

Action for Increasing Diversity, Market Access, and Capacity in Oncology Registration Trials—Is Africa the Answer? Report From a Satellite Session of the Accelerating Anti-Cancer Agent Development and Validation Workshop

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abstract

Patients of African ancestry are not well-represented in cancer clinical trials despite bearing a disproportionate share of mortality both in United States and Africa. We describe key stakeholder perspectives and priorities related to bringing early-stage cancer clinical trials to Africa and outline essential action steps. Increasing Diversity, Market Access, and Capacity in Oncology Registration Trials—Is Africa the Answer? satellite session was organized at 2021 Accelerating Anti-Cancer Agent Development and Validation Workshop. Panelists included representatives of African Organization for Research and Training in Cancer, Uganda Cancer Institute, Uganda Women's Cancer Support Organization, BIO Ventures for Global Health, Bill & Melinda Gates Foundation, the US Food and Drug Administration, Nigeria's National Agency for Food and Drug Administration and Control, Bayer, and Genentech, with moderators from ASCO and American Cancer Society. Key discussion themes and resulting action steps were agreed upon by all participants. Panelists agreed that increasing diversity in cancer clinical trials by including African patients is key to ensuring novel drugs are safe and effective across populations. They underscored the importance of equity in clinical trial access for patients in Africa. Panelists discussed their values related to access and barriers to opening clinical trials in Africa and described innovative solutions from their work aimed at overcoming these obstacles. Multisectoral collaboration efforts that allow leveraging of limited resources and result in sustainable capacity building and mutually beneficial long-term partnerships were discussed as key to outlined action steps. The panel discussion resulted in valuable insights about key stakeholder values and priorities related to bringing early-stage clinical trials to Africa, as well as specific actions for each stakeholder group.

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PURPOSE AND METHODS

Noncommunicable diseases, including cancer, are the leading cause of mortality in all regions of the world. Cancer outcomes vary by race and ethnicity because of differences in environmental exposures and cancer incidence,¹ tumor biology,²⁻⁶ treatment side effects,^{7,8} and socioeconomic determinants of health.⁹ In Africa, cancer prevalence and mortality are projected to rise substantially by 2040¹⁰ because of increased longevity and adoption of more sedentary Western lifestyles and diets.

The availability of cancer clinical trials reflects a country's clinical research capacity and is likely associated with the provision of evidence-based cancer care and improved

patient outcomes.¹¹ Although countries in Africa account for a very small percentage of worldwide cancer clinical trials,^{12,13} including 1,376 trials total and 444 active trials (Table 1, Fig 1, on the basis of data from ClinicalTrials.gov), the trials that have been performed have resulted in practice-changing insights.¹⁴⁻¹⁶ These studies are particularly important given that, compared with patients in Europe and North America, patients in Africa respond to treatment differently because of cancer biology,^{3,5} nutritional status, and HIV coinfection.¹⁷

Barriers to conducting cancer-related and other clinical trials in African countries¹⁸⁻²¹ and other low- and middle-income countries include insufficient financial and human capacity, including individuals trained in bioethics for clinical trial protocol

ASSOCIATED CONTENT

Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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CONTEXT

Key Objective

We describe key stakeholder perspectives and priorities related to bringing early-stage cancer clinical trials to Africa and outline essential action steps.

Knowledge Generated

Priorities of patient advocacy representatives, oncology research organizations, pharmaceutical companies, and regulatory agencies included increasing both diversity and equity in early-stage cancer clinical trials to improve generalizability of results and build long-term sustainable collaborations with partners in Africa. Such multisectoral collaboration allowed for leveraging of limited resources and was key to outlined action steps and increasing access to early-stage clinical trials in Africa.

