

ADDRESSING
Disparities
IN CANCER CLINICAL TRIALS

**2022 Summit:
A Recap and a Roadmap to More Equitable Accrual**

Presented by

GEORGIA
core

GASCO
GEORGIA SOCIETY OF CLINICAL ONCOLOGY



Presented by



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Executive Summary

In September 2022, the Georgia Center for Oncology Research and Education (Georgia CORE) and the Georgia Society of Clinical Oncology (GASCO) held a one-day summit exploring opportunities and evidence-based interventions to address disparities in cancer clinical trials. The summit included expert presentations, panel discussions with leaders from provider organizations throughout Georgia, and breakout sessions to allow participants to critically discuss the information presented. Following the summit, a working group evaluated the event and elected to draft proceedings summarizing key areas that will decrease disparities in clinical trial accrual and improve cancer care for all Georgians.

Under-enrollment of minority populations in cancer trials has been an ongoing challenge in cancer research, and it is ultimately detrimental to all people who would benefit from more accurate, and well-studied, cancer treatments.^{1,2} Reduced minority participation raises questions about “the generalizability of results for clinical decision making and contributes to persistent racial disparities in cancer outcomes.”¹ Additionally, clinical trials provide access to cutting edge treatments, and increasing minority enrollment helps address disparities caused by structural problems.³

Disparities primarily arise due to system related and healthcare provider related barriers with patient decision making playing a much smaller role.^{3,4} Anyone desiring to improve enrollment participation for all individuals in cancer trials needs to evaluate possibilities for realigning incentives and removing barriers.

Structural problems are defined by trial availability and geography; however, bias and trial design also impact patients’ access to clinical trials.³⁻⁵ Roadblocks are multisectoral, multifactorial, and multilevel, and a broad array of stakeholders need to be engaged to improve cancer clinical trial accrual in Georgia-immediately.

To that end, summit participants identified **four potential target areas** to enhance clinical trial accrual among minority patients.

1. **Adjusting cancer clinical trial design**
2. **Providing trial navigation for all**
3. **Enhancing public education and awareness of crucial cancer clinical trials and treatment opportunities**
4. **Identifying potential policy opportunities**

The State of Cancer Care in Georgia

Georgia has a diverse set of key stakeholders dedicated to cancer care, education, and advocacy. In 2001, under the leadership of Governor Roy Barnes, a new initiative was implemented to make Georgia a premier leader in cancer treatment and research.⁶ The Georgia Cancer Coalition was created from tobacco settlement funds with the strategic vision of improving cancer outcomes in Georgia from the 4th quartile nationally to the 1st quartile. Unique about this approach was the coordination of public and private investors with academic and community healthcare institutions, implementing changes throughout the state.

At the same time, Regional Cancer Coalitions were formed to address screening and prevention opportunities for clients at the front line. Georgia CORE emerged in 2003 with a focus on attracting more clinical trials and increasing research to improve cancer care for Georgians in all areas of the state. The 2001 initiative also resulted in Winship Cancer Institute of Emory University in Atlanta becoming the first National Cancer Institute (NCI) designated cancer center in Georgia, and Winship eventually achieved NCI comprehensive status in 2017.

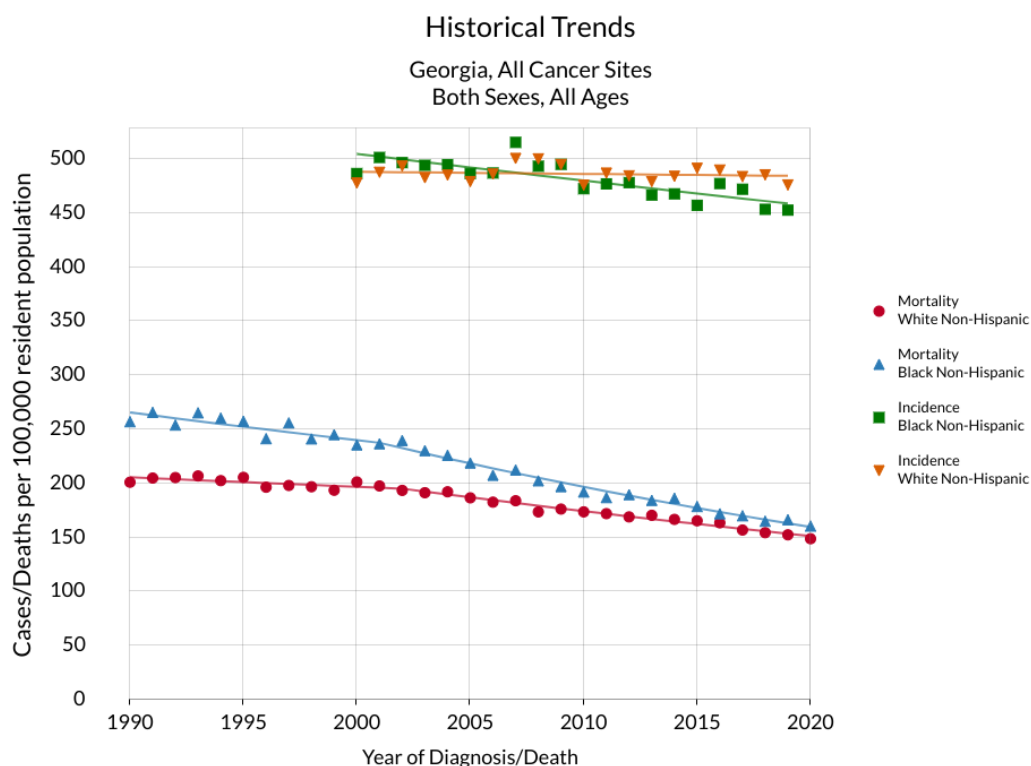


The Georgia Society of Clinical Oncology (GASCO), founded in 1986, is a nationally respected state professional society of physicians, practice administrators, and other healthcare professionals interested in clinical oncology.⁷ GASCO provides opportunities for networking, advocacy, and education to support the attainment of state cancer control plan objectives, advocates for cancer providers, and aims to guide the integration of cancer care through collaboration.⁷ Joining with Governor Barnes' 2001 initiative, GASCO has been a key partner in developing and maintaining Georgia's statewide cancer research network, and GASCO continues to advocate at the state and national level, in collaboration with the American Society of Clinical Oncology (ASCO), to improve the state of cancer care for all Georgians.^{7,8}

Georgia's first Comprehensive Cancer Control plan was drafted in 2001 and served as the reference point for cancer control efforts for five years.⁶ As it worked to improve the quality of cancer care throughout the state, the Georgia Cancer Coalition commissioned an Institute of Medicine study in 2004 that led to the definition of 52 measures to serve as guideposts for state cancer control activities, and in response, Georgia's Comprehensive Cancer Control plan was first revised in 2006 to create a "living" document that allows for continuous input and updating as contextual elements change.⁶ The latest edition of the plan, 2019-2024, aims to achieve significant progress in the areas of equity, translational research,

communications, advocacy, and surveillance over its five-year period: to accomplish these goals, the plan advocates for supporting prevention efforts with a focus on HPV prevention, increasing early detection by expanding access to screening, facilitating statewide access to palliative care, improving survivors' quality of life, and maintaining excellence in diagnosis and treatment of cancers by addressing cancer treatment disparities.⁹

Progress has been made, but Georgia still has work to accomplish to become a national leader in both cancer treatment and research.¹⁰ An estimated 58,970 Georgians will be diagnosed with cancer in 2022, and 18,750 Georgians will die from cancer this year.¹¹ Georgia has an elevated incidence of cancer, with an age adjusted incidence rate of 468.5 per 100,000 per year, compared with the national average, 448.6 per 100,000 per year.¹² Both cancer incidence and mortality rates have been trending downward in Georgia since 1990.¹²



Notes:
Created by statecancerprofiles.cancer.gov on 11/18/2022 2:27 pm.
Regression lines calculated using the Joinpoint Regression Program (Version 4.8.0.0)

For Hispanic incidence data, NHIA (NAACCR Hispanic Identification Algorithm) was used for Hispanic Ethnicity (see Technical Notes).
Source: Incidence data provided by the National Program of Cancer Registries SEER*Stat Database - United States Department of Health and Human Services, Centers for Disease Control and Prevention.
Rates calculated by the National Cancer Institute using SEER*Stat. Rates are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). Rates are for invasive cancer only (except for bladder cancer which is invasive and in situ) or unless otherwise specified. Population counts for denominators are based on Census populations as modified by NCI. The US populations included with the data release have been adjusted for the population shifts due to hurricanes Katrina and Rita for 62 counties and parishes in Alabama, Mississippi, Louisiana, and Texas. The US Population Data File is used with SEER data.
Rates and trends in this graph are computed using the same standard for malignancy. For more information see malignant.html
Source: Death data provided by the National Vital Statistics System public use data file. Death rates calculated by the National Cancer Institute using SEER*Stat. Death rates (deaths per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). Population counts for denominators are based on Census populations as modified by NCI. The US populations included with the data release have been adjusted for the population shifts due to hurricanes Katrina and Rita for 62 counties and parishes in Alabama, Mississippi, Louisiana, and Texas. US Population Data File is used with mortality data.
Due to data availability issues, the time period used in the calculation of the joinpoint regression model may differ for selected racial groups or counties.

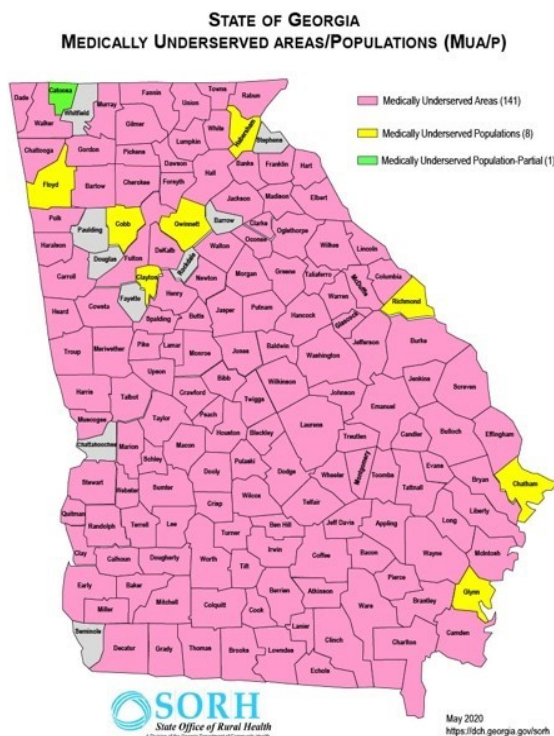
Data on clinical trial accrual at the state level can be hard to come by, but clinical trial accrual disparities are well documented at the national level.¹⁻³ There is little evidence to suggest that Georgia differs markedly from the national pattern, and if it does, evidence of other documented treatment disparities suggest that trial accrual disparities would exceed national averages. Disparities in life expectancy exist for Georgians diagnosed with cancer.

In Georgia, age adjusted incidence rates for Black patients are 462.3 per 100,000 per year with White patients at 485.1 per 100,000 per year; however, a look at age adjusted mortality rates reveals an inverse relationship with Black patients dying at a rate of 166.6 per 100,000 per year as opposed to 155.1 for White patients.¹² Notably, disparities in overall mortality rates have narrowed over the past 20 years, but they have not disappeared, nor do they reflect the relative incidence of cancer for their respective populations. Further dissection of the data reveals even more significant disparities. For example, Black men have a higher lifetime probability of developing and dying from prostate cancer, averaging 40.5 age adjusted deaths in Georgia per 100,000 per year as opposed to White men whose rates are 16.6 deaths per 100,000 per year in Georgia.¹²

Evidence shows that Black patients routinely receive lower quality care than White patients. Black men receive less screening, with prostate cancer patients less likely to receive MRIs and high sensitivity PET scans.^{13,14} Disparities in surgical treatment and radiation treatment have also been reported.^{15,16} Black women on average experience significant delays to diagnostic evaluation, 45 days as opposed to 26 days for White women, with a likely 1.6-fold increase in the odds of breast cancer mortality.¹⁷ At the same time, many studies have shown that in clinical settings Black patients do not differ in treatment duration, progression, or survival compared to White patients, demonstrating the value in trial accrual for addressing harms caused by structural disparities.^{18,19}

Evidence shows that Black patients routinely receive lower quality care than White patients.

