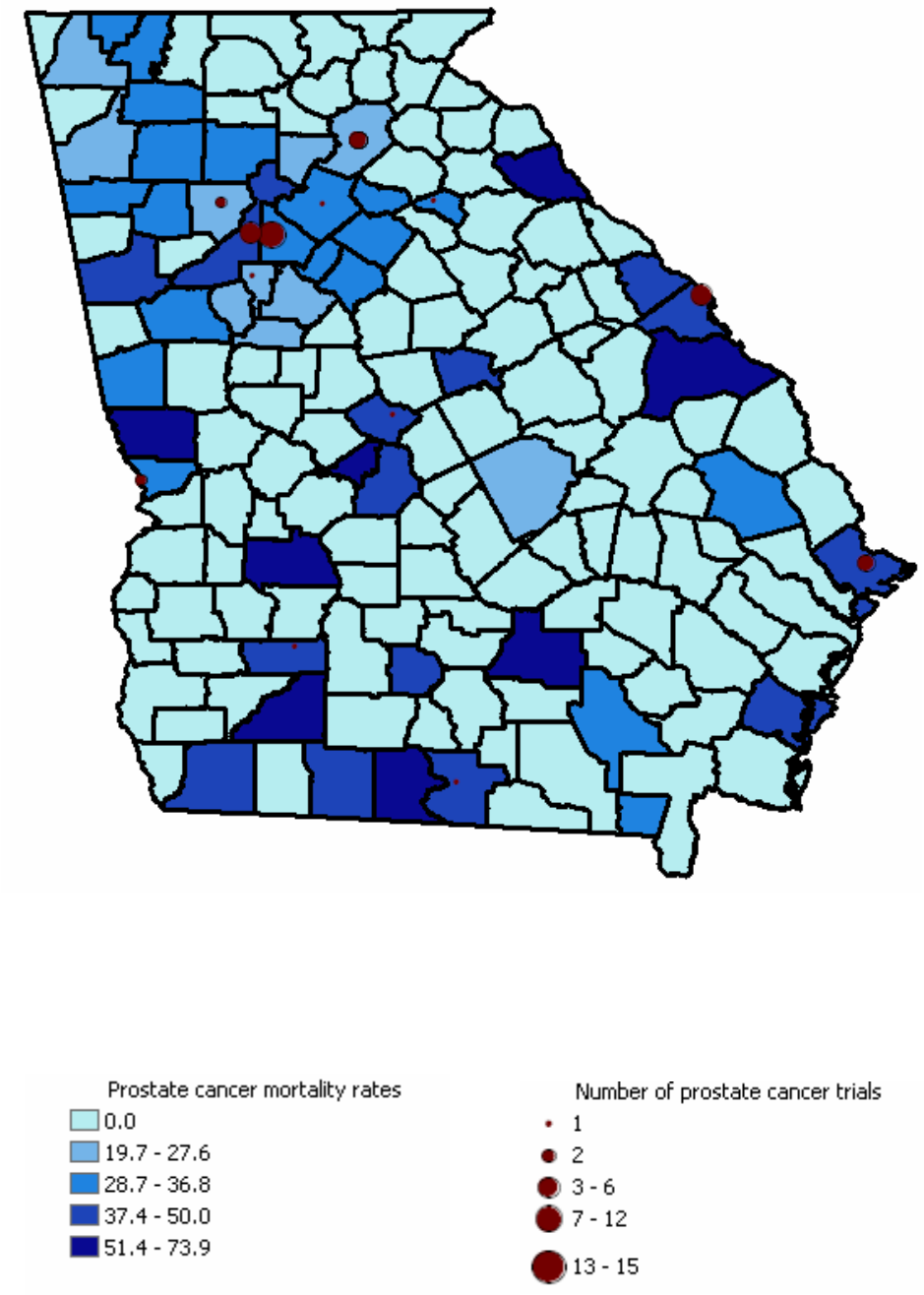

Table 4.12 Presence of Cancer Trials in Georgia Counties with Highest Level Prostate Cancer Mortality Rates

County	Prostate Cancer Incidence Rate	Presence of Prostate Cancer Clinical Trials
Burke	73.9	No
Peach	66.2	No
Harris	63.1	No
Brooks	60.2	No
Mitchell	58.8	No
Elbert	52.5	No
Sumpter	51.6	No
Coffee	51.4	No

There were also no cancer clinical trials found in counties with the highest prostate cancer mortality rates. This finding is interesting, particularly since the death rates for prostate cancer are higher than those of breast and colorectal cancers. Also, many of the counties with the highest prostate cancer mortality rates are in Southeast Georgia were there are no more than 5 trials in the entire region.