Relevance

The discussion among key stakeholders resulted in valuable insights about key stakeholder values and priorities related to bringing early-stage cancer clinical trials to Africa, as well as specific agreed-upon actions for each stakeholder group to bring registration clinical trials to patients.

evaluation^{22,23}; weak regulatory systems, resulting in slow review of clinical trial protocols and new drug applications; lack of supportive research environments; and competing demands on time and resources.²⁴⁻²⁷ Guiding principles for expanding access to clinical trials for patients in Africa,²⁸ as well as clinical trial design and implementation considerations in the region,^{15,27} have been outlined, including funding and technical support for local investigator-initiated clinical trials, on the basis of existing needs and resources that have the greatest potential to improve patient care.^{14,15,24,29}

To improve awareness about perspectives of cancer research organizations, patient advocacy groups, regulatory agencies, pharmaceutical companies, and global health nonprofit organizations as they relate to expanding cancer clinical trials capacity in Africa (including participation in registration trials)—and promote dialog and joint action among these key stakeholder groups—we convened the satellite session Increasing Diversity, Market Access, and Capacity in Oncology Registration Trials—Is Africa the Answer? at the 2021 Accelerating Anti-Cancer Agent Development and Validation Workshop (Data Supplement). Panelists included three representatives of African research organizations and cancer-focused academic institutions (B.A., J.O., and F.O.); one leader of an African patient advocacy organization (G.N.); three representatives of regulatory agencies, one from Nigeria (M.C.A.) and two from the United States (K.A. and L.F.-A.); two representatives of global pharmaceutical companies (C.K. and J.F.); and two representatives of US-based global health nonprofit organizations involved in health care in Africa (T.N. and J.D.). Clinical oncologists representing US-based oncology professional organizations and academic cancer centers (B.C. and J.G.) moderated the session.

Themes that emerged from the panel presentations and discussion included diversity, equity, and importance of partnerships and collaborations in including African

countries in early-stage cancer clinical trials. In this publication, we describe each theme, enumerate associated action items, and outline potential impacts.

DIVERSITY IN CLINICAL TRIALS IS KEY TO ENSURING CANCER DRUGS ARE EFFECTIVE ACROSS POPULATIONS

Clinical trials are required to determine the safety and efficacy of new products in all patient populations. Participants agreed that the efficacy of standard-of-care cancer drugs in African patients, and patients of African ancestry more broadly, has not been studied sufficiently. Less than 1% of international trials submitted to the US Food and Drug Administration (FDA) for approval of cancer drugs enroll participants from clinical sites in Africa. Most trials that do enroll patients in sub-Saharan Africa typically focus on postmarketing surveillance. Even in the United States, where 20% to 25% of participants in global clinical trials are enrolled, only 2%-4% of participants are of African descent.^{30,31} The representatives of African academic institutions and research organizations emphasized that, on the basis of their clinical experience, the lack of inclusion in registration trials of participants either from Africa or of African descent likely contribute to greater rates of treatment failure and poorer outcomes in African patients.

Panel participants shared their perspectives about reasons for the dearth of clinical trials in sub-Saharan Africa. Representatives of the African Organization for Research and Training in Cancer (AORTIC) and the Uganda Cancer Institute (UCI) described the low priority placed on research, including by country governments, resulting in inadequate funding, insufficient infrastructure (including internet), and insufficient numbers of teams proficient in good clinical practice. Representatives of pharmaceutical companies Bayer (Pittsburgh, PA) and Genentech (South San Francisco, CA) described previous concerns about regulatory infrastructure, data quality and integrity, and patient safety, currently being addressed by these

TABLE 1. Current Cancer Clinical Trials in Africa

Country	Studies
Algeria	6
Botswana	3
Burkina Faso	5
Cameroon	3
Congo, The Democratic Republic of the	4
Côte D'Ivoire	6
Egypt	246
Ethiopia	2
Gabon	1
Ghana	2
Kenya	9
Madagascar	4
Malawi	11
Mali	4
Mauritania	1
Morocco	5
Niger	1
Nigeria	11
Rwanda	3
Senegal	6
South Africa	132
Sudan	1
Swaziland	4
Tanzania	7
Togo	2
Tunisia	5
Uganda	8
Zambia	2
Zimbabwe	4
Total	444

companies through several novel initiatives. From the patient advocacy perspective provided by the leader of the Uganda Women's Cancer Support Organization (UWOCASO, Kampala, Uganda), barriers included lack of understanding among patients about clinical trial procedures and benefits, concerns about drug safety, logistical barriers, gaps in treatment capacity, and insufficient engagement of patient advocates by researchers and regulatory agencies.