Georgia Department of Community Health: State Medically Underserved Areas/Populations



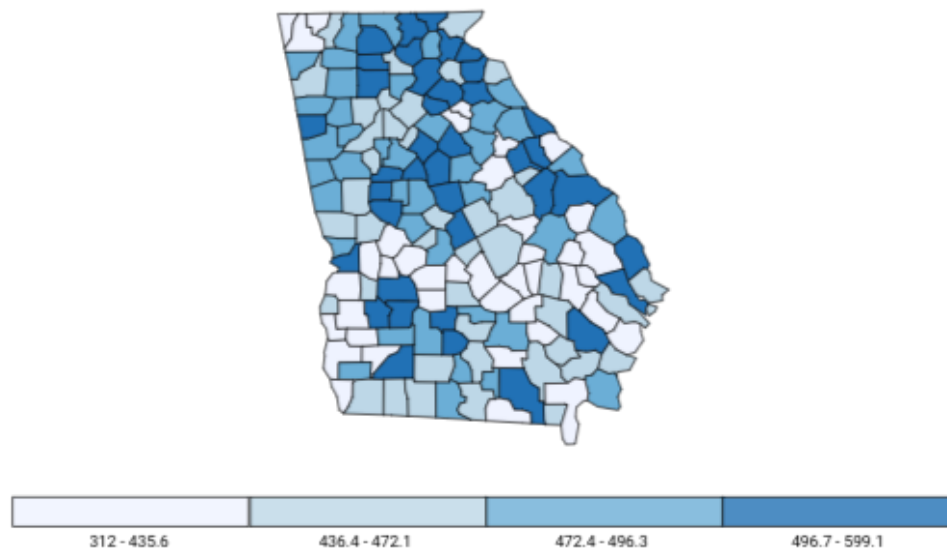
Source – State Medically Underserved Areas/Populations (Mu/P) Georgia Department of Community Health: State Office of Rural Health; <https://dch.georgia.gov/divisionsoffices/state-office-rural-health/sorh-maps-georgia>, May 2020. Retrieved November 10, 2022.

Furthermore, rural populations in Georgia bear the brunt of the state's cancer burden. 71.1% of Georgia's population, living in 149 of 159 counties, are medically underserved according to state defined criteria, and nearly 54% (85/159) of Georgia's counties are classified as rural based on the 2013 Rural-Urban Continuum Codes.^{20,21} Georgia's cancer mortality hotspots are concentrated in the eastern Piedmont to Coastal Plain, southwestern rural Georgia, and northern rural Georgia.²⁰ Hotspot counties generally have a higher proportion of non-Hispanic Black adults,

older adults, greater poverty, limited access to healthy food, and more rurality.²⁰ For all cancers, age adjusted mortality rates are higher in hotspot counties.²⁰ Differences in outcomes ascribed to rurality are likely related to healthcare access, and when clinical trial data are used to evaluate patient outcomes, rural and urban patients fared similarly, indicating that access to uniform treatment strategies can resolve geographically related disparities in cancer outcomes.²² Recognizing that key systemic barriers to equitable clinical trial accrual are trial availability and geography, the relative increased burden on rural populations creates an additional hurdle for stakeholders to address.

Rate of New Cancers in Georgia

All Types of Cancer, All Ages, All Races, and All Ethnicities, Male and Female, 2015-2019



Source - U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2021 submission data (1999-2019): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; released in June 2022.

Finally, cancer is expensive. In 2019, the patient cost of cancer care in the United States exceeded \$21 billion with out-of-pocket costs of \$16.22 billion and patient time costs of \$4.87 billion: among adults aged 65 or older annual out of pocket costs for medical services averaged patients in the initial phase of care \$2,200 with patients in the end-of-life phase of care averaging \$3,823.²³ Drug costs added an additional \$243 and \$127 respectively.²³ In 2010, Georgians spent \$3.7 billion and missed more than 1 million days of work due to their illness leading to \$243 million in lost productivity.²⁴

While some progress has been made in making Georgia a leader in cancer treatment and research, there is still more to accomplish to improve the quality of care for all patients, survivors and caregivers, especially those patients experiencing the impact of unequal access to cutting-edge cancer treatments. As they have for the past 20 years, Georgia CORE and GASCO are working together to strengthen the quality of cancer care by marshaling multiple cancer-focused entities into a unified force to help Georgians understand and fight the disease. Through Georgia CORE's collaborative focus on enhancing research and attracting clinical trials, the goal is to continue to reduce the cancer burden in Georgia especially for minority and rural populations. To achieve that goal, change must happen.

Adjusting Cancer Clinical Trial Design

The first major area to be addressed is clinical trial design. Many aspects of trial design have the capacity to contribute to accrual disparities ranging from initial decisions about enrollment eligibility to barriers related to emotional strain, overall acceptance, time, and money. **Summit participants identified and discussed ideas** for responding to four key improvement areas that stakeholders can focus on to reduce disparities in clinical trial accrual including:

- Expanding minimum eligibility criteria,
- Making consent documents easier to read and understand,
- Increasing access to somatic and germline testing; and
- Using trial design to address systemic barriers to trial enrollment.

Expanding Minimum Eligibility Criteria

At the summit, minimum eligibility criteria were frequently referenced as an area where trial design can improve, and there is a growing consensus that minimum eligibility criteria are typically too narrow. A recent series of reports by the American Society of Clinical Oncology (ASCO) and the Friends of Cancer Research (FCR) reviewed common minimum eligibility criteria, finding many to be unnecessarily restrictive at the cost of significantly reducing eligible populations, accrual rates, and excluding historically marginalized populations.²⁵⁻³¹ As a result, the four working groups convened by ASCO and FCR provided updated recommendations regarding wait time between therapies (washout period), prior therapies, concomitant medications, laboratory references ranges and test intervals, and performance status: Harvey and others conducted a retrospective, observational analysis using electronic health records on three of the recommendations, noting a doubling of the eligible population and leading to more representative samples if incorporated.^{26,28}

There is a growing consensus that minimum eligibility criteria are typically too narrow.

The primary reasons for not expanding eligibility criteria are safety related; however, recent research has found that many criteria are not scientifically justifiable.²⁸ Most patients are excluded due to hepatic and renal dysfunction, and these criteria are often sufficiently stringent to exclude more people than necessary.³² Many of the traditional criteria particularly exclude Black patients from clinical trial participation and are often not medically justifiable.^{32,33} For example, Black patients were found to be differentially excluded from pancreatic cancer trials due to criteria related to hypoalbuminemia, Hepatitis B and C, recent coronary stenting, renal dysfunction, and uncontrollable diabetes mellitus, but revising criteria to eliminate historical, controllable, and manageable medical conditions,

particularly the diabetes mellitus criterion for which pancreatic cancers are often diabetogenic, eliminated the difference.³³

If patients are excluded from clinical trials, they will typically receive standard of care treatments, and several studies examining these patients have found that their lack of tolerability of standard of care cannot be used to justify excluding them from clinical trials.



Karim and others observed that patients found to be ineligible, most often because of advanced age and heart disease, go on to tolerate and even improve with standard of care treatment.³⁴ Another study found that lymphoma patients are significantly more likely to die from the disease than of any complications resulting from treatment.³⁵ Finally, a novel study using artificial intelligence found that eliminating many common exclusions has little effect on trial

hazard ratios while likely benefiting excluded populations.³⁶ In all cases, researchers concluded that many of these patients would have benefited from access to clinical trials despite the criteria that excluded them.

Given the negative impact of overly narrow minimum eligibility criteria on patient eligibility, accrual rates, and population diversity, it makes sense to eliminate unnecessary criteria while retaining scientifically justifiable criteria necessary for the integrity of the trial. At times where social determinants of health intersect with scientifically justifiable criteria, excluding greater numbers of historically marginalized populations from enrolling, principal investigators should take disparities into account and make provisions for accruing more representative samples. Policy makers and funding organizations can take steps to realign incentives to allow for greater flexibility in eligibility criteria and to encourage outlining inclusion and exclusion criteria that include the greatest number of patients possible. Narrow minimum eligibility criteria are not the only feature of trial design to contribute to disparities in accrual but addressing them will go a long way to giving more patients access to clinical trials.

Making consent forms easier to read and understand

A major topic of conversation at the summit was the consenting process, and the relative complexity of consent forms was a particular theme raised by a variety of stakeholders from administrative personnel to healthcare providers. Concerns about whether most consent forms are understandable have existed for as long as there have been consent forms, and interventions to improve understanding have varied from reducing the reading level of

language, to the inclusion of graphics, and even to adjustments of the spatial arrangement of words on the page.^{37,38} Making consent forms more readable is a part of a more complex problem, informing patients and their families about the nature and benefits of clinical trials in order to facilitate patient entry into clinical trials.

Summit participants discussed the challenge of ensuring patients are informed about clinical trials in which they are enrolling yet simplifying the process as much as possible. Participants referenced a variety of concerns. One panelist emphasized that consent forms are too often hard to read for the average person, written at reading levels above the national

The study team had not made provisions for translation of the consent form.

average. Another shared an experience where a patient was prepared to enroll in the clinical trial but was unable to do so because she could not read English, even though her spoken English was excellent, and the study team had not made provisions for translation of the consent form. Others expressed concerns about limited resources and time constraints preventing proper informed consent. Participants' experiences underscore the

reality that making consent forms understandable must go beyond just the words on a page: principal investigators must consider how consent forms influence and integrate into the overall consenting process.

Two areas must be considered. First, is the form readable? Second, does the form facilitate the kind of communication between physicians, other healthcare providers, staff, and patients that leads to greater understanding and trust for all involved? For the first concern, data is mixed. Eun Jin Kim and Su Hyun Kim found that simplified forms improved objective and subjective understanding in a randomized trial of 150 patients: notably, the intervention consent form in the study included, "plain language, short sentences, diagrams, pictures, and bullet points."³⁹ Another study examined HIV clinical trials and use of concise consent forms, making use of, "simplified sentences and words, reduced repetition, and... tables and bulleted lists," and it found that the concise forms neither hindered nor improved patient understanding or satisfaction with the consent process.⁴⁰

Grady et al also found that increased understanding was predicted by age, race, education, and prior experience with clinical trials: evaluating whether patients could correctly answer a survey question about randomization, they noted that correct answers were independently more likely from patients that were young, white, or better educated, and at sites that had conducted more studies.⁴⁰

A 30-year retrospective by Tam and others identified that the proportion of patients who understand informed consent had not increased in the three decades prior to 2013.⁴¹ They also found variation in areas of understanding, with many more patients struggling to

understand and remember details about experimental design, such as placebo and randomization, while better retaining information about benefits, freedom to withdraw, and the nature of the study.⁴¹ Analysis of covariates also revealed critical illness, less education, and living in low income countries decreased the likelihood that patients would understand key aspects of the clinical trial.⁴¹ Both large international studies suggest that there is an upper limit to the impact of improving consent forms, and improvements need to be accompanied by adjustments in other areas of the consenting process.

Which leads to the second area, do consent forms facilitate communication between physicians, other healthcare providers, staff, and patients? **Summit participants were quick to point out the relative complexity of recent clinical trials**, and several asked the rhetorical question, “if physicians can’t understand the clinical trials, how can we expect patients to?” Trial complexity is a potential reason raised by Tam as a possible explanation for why relative understanding may appear stagnant.⁴¹ Due to this complexity and other factors, it is important for physicians, staff, and patients to be able to function as a team, and well written and implemented consent forms may facilitate better teamwork by improving communication.

“If physicians can’t understand the clinical trials, how can we expect patients to?”