Chapter V- Discussion

Cancer is a serious public health problem across the state of Georgia. In an effort to identify potential health disparities regarding cancer clinical trials, an analysis of trials by location, cancer type, cancer incidence rates, cancer mortality rates and racial patterns in Georgia counties was conducted. To the best of our knowledge, this paper represents the first study to examine the number of cancer clinical trial listings across the state of Georgia by major cancer type, incidence rates, mortality rates, and geographic distribution of racial patterns. Recent studies suggest that location of and distance to treatment centers affect a patient's decision on whether or not to enroll in a clinical trial (Celaya et al. 2006). This is important because cancer clinical trial participation is low and barriers to cancer clinical trials access should be minimal (Comis 2003). This study did not focus on childhood cancer clinical trials because there is a 60 percent accession rate of cancer clinical trials in pediatric patients. This is substantially higher than the estimated 3 percent of adult cancer patients who participate in clinical trials (NCI 2001).

In this study, the entire dataset was not found in a central location. Information was gathered from various sources, including the Georgia Division of Public Health Office of Health and Information Policy, the Georgia Comprehensive Cancer Registry, the Georgia Cancer Trials Database, and community oncology practices. These sources provide valid data regarding cancer trial locations in Georgia, geographic display of Georgia counties and cancer incidence and mortality rates in the state, respectively. The analysis was

sconducted using GIS software. GIS provides the means for identifying and displaying geographic patterns, thus providing a useful investigation tool for cancer screening, mortality and incidence rates. In addition, GIS can be used to examine geospatially-related questions regarding availability of cancer clinical trials in Georgia.

This study found that the largest number of cancer clinical trials in Georgia were concentrated primarily in metro Atlanta counties. While this data was not directly comparable to previous published studies, findings from this study can be used as introductory information to further understand cancer clinical trial availability in Georgia. Findings from this study also suggest that there are disparities in cancer clinical trial access as defined by locations across the state. Tables 4.5-4.12 show that counties with the highest rates of incidence and mortality for breast, colorectal, lung and prostate cancers have little or no cancer clinical trials available.

Results from this study are demonstrative of the problems facing cancer clinical trial availability (directly) and cancer clinical trial enrollment (indirectly) in Georgia. This issue is not unique to Georgia. The nation as a whole suffers from few availability of cancer clinical trials for disparate populations (Comis, 2003). Lack of sufficient availability of trials has proven to be a barrier to enrollment. This is an important issue because cancer clinical trials are crucial in the evaluation of safe and effective new drug treatments. Since clinical trials rely on volunteers, it is critical to make trials available and accessible to cancer patients. This may reduce disparities regarding treatment options and give cancer patients treatment alternatives to a disease perceived often times as a death sentence.

This study also found that 42.1 percent of the cancer clinical protocols offered in Georgia were in the four major cancer types (23% breast, 10% colorectal, 14% lung, and 6% prostate, see Figure 4.2). This finding raises questions regarding whether 42.1 percent of all cancer clinical protocols being in the major four cancers is sufficient, particularly since the major cancer types account for 58 percent of all cancer diagnoses and 53 percent of all cancer deaths (Singh 2005), . This is an important issue because breast, colorectal, lung, and prostate cancer protocols did not make up half of the cancer trials offered in the state; however, they account for more than half of cancer diagnoses and deaths.

This study also found that the majority of breast and lung cancer ongoing trials were in metro Atlanta counties compared to rural counties. As of March 2007, there were only 15 counties in the state offering cancer clinical trials. This study also found that 55.8 percent of the trial listings were located in metro Atlanta counties. This study also found that no trials were offered in counties with the highest colorectal, lung and prostate cancer incidence rates. In addition, less than six trials were found in counties with the highest incidence rates of breast cancer. This is important when answering the question of whether cancer clinical trials are adequately available in the state. Findings in this study show that the highest distribution of cancer trials by major cancer type appears mostly in metro Atlanta counties.