Representatives of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC, Lagos, Nigeria) and FDA discussed the importance of recruiting a diverse population of patients to cancer clinical trials to ensure applicability of results³² and noted that sustainable partnerships and collaboration should be the goal of these efforts.

EQUITY IN ACCESS TO CLINICAL TRIALS AND CANCER CARE PRODUCTS IS A PRIORITY FOR PATIENTS, REGULATORY AGENCIES, CANCER-FOCUSED CIVIL SOCIETY, AND PHARMACEUTICAL COMPANIES

The panelists underscored the importance of ensuring equitable access to clinical trials for patients in Africa.

Panelists from Bayer and Genentech described their commitment to improving equity in cancer care and drew parallels between ensuring access to new medications for African patients and for underserved minority patients in the United States. Examples cited by the panelist from Genentech included a successful effort to recruit US underserved and racial/ethnic minority patients into a phase III clinical trial of its drug tocilizumab for COVID-19 pneumonia by working directly with these communities.³³ This effort resulted in fast trial accrual and emergency authorization of tocilizumab. Another example was a study of ocrelizumab for multiple sclerosis exclusively among patients of African descent, who are known to have a more severe clinical course and worse outcomes, in both Kenya and the United States.³⁴ This successful effort prompted the company to consider additional clinical trials, including in oncology, in sub-Saharan Africa.

Ensuring sustainable research partnerships and long-lasting health care system improvements was a priority for both regulatory agencies and pharmaceutical companies. The panelist from Bayer described conducting needs assessments in Ghana and engaging local experts for prostate cancer capacity building and health care systems strengthening, to ensure sustainable improvements in cancer care. Both the Bayer and Genentech panelists recognized that the considerations for driving equity do not stop after a trial is completed and that plans for market entry and sustained access should be incorporated into research and business strategies.

MULTILEVEL, MULTISECTORAL COLLABORATION IS KEY TO BRINGING MORE CLINICAL TRIALS TO AFRICA

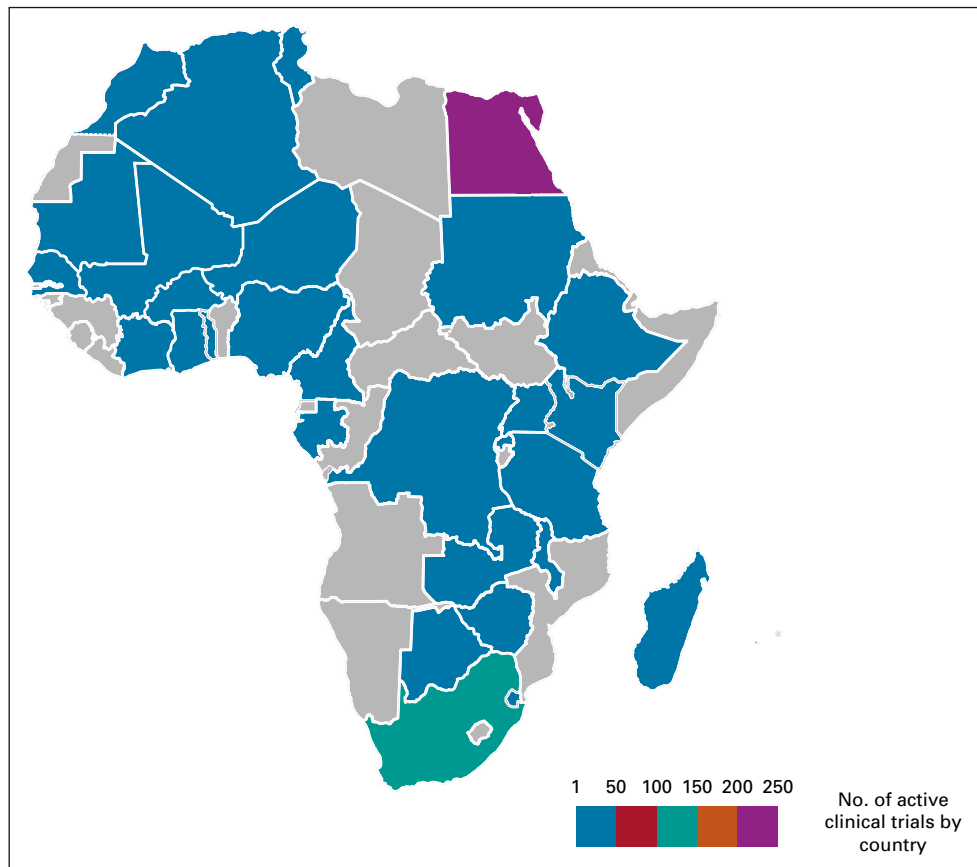
Aligning Stakeholder Priorities and Drivers