In fact, consent forms may be used to facilitate better conversations between patients and their healthcare providers: physicians typically do a good job of using accessible language but are less reliable at covering all the elements critical to informed consent.⁴² Well written and simplified consent forms could serve as a reference for physicians to guide the process of conversation informing patients about clinical trials. Likewise, the timing in which consent forms are provided may play a role in comprehension, with patients who receive forms prior to the clinic visit at which they sign the consent form showing better understanding.⁴⁰



Consent forms play an important role in informing patients about clinical trials, and they are at the center of key educational moments in the patients’ treatment journey. Further research into methods to make them more effective is warranted. In any event, principal investigators may take steps in the design process to create concise/simplified

forms designed to better convey information, providing healthcare providers with a tool to enhance conversations about upcoming clinical trial enrollment. Investigators should also consider the circumstances in which consent forms are presented to the patient to ensure adequate time for patients to become acquainted with the material.

Finally, consent forms are a part of the larger educational process, and ideally, they should function in tandem with other efforts to educate patients, families, and communities about specific clinical trials and clinical trials in general. Investigators and care teams can utilize well written forms to enhance health literacy and to combat ignorance to better accrue historically excluded populations. As such, all stakeholders should advocate for the highest quality forms possible as well as the training and infrastructure necessary to support investigators in designing high quality documents. **Summit participants discussed several ideas to explore including:**

- Using video to better inform patients about trial design and the consent process;
- Implementing teach back methodologies; and
- Training trial designers with mock consents involving real time feedback.

Some of these ideas will be explored in-depth further below.

Increasing access to genetic counseling, somatic testing, and germline testing

One final aspect of clinical trial design that was discussed at the summit was the growing number of trials utilizing precision medicine featuring somatic and germline testing. Genomic and transcriptomic profiling have proven useful for improving therapy

Access to precision medicine, particularly genetic counseling and germline and somatic testing, may be limited by age, ethnicity, and insurance status.

recommendations and patient outcomes, but access to precision medicine, particularly genetic counseling and germline and somatic testing, may be limited by age, ethnicity, and insurance status.⁵⁰⁻⁵² Due to the power of precision medicine to improve patient outcomes, ensuring equal access should be a priority for anyone concerned with existing disparities in clinical trial accrual.

Genetic assessment is growing to be an important part of cancer care, and genetic tests are either somatic or germline. Somatic tests evaluate changes in the genes of tumor cells to identify potential targeted therapy and immunotherapy options. Germline tests evaluate a patients' normal genetic composition, and they seek to identify hereditary biomarkers and mutations associated with cancer which can be used for risk assessment and treatment. Pre and post testing, patients may be referred to

genetic counseling to help them understand the implications of their test results for their families and themselves. Unfortunately, among all cancer patients receiving tumor-normal sequencing, Black patients are less likely to be informed of their results or to complete counseling.⁵³ Gaps like this along with possible limitations due to barriers related to age and insurance highlight current disparities in the burgeoning field of precision cancer treatment.

Clinical trial design may be used to address these disparities. One way to expand access to precision cancer treatment is expanding access to genetic counseling and testing, particularly for older adults.⁵⁰ Access to counseling provides necessary education that helps patients understand the importance of somatic and germline testing. Understanding genomics can be complex, and there are myths that can further complicate understanding, but navigation by trained individuals can help convince patients of the importance of consenting to genetic testing. Building counseling and testing into the screening process for clinical trials where possible, making it standard operating procedure for everyone, would surmount existing hurdles to access for historically marginalized groups. Streamlining processes by ensuring that non-geneticist clinicians can initiate genetic testing, through training and education, is one way to implement universal testing while working with existing resources and keeping costs down.⁵⁴



Expanding access to somatic and germline testing through trial design also can be used to address barriers related to trial availability. One value of genomic biomarkers is that they may be used in the selection of active immunotherapy or gene directed therapy for patients whose tumor type would not be individually studied.⁵⁵ In other words, patients typically ineligible for trials due to availability, if they have a rare or otherwise understudied tumor type for example, may become eligible as trials open that seek cross sections of the population based on genomic biomarkers rather than tumor type. These trials may result in an increase in the complexity of the overall clinical trial design, using master protocols such as basket trials, umbrella trials, or platform trials.⁵⁵ Basket trials are tissue agnostic examining drugs that target gene specific defects. Umbrella trials evaluate multiple treatments in different genomic subsets for a single histology. Platform trials are designed to evaluate multiple hypotheses using a single protocol to yield faster results at a lower cost.⁵⁵ The resulting increase in complexity may be a challenge for implementation; however, expanding trials in these formats would be invaluable to patients with limited options.

Like many of the action items outlined in this report, different stakeholders have different opportunities for implementing change. Principal investigators can introduce universal genomic screening and counseling into their trial design as a means of decreasing disparities in trial accrual. Clinicians and patients can advocate for increased testing access, and policy makers can incentivize and assist in funding new efforts to expand clinical trials utilizing precision medicine to their constituent populations. Institutional leaders can initiate new strategic planning, arranging and expanding existing infrastructure, to make clinical trials utilizing precision medicine feasible in their local area.

Using Trial Design to Address Systemic Barriers to Trial Enrollment

Trial design can be used to directly address existing systemic barriers in order to improve clinical trial accrual. Age, race, insurance status, and geography are all barriers to clinical trial enrollment: one large study examining these barriers, controlling for specific factors related to pancreatic cancer, found that social determinants of health are associated with clinical trial enrollment.⁵ Enrollment for Black patients and those on Medicaid has not risen at parity with the general population's clinical trial enrollment rates. Each year of increasing age decreased the odds of enrollment by 4% and living in the South meant patients had less than half the odds of enrolling compared with the Northeast. Higher levels of neighborhood education were associated with enrollment.⁵ Assuming Eskander and others' findings are at all generalizable to other areas of cancer treatment, then each social determinant of health identified is an opportunity where targeted design changes may improve clinical trial accrual.

Some targeted changes are addressed in other sections of this paper including consent forms, inclusion criteria, education, and navigation. Conversations at the summit, as well as a survey



of current literature, identified two additional areas of trial design to consider, location and cost. Some recent steps have been taken nationally to address factors related to cost. Effective January 1, 2022, the Clinical Treatment Act requires Medicaid to cover all routine patient care costs regardless of

whether the patient is receiving standard of care treatment or enrolled in a clinical trial. Medicaid coverage of routine care costs is a major step in addressing cost as a factor in disparities in clinical trial enrollment. In Georgia, just over 58% of all nonelderly people covered by Medicaid are Black or Hispanic even though just over 58% of the population is White, and Black and Hispanic patients are twice as likely to be covered by Medicaid compared with White ones.^{12,43}

However, there are still more cost related barriers that clinical trial design may address. **Summit participants identified several out-of-pocket costs that patients may incur** while participating in clinical trials including food, lodging, lost work time, and childcare. All these areas are not traditionally covered by insurance, but the added costs of participating in clinical trials may be significant to a family with limited income at or near the poverty line. As such, including reimbursement opportunities, along with clinical trial navigation to assist in accessing those opportunities, can improve clinical trial recruitment rates.^{44,45} Patients alone do not bear the cost of clinical trial participation: clinicians also invest time and money. A 2021 survey of physicians found that most physicians favor trials addressing these costs in the form of reimbursements for the added infrastructure required by the trial design, such as paying for materials related to monitoring trial activity like electronic tools, software, and additional staff.⁴⁶ Notably, physicians are also aware of the potential for conflicts of interest in discussing these kinds of reimbursements.⁴⁶ So any design adjustments should take physician incentives into consideration.

Location is another major factor associated with clinical trial participation. Geography has a major impact on the feasibility of patient participation as it is correlated with travel time, cost, and culture. **One summit participant shared a story about a man who agreed to travel 100 miles to Emory University to participate in a clinical trial;** however, upon arrival, he was unable to find parking and unfamiliar with the city. He drove home deciding that the distance, geographically and culturally, was too great to be worth the benefits of clinical trial participation. This example is especially poignant given Eskander's finding that patients living in the Southeast are less likely to participate in clinical trials addressing pancreatic cancer.

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Assuming this finding is generalizable to most cancers, this means that efforts to address the characteristics of southern populations are especially necessary. Possible solutions to geographic challenges could include:^{47,48}

- Minimizing the number of patient visits;
- Opening trials at smaller centers;

- Enhancing utilization of telemedicine;
- Seeking out diverse geographic areas deliberately for trial sites;
- Creating diverse teams matching the demographic make-up of the region;
- Utilizing home health care for specimen collection and clinical trial monitoring; and
- Educating about implicit bias to improve provider insights about the challenges that minority populations experience.

Summit participants also highlighted that **principal investigators could include design criteria to promote the accrual of rural populations** such as emphasizing affordability in small settings.

Finally, one idea for continuing to improve clinical trials across the board is embedding research teams in clinical trials to explore questions related to accrual and design effectiveness.⁴⁹ Continued generation of knowledge in the area of clinical trial accrual is necessary to be sure that sufficient evidence is available for continued improvement. An investment today means opportunity tomorrow.

Summit participants agreed that **all individuals can advocate for research aimed at improving clinical trial design and accrual**. Some of these recommended adjustments are entirely at the behest of principal investigators and their teams; however, physicians, other healthcare providers, and patients can advocate for expanding access to those restricted from clinical trials because of cost and location. Policy makers have opportunities to develop legislation like the Clinical Treatment Act that assists with funding clinical trials while also maintaining quality and safety.

Key Points and Action Plans for Adjusting Cancer Clinical Trial Design

Key Points	Action Plans
Expand minimum eligibility criteria to further increase access to clinical trials: many criteria can be relaxed without risking patient safety.	Convene a panel of experts to assess the 2021 ASCO and Friends of Cancer Research (FCR) recommendations and continue to educate Georgians about new guidelines/recommendations.
Justify minimum eligibility criteria based on scientific criteria, especially where some criteria intersect with social determinants of health; try to accrue representative population samples.	Increase awareness about potential new trials' eligibility criteria and recognize trials that take steps to ensure their minimum eligibility criteria are expanded yet scientifically justifiable.
Simplify consent forms to enhance patient understanding, and use multi-modal educational tools such as bulleted lists, graphics, plain language, and short sentences.	Inform stakeholders and advocates for consent form simplification. Develop an adaptable Georgia centered educational program and sample materials to teach design principles for simplifying consent forms.
Address cost and geographic barriers by adjusting clinical trial design.	Consider building reimbursements for food, lodging, lost work time, and childcare to remove cost barriers to enroll on a clinical trial. Manage geographic barriers by minimizing patient visits, utilizing telemedicine, opening trials at smaller centers, seeking out deliberately diverse geographic regions, building treatment teams representative of regional diversity, and educating healthcare providers about implicit bias.
Use clinical trial designs to educate about and access somatic and germline testing, giving patients access to essential tools for fighting cancer.	Evaluate strategic opportunities to make somatic and germline testing a focal point of ongoing patient advocacy to promote use in new clinical trials.
Open more clinical trials to focus on the use of precision medicine and this may provide opportunities for patients who may not otherwise have access to a trial.	Support opening more precision medicine trials in Georgia through advocacy, development, and education.

Providing Trial Navigation for All

Clinical trial navigation is a key tool in addressing cancer treatment disparities, including disparities in trial accrual. **Summit participants repeatedly emphasized the importance of navigation to clinical trial accrual and retention.** Patient navigation has been shown to increase the rate at which patients complete clinical trials as well as to produce better informed patients.⁵⁶ Fouad et al. found that in a trial where oncology patient navigators were used, patients were nearly 5 times more likely to complete the trial in which they were enrolled, and other studies have shown patient improvements in knowledge, clinical trial participation, and satisfaction.^{57–59} Studies about navigation in clinical trials are a subset of studies examining patient navigation’s usefulness in expanding access to care for patients in resource poor settings, and others have found navigation improves pain outcomes, access to early supportive care, access to planning, and access to survivorship care.^{60,61} A cancer diagnosis is a destabilizing event for everyone, and navigation assists in orienting patients toward the resources they need to overcome cancer.