When investigating the major cancer types by incidence rates and number of trials, it is important to study racial disparities. Due to limitations with incidence and mortality data available from the Georgia Comprehensive Cancer Registry, the African American population was the only racially diverse group analyzed in this study. This study found

that no colorectal, lung, and prostate trials were available for African Americans in counties with the highest incidence rates. In addition, 2 of the 9 counties with the highest breast cancer incidence rates for African American women had trials available. Therefore, this study shows that there is a disparity among the African American population in Georgia, regarding the number of trials available to new cancer patients. This also implies that strategic planning is needed to address the cancer clinical trial availability for minority patients in the state.

This study also found that there were no cancer clinical trials available for counties with the highest mortality rates for breast, colorectal, lung and prostate cancers. This finding indicates that there are no trials available in counties where patients are dying the most. This is disheartening, particularly for counties with the highest breast and prostate cancer mortality rates because there were no trials available within 50 mile proximity.

Generally, disparities in medical care exist in the following populations: minorities, rural residents, and the elderly. Since the enactment of the National Institutes of Health's Revitalization Act of 1993, many cancer researchers have place an increased focus on recruiting underrepresented populations in clinical trials (McCray 2000). As Georgia invests the state-allotted tobacco settlement money in cancer research, it is important to leverage these funds to decrease the level of the asymmetry of information regarding cancer clinical trial locations and availability. Findings from this study suggest that there are not an adequate number of cancer clinical trials available in counties experiencing the highest burden of the disease.

Strengths of this study include that the data was obtained from Georgia's only state-specific cancer clinical trial database. This is particularly important since there are

various cancer clinical trial registries with different reporting techniques. Having a state-wide cancer clinical trial database helps with the accuracy of the cancer clinical trial listings. The Georgia Cancer Trials database is vital because it details the exact locations where cancer trials are offered, which is not the case with the national cancer clinical trial database. Oftentimes, clinicaltrials.gov will list the state and cities only, with no indication of the actual location of the trial.

An additional strength of this study is the use of GIS to map cancer clinical trial locations. This is particularly helpful since cancer incidence and mortality reporting is done using this software. GIS allows more precise plotting of cancer trial locations compared to other mapping software. In addition, exact addresses where used in this study to increase accuracy of the point data. Also, the information retrieved for the Georgia Cancer Trials database was verified with oncology practices across the state to ensure accuracy.

It is important to discuss limitations involved in the study. First, there were duplicates found with the Georgia Cancer Trials database. As stated previously, cancer clinical trials are required to be registered. Consequently, there is no centralized registration database to ensure non-duplicative listings of oncology practices. There were numerous inconsistencies found with the way trials were listed by oncology practice/ institution. For example, The Medical Center- John B. Amos Cancer Center was listed as both “The Medical Center” and as “John B. Amos Cancer Center”. At first glance, it was not apparent that this was the same institution. However, after sending the report to the site and discussing with their clinical research staff, it was found that this was the same

site and research staff entering the data into the national database was using different forms of the organization's name.

This type of error was also found at Eisenhower Medical Center, Nancy N. and J. C. Lewis Cancer and Research Pavilion at St. Joseph's/Candler, Northside Hospital Cancer Center, Medical College of Georgia Cancer Center, and Charles B. Eberhart Cancer Center at DeKalb Medical Center. Each location appeared at least twice in the database under variations of their true name. These inconsistencies were noted and corrected in the Georgia Cancer Trials database as well as the dataset for this study.

The existence of multiple practices and reporting were also limited this study. Many oncology practices have satellite clinics that are not currently being captured in the national database. For example, Wellstar Health System has numerous satellite facilities. All of these facilities may not be listed in the national or Georgia Cancer Trials database. This is an issue of user error where the individual entering information at the oncology practices does not give all satellite locations and the time of data entry. However, this issue does not account for a significant change in the trial listing. Many of the satellite locations are in the same counties as the parent institution.

This study was also limited by the availability of cancer morbidity and mortality data available from the Georgia Comprehensive Cancer Registry. The mortality rate for African Americans by county was not included in this study due to the lack of data from a significant number of counties. Much of the data regarding African American cancer mortality rate by county was suppressed. Therefore, the data was not useful to compare cancer clinical trial availability as it relates mortality rates of African American patients

because mortality rates were not able to be captured (value was less than five) in most of the counties.