Panelists agreed that partnerships between African and international stakeholders are critical to expanding high-quality cancer clinical trial activities in Africa. They emphasized the importance of understanding and aligning with priorities and values of key stakeholders in developing and executing collaborations.

AORTIC and UCI representatives strived for improved cancer outcomes for African patients through research and clinical trial capacity building, as well as African investigator-led trials that are both clinically and culturally relevant. They advocated for inclusiveness, collaboration, stronger regulatory frameworks, and Afrocentric approaches.

The patient representative from UWOCASO emphasized the patient advocacy values of improved access to both novel and standard-of-care treatments for patients and

FIG 1. Heat map of current cancer clinical trials in Africa.



inclusion of patient advocates as equal partners in clinical trial planning.

NAFDAC and FDA representatives prioritized ensuring patient health and safety first, followed by data quality, integrity, and applicability to their patients. FDA representatives particularly emphasized compliance with regulations governing clinical trial conduct, including data collection, documentation, and analysis.

Industry representatives highlighted the importance of equitable access, capacity building, and sustainable partnerships. They emphasized the need for quality data, strong regulatory systems, market access, local expertise to facilitate trial implementation, ability to mitigate risk, and need to have a sustainable business model.

The panelists from BIO Ventures for Global Health (BVGH, Seattle, WA) and Bill & Melinda Gates Foundation (BMGF, Seattle, WA) described their support of African countries in bringing high-quality, impactful cancer clinical trials to their patients, including by working together with country regulatory agencies and local investigators.

Building on Prior Successes and Lessons Learned

HIV/AIDS. Panelists noted that successful multidisciplinary HIV/AIDS research and clinical care collaborations in African countries—in which robust prevention and treatment programming led to a significant decline in HIV incidence³⁵—can

serve as models. Capacity and infrastructure developed by the HIV/AIDS community in Africa can be leveraged to build African-led and -driven oncology initiatives, such as UCI (which partners with global institutions including the Fred Hutchinson Cancer Research Center [Fred Hutch]). HIV/AIDS collaborations offer important lessons, including (1) the imperative to focus on humanitarian aims and equity; (2) considering a return on investment that recognizes the positive impact of a low-cost treatment on patient mortality and quality of life; (3) ensuring that clinical trials do not exacerbate existing inequalities in health care access; (4) involving local stakeholders as equal partners in protocol design to avoid skewing research agendas to that of the funders; (5) ensuring that true informed consent is collected and that treatment will be available after the study ends and once the drug is approved; (6) considering and mitigating the effects of brain drain, or exodus of trained personnel, to higher-income countries as a result of cancer clinical trials; (7) avoiding postal research (sending biological samples) and parachute research (sending researchers to conduct short-term projects); and (8) treating African clinical trial experts as equal partners and giving them credit in international meetings and publications.^{36,37}

