Goals

This revolutionary one-day event brought together multidisciplinary voices to workshop solutions and align on key interventions with the ultimate goal of increasing colorectal cancer clinical trial participation and saving lives.

An expert advisory committee supported the planning of this event by establishing a foundation of existing knowledge and best practices across the field, supporting the Alliance in collecting patient perspectives, and conducting robust research to identify key domains for change in colorectal cancer clinical trials. These efforts have led to the development of today’s agenda to ensure a thoughtful and strategic approach to crafting impactful solutions that will move the needle in clinical trial participation.
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<tr>
<td>Dr. Ariel E Aguiló</td>
<td>Labcorp</td>
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<td>Deborah Ausman</td>
<td>Arcus Biosciences</td>
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<td>Dr. Ruma Bhagat</td>
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<td>Lora Black</td>
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<td>Association of Community Cancer Centers</td>
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<td>Tricia Bolton</td>
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<td>John Bostick</td>
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<td>Tammy Boyd</td>
<td>American Cancer Society Cancer Action Network</td>
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<td>Ryan Brown</td>
<td>Science 37</td>
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<td>Dr. Danielle Carnival</td>
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<td>Dr. Sandra Casak</td>
<td>Food and Drug Administration (FDA)</td>
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<td>Zeena Chi</td>
<td>Genentech</td>
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<td>Stephanie Chua</td>
<td>Mirati Therapeutics</td>
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<td>Nicolas Clifford</td>
<td>Pancreatic Cancer Action Network</td>
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<td>Oncology Nursing Society</td>
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<td>Gregory Dennis</td>
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<td>Lee Dranikoff</td>
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<td>Susannah Fox</td>
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<td>Dr. Elizabeth Franklin</td>
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<td>Melvin Guerrero</td>
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<td>Allison Harvey</td>
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<td>Dr. Elise Horvath Walsh</td>
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<td>Yunnan Jiang</td>
<td>McKinsey &amp; Company</td>
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## Attendees (2/2)

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<tr>
<td>Marcie Klein</td>
<td>Colorectal Cancer Alliance</td>
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<td>Michele Lacy</td>
<td>Metro-Minnesota Community Oncology Research Consortium</td>
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<td>Krystin Larkin</td>
<td>Amgen</td>
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<td>Dr. Christopher Lieu</td>
<td>University of Colorado</td>
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<td>Yasmeen Long</td>
<td>FasterCures</td>
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<td>Pam Mangat</td>
<td>American Society of Clinical Oncology</td>
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<td>Patrick Mahoney</td>
<td>National Cancer Institute</td>
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<td>Misha Mathur</td>
<td>VOZ Advisors</td>
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<td>Dr. Betty MBOM</td>
<td>Independent</td>
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<td>Kim Newcomer</td>
<td>Colorectal Cancer Alliance</td>
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<td>Angele Russell</td>
<td>Colorectal Cancer Alliance</td>
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<td>Mary Salazar</td>
<td>University of Texas Health Science Center</td>
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<td>Michael Sapienza</td>
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<td>Susan Schaeffer</td>
<td>The Patients’ Academy for Research Advocacy</td>
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<td>Dr. Marya Shegog</td>
<td>Lazarex Foundation</td>
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<td>Jamee Telford</td>
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<td>Sarah Tencer</td>
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<td>Kim Thiboldeaux</td>
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<td>Ronnie Todaro</td>
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<td>Tim Turnham</td>
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<td>Dr. James Ward</td>
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<td>Kia Williams</td>
<td>Relevant Solutions Group</td>
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<td>John Woerner</td>
<td>Colorectal Cancer Alliance</td>
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<td>Dr. Carolyn Wong Simpkins</td>
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Keynote Address

Dr. Danielle Carnival, PhD
White House Cancer Moonshot
Keynote Address

The Summit began with a keynote address from Dr. Danielle Carnival.

