



Penn Medicine

Abramson Cancer Center

Feasibility, acceptability, and utility of a Minority Accrual Toolbox for investigators conducting cancer treatment clinical trials

Campbell Loi with Carmen Guerra MD, MSCE, FACP and Brenda Castillo MD

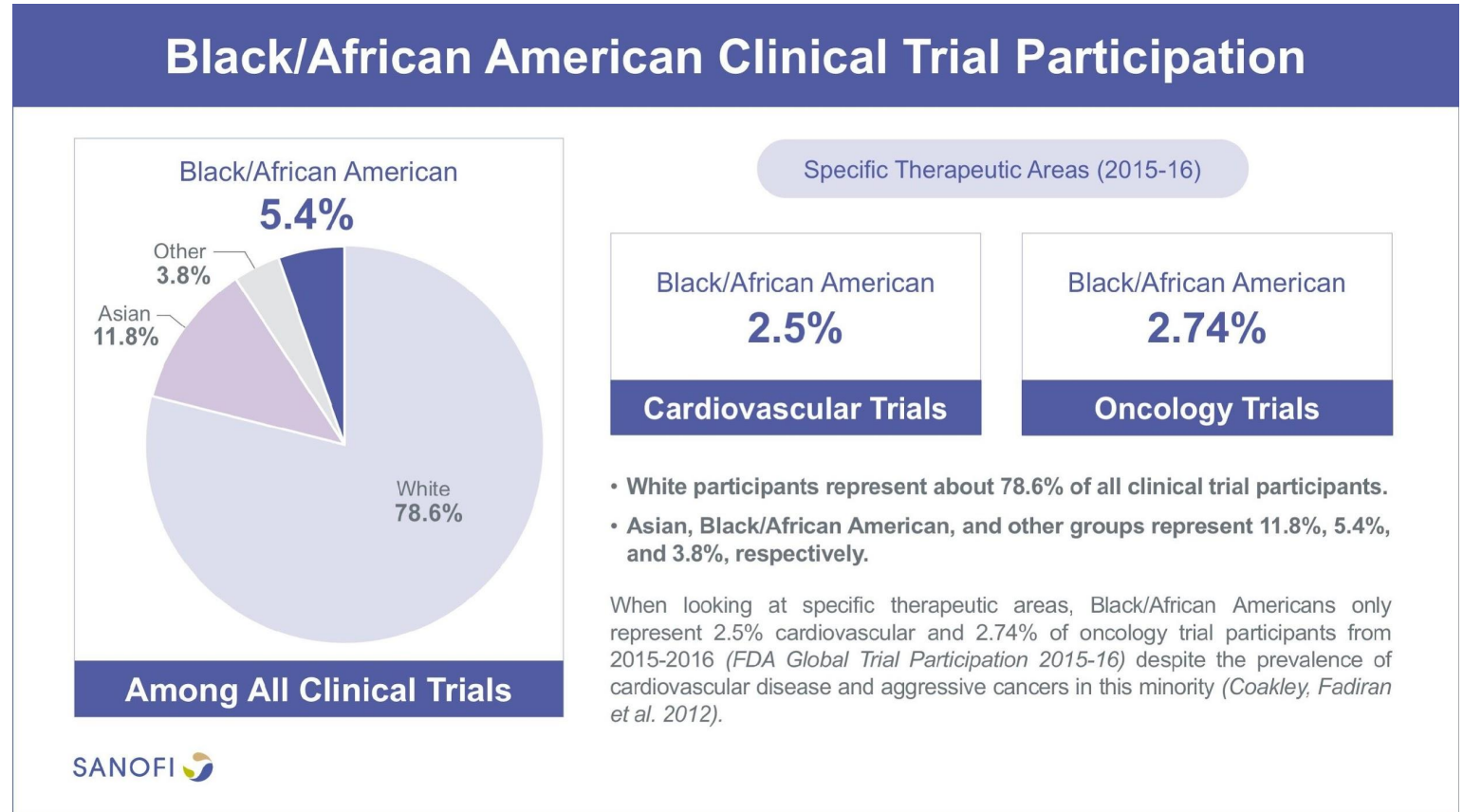
SUMR Symposium

Tuesday August 15, 2023



Racial Disparities in Cancer Clinical Trials (CCTs)

- ▶ African Americans and Latinos comprise 13% and 19% of the U.S. population, respectively, yet each group accounts for less than five percent of trial participants (US Census, 2020; FDA, 2018).



Source: Sanofi, 2019

Implications of CCT Disparities