Oncology collaborations in sub-Saharan Africa. Multiple successful initiatives and partnerships that focus on addressing disparities in cancer diagnosis and treatment

and increasing access to cancer clinical trials already exist in Africa (Table 2). There are examples of successful building of oncology clinical trial capacity in Nigeria in collaboration with University of Chicago⁴³ by the Prostate Cancer Trans-Atlantic Consortium²⁸ and by BVGH in several sub-Saharan African countries.²⁸ Robust and long-standing collaborations to build local cancer research capacity and improve patient care include the Partners in Health—Rwanda Military Hospital,⁴⁴ University of California, San Francisco—Ocean Road Cancer Institute in Tanzania,⁴⁵ University of Washington/Fred Hutch—UCI,¹⁴ University of Pennsylvania—Botswana Partnership,⁴⁶ University of North Carolina Chapel Hill—Malawi,^{15,16} and University of Chicago—University of Ibadan, Nigeria.

Examples Discussed by Panelists

The panelist from UWOCASO described the key role of patient advocate volunteers in connecting patients to clinical trials at UCI. Such volunteers use their own experience as patients to provide reassurance and accurate information. UWOCASO partners with UCI to provide patient support during treatment and reduce loss to follow-up.

The UCI panelist described the mutually beneficial partnership with Fred Hutch, including in designing and implementing early-stage clinical trials that provided critical insights into treatment of Burkitt's lymphoma.⁴⁷ The UCI-Fred Hutch

collaboration provided essential resources for research and clinical trial capacity building and resulted in sustainable investment from the Ugandan Government in cancer care after seeing its success and impact on patient outcomes.

NAFDAC and BMGF have partnered to tailor BMGF's online platform to enable expedited and paperless review of clinical trial protocols in Nigeria.

BVGH has worked on improving access to cancer clinical trials by evaluating and showcasing cancer clinical trial infrastructure and human capacity, as well as the experience and research interests of individual clinical investigators in sub-Saharan Africa.

The Bayer and Genentech panelists emphasized their companies' commitment to corporate responsibility and sustainability. The Genentech panelist shared the company's experience of creating a sub-Saharan Africa leadership team in charge of a 5-year plan to help optimize regulatory and human resource infrastructure, data quality, and patient safety at global sites participating in the company's clinical trials. As a result, in addition to South Africa, the company was able to open cancer clinical trials in Kenya, Uganda, Nigeria, Morocco, and Algeria. A feasibility assessment for a phase I study of lung and colorectal cancer in Kenya is ongoing. The panelist from Genentech also described a coinvestment project with the Government of Côte d'Ivoire that resulted in improved access to cancer drugs for patients and a doubling of sales for the company.

The Bayer panelist shared the company's philosophy about the necessity of assessing a site or country before the initiation of clinical trials, including (1) complete adherence to good clinical practice and ethical protocols; (2) regulatory landscape; (3) market access capability and patterns; and (4) intellectual property protection, legal, and compliance landscapes to ensure patient safety, protection of patient rights, and sustained equitable access to novel therapies. Both Bayer and Genentech emphasized the importance of local experts to advise companies about clinical trial design and information on clinical trial site capabilities, quality, and compliance. Both Bayer and Genentech looked to BVGH, AORTIC, and other global health research and nonprofit organizations to bring key stakeholders together for dialog and collaboration.

The FDA representatives described decades of experience of working with other regulatory agencies around the world to share experiences and data and conduct collaborative reviews⁴⁸ and inspections for marketing applications. They voiced eagerness to collaborate with regulatory agencies in sub-Saharan Africa for the same purpose.

ACTION ITEMS

Session participants agreed that cancer research institutions, professional organizations, pharmaceutical companies, patient advocacy groups, and global health non-profit organizations need to encourage collaboration through

TABLE 2. Initiatives and Research to Improve Cancer Care and Clinical Trial Access in Sub-Saharan Africa