The address reiterated the urgency in improving experiences of people living with and surviving cancer by:
- Investing in innovation and research
- Ensuring more Americans have access to existing tools

Summit participants were encouraged to “bring their boldest thinking to the fight” and focus their energy throughout the day on:
- Sharing their stories, ideas, and knowledge
- Exploring ways to find better ways to support patients with information, compassion, and guidance

Dr. Carnival was appointed by President Biden as the White House Cancer Moonshot Coordinator in February of 2022 in a presidential effort to “end cancer as we know it.”
Marketing & Messaging Trust in Clinical Trials

Peter Garrett
National Cancer Institute

Ryan Brown
Science 37

Michele Lacy, RN, BSN, OCN
Metro-Minnesota Community Oncology Research Consortium
Panel 1: Messaging Trust in Clinical Trials

**Key Takeaways:**
- Messaging matters as part of fully informed patient choice and known clinician bias
- We should bring more awareness to positive trials outcomes and clinical trials as a care option
- Consider messaging outside of just diagnosed patients; individuals learn about trials too late because there is not enough broad messaging to generate public awareness (debate about ROI given lack of buy-in without a connection)
- Ensure messages are meeting people where they are and highlighted where people are already going
- For messaging to be culturally competent, trials also need to be designed to be culturally competent

Panelists also shared current initiatives that could be utilized or expanded, including:
- National Cancer Institute’s Cancer Information Service, including the “live chat” feature to prioritize trials for patients, fill high priority studies, and enhance search capabilities
- The Metro-Minnesota Community Oncology Research Consortium clinical protocol emphasizing that every patient has the right to know if there is a clinical trial opportunity available to them and enrolls over 650 patients in clinical trials each year
- ASCO’s “Just Ask” initiative ensuring that every team member serves as a trial ambassador and messenger
Messaging Trust: Breakout Session Solutions
Solution 1: Marketing campaign with theme “Clinical Research is a Clinical Care Option”

What is the clear problem statement?
- The general population is not aware of clinical trials and/or has misconceptions about clinical trials
- Trials are not trusted and considered a clinical risk, including misperception about being randomized to a placebo group
- Need for normalizing trials so they are considered from the beginning

Definition of solution statement:
- A marketing campaign with the theme “Clinical Research IS a Clinical Care Option”

What attributes would make this solution successful?
- “Prime the pump” so people are prepared to consider trials before they are diagnosed
- Potential to collaborate across multiple oncology areas with consistent messaging
- Could focus messaging on cancer screening appointments

Major action steps required to implement the solution:
- Tie in existing messaging campaigns, e.g., Cancer Moonshot messaging
- Work with biopharma companies, i.e., “this drug was brought to you by people like you who participated in a clinical trial”
- Test comparative language for more precise impact (e.g., “study” vs. “trial”)

Institutions, skills, partners, funding, and other resources needed to drive the solution:
- Marketing experts at major pharmaceutical companies & other cancer nonprofits
- NCI and other campaign partners

Consideration:
Debate around broad messaging to the public vs. targeted messaging direct to already diagnosed cancer patients. Weigh cost of messaging efforts and the benefit of public awareness. One option is a hybrid approach, with public campaigns in media targeting at-risk populations (e.g., AARP).
Solution 2: HCP Toolkit for discussing clinical trials with patients

**What is the clear problem statement?**
- Many providers don’t know about trials (and don’t have time to learn)
- Often team members do not know how to talk to patients about trials

**Definition of solution statement:**
- Develop a toolkit for HCPs to discuss trials with patients

**What attributes would make this solution successful?**
- Existing trust in HCPs when diagnosed with a serious illness.
- Builds on solution in #1 (campaign)

**Major action steps required to implement the solution:**
- Develop a piece of trial summary collateral to hand to patients or include after-visit summary to link to prior clinic conversation
- Build metric into quality standards (i.e., if they talked to patients about a trial)
- Ensure adequate referral systems to address patient questions in a timely fashion

**Institutions, skills, partners, funding, and other resources needed to drive the solution:**
- ASCO, ACCC, and other oncology trade associations
- EHR/integrated solutions
- Clinical trial navigators

**Considerations**
If doctor is not involved in the study, they may not want to lose the patient
Must be a small ask for oncologists – easy link to a different team member or a different entity
Solution 3: Create measurable standards and evaluate quality of patient experience

What is the clear problem statement?
• Patients have varying experiences and perceptions about participating in clinical trials with no standard for the experience

Definition of solution statement:
• Create industry-wide quality standards around all aspects of trial awareness and participation (can be iterative by region) with a parallel marketing campaign to promote sites who meet these standards

What attributes would make this solution successful?
• Clear, measurable standards that can be evaluated annually
• Peer-to-peer institutional rivalry (“bragging rights“)
• Patient input throughout the process
• Data shows patients get better care at institutions that do trials (even if they are not on a trial)
• Could include consistent language about trials to pre-appointment questionnaires, such as “Has your provider discussed the benefits and risks of a clinical trial” or “Would you like to learn more about clinical trials?”