Another limitation of the study deals with capturing the cancer clinical trial listings by counties. This may limit the study because patients are not confined to participating solely in cancer clinical trials offered in their counties of residence. In many cases, patients must travel outside of their residing county, and maybe outside of their state, in order to enroll in a cancer clinical trial. For example, patients outside of DeKalb County may be participating in cancer clinical trials at the Emory Winship Cancer Institute. This study may be limited in scope because it assesses whether trials are located in counties with the highest disease burden and does not account for patient travel from other counties, mainly because data regarding patient accrual and travel distance was not available for this study.

The lack of data regarding the number of patients enrolled in cancer clinical trials gives rise to another limitation of this study. This information would provide further indication of where most patients enroll and how far the travel to participate in a cancer clinical trial. There have been discussions from the Georgia Center for Oncology Research and Education regarding the feasibility of collecting patient accrual data. Collection of this data is important to achieve the objective 6.1 of the Institute of Medicine Report on Assessing the Quality of Cancer Care in Georgia (Eden and Simone 2005).

Because travel distance to the clinical trial location is a major factor in participation, particularly in minority communities, it is important to have some baseline information regarding cancer clinical trial availability at the county level. Joining the number of trials

by county with the cancer incidence and mortality rates may limit the scope of this paper. More data should be collected regarding how far cancer patients travel to participate in cancer clinical trials in Georgia to better understand whether an appropriate number of cancer clinical trials are being offered in the state at the local level.

It is important to capture information regarding how many cancer clinical trials is considered sufficient, particularly in rural counties. This study found that counties outside of the metro area had substantially less trials than metro Atlanta counties. This is important because protocol availability is limited to participating sites. This is particularly important because there is a large area in the southeast portion of the state that has no cancer clinical trials offered. This study found that Chatham County was the closest county in that region with a large density of trials. It was also the county with the largest density of trials outside of metro Atlanta counties. However, this raises the question of whether or not patients in this area would be willing to drive to Chatham County to participate in a cancer clinical trial.

It is the recommendation of this paper that Georgia invest resources to collect data regarding how many cancer patients participate in cancer clinical trials and where cancer clinical trial participation is the highest. This would not only help to assess the quality of clinical cancer care in the state, but it will also give the medical community pertinent information about whether there are enough trials available for those who wish to participate. This information would also indicate the type of trials that accrue patients and which oncology practices conduct the most clinical research. This data can be compared with cancer morbidity and mortality data to see if the cancer clinical trials that accrue the most patients, actually reflect the burden of cancer in the state. Furthermore, it would

answer whether patients are being accrued to studies that are in the “Big Four” cancer types: breast, colorectal, lung, and prostate cancers.

It is hopeful that findings from this study will assist with determining disparities in cancer clinical trial availability and state cancer planning. This study should spark interest in and resources towards securing a strategic approach to the offering of cancer clinical research in Georgia. It should also trigger discussion regarding the following three questions:

1. What do we want the cancer clinical trial picture to look like in 2, 5, 10 years?
2. What is an adequate number of cancer clinical trials, by a specific parameter?
3. How will we secure strategic placement of cancer clinical trials across Georgia?

With an estimated 36,000 Georgians diagnosed with cancer annually (Singh et al. 2005), this analysis should help define baseline data and help guide future cancer research planning. The purpose of this study was to determine the density of cancer clinical trial locations within the state. This study found that being a resident of metro-Atlanta or living in a county with a medical schools present increased the probability of cancer clinical trial availability. However, more trials were found to be available per cancer patient outside of metro Atlanta counties.

The social implications of this study are important in ensuring the availability of and access to cancer clinical trials across the state. This is particularly critical in minority populations who are generally more susceptible to cancer. African American men and

women have an increased likelihood of developing cancer in their lifetime (Singh et al 2005). This study found that, in Georgia, disparities exist in both cancer morbidity and cancer clinical trial availability. Density of cancer clinical trials is higher in metro-Atlanta. Therefore, areas located outside of metro-Atlanta have unequal distribution of cancer trials. The cancer burden is higher in minorities and rural patients. In addition, counties with medical schools had an increased chance of having a substantial number of cancer clinical trials compared with other non metro counties.