Area of Collaboration	Partner Organizations and Projects
Bridging disparities in cancer care and clinical trial access	AORTIC, advocacy for clinical trial capacity building ²⁸
	BVGH AAI and AC ³ T ²⁸
	CaPTC ²⁸
	EDCTP ³⁸
Clinical trial regulatory frameworks and guideline harmonization	MARC project ²⁸
	A call for multidisciplinary regional collaboration to develop accreditation standards and technical support for the development of CTUs ³⁹
	National Medicines Regulatory Authorities initiatives to harmonize regulatory frameworks and guidelines ⁴⁰
	Evaluating acceptability and implementation of GCP guidelines for clinical trials ⁴¹
	Development of GCP-compliant data management guidelines for multinational clinical trials ⁴²

Abbreviations: AAI, African Access Initiative; AC³T, African Consortium for Cancer Clinical Trials; AORTIC, African Organization for Research and Training in Cancer; BVGH, BIO Ventures for Global Health; CaPTC, Prostate Cancer Trans-Atlantic Consortium; CTU, clinical trial unit; EDCTP, European and Developing Countries Clinical Trials Partnership; GCP, good clinical practice; MARC, Mapping African Research Ethics Capacity.

TABLE 3. Stakeholder Values/Priorities and Action Items to Improve Equity and Diversity in Cancer Clinical Trials Through by Building Capacity for Registration Cancer Clinical Trials in Africa

Stakeholder Group, Values, and Experience	Action Items
<p>African Cancer Research Institutions</p> <p>Values: including African patients in clinical trials to ensure that results are applicable; improved patient outcomes; clinical trial capacity building; local investigator-led trials; stronger regulatory capacity; and government support</p>	<p>Prioritize building clinical trial capacity, including seeking technical assistance and funding for staff training and proper facilities from pharmaceutical companies, ministries of health, academic institutions, global health nonprofit organizations, and cancer-focused clinical societies.</p> <p>Improve the global visibility of sites qualified to conduct clinical trials by, for example, submitting profiles to the online platform managed by BVGH (AC³T).</p> <p>Demonstrate the impact of research on local populations to ensure government buy-in, prioritization, and allocation of resources.</p> <p>Work together with regulatory agencies to optimize processes of clinical trial initiation and drug approval.</p> <p>Incentivize clinical trial training and design by local investigators, including through provision of protected time and career advancement opportunities.</p> <p>Ensure that clinical trials do not interfere with the quality of routine patient care.</p> <p>Involve/empower patient advocates to participate in clinical trial procedure approval and ask for their help with patient education and recruitment.</p>
<p>Patient advocacy groups</p> <p>Values: high-quality cancer care, including novel treatments, partnering for clinical trial design and implementation</p>	<p>Advocate for patient access to cancer clinical trials through discussions with policymakers, ministries of health, and regulatory agencies.</p> <p>Work together with clinical investigators, pharmaceutical companies, and regulatory agencies to make sure trials are relevant and not burdensome for patients.</p> <p>Support cancer research organizations and pharmaceutical companies in patient education and recruitment.</p> <p>Use the availability of clinical trials to encourage African patients to seek care in-country (v abroad)</p>
<p>Regulatory agencies (in Africa, unless noted otherwise)</p> <p>Values: patient safety and clinical trial data applicability to patients</p>	<p>Collaborate with in-country cancer-focused research organizations and other key stakeholders to provide relevant training in bioethics and GCP to regulatory agency employees.</p> <p>Collaborate with in-country cancer-focused research organizations and other key stakeholders (such as pharmaceutical companies and global health nonprofit organizations) and leverage technology to achieve a transparent, relatively uncomplicated, and relatively quick process for launching new clinical trials and drug approvals that aligns with international standards.</p> <p>Advocate for inclusion of patient advocates in clinical trial protocol review and implementation.</p> <p>Allocate funding to build clinical trial capacity at cancer-focused medical centers.</p> <p>Establish partnerships with foreign regulators, akin to the international GCP collaboration among regulatory agencies in Canada, Europe, Japan, United Kingdom, and the United States to share data and experiences and conduct collaborative inspections for marketing applications.</p> <p>Encourage investigators to include racially and ethnically diverse patient populations in their trials, including through education/training about the value of diversity in clinical trials and incentives such as funding for trials aimed at specific racial or ethnic minority populations on the basis of strong scientific justification.</p> <p>(For regulatory agencies in high-income countries) Offer technical assistance to help African regulatory agencies refine processes for clinical trial implementation.</p>