Major action steps required to implement the solution:
• Explore existing quality standards programs to see if this can be added

Institutions, skills, partners, funding, and other resources needed to drive the solution:
• Potential to work with NIH on a Center of Excellence Program
Fostering Readiness for Community-Based Cancer Research

Leigh Boehmer, PharmD, BCOP
Association of Community Cancer Centers

Lora Black
Sanford Research

Ruma Bhagat, MD, MPH
Genentech
Panel 2: Fostering Readiness for Community-Based Cancer Research

Key Takeaways:
- “Community oncology belongs in cancer research & cancer research belongs in community oncology”
- Barriers and facilitators of clinical trial enrollment can exist at the institutional, structural, provider, and patient levels

Current State:
- 80% of trials take place in 20% of sites while 80% of care is at community centers
- Community oncology programs lack tools, resources, and applicable best practices

Considerations for industry sponsors:
- Sponsors must reduce the burden of participation in clinical trials for patients AND sites
- Industry sponsors need to target and partner with community oncology programs to design and conduct research serving understudied and underserved patients
- Root cause – we need an environment where we can trust the data for the trial to happen in the community!

Current examples that could be expanded or strengthened include:
- ASCO-ACCC research initiative
- Implicit Bias Training Program – Just Ask
- NCI Community Research Program (NCORP) featuring a central clinical trials office (enrollment is in the double digits compared to typical 3-5%)

5 Pillars of Research Readiness:
- Diversity, equity, inclusion, and access
- Institutional commitment
- Human capital (including community engagement)
- Research reimbursement; financial incentives/support
- EHR interoperability and data capture/management systems

Strategies can include:
- Opening of rural sites
- Telemedicine
- Financial support for travel & lodging plans, such as patient stipends
- Equipping local labs,
- Centralized regulatory teams with PI oversight
- Enhanced use of clinical trial navigators and research-dedicated Nurse Practitioners
Community-Based Cancer Research: Breakout Session Solutions
Solution 1: Hospitality best practice tenants

Clear problem statement:
• Clinical trial recruitment needs to be patient-centered and culturally competent

Definition of solution statement:
• We will enhance culturally competent patient experience in clinical trials using tenants of hospitality so that we can build trust in patients to increase the participation

What attributes would make this solution successful?
• Encourage those conducting clinical trials to embrace nine tenants of hospitality: welcoming, knowledgeable, efficient, well-timed, flexible, consistent, communicates effectively, instills trust, exceeds expectations

Major action steps required to implement the solution:
• Partner with hospitality experts and explore human-centered design model (example: Cleveland Clinic)
• Convene a “think tank” of stakeholders such as hospitality, patients, communities, and researchers to develop ideas
• “Best practice” meeting to create effective communications and tactics for patients on trials
  • Knowledgeable patients to be the evaluators (one group of evaluators) – we want to know X at this time and why
• Dissemination of best practices / measurable outcomes
• Implement at partner sites to determine metrics/measurements and study impact across sites

Institutions, skills, partners, funding, and other resources needed to drive the solution:
• Hospitality and human-centered design expert
• Patient and other stakeholders
Solution 2: Minimum standards for staff education

Clear problem statement:
• Lack of tools, resources, and best practices for community oncology programs to use to successfully grow their cancer portfolio

Definition of solution statement:
• Invest in staff education to sustain pipeline of research employees with an eye towards the future

What attributes would make this solution successful?
• Established career ladder
• Education / training opportunities that are culturally competent and address historic context (opportunity for patients to help train professionals)
• Awareness among young people about the career field, including a universal job description
• Compensation that is standardized / competitive

Major action steps required to implement the solution:
• Establish minimum standards (certification, licensing)
  • Incorporate hospitality tenants into protocol design creation process
• Talking points: What is a CRV? What’s the pathway?
• Develop a scoring system (KPIs or other metrics) to promote change and incentivize accountability

Institutions, skills, partners, funding, and other resources needed to drive the solution:
• Pharma, HBCUS, ONS, community colleagues, ACRP, university / career services, ESOL prog, NMEF, NIH, OSDP/other FEDS, FDA, FLOTAS, American Academy of Clinical Research, NCI
Clinical Trial Patient Navigation

Elizabeth Franklin, PhD, MSW
Sanofi

Tammy Boyd, Esq.
ACS CAN

Mary Salazar, DN, NP
Mays Cancer Center –
UT Health San Antonio
Panel 3: Clinical Trial Patient Navigation

Key Takeaways:

Navigation is not just a value-add, it is critical to functioning.