It is important to note that there is an Atlanta Community Clinical Oncology Program (Atlanta CCOP) that was initiated in 1993 by NCI to provide more access to cancer clinical trials among community oncology practices in the Atlanta area. Saint Joseph's Healthcare of Atlanta is the parent institution for the Atlanta Regional CCOP (http://www.atlantaccop.org/). There are eight institutions involved with Atlanta Regional CCOP: Saint Joseph's Hospital of Atlanta, Charles B. Eberhart Cancer Center at DeKalb Medical Center, Northside Hospital, Piedmont Hospital, Wellstar Cobb Hospital, Kennestone Cancer Center at Wellstar Kennestone Hospital, Southern Regional Medical Center, and Gwinnett Health System. CCOP protocols are offered at all of the CCOP locations. This increases the availability of cancer clinical trials in the previously listed Atlanta oncology practices. These protocols may be present in community practices across the state, but because those practices are not a part of the Atlanta Regional CCOP, it is not guaranteed that the CCOP trials will be available.

In an effort to make more trials available across the state, it is the recommendation of this paper that non-Metro Atlanta oncology practices be allowed to participate in Atlanta Regional CCOP trials. This would ensure that smaller practices that wish to increase their

offerings of cancer clinical trials would easily be able to do so. In addition, this would instantly increase the cancer clinical trial listings across Georgia. This type of schema is similar to businesses that franchise their organizations in an effort to reach a wider audience to increase profits. Increasing access to Atlanta Regional CCOP trials in non-Metro Atlanta areas would help to make trials available to a larger number of cancer patients in an effort to decrease disparities and adverse outcomes. This may require a statewide collaboration using members of the Georgia CORE network and partnerships with the Atlanta Regional CCOP.

Furthermore, this study recommends that Georgia focuses on a strategic approach to the placement or dispersal of cancer clinical trials. It is important for patients to have a variety of options regarding cancer clinical trials. This may require investing resources in pilot programs for clinical research in counties which showed minimal cancer trial availability, particularly in Floyd, Lowndes and Muscogee counties.

There are an estimated 5,000 trials offered in the United States (NCI 2001). Though this study found that Georgia has 321 protocols, totaling 961 listings, a large portion of the total trials were located in metro-Atlanta counties. Therefore, researchers, public health officials, and cancer advocates should secure equitable access of cancer trials across the state. Findings of the study showed that there are disparities in the availability of cancer clinical trials across the state, particularly in rural and non Metro-Atlanta areas. This is particularly important since this study found that counties with the greatest disease burden had no trials available. Therefore, a concerted effort should be made to ensure that trials are available in or near counties with the highest cancer incidence and mortality rates.

It is also the recommendation of this study that oncologists and public health officials in the state adopt a plan to address clinical trial disparities, specifically targeting counties outside of the metro-Atlanta area. First, officials should ensure an adequate number of trials be available across the state by increasing the number of trials available at existing sites. This may require a fund source for increased staffing capacity.

Results from this study showed that the cancer clinical trial listings across counties varied from 4 to 227. The baseline data found in this study should provide the oncology community and public health officials with information about the state of cancer clinical trials in the state and where the researchers want the state to be in the next 5,10, and 15 years. This is particularly important in counties that lack the presence in the metro area as well as counties that lack medical schools. This is a huge issue because it implies that there is disproportionate access to cancer trials.

In conclusion, this study set out to answer three important questions regarding cancer clinical research in Georgia: 1) what is the geographic distribution of cancer clinical trials in Georgia, 2) are cancer clinical trials available in counties with the highest burden of disease, and 3) is there a disparity in cancer clinical trial locations as it relates to racial pattern? Findings from this study showed that in March 2007, there were 321 protocols for cancer clinical trials offered at 46 sites across the state. This study also suggests that there were no trials available in counties with the highest cancer incidence and mortality rates for colorectal, lung and prostate cancers. Thirdly, there were similar findings when viewing the number of trials available for African American cancer patients, by incidence rate.

This study addresses the issue of information asymmetry by providing the number of cancer clinical trial locations in Georgia and identifying disparities associated with cancer trial locations and where the disease burden is greatest. This study also shows the importance of having baseline information to display the state of cancer clinical research. As the second leading cause of mortality in the state, billions of dollars have been invested in cancer clinical research. It is important to invest resources in reducing this disproportionate gradient of information and cancer disparities across the state.