(Continued on following page)

TABLE 3. Stakeholder Values/Priorities and Action Items to Improve Equity and Diversity in Cancer Clinical Trials Through by Building Capacity for Registration Cancer Clinical Trials in Africa (Continued)

Stakeholder Group, Values, and Experience	Action Items
<p>Global pharmaceutical companies</p> <p>Values: equitable access to novel treatments, sustainable partnerships with local experts for trial capacity building, regulatory compliance, data quality, and market access</p>	<p>Partner with institutions that are developing clinical trial infrastructure in Africa.</p> <p>Allocate funding to build sustainable clinical trial infrastructure (eg, personnel training and equipment upgrades) within larger Africa program budgets.</p> <p>Prioritize Africa, for clinical trials as well as market entry and sustained access, early in the lifecycle planning for new products.</p> <p>Incorporate diversity at the planning stages of cancer clinical trials, including biomarkers that are enriched in local populations and therapies that are more relevant to subgroups of patients in specific regions, instead of assessing retrospectively following trial completion.</p> <p>Align with African regulatory agencies and governments to ensure market access and continued drug accessibility for patients before clinical trial implementation.</p> <p>Connect cancer experts who have experience with clinical trial design and implementation to investigators in African countries, for both mentorship and collaboration.</p> <p>Share experiences related to clinical trial capacity building in Africa with other pharmaceutical companies.</p> <p>Document and disseminate challenges and solutions related to clinical trial implementation in Africa.</p> <p>Leverage resources such as BVGH's AC³T online platform to identify and connect with qualified clinical trial sites in Africa.</p> <p>Advocate for inclusion of in-country patient advocates to ensure clinical trial fit to patient needs and the local context.</p> <p>Advise regulatory agencies about clinical trial timelines to ensure timely approval of protocols.</p>
<p>Global health nonprofit organizations</p> <p>Values: bringing high-quality clinical trials to African patients through collaboration with regulatory agencies and local investigators</p>	<p>Connect African regulatory agencies, ministries of health, and cancer-focused medical and research centers to experts and funding opportunities necessary to build regulatory and clinical trial capacity, including fostering mentorship/apprenticeship relationships with experts who are experienced in running clinical trials.</p> <p>Prioritize investments in African-led clinical trials (vs. trials led by entities based in high-income countries) that have the greatest potential to improve patient care.^{10,11,20,37}</p> <p>Advocate for inclusion of patient advocates as equal partners at the table.</p> <p>Provide technical expertise related to price negotiations and ensuring access to cancer drugs after clinical trials are completed.</p> <p>Provide opportunities for clinical trials workforce development, especially through training.</p> <p>Foster networking among African clinical trialists.</p>
<p>ASCO</p> <p>Values: improving diversity and equity in clinical trials</p>	<p>Provide opportunities for continued dialog between stakeholders through future meetings</p> <p>Provide professional development opportunities for young oncology professionals</p> <p>Partner in increasing capacity of the oncology workforce in the region</p> <p>Provide opportunities for training in quality monitoring and reporting</p> <p>Collaborate in trainings in clinical trials design and conduct</p> <p>Create opportunities for funding global oncology research focused on low- and middle-income regions</p> <p>Partner in education on advancements in cancer care and research, including that performed in Africa</p>

Abbreviations: AC³T, African Consortium for Cancer Clinical Trials; BVGH, BIO Ventures for Global Health; GCP, good clinical practice.

creative partnering models and funding mechanisms that prioritize cross-institutional and cross-country alliances (Table 3).³⁶ In addition to expanding access to care, such partnerships should focus on building both clinical trial and standard-of-care treatment capacity, empowering more African patients to participate in trials by partnering with patient advocates, and strengthening African regulatory agencies.