Clinical trial navigation is a flexible expression that may encompass several roles. **Summit participants’ understanding of navigation may be summed up as the process of learning the patients’ needs and then responding to them.** Navigation interventions have included both professional navigators as well as trained lay navigators drawn from patients, family members, or other parties with clinical trial experience: recent research also often uses the term nonclinical navigator when referring to trained lay navigators.^{56,62,63,64} Professional navigators often assist patients in overcoming barriers to trial participation by assisting with communication, referrals, service arrangements, and proactive education.⁶²

Navigators have been used to bridge cultural and language gaps between clinicians and patients.

Other professional navigators have been involved in identifying all clinical trials available to patients in their geographical area, based on clinical data and patient preferences, helping patients to bridge the clinical trial availability gap that accounts for a large percentage of clinical trial disparities.⁶³

Trained lay navigators have also been helpful in improving access to clinical trials. Typically, lay navigators have been used to bridge cultural and language gaps between clinicians and patients.

McClung et al. explored the use of lay navigators with Chinese patients finding improvements in knowledge and participation.⁵⁸ Fouad et al. partnered with, “individuals matching the demographic characteristics of the patients,” in order to provide two levels of services to patients, education and tailored support, including assistance with travel and lodging, appointment reminder calls, social worker referrals when appropriate, peer support, and linking the patient to other community resources. They found

that patients were significantly more likely to complete clinical trials in which they had enrolled.⁵⁷

Bridging cultural gaps was a common topic at the disparities summit: **participants were quick to note that cultural variation occurs in many dimensions, ranging from ethnic diversity to age variation**, and participants also emphasized that, “rural patients require a distinct set of cultural competencies leaning on tradition and concentric circles of familiarity common in rural settings.” Participants spoke about patients’ commonly expressed lack of trust in urban environments and those individuals having a stigma toward medical care in these “big places.” Trial navigators could be an essential tool for bridging the urban and rural divide growing increasingly common in the United States. Participants repeatedly emphasized the value of having individuals who have experienced clinical trial treatment and are similar to them with respect to race and ethnicity deliver the message effectively, and repeated a belief that lay navigators can bridge gaps in culture and education to improve trial accrual among people of color and rural populations.

Thanks to the flexible and multi-faceted nature of trial navigation, increasing accessibility to trial navigation is a multi-level task. Solutions may be equally flexible and targeted to local level needs. **Summit participants especially emphasized the need for resources to support the navigation processes.** Principal investigators should elect to build navigation into their trial budgets and treatment plans if the opportunity exists. Policy makers can elect to make funds available to bolster navigation programs in Georgia. Administrators can take this opportunity to examine and promote institutional policies favorable to the establishment and maintenance of patient navigation programs. At the local level, clinicians may elect to organize patient navigation volunteer networks to assist people in their local communities with navigating the cancer care continuum: local networks could be particularly helpful in bridging the urban rural gap in quality cancer care.

Key Points and Action Plans for Providing Trial Navigation for All

Key Points	Action Plans
Design navigation programs that are patient focused and, flexible with the goal of overcoming disparities in clinical trial accrual.	Assess Georgia’s clinical trial sites to identify the extent of investment in patient navigation. Design and implement an adaptable professional and patient navigation program for small clinics in rural Georgia. Advocate for universal patient navigation in all clinical trials present in Georgia.
Employ a spectrum of navigators that include professional nurse or social work navigators or patient navigators to help bridge cultural divides and provide tailored support.	Support educational institutions in patient navigation programs/degrees to provide a pipeline of individuals to fulfill these roles.

Enhancing Public Education and Awareness

Expanding health literacy was a prime concern among summit participants, and **most participants agreed that health literacy is a driving factor in clinical trial accrual.** Educating the general public is a major concern. One theme that emerges when examining solutions to ending disparities in trial accrual is that patients' prior education affects their ability to advocate for themselves and make optimal decisions. Likewise, providers make decisions about which patients to try to accrue for clinical trials, and bias, conscious or unconscious, can affect decision making. As such, a robust general education program on clinical trials and implicit bias training for providers are valuable tools for addressing disparities in clinical trial accrual. Additionally, messaging and education must also help to motivate providers to advocate for clinical trials.

Enhancing Community Awareness of Clinical Trials

First and foremost, expanding health literacy is a community project that is the responsibility of every single community member. In 2015, Margo Michaels and others built upon previous findings to propose five principles for effective education in community settings.^{65,66} First, educators must recognize that the needs of the general public are different from those of patients faced with a decision: educators should focus on access to care, dispelling common myths, and provide ways for people to act.

One example of an actionable tool for the general public is a conversation card designed to facilitate discussions about clinical trials among families and friends. Examples of addressing myths may include reassuring people that clinical trials are safe, provide the same or better than standard of care treatments, and that patients in clinical trials are not “guinea pigs” being experimented on without agency. Often myths are birthed from fragments of truth. **Summit participants pointed to well known examples** such as the Tuskegee Syphilis Study and the case of Henrietta Lacks as real-life examples that may create and perpetuate mistrust of clinical research in communities of color. The history of clinical trials must be faced and discussed so that more people understand that past abuses have been addressed and ethical controls have been put into place to prevent them from ever happening again.

One example of an actionable tool for the general public is a conversation card designed to facilitate discussions about clinical trials among families and friends.

Second, community education is most effective when delivered peer to peer through trusted local sources: training community leaders, such as local officials, pastors, and teachers, to educate others can create a ripple effect reaching more people.⁶⁶ Third, diversity in

populations necessitates targeted interventions designed to address the specific needs of a local area: identification of specific needs can be done with the help of community leaders tuned in to the community.⁶⁶ Examples of free screening and educational events include men's fellowship breakfasts, women's days, Dia de la Familia Latina, creating speaker networks, and Hats and High Tea for Breast Cancer Awareness.⁶⁶

Fourth, cancer clinical trial education must be part of long-term efforts to create trust and culturally competent care.⁶⁶ Fifth, educational outcomes should be measured using more than clinical trial accrual, and program success should be measured by assessing increasing knowledge/changing attitudes, increasing peer discussions about trials, and the extent of inquiry about trials.⁶⁶ With these five principles, and new technologies, educational tools can be designed to promote better health literacy among the general public.

Warnings in advertising contain federally mandated information about side effects, so the average person may be primed to view new treatments as risky.

The five principles are intuitive to many health care professionals, and summit participants made use of them during their breakout conversations about dispelling myths among communities of color. **Participants noted that plenty of incorrect and inaccurate information is available to the average person** through social media and other sources: they also observed that a significant portion of health communications aimed at patients are advertisements framed around adverse events. Furthermore, warnings in advertising contain federally mandated information about side effects. Thus, the average person may be primed to view new treatments as risky. Summit participants suggested that this information imbalance can be corrected through a variety of solutions. Notable among them was a suggestion that pharmaceutical companies invest more resources in general awareness campaigns about the importance of clinical trial participation including general education about

clinical trial research arms. Participants also emphasized the need for community partnerships spanning as many influential people as possible. They observed that faith-based communities are an excellent resource, but pastors alone cannot improve trial accrual in communities of color and rural areas. Improving health literacy in a community requires becoming a part of it and utilizing the resources and existing social networks that are already there.

To expand health literacy, a variety of educational solutions have been tested, and simple educational materials do appear to improve patients' willingness to participate.⁶⁷ Other studies have gone beyond brochures and questionnaires to find novel ways to educate patients and their families. Pelto and others conducted a pilot study using adaptable video

content, and they found a small but significant increase in knowledge.⁶⁸ This contrasts with an older study that found no significant improvement in objective knowledge using video content as an educational tool; however, in both cases patients and their families reported positive experiences, with the videos helping them to feel prepared to talk to their physician and be comfortable with enrolling in a clinical trial.^{68,69} Compared to brochures with or without pictures, animations have merit.⁷⁰ Incorporating educational materials into patient portals for colorectal patients has improved trial recruitment; however, the same study found that differential access to technology due to social determinants of health may reduce the effectiveness of this intervention.⁷¹ Decision aids, self-guided linear tools that may be embedded into websites, also improve patients' accrual and retention of objective information as well as confidence about their choice to participate.⁷²



Social media also has significant power to improve the clinical trial literacy of the general public: participants at the National Cancer Institute's Clinical Trials and Social Media Conference agreed that social media is a major shaper of national conversations on healthcare.⁷³ Social media is a uniquely democratized tool providing opportunities for survivors, families, physicians, and other stakeholders to get involved in public

education surrounding clinical trials, but more deliberate efforts are needed to organize sophisticated and effective social media campaigns.⁷³ Content creators and experts need to come together to facilitate opportunities to show real, diverse, ordinary, and hopeful people's treatment stories in order that everyone might see themselves as a potential clinical trial participant.⁷³ Rural patients and people of color deserve to see themselves as potential participants too. Furthermore, social media presents an opportunity to offer clear value propositions around clinical trials using plain language and direct communication.⁷³

The diverse options for public and patient education suggest that a design approach aimed at stacking the benefits of interventions could be highly effective. Multimedia options are duplicatable and inexpensive to maintain. Institutional websites and social media pages can create or purchase educational materials that make use of video, text, decision aids, and other material: then they can create a networked hub for those materials guiding patients down multiple avenues for acquiring the basic knowledge they need to understand and interact with clinical trials. Meanwhile, institutions and providers can emphasize partnerships with local leaders and grassroots campaigns as a means of generating greater awareness. **Summit participants referenced ongoing efforts in the form of barbershop**

talks and rural health fairs, and the work of public education is already ongoing. Better tools and practices will help to enhance those efforts.

Minimizing the Impact of Bias in Clinical Settings

On the flipside, intra-institutional professional education is also necessary. **One participant shared a story about a senior healthcare executive who had no idea that their institution offered clinical trials.** Ideally, everyone within the institution should have some knowledge of clinical trials and the reason for hosting them. A lack of knowledge about clinical trial disparities, as well explicit and implicit bias, may also affect clinical trial accrual. Past studies have suggested that physician behaviors, such as under prescribing pain medication or unnecessary variation in diagnoses, correlate with gender, age, ethnicity, and other patient characteristics.⁷⁴ A small study recently corroborated that at least some clinical trial staff perceived recruitment interactions with minority patients to be more challenging: potential minority participants were viewed as less-than-ideal candidates, clinic level barriers and negative perceptions led to providers withholding opportunities, some respondents perceived race to be irrelevant to consideration for clinical trials, and that addressing misconceptions and building trust were a common strategy for approaching minority patients.⁷⁵ **An awareness of these attitudes was also expressed by summit participants.** Another recent study found that providers at St. Jude Children's Research Hospital had a paucity of prior exposure to implicit bias self-assessment and education, but that this lack of self-assessment and education did not appear to influence recommendation for trial enrollment.⁷⁶

Notably, the settings between the two studies are very different, but two features stand out when comparing them. First, advocates for reducing clinical trial disparities should understand that, for better or worse, race is a factor that principal investigators, healthcare providers, and staff may not explicitly consider when accruing patients. Choosing not to consider race may fit a pattern of moving away from historic pattern of systematized discrimination based on race in the United States, but it comes at the risk of failing to recognize the legacy of barriers implemented with that same systematized discrimination. Second, the St. Jude example is particularly helpful: the authors speculate that pediatric oncology, a historically clinical trial centric field, may offset the effects of any implicit bias since almost all patients are offered clinical trial opportunities at some point during their treatment.⁷⁶ **Summit participants noted repeatedly that writing clinical trial protocols and providing resources for screening, informing, and asking every single patient about clinical trial participation would**

Race is a factor that principal investigators, healthcare providers, and staff may not explicitly consider when accruing patients.

ensure that everyone has an opportunity to consider participating. Knowing that patient acceptance rates do not differ all that much, just asking every single patient could impact accrual disparities.³

In short, a systemic adjustment could account for some disparities due to unconscious bias; however, training staff to recognize bias is necessary. Understanding disparities, and the impact of one's environment on unconscious beliefs and attitudes, may have positive effects impacting other areas of accrual, such as promoting equity in time and effort spent on accruing patients regardless of their individual characteristics. In the end, educating the public is a complex problem that must be addressed with tailored solutions fitted to unique circumstances, and everyone has an opportunity to participate.