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Appendix A

Georgia Cancer Clinical Trial Protocols

1.	#123
2.	0230B
3.	0405-2006
4.	0414-2006
5.	0466-1998
6.	0533-2003
7.	0596-2004
8.	0693-2002
9.	1 R01 MH071580-01A2
10.	10105
11.	1048-2001
12.	11800
13.	11961
14.	1341-2004
15.	1342-2004
16.	136
17.	150106
18.	174-2004
19.	198-2002
20.	20040213
21.	2005_010
22.	26866138CAN2007
23.	3160A4-200
24.	3410
25.	553
26.	60104
27.	70103
28.	9665
29.	9760
30.	Å6-003
31.	A8501001
32.	ACORN AEJSINS0601
33.	ACORN ALJBMM0502
34.	ACORN ALSSNBC0401
35.	ACORN ALSSOPR0501
36.	ACORN B9E-US-S377
37.	ACORN H3E-MC-JMEN
38.	ACORN H6Q-MC-JCBJ(b)
39.	ACORN INS0601
40.	ACOSOG-Z1031
41.	ACOSOG-Z6041

42.	ACOSOG-Z9001
43.	ACRIN-6673
44.	AMC-038
45.	AMD3100-2112
46.	American BioSciences-CA023
47.	Amgen-20060136
48.	AMGEN A147
49.	AMGEN A244
50.	ANTISOMA-AS1404-203
51.	AOI-206
52.	AOI-208
53.	AOI-211
54.	AOI-215
55.	APP-C2006-01
56.	AVF3430n
57.	AVF3671g
58.	AVF3693g
59.	AVF3694g
60.	AVF3991n
61.	Bayer-11961
62.	BIOCRYST-BCX1777-T-04-201
63.	BIOVEST-BV301
64.	BMS-CA183001
65.	BMTCTN-0102
66.	BMTCTN-0201
67.	BRE 0303
68.	CA183-002
69.	CA225251
70.	CALGB-100104
71.	CALGB-10105
72.	CALGB-20203
73.	CALGB-30406
74.	CALGB-30407
75.	CALGB-40101
76.	CALGB-49907
77.	CALGB-50203
78.	CALGB-50303
79.	CALGB-70301
80.	CALGB-80101
81.	CALGB-90202
82.	CALGB-90401
83.	CALGB-9665
84.	CALGB-C80405
85.	CAMN107A2109
86.	CAN-NCIC-LY.12

87.	CAN-NCIC-MA.27B
88.	CAN-NCIC-MA27
89.	CAN-NCIC-MAP3
90.	CAN-NCIC-MY10
91.	CB01-202
92.	CCBX001-049
93.	CCCGHS-NCI-T98-0085
94.	CCCWFU-71103
95.	CCCWFU-98301
96.	CDC-NCCDPHP-R-01-PH-000018
97.	CG53135-CLN-12
98.	CICL670AUS03
99.	CLTR0105-201
100.	CMM-95079
101.	CONCEPT L-9444
102.	CP02-0452
103.	CP02-0555
104.	CR008566
105.	CSU-GCC-161
106.	CTKI258A2103
107.	CTSU E2805
108.	CYC202-06-14 (A1)
109.	CZOL446 EUS24
110.	CZOL446E2352
111.	CZOL446GUS63
112.	D9902B
113.	DFCI-04006
114.	DOCET_L_00712
115.	DUMC03
116.	E1Y03
117.	ECOG-1697
118.	ECOG-1900
119.	ECOG-1C99
120.	ECOG-1Y97
121.	ECOG-2602
122.	ECOG-5501
123.	ECOG-5597
124.	ECOG-5998
125.	ECOG-E1302
126.	ECOG-E1B03
127.	ECOG-E1F03
128.	ECOG-E2204
129.	ECOG-E2501
130.	ECOG-E2603
131.	ECOG-E2805