Patient navigation works
- Proven cost benefits and patient outcomes
- Most effective way to address health equity
- How do we leverage policy to implement these processes we know will get patients in the door?

Navigation is a team sport, and staffing is critical
- Teams need nurse navigators, social workers, patient navigators, and financial counselors

Barriers:
- Not enough navigators, and navigators don’t exist in every system
  - Navigators are especially crucial for decentralized clinical trials
- Barriers to reimbursement
  - How do we utilize existing codes to pay for navigators?
- Lack of validated tools for screening
- Patient transportation

Current examples that could be expanded or strengthened include:
- ACS National Navigation Roundtable
- ACS CAN navigation capacity building grants
  - Currently funds 14 sites designated by NCI
- Current bills introducing policy pathways for navigators, such as Medicaid reimbursement
  - Certain states have successful reimbursement models that could be adapted to the federal level
- Established standards of navigation – could be expanded to specifically include clinical trial navigation
- Navigators imbedded in insurance companies
  - Hesitations around if focus is on patient or bottom line
  - Need for separate team for case review to counter conflict of interest
Patient Navigation: Breakout Session Solutions
Solution 1: Clinical Trial Navigator Pilot Program

What is the clear problem statement?
- Patients need access to something or someone they trust in who is knowledgeable in prioritizing US trial options
- Healthcare executives do not invest in navigators, and may require more direct tie to financial success of including more navigators

Definition of solution statement:
- Launch centralized clinical trial navigator pilot program for timely, local information about trials

What attributes would make this solution successful?
- Data-driven
- Follows up to ensure patients enroll and determine why; follows up on number of patients engaged
- Incorporates lessons learned from others & documents own lessons learned
- Establishes a “center of excellence” or common standards for clinical trial navigators
- Documents success of engaging trained navigators to inspire investment
- Ensures centralized navigators are knowledgeable about clinical trials both in their assigned region and nationally

Major action steps required to implement the solution:
- Utilize existing infrastructure and pre-existing funding streams and other sources (ClinWiki) and Alliance’s existing relationships
- Public education and marketing to generate traction
- Focus group of current navigators

Institutions, skills, partners, funding, and other resources needed to drive the solution:
- Pharma - pay for navigators (grant, study budget)
- Collaborate with other nonprofits to raise money and raise awareness - Lazarex Foundation; ACCC/NCI/AONN; clin-wiki online resources; large patient care networks who have practice in place
Solution 2: Co-sponsored training program for clinical trial navigators

What is the clear problem statement?
- Many navigators don’t have a training plan
- Patients need access to someone they can trust who is knowledgeable of trial in the US, with the time and skills to help prioritize

Definition of solution statement:
- Co-sponsored training program for clinical trial navigators (Alliance & AONN)

What attributes would make this solution successful?
- Experienced and competent navigators with geographic diversity and community diversity
- System of continuing education
- Training is accomplished through a lens of DEI and access
- Satisfied customers! (Patients and caregivers)

Major action steps required to implement the solution:
- Establishment of standardized curriculum and metrics
- Steering Committee for ongoing guidance
- Check in with patients and caregivers to ensure satisfaction
- Develop online and in-person education

Institutions, skills, partners, funding, and other resources needed to drive the solution:
AONN, ONS (certification); pharma (fundraisers); financial counselors; peer navigators, social work navigators – experts in the field; healthcare systems to create positions and hire navigators; universities for training and geographic diversity

Timeline: First year = build out framework and secure promise of funding from key partners
Next Steps
The Alliance is developing a plan for:

• Marketing & messaging to patients and providers
• Advocacy for patient navigators and quality standards in clinical trial recruitment
• Community practice tenants to improve patient experience with communication & recruitment of trials
• Investing in staff education and minimum knowledge requirements
• Designing a navigation program along with training/certification for clinical trial navigators
• Piloting the use of patient navigators in collaboration with community clinics
• Improving the organization’s navigation program through live and digital platforms