The ASCO and the American Cancer Society, organizers and moderators of this Accelerating Anti-Cancer Agent

Development and Validation satellite session, have a strong commitment to achieving diversity and equity in cancer clinical trials. Using their name recognition and convening power, these organizations were able to stimulate dialog on an international scale through this panel. These organizations are leveraging their influence, networks, and convening power to stimulate dialog across sectors and international borders, including through this panel session. Together, they are committing to continue the momentum for building a robust clinical trials infrastructure in sub-Saharan Africa, through partnerships with African cancer institutions, professional societies, cancer clinicians, researchers, patient advocates, industry, regulatory agencies, and all stakeholders.

Action items for each group of stakeholders were based on each group's values and priorities and focused on improving diversity and equity in registration cancer clinical trials by building clinical trial capacity in Africa.

African cancer research institutions will collaborate with key stakeholders to lead: (1) building clinical trial capacity, including by incentivizing clinical trial training of and design by local investigators and working with patient advocates to promote patient education and recruitment; (2) working with regulatory agencies to optimize clinical trial initiation and drug approval; (3) ensuring government buy-in by showing impact of clinical trials on patient outcomes; and (4) integrating clinical trial processes into high-quality patient care.

Patient advocacy groups will play an essential role in obtaining buy-in for clinical trial participation from patients and advocating for resources for clinical trial capacity building with key stakeholders.

Regulatory agencies in Africa will collaborate with other key stakeholders to streamline clinical trial opening and drug approval and ensure data integrity and applicability. The agencies will also encourage pharmaceutical companies and investigators to devise strategies to include racially and ethnically diverse patients, as well as underserved patients, in their trials.

Global pharmaceutical companies will focus on: (1) building clinical trial capacity in Africa and including patient advocates early to ensure that trials are appropriate to the local context; (2) prioritizing Africa for clinical trials and

considering diversity at the planning stages of clinical trials; (3) connecting cancer clinical trial experts to African clinical investigators for mentorship; and (4) working with country regulatory agencies to meet trial timelines and with governments to ensure drug accessibility and market access after drug approval.

Global health nonprofit organizations will connect key stakeholders to funding, training opportunities, and mentors for building clinical trial capacity, including by prioritizing investment in African investigator-led trials.^{10,11,20,37} They will also lend their expertise in price negotiation to ensure drug access after trial ending.

ASCO will (1) facilitate dialog and collaboration of key stakeholders; (2) collaborate to increase clinical trial capacity in the region, including through training; (3) create funding opportunities for cancer research in low- and middle-income countries; and (4) create professional development opportunities and cancer care and research education opportunities, including in Africa.

ANTICIPATED IMPACTS

Achievement of the proposed action items will lead to improved access for African patients to locally relevant investigator-initiated clinical trials and to registered products with safety and efficacy that have been validated in African populations, resulting in better clinical outcomes. The knowledge and experience gained in improving equitable access to novel drugs in underserved settings can be leveraged to do the same for underserved patients in high-income countries.

In conclusion, diversity, market access, and capacity in oncology registration trials can be improved by implementing trials in Africa in partnership with local investigators, patient advocates, and regulatory agencies. Our panel discussion about strategies for improving diversity and equity in clinical trials, which were priorities for all panelists, resulted in valuable insights about the values and priorities of key stakeholders related to bringing early-stage clinical trials to Africa. The discussion generated specific action items for each group of stakeholders on the basis of their priorities, that, once implemented, will result in increased applicability of trial data to broader groups of patients, more equitable care, and improved patient outcomes in Africa and globally.

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DISCLAIMER

This article reflects the perspectives of individual authors and should not be construed to represent official views or policies of the US FDA.

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Employment: Genentech

Leadership: Genentech

Stock and Other Ownership Interests: Genentech/Roche

Travel, Accommodations, Expenses: Genentech

Bill Cance

Stock and Other Ownership Interests: FAKnostics LLC (I)

Patents, Royalties, Other Intellectual Property: I have intellectual property that is licensed to FAKnostics LLC

Other Relationship: FAKnostics LLC

Julie Gralow

Consulting or Advisory Role: Genentech, AstraZeneca, Roche, Novartis, Seattle Genetics

No other potential conflicts of interest were reported.

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