132.	ECOG-E2902
133.	ECOG-E2Z04
134.	ECOG-E3204
135.	ECOG-E3803
136.	ECOG-E3903
137.	ECOG-E4203
138.	ECOG-E4402
139.	ECOG-E4903
140.	ECOG-E5202
141.	ECOG-E5204
142.	ECOG-E6202
143.	ECOG-E6501
144.	ECOG-PACCT-1
145.	ECOG-S9346
146.	ECOG PACCT-1
147.	Eli Lilly B9E-US-S182
148.	Eli Lilly B9E-US-S377
149.	Eli Lilly H6Q-MC-JCBJ
150.	ENRICH Study
151.	EU312-97
152.	EU822-03
153.	FCCC-FCRB-04-003-P
154.	FHCRC-1938.00
155.	FHCRC-1992.00
156.	FHCRC-2054.00
157.	G-0029
158.	G-0034
159.	GOG-0130E
160.	GOG-0136
161.	GOG-0146O
162.	GOG-0146Q
163.	GOG-0187
164.	GOG-0188
165.	GOG-0192
166.	GOG-0198
167.	GOG-0199
168.	GOG-0204
169.	GOG-0206
170.	GOG-0209
171.	GOG-0210
172.	GOG-0211
173.	GOG-0212
174.	GOG-0218
175.	GOG-0219
176.	GOG-0222

177.	GOG-0227c
178.	GOG-0232B
179.	GOG-173
180.	GOG-174
181.	GOG-175
182.	GSK-EGF103659
183.	GSK-EGF30008
184.	GV-001.004
185.	H57/CCH420680-05
186.	HN 0501
187.	Hx-CD4-110
188.	IBCSG-24-02
189.	IBCSG-25-02
190.	IBCSG-27-02
191.	IRB3 021-2005
192.	JHOC-J0252
193.	JNJ-26866138-LYM-3001
194.	KOS-202/NO18401
195.	LCCC 0512
196.	M05-780
197.	MCC-0203
198.	MCC-0502
199.	MCSP-00-0107
200.	MDA-ID-00156
201.	MDX010-20
202.	MGH-000084
203.	MILLEN.EVERECT
204.	NABTT-0306
205.	NABTT-0307
206.	NABTT-0401
207.	NABTT-0404
208.	NABTT-0501
209.	NABTT-0503
210.	NABTT-0504
211.	NABTT-2201
212.	NABTT-9806
213.	NABTT-9902
214.	NABTT-9910
215.	NCCTG-N0147
216.	NCCTG-N0177
217.	NCCTG-N01C5
218.	NCCTG-N02C4
219.	NCCTG-N0434
220.	NCCTG-N0437
221.	NCCTG-N04C7

222.	NCCTG-N9943
223.	NCI-04-C-0001
224.	NCI-06-C-0043
225.	NCI-7306
226.	NCI-92-C-0137M
227.	Novacea 011-007
228.	Novacea 011-015
229.	NSABP-B-36
230.	NSABP-B-37
231.	NSABP-B-38
232.	NSABP-B-39
233.	NSABP-B-40
234.	NSABP-B-42
235.	NSABP-C-09
236.	NSABP-C-10
237.	NSABP-R-04
238.	NTI-0303
239.	NTI 0501
240.	ONCOTHER-20052183
241.	ONCOTHER-MAC001
242.	OSI-774-203
243.	OSI-774-302
244.	OSI3364g
245.	PC B305/02
246.	PC B305/04
247.	Perifosine 212
248.	Perifosine 217
249.	POI-02818
250.	RTOG-0123
251.	RTOG-0212
252.	RTOG-0214
253.	RTOG-0232
254.	RTOG-0233
255.	RTOG-0247
256.	RTOG-0320
257.	RTOG-0421
258.	RTOG-0424
259.	RTOG-0521
260.	RTOG-0522
261.	RTOG-0525
262.	RTOG-L-0117
263.	SEGO_DOXIL_CONS2005
264.	STAN-973
265.	STR 0303
266.	SWOG-8947