Encouraging Providers to Advocate for Clinical Trials

Providers are a key component in the accrual process, and so they must be aware, unbiased, and motivated to advocate for clinical trials and educate patients. Human beings respond to incentives, and the added burden of presenting clinical trials to patients may affect provider motivation and disincentivize them from pursuing trials and patients that are perceived to strain a clinic's resources. As such, trial design should factor in clinical support and messaging that emphasizes motivating all providers to advocate for clinical trials. Providers rarely do not understand the value of clinical trials; however, misconceptions do exist. Additionally, institutional concerns and resources may affect providers' willingness to advocate for clinical trials. Having institutional and team support can alleviate burdens on providers, such as time spent outlining details related to trial participation. Ensuring that providers champion trials offer patients reassurance that team leaders at all levels endorse participation.

Implicit bias was addressed above; however, sometimes providers have more basic misconceptions about clinical trials, and care team partners beyond the oncology clinic, such as primary care physicians, can be less informed about clinical trials than oncologists.⁷⁷ Additional training for care teams correcting misconceptions about the value of clinical trials may be beneficial to encourage providers to greater advocacy. For example, **a brief disagreement in one panel at the summit over the real cost of clinical trials, along with other evidence on the topic, suggests a need for deeper study** and subsequent provider education on the costs and benefits of clinical trials to specific institutions: in turn, providers

concerned about resource drain from hosting clinical trials may find their concerns alleviated.⁷⁸

Institutional and resource constraints may also negatively affect provider enthusiasm for clinical trials. Barriers may include physician time constraints and other factors, with reports from doctors emphasizing issues keeping track of requirements, lacking time to explain trials to their patients, and time constraints related to patient tracking and regulatory compliance.^{79,80} **Time consuming paperwork and dealing with other regulatory burdens were mentioned by summit participants** over the course of the summit, and participants viewed this as a barrier to increasing accrual. Provider concerns about time in part stem from fears about a lack of necessary infrastructure and a lack of institutional support.⁷⁸⁻⁸⁰

Some means of addressing providers' concerns are available. One option is providing more resources: streamlined regulation, more funding, increased support staff, and easier access to ancillary services could assist in boosting provider morale.⁷⁹ In fact, a recent interim report by the NCI Clinical Trials Translational Research Advisory Committee has recently approved an interim set of guidelines for streamlining adult, late phase, Investigational New Drug (IND) exempt trials: the primary focus of the new recommendations is limiting data collection in late phase trials to material essential to the objectives of the trial.⁸¹ Alternatively, in resource poor settings, clinical work credits, academic credits, clear communication, public recognition, and emphasizing moral factors may help to motivate providers and maintain morale.^{78,79}

One summit participant and rural provider emphasized that resources in his setting only allowed for trials with sufficient support and minimal burden, including just-in-time enrollment. Like many physicians, he

found resources to be a challenge; however, he was sufficiently motivated to pursue hosting clinical trials. Available support networks and quality trial design gave him the opportunity to do so. How many more rural clinics would participate in clinical trials if they were aware of similar options?



Administrators, executives, principal investigators, and other leaders have a role to play in ensuring providers understand and are supported as a part of the clinical trial process. Communication from the senior levels of an organization can prioritize clinical trials, or it can stifle the desire to participate in cutting edge research. Resourcing providers to both provide standard of care and to accrue patients for clinical trials is essential. In areas where resources are scarce, other means of motivation should be emphasized at a minimum.

At the same time, continuing professional education is valuable, and advocates for clinical trials must provide opportunities for providers to learn about the benefits of clinical trials and the means to change their institutional culture in places disinterested in pursuing trial participation. Sharing information about care networks seeking to make clinical trials more accessible is a must to ensure that all providers, regardless of circumstance, have the necessary tools to provide the highest quality care for their patients.



Key Points and Action Plans for Enhancing Public Education and Awareness

Key Points	Action Plans
Focus on access to care, dispelling myths, and offering opportunities for action.	Develop a sample curriculum with simple action items, like handing out conversation cards, to provide to local communities.
Develop peer-to-peer information streams and targeted interventions based on community needs given they are more effective than one-size-fits all approaches.	Recruit and empower local community leaders to become advocates for clinical trial accrual.
Use multimedia tools such as video, animations and decision aids that are inexpensive and easy to maintain.	Design and develop multimedia educational tools for use in Georgia.
Emphasize grass roots relationships and social media outreach tools that are aligned and look like the community. Provide opportunity for a prospective patient to see themselves as potential clinical trial participant.	Launch a social media advocacy campaign aimed at representing the diversity of people in clinical trials. Attach the campaign to specific advocacy events in local communities.
Raise awareness and offer intra-institutional professional education to inform care teams, support personnel and administration about the value of clinical trials as well as implicit bias.	Encourage implicit bias training at Georgia healthcare institutions/practices and provide continuing education opportunities addressing bias. Encourage principal investigators and their teams to set aside time to educate other institutional personnel on the role and value of clinical trials.
Implement universal screening, informing, and asking all patients about clinical trial participation. This may counter individual implicit biases.	Assess Georgia clinical trial sites, and advocate for implementing universal screening and “just ask” policies where necessary.
Update and inform providers, including those outside oncology such as primary care professionals about the benefits of clinical trials.	Provide extra opportunities for continuing education to providers in Georgia including outreach to primary care providers about how they can appropriately inform patients about clinical trials.
Support healthcare providers with infrastructure to provide both standard of care and access to clinical trials.	Support education to healthcare providers in research programs about methods to increase funding for additional research personnel, patient navigation, and infrastructure.

Other Opportunities

Several other opportunities stand out for investigators in Georgia including participation in a pilot program sponsored by the American Cancer Society and conducting further research specific to Georgia. At the summit, Mark Fleury, PhD, gave a presentation on the American Cancer Society's (ACS) "Blue Button" pilot project, and **he informed summit participants that ACS is currently seeking 1-3 clinical implementation partners to test their new search tool.**

Recognizing that 77% of patients do not participate in clinical trials because there is no trial for which they are eligible: ACS began a project to help patients find and enroll in clinical trials. "Blue Button" is a matching service that helps clinical trials accrue patients, and helps patients locate clinical trials, by connecting electronic health records with a clinical trial database. It is built around a new HL7 FHIR accelerator that is, "a community and a platform to accelerate interoperable data modeling and implementation around mCode, leading to step change improvements in cancer care and research"⁸²

Using the search function of "Blue Button," Dr. Fleury was able to identify up to 29 unique trials in the Atlanta area within 20 miles of the 30303-zip code for breast cancer patients. When expanded up to 100 miles, the tool returned up to 32 unique trials. Notably, "Blue Button" could be a powerful tool for healthcare systems or community practices open to cooperation and patient referrals to address disparities in clinical trial accrual.

Next steps for "Blue Button" include finalizing technical validation for cancers of the brain, lungs, colon, and bladder. Criteria for potential clinical implementation partners include the capacity to conduct pilot and associated data collection, interest in optimizing clinical trial participation, having most patients prescreened for available clinical in the geographic area with some trials available offsite, open to multiple options for other nearby sites for referral, and an Epic electronic health record system.

Georgia needs further evaluation of and investment in its cancer care.

Second, Georgia needs further evaluation of and investment in its cancer care. Some areas thrive while others do not, and detailed and specific research may unlock ways for Georgia to bridge these gaps. Between 2009 and 2020, the state of Georgia has reallocated Master Tobacco Settlement Funds away from cancer prevention creating a net public disinvestment in cancer prevention.¹⁰ Research aimed at understanding and mitigating the cost of cancer to Georgians, both in terms of dollars and lives, could be very valuable in justifying public reinvestment in cancer prevention. Additionally, this paper has highlighted the diverse and targeted nature required of interventions seeking to address disparities, and further information about specific community needs would help care centers identify areas for

improvement. Given the current status of cancer care in Georgia, evaluating opportunities for and investing in improved cancer care in the state would have a disproportionate positive impact on rural communities and minority populations.

Key Points and Action Plans for Other Opportunities

Key Points	Action Plans
Identify potential partners for new technology to decrease the barriers to clinical trial accrual. Blue Button is an example of a powerful new search tool designed to find all clinical trials a patient may qualify for in each geographical distance.	Support the American Cancer Society's interest in recruiting 1-3 clinical implementation partners to test the tool.



Identifying Effective Public Policy

Finally, representatives of Georgia's oncological community must look toward future policy opportunities that can affect multiple systems, factors, and levels simultaneously. Effective policy can drive systemic change and improve clinical trial accrual in Georgia. The recent passage of the federal Clinical Treatment Act is cause for celebration. Effective January 1, 2022, the Clinical Treatment Act requires Medicaid to cover all related routine patient care costs regardless of whether the patient is receiving standard treatment or enrolled in a clinical trial. As noted above, the Clinical Treatment Act is an essential component to lowering financial barriers to clinical trial participation, and it has the potential to make a significant impact on disparities in clinical trial accrual given that the disproportionate share of nonelderly Medicaid recipients in Georgia are persons of color.



Unfortunately, not all recent policy efforts have been radically successful. The Food and Drug Administration's 2015 five-year action plan sought to improve representation in clinical trials through nonbinding recommendations and efforts to boost reporting transparency, in the form of a new Drug Trials Snapshots tool; however, recent research using Drug Trials Snapshots showed that over the five-year period relative representation of African American participants to Caucasian participants has remained steady and that only 20% of studies include race specific reporting of benefits and risks despite new requirements.⁸³ Green and others go on to explore possible recommendations for improving accrual, including minimum thresholds for trial accrual centered on ensuring trial participants' mirror disease

demographics and modifying approval processes such that drug approvals are delayed or require further follow up studies with more representative populations.⁸³ While new federal regulation may not be feasible, or necessarily desirable, the case of the Food and Drug Administration's 2015 five-year action plan illustrates the reasons why policymakers should focus on tangible incentives.

Changes in the legislative landscape impact clinical trials at the macro level, and policy changes that enable patients to access new treatments faster may incentivize investment in more clinical trials. ASCO is currently promoting two initiatives at the federal level. The Improving Seniors Timely Access to Care Act (H.R. 3173/S. 3018) aims to streamline the prior authorization process within Medicare Advantage by creating a digital prior authorization process, requiring reporting on prior authorization use, and creating accountability measures based on timeliness of determination.⁸⁴ The Medicare Multi-Cancer Early Detection Screening Coverage Act (H.R. 1946 / S. 1873) aims to overcome access barriers Medicare beneficiaries experience by creating a pathway for timely coverage of multicancer early detection tests once they are approved by the Food and Drug Administration.⁸⁴ While neither policy is directly related to clinical trials, advocating for regulations that allow companies to bring new products to market speedily but safely benefits everyone.

By targeting counties with low screening rates and deploying navigators to boost those rates every five years, Delaware made significant progress.

Georgia lawmakers can look to other state level oncology programs for inspiration. Delaware's investment in cancer care has moved it from the 2nd highest all site cancer mortality in the nation to 15th.⁸⁵ Using 1998 Tobacco Settlement Funds, Delaware deployed their Screening for Life Program and Delaware Cancer Treatment Program, each of which is designed to address gaps in cancer care access.⁸⁶ Notable is their successful use of patient navigators in reducing treatment disparities by targeting counties with low screening rates and deploying navigators to boost those rates every five years Delaware made significant progress.⁸⁶ Texas is currently the gold standard for investment in cancer care with the largest state cancer research investment in the history of the United States, a \$6 billion 20-year grant making initiative aimed at expediting innovation, expanding life science infrastructure, and enhancing research prowess in the state.⁸⁷ In 2019, the Cancer

Prevention and Research Institute of Texas estimated that their first \$2.4 billion in grants awarded generates an annual \$1.4 billion in economic activity and supports 10,000 jobs.⁸⁸ Using models like Texas and Delaware to boost Georgia's investment in cancer care, especially including efforts to attract new clinical trials, engage the best and brightest new

talent, and expand clinical trial infrastructure into rural Georgia, would be beneficial to all residents of the state.

Key Points and Action Plans for Identifying Effective Public Policy

Key Points	Action Plans
Focus on tangible incentives when suggesting new initiatives to policy makers.	Support ASCO as it promotes two federal initiatives which address overall costs and barriers to cancer care.
Boost support for clinical trials that will ultimately benefit all Georgians and the Georgia state economy.	Explore potential programs and advocacy efforts to strengthen state statutes related to clinical trials.

Conclusion and Integrative Remarks

Disparities in clinical trial accrual have been a long running challenge. Failing to focus on accruing minority populations to clinical trials raises questions about the generalizability of treatment results and may ultimately prevent too many people from accessing cutting edge treatments that may save lives. Fortunately, solutions exist that can address disparities in clinical trial accrual ensuring equitable access to clinical trials for all people regardless of race, ethnicity, place of residence, socioeconomic status, level of education, or other confounding factors.

Primary barriers to clinical trial accrual are related to geography and to availability, with many secondary barriers to consider including low health literacy, a need for navigation in a complex system, financial hardship, understaffing, under resourcing, and more. Roadblocks are multisectoral, multifactorial, and multilevel, and a broad array of stakeholders need to be engaged to improve cancer care in Georgia tomorrow.

To that end, summit participants identified **four potential target areas** to enhance clinical trial accrual among minority patients.

- 1. Adjusting cancer clinical trial design**
- 2. Providing trial navigation for all**
- 3. Enhancing public education and awareness of crucial cancer clinical trials and treatment opportunities**
- 4. Identifying effective public policy**

Adjustments to trial design and expanding patient access to trial navigation have the greatest potential to address primary barriers to access. By expanding the potential patient pool, through design choices such as expanding inclusion criteria, opening more trials in rural or underserved areas, building in support for additional patient and provider costs, opening trials utilizing precision medicine to capture patients whose tumor types are unlikely to be studied, and developing sophisticated search tools ensuring clinicians can locate all local clinical trial opportunities, more people will have access to clinical trials, and sections of the population historically disadvantaged due to clinical trial location or availability will have more opportunities to voluntarily participate. Expanded access to navigation assists with both recruitment and retention of patients, raising the odds of long-term success for both patients and the clinical trial. A cancer diagnosis is a harrowing and overwhelming experience for anyone and having a guide and advocate to navigate the complexities of healthcare during that time is essential.

Education is essential for overcoming secondary barriers, especially those related to patient or provider hesitation. Myths must be dispelled, whether they be about race or “mad science”

experiments. Basic health literacy should include an understanding of how new healthcare treatments are developed. Patients without such an understanding are vulnerable to misinformation and myths: lacking a strong health literacy foundation, misunderstanding may also be more likely which complicates the informed consent process. As such, continued efforts to inform communities through targeted interventions tailored to their needs and circumstances are essential. In fact, principal investigators and providers should seek to structure clinical trials, for example by building in translation into the consenting process, in such a way as to allow providers to educate and inform patients, making room for varying needs among clinical trial participants.

Finally, policy makes a significant impact in all areas. Regulatory measures that slow or block access to cutting edge treatments should be implemented only when necessary to protect the safety of patients, and they should be reexamined and adjusted as needed. Public support for clinical trials, both in the form of funding and affirmation, can help smooth the way for increasing the number, variety, and availability of trials in the state of Georgia.

Everyone is affected by cancer, and ending cancer is everyone's responsibility. There are many ways to contribute. For too many, their access to cutting edge treatment is defined by where they live, the color of their skin, or how much money they make. To make a difference, stakeholders must advocate, educate, and knock down barriers to trial accrual. If each person does what they can, equal access to clinical trials is achievable.



Appendices

Appendix A: Summit Agenda, Descriptions, and Breakout Session Reports



8:30 AM	WELCOME Jean Sumner, MD, Dean, Mercer University School of Medicine Sharad Ghamande, MD, Georgia Cancer Center, Augusta University, GASCO President
8:45 AM	KEYNOTE – Defining the Problem and evidence based interventions (EBIs) Bradley Carthon, MD PhD, Winship Cancer Institute, Emory University
9:15 AM	PANEL DISCUSSION: Current Efforts for Diversity in Clinical Trials <i>Topic Description:</i> Twenty years ago, Georgia’s leaders made cancer research and clinical trials a priority for the state. There has been an eight-fold increase in the number of clinical trials since then, but barriers to participation remain. This panel of experts will discuss current availability of clinical trials, the types of trials available and initiatives to increase the reach of these trials, and the advances that have been made relating specifically to diverse populations. Facilitator: Crain Garrot, MD, Georgia Cancer Specialists Panelists: Trena Davis, BSN RN CCRC, Northeast Georgia Medical Center Theresa Gillespie, PhD MA FAAN, Winship Cancer institute, Emory University Anand Jillella, MD, Georgia Cancer Center, Augusta University Margaret A. Ferreira, MS, RN, OCN, Northside Hospital Cancer Institute

10:10 AM **PANEL DISCUSSION: Barriers to Participation for Diverse Populations**
Topic Description: Studies have shown, and the COVID-19 pandemic has clearly demonstrated, that there are barriers to participation in clinical trials. A deficiency of information and access to clinical trials is heightened for Black, Asian, Hispanic, and other ethnic and racial minorities. Rural residents also suffer from diminished access to cutting edge research and treatments. This panel of experts will discuss the impediments they see in their practices and hospitals to increased equity to cancer clinical trials.

Facilitator: Brian Rivers, PhD MPH, Morehouse School of Medicine

Panelists:

Rodolfo Bordoni, MD, Georgia Cancer Specialists

Chirag Jani, MD, Phoebe Putney Medical Center

Pooja Mishra, MBA/MHA FACHE, Grady Health System

Jayanthi Srinivasiah, MD, Georgia Cancer Specialists

11:15 AM **BREAKOUT SESSIONS**

From the Beginning: Educating and Empowering Patients at Initial Diagnosis

Session Description: Are patients being informed of potential clinical trials at initial diagnosis? How can this be done effectively and compassionately? In this session, participants will discuss practical ideas to include the introduction of the possibility of clinical trials in these initial interactions.

Facilitators: Andrew Weatherall, RN OCN CCRC, Atrium Health Navicent

Increasing Accruals through Improving the Consenting Process

Session Description: After a patient shows interest in participating in a clinical trial, there are often process centered barriers, healthcare system barriers and, patient barriers such as language or cultural impediments that make it difficult to accrue and retain diverse patients on a clinical trial. Session attendees will discuss these difficulties and potential improvements in the consenting process that could yield a more diverse patient population.

Facilitators: Mary Egan, BS CCRC & Kylie Graden, BSA, University Cancer & Blood Center

Easing Socioeconomic Barriers to Participation

Session Description: Patients who are socioeconomically disadvantaged may have multiple barriers to participation including transportation, housing/hoteling, absences from work, or home health care. This session will explore data about socioeconomic disparities and engage in a discussion about potential actions to alleviate some of these barriers.

Facilitators: Ajay Nooka, MD MPH FACP, Emory University

- 12:30 PM **The Patient's Perspective**
Kimberly Michelle Smith, Patient Survivor & Advocate and Sheryl Gabram, MD MBA, Chief Scientific Officer, Georgia CORE
- 1:00 PM **Blue Button Project: Innovations in Data Sharing/Matching Services**
Mark Fleury, PhD, Principal, Policy Development-Emerging Science, American Cancer Society Cancer Action Network
- 1:45 PM BREAKOUT SESSION 2

Dispelling Myths in Communities of Color

Session Description: Many of us may think we know why communities of color have a lower rate of participation in clinical trials, but do we really? And what can be done to dispel myths and focus on real impediments to participation in these communities? Attendees in this session will identify the myths and discuss how to work with members of communities of color to heighten participation.

Facilitators: Pamela Cooper and Roland Matthews, MD, FACOG, Morehouse School of Medicine

Converting the Masses: Encouraging Physicians to Accrue to Clinical Trials

Session Description: A recent NIH study found that only 10 to 20% of physicians inform their cancer patients about clinical trials. This session will focus on practical ways healthcare systems and providers can encourage and support community physicians in their efforts to refer patients for clinical trial participation.

Facilitators: Cheryl Jones, MD and Binta Auta, Northside Hospital Cancer Institute

Expanding Rural Access and Outreach

Session Description: Many of Georgia's rural communities have limited access to cutting-edge clinical trials and treatments. In this session, participants will identify barriers for rural residents and seek to identify solutions for this population.

Facilitators: Harsha Vyas, MD, Cancer Center of Middle Georgia and Chris Scoggins, MPH, Georgia Rural Health Innovation Center

- 3:00 PM **Breakout Group Reports and Action Items**
Andrew Pippas, MD (Chair, Georgia CORE), Director, Medical Oncology, Piedmont Columbus
- 3:45 PM **Closing Remarks**
Andrew Pippas, MD (Chair, Georgia CORE), Director, Medical Oncology, Piedmont Columbus

Breakout Session Reports

Session 1 From the Beginning: Educating and Empowering Patients at Initial Diagnosis

- The group affirmed the need for basic clinical trial education prior to asking about specific enrollment, and suggested identifying key stakeholders responsible for educating the community such as institutions, research teams, physicians, and navigators.
- Session members emphasized doing what we say and keeping the patient the priority while building out multiple avenues for education including social media, paid advertising, patient portals, navigators, survivors and their supporters, community outreach, and conducting internal education.
- A need for support from key decision makers in the healthcare institution was also highlighted. Every cause needs a champion, and leaders set budgets, culture, and organizational priorities.

Session 2 Increasing Accruals Through Improving the Consenting Process

- Awareness of clinical trials needs to be prioritized from the beginning of a patient's treatment journey. General awareness and education ease the consenting process.
- Everyone on the treatment team should be trained and prepared to support trial accrual by answering questions and directing patients to more information: training for treatment teams should be a standard component of employee orientation.
- The consent conversation must be a conversation, and clinicians must have the tools and training to be able to provide patients what they need to make the right decision for them. Mock consent conversations, teach back methods, and simple informational videos were all tools highlighted by the group.

Session 3 Easing Socioeconomic Barriers to Participation

- The number one way to improve accrual is to just ask every patient, and educate every patient, about clinical trial participation. Then systematically ask again down the line if they decline.
- Underinsured patients may experience unanticipated financial hurdles, and researchers must try, in partnership with financial backers, to anticipate those hurdles and address them through extra funding or other means.
- 3rd party vendors and community participants can be organized and utilized more effectively. Standard language and procedures across the spectrum of care can enable better teamwork.

Session 4 Dispelling Myths in Communities of Color

- Some concerns are very real, and those concerns may be based on personal experience. For example, patients who are also undocumented immigrants have legitimate concerns about handing over information and accepting assistance due to fear of deportation.
- Our communities are very aware of past abuses, and providers should be able to clearly discuss that history and how things have changed.
- In order to address concerns and dispel myths, institutions must be able to bridge the gap by fostering trust and developing partnerships with people and groups who understand patients' experiences and concerns such as local leaders, lay navigators, and communities of faith.

Session 5 Converting the Masses: Encouraging Physicians to Accrue Clinical Trials

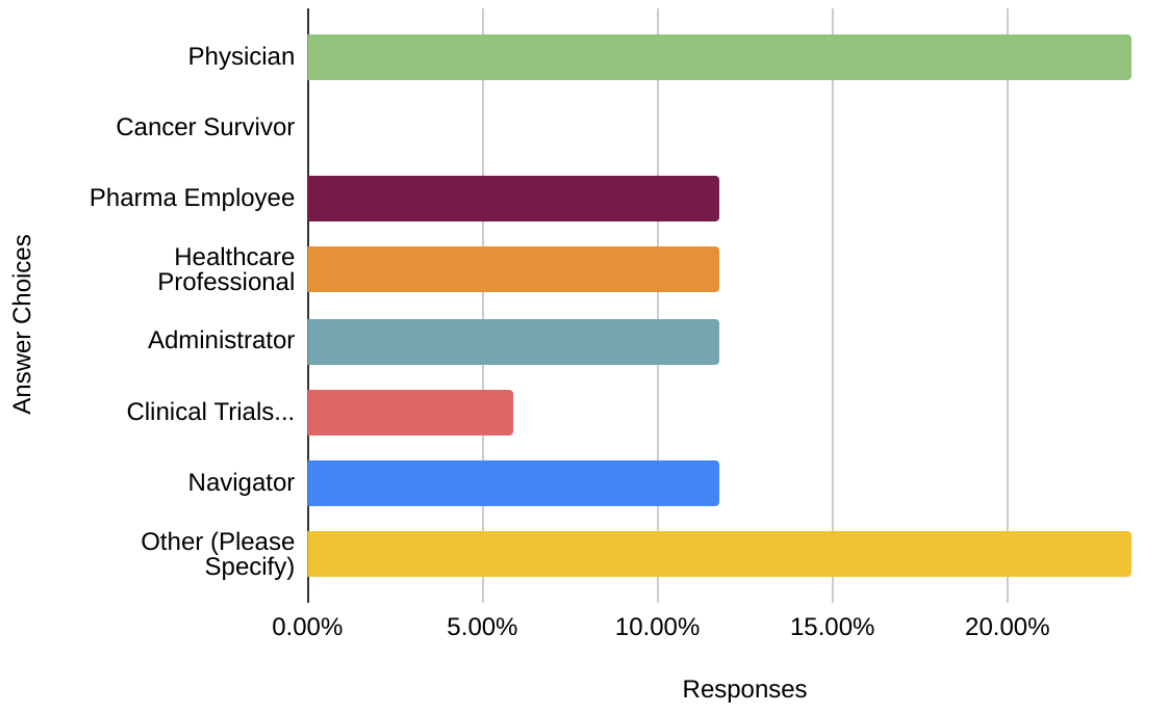
- Everything begins with education, ensuring providers and patients understand the importance of clinical trials. Following education, it is essential to maintain awareness and keep providers up to date using continual cues, such as email blasts, reminders in the electronic medical record (EMR), and continuing education opportunities.
- The biggest obstacle for many is disconnected information. Disparate hospital systems with EMRs that do not communicate with each other discourage necessary collaboration.
- Physicians of all specialties can and should be involved in advocating for clinical trials.

Session 6 Expanding Access and Outreach

- Challenges for expanding access and outreach include transportation, geography, finance, broadband access, and culture.
- There are very few silver bullets for making major strides in access and outreach. Gradual incremental changes in key areas are the solution, and they will require asset-based community development in concert with broad partnerships.
- Rural communities require their own type of cultural competency. Better understanding of the sense of resiliency in rural communities, and decisions related to the quality and end of life, may help to improve clinical trial accrual.

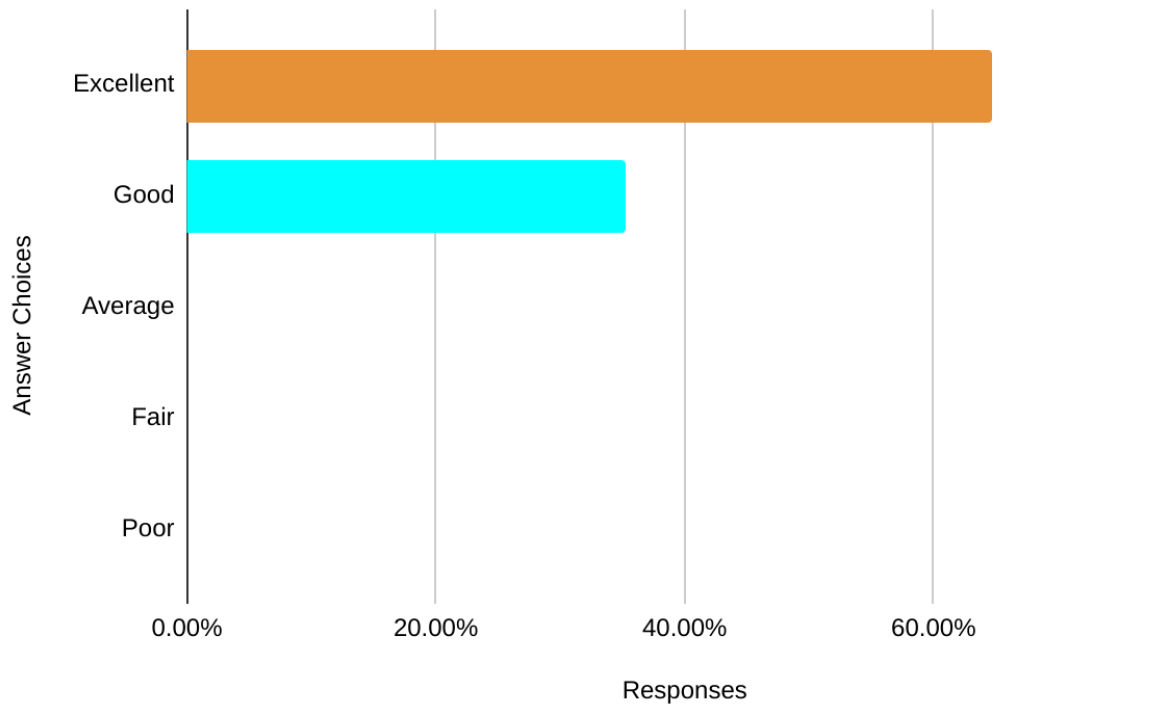
Appendix B: Survey Results

Q1 What best describes your role?



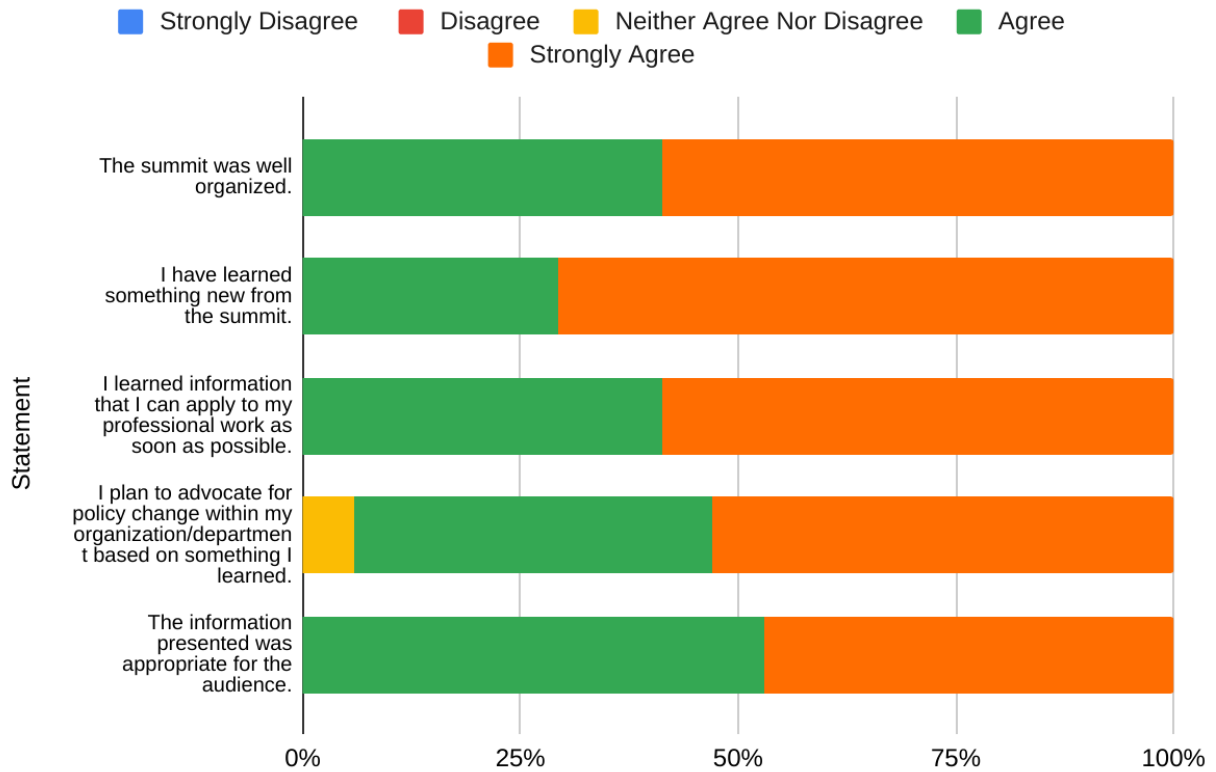
Answer Choices	Responses	
Other (Please Specify)	23.53%	4
Navigator	11.76%	2
Clinical Trials...	5.88%	1
Administrator	11.76%	2
Healthcare Professional	11.76%	2
Pharma Employee	11.76%	2
Cancer Survivor	0%	0
Physician	23.53%	4
Total		17

Q2 How would you rate the overall summit?



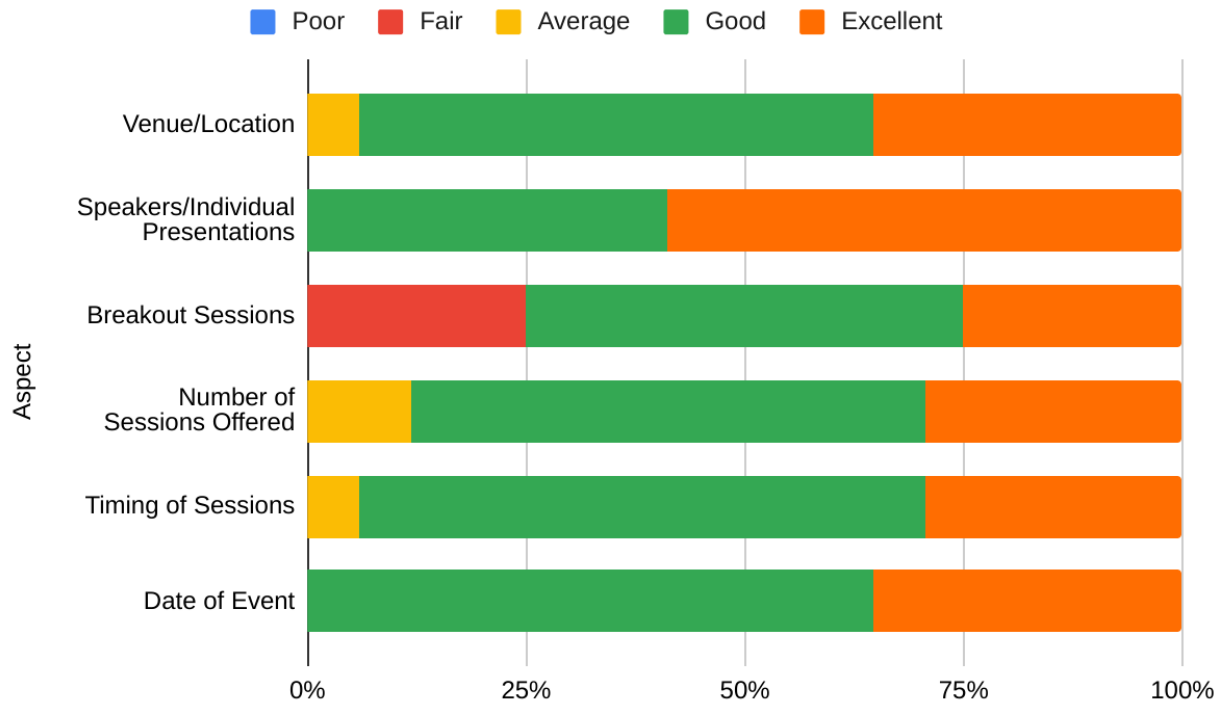
Answer Choices	Responses	
Poor	0.00%	0
Fair	0.00%	0
Average	0.00%	0
Good	35.29%	6
Excellent	64.71%	11
Total		17
Weighted Average		4.65

Q3 Select your rating for how much you agree with the statements below:



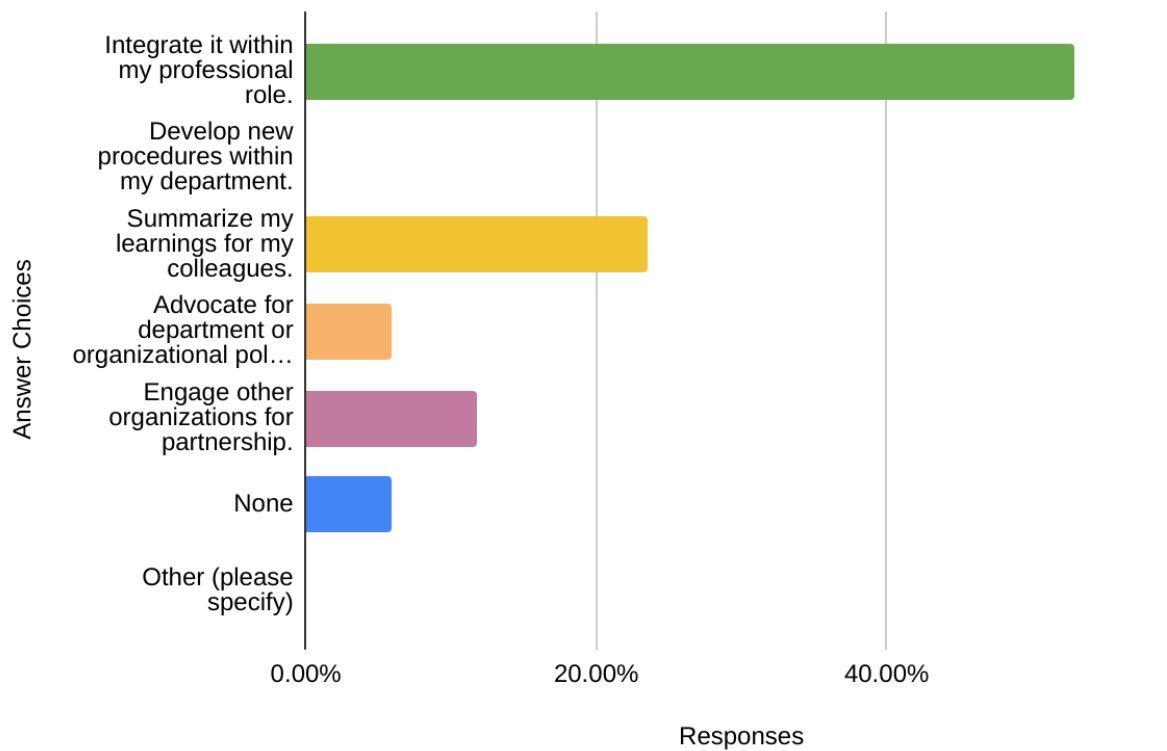
Statement	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree	Total
The summit was well organized.	0.00% 0	0.00% 0	0.00% 0	41.18% 7	58.82% 10	17
I have learned something new from the summit.	0.00% 0	0.00% 0	0.00% 0	29.41% 5	70.59% 12	17
I learned information that I can apply to my professional work as soon as possible.	0.00% 0	0.00% 0	0.00% 0	41.18% 7	58.82% 10	17
I plan to advocate for policy change within my organization/department based on something I learned.	0.00% 0	0.00% 0	5.88% 1	41.18% 7	52.94% 9	17
The information presented was appropriate for the audience.	0.00% 0	0.00% 0	0.00% 0	52.94% 9	47.06% 8	17

Q4 Please indicate your satisfaction with the following aspects of the event:



Aspect	Poor	Fair	Average	Good	Excellent	Total	Weighted Average
Venue/Location	0.00% 0	0.00% 0	5.88% 1	58.82% 10	35.29% 6	17	4.29
Speakers/ Individual Presentations	0.00% 0	0.00% 0	0.00% 0	41.18% 7	58.82% 10	17	4.59
Breakout Sessions	0.00% 0	25.00% 4	0.00% 0	50.00% 8	25.00% 4	16	3.75
Number of Sessions Offered	0.00% 0	0.00% 0	11.76% 2	58.82% 10	29.41% 5	17	4.18
Timing of Sessions	0.00% 0	0.00% 0	5.88% 1	64.71% 11	29.41% 5	17	4.24
Date of Event	0.00% 0	0.00% 0	0.00% 0	64.71% 11	35.29% 6	17	4.35

Q5 How do you plan to utilize the information learned in the summit?



Answer Choices	Responses	
Integrate it within my professional role.	52.94%	9
Develop new procedures within my department.	0.00%	0
Summarize my learnings for my colleagues.	23.53%	4
Advocate for department or organizational policy change.	5.88%	1
Engage other organizations for partnership.	11.76%	2
None	5.88%	1
Other (please specify)	0.00%	0
Total	17	

Q6 What is a key takeaway that should be communicated to the public and to policy makers?

- We have a lot of work to do in Georgia
- Clinical trials are important for all patients
- Clinical trials are available, and we need to make sure people know about them
- Shared information creates better options for patient involvement in clinical research
- Diverse representation in clinical trials is vital
- The differences between urban and rural Georgia are significant, and it is urgent that the state bridge the divide. Rural Georgia needs major medical infrastructure investment
- Expansion of clinical trial navigation is an idea worth exploring
- Patient navigation is essential care
- We must educate the community about the importance of clinical trials and dispel myths and misconceptions about them
- We must target our education to be sure patients, communities, and professionals get the information they need
- Health literacy is a must for doctor-patient communication
- All patients should have access to care

Q7 What was the most important thing you learned at the summit?

- Teamwork matters
- More needs to be done to improve access to clinical trials in rural areas
- Not all researchers are aware of recruitment tools that sponsors provide
- Go where the people are
- Resources and clinical trials that are available need to be discussed starting on day 1
- Clinical trials are not only a last resort, and they are crucial for patient care
- Patients face many kinds of adversity, and care plans should factor these in
- We must be solutions oriented
- Policy work is going on at the federal level and the summit pointed out some helpful publications to learn more about disparities in clinical trials
- We can make a difference

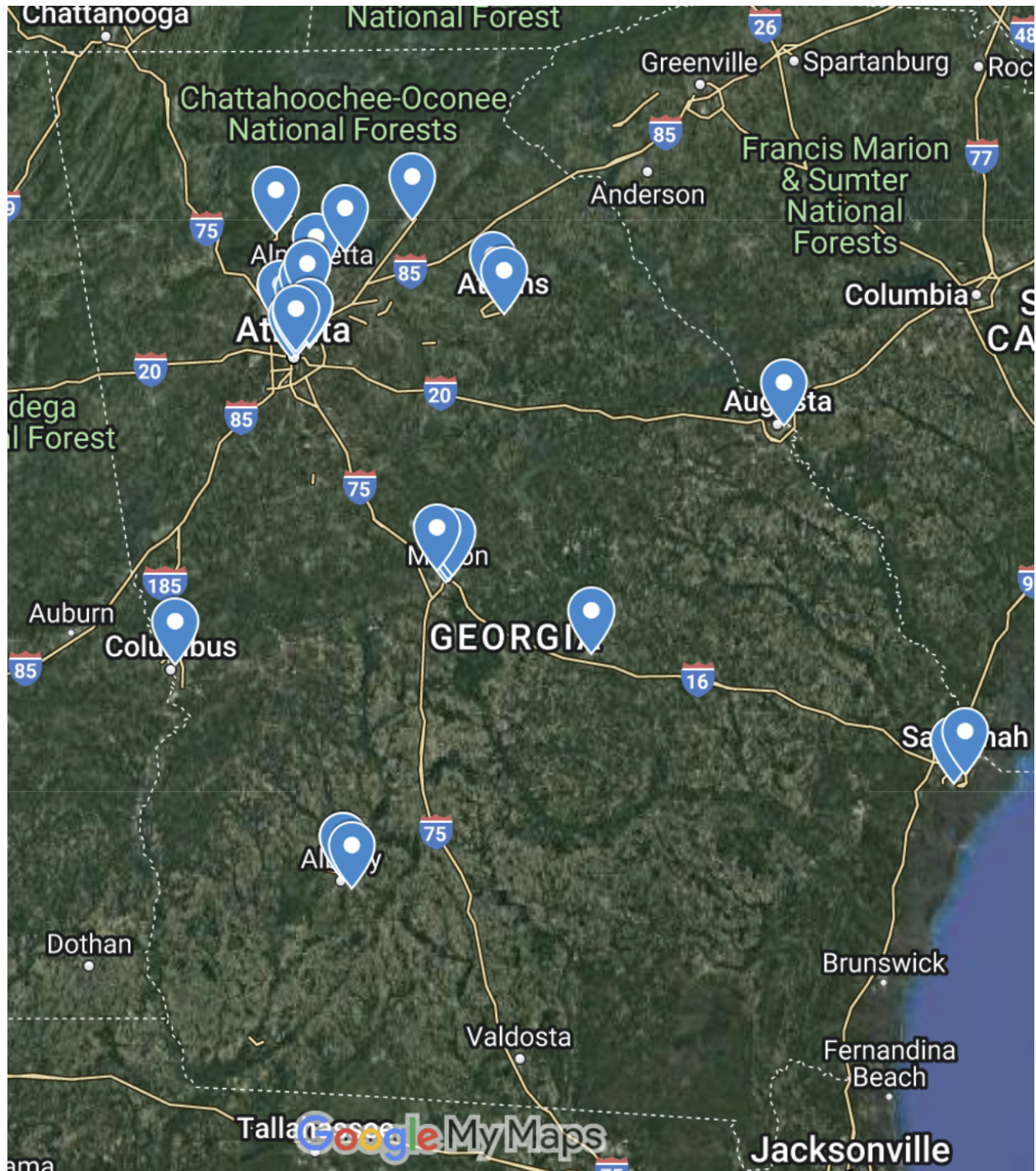
Q8 What, if anything, did you dislike about the event?

- The breakout sessions all in one room
- More specific directions to the site would have been useful
- Parking felt limited
- The preconception that health care inequity can only be defined by the color of the skin

Appendix C: Presenters/Facilitators and Their Affiliations in Order of Appearance

Jean Sumner, MD, Dean, Mercer University School of Medicine
Sharad Ghamande, MD, Georgia Cancer Center, Augusta University, GASCO President
Bradley Carthon, MD PhD, Winship Cancer Institute, Emory University
Crain Garrot, MD, GA Cancer Specialists
Trena Davis, BSN RN CCRC, Northeast Georgia Medical Center
Theresa Gillespie, PhD MA FAAN, Winship Cancer institute, Emory University
Anand Jillella, MD, Georgia Cancer Center, Augusta University
Margaret A. Ferreira, MS, RN, OCN, Northside Hospital Cancer Institute
Brian Rivers, PhD MPH, Morehouse School of Medicine
Rodolfo Bordoni, MD, Georgia Cancer Specialists
Chirag Jani, MD, Phoebe Putney Medical Center
Pooja Mishra, MBA/MHA FACHE, Grady Health System
Jayanthi Srinivasiah, MD, Georgia Cancer Specialists
Andrew Weatherall, RN OCN CCRC, Atrium Health Navicent
Mary Egan, BS CCRC, University Cancer & Blood Center
Kylie Graden, BSA, University Cancer & Blood Center
Ajay Nooka, MD MPH FACP, Emory University
Kimberly Michelle Smith, Patient Survivor and Advocate
Sheryl Gabram, MD MBA, Chief Scientific Officer, Georgia CORE
Mark Fleury, PhD, Principal, Policy Development-Emerging Science, American Cancer Society Cancer Action Network
Pamela Cooper, Morehouse School of Medicine
Roland Matthews, MD, FACOG, Morehouse School of Medicine
Cheryl Jones, MD, Georgia Cancer Specialists
Binta Auta, Northside Hospital Cancer Institute
Harsha Vyas, MD, Cancer Center of Middle Georgia
Chris Scoggins, MPH, Georgia Rural Health Innovation Center
Andrew Pippas, MD (Chair, Georgia CORE), Director, Medical Oncology, Piedmont Columbus

Appendix D: Map of Participant Institutional Affiliation



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