267.	SWOG-9007
268.	SWOG-S0008
269.	SWOG-S0016
270.	SWOG-S0028
271.	SWOG-S0106
272.	SWOG-S0124
273.	SWOG-S0220
274.	SWOG-S0221
275.	SWOG-S0226
276.	SWOG-S0230
277.	SWOG-S0232
278.	SWOG-S0306
279.	SWOG-S0307
280.	SWOG-S0309
281.	SWOG-S0329
282.	SWOG-S0331
283.	SWOG-S0334
284.	SWOG-S0350
285.	SWOG-S0414
286.	SWOG-S0415
287.	SWOG-S0424
288.	SWOG-S0425
289.	SWOG-S0429
290.	SWOG-S0430
291.	SWOG-S0434
292.	SWOG-S0435
293.	SWOG-S0508
294.	SWOG-S0509
295.	SWOG-S0511
296.	SWOG-S0515
297.	SWOG-S0536
298.	SWOG-S9704
299.	SWOG-S9910
300.	SWOG-S9921
301.	SWOG-S9925
302.	SWOG BMT CTN 0102
303.	TG-001
304.	TM-601-002
305.	TRIAD BOI/Muscositis
306.	U2963n
307.	UCLA-0307121-01
308.	UCSD-040749
309.	UMN-2004UC035
310.	VBLT980-04
311.	VSLI-06-ALL

312.	VU-VICC-HN-0501
313.	WCI-1078-05
314.	WCI-752-02
315.	WCI1950-04
316.	WCI901-04
317.	WCI957-04
318.	WILEX-WX-2003-07-HR
319.	XCYTE-XT004
320.	XL119-001
321.	XT009

Appendix B

Cancer Clinical Trial Listing by Institution

Institutions		Number of trials	Percent
	Atlanta Cancer Care - Roswell	8	.8
	Atlanta Cancer Care at St. Joseph	1	.1
	Augusta Oncology Associates - Walton Way	49	5.1
	Blood and Marrow Transplant Group of Georgia	4	.4
	Central Georgia Cancer Care, PC - Macon	12	1.2
	Charles B. Eberhart Cancer Center at DeKalb Medical Center	43	4.5
	Clayton State University	1	.1
	Cobb Memorial Hospital	1	.1
	Columbus Clinic, PC	2	.2
	Curtis & Elizabeth Anderson Cancer Institute at Memorial Health University Medical Center	82	8.5
	Eisenhower Army Medical Center	7	.7
	Emory Crawford Long Hospital	10	1.0
	Georgia Cancer Center for Excellence at Grady Memorial Hospital	8	.8
	Georgia Cancer Specialists - Northside Office	1	.1
	Georgia Cancer Specialists - Tucker	5	.5
	Georgia Urology - Atlanta	3	.3
	Gwinnett Medical Center	34	3.5
	Harbin Clinic	7	.7
	Kennesaw State University	1	.1
	Kennestone Cancer Center at Wellstar Kennestone Hospital	38	4.0
	Medical Center of Central Georgia	32	3.3

	Medical College of Georgia Cancer Center	43	4.5
	Medical Oncology Associates, PC	2	.2
	Morehouse School of Medicine	1	.1
	Mount Vernon Clinical Research, LLC	1	.1
	Nancy N. and J. C. Lewis Cancer and Research Pavilion at St. Joseph's/Candler	37	3.9
	Northeast Georgia Cancer Care, LLC	17	1.8
	Northeast Georgia Medical Center	47	4.9
	Northside Hospital Cancer Center	39	4.1
	Northwest Georgia Oncology Centers, PC - Marietta Center	17	1.8
	Peachtree Hematology and Oncology Consultants, P.C.	11	1.1
	Pearlman Comprehensive Cancer Center at South Georgia Medical Center	26	2.7
	Phoebe Cancer Center at Phoebe Putney Memorial Hospital	24	2.5
	Piedmont Hospital	40	4.2
	Saint Joseph's Hospital of Atlanta	37	3.9
	South Fulton Medical Center	4	.4
	Southeastern Gynecologic Oncology, LLP - Northside	2	.2
	Southern Regional Medical Center	36	3.7
	Spalding Oncology Services	4	.4
	Suburban Hematology-Oncology Associates, PC	8	.8
	Summit Cancer Care	2	.2
	The Medical Center Inc., John B. Amos Community Cancer Center	31	3.2

	Veterans Affairs Medical Center - Atlanta (Decatur)	21	2.2
	Veterans Affairs Medical Center - Augusta	4	.4
	WellStar Cobb Hospital	35	3.6
	Windy Hill Hospital	4	.4
	Winship Cancer Institute of Emory University	119	12.4
	Total	961	100.0

Appendix C

Georgia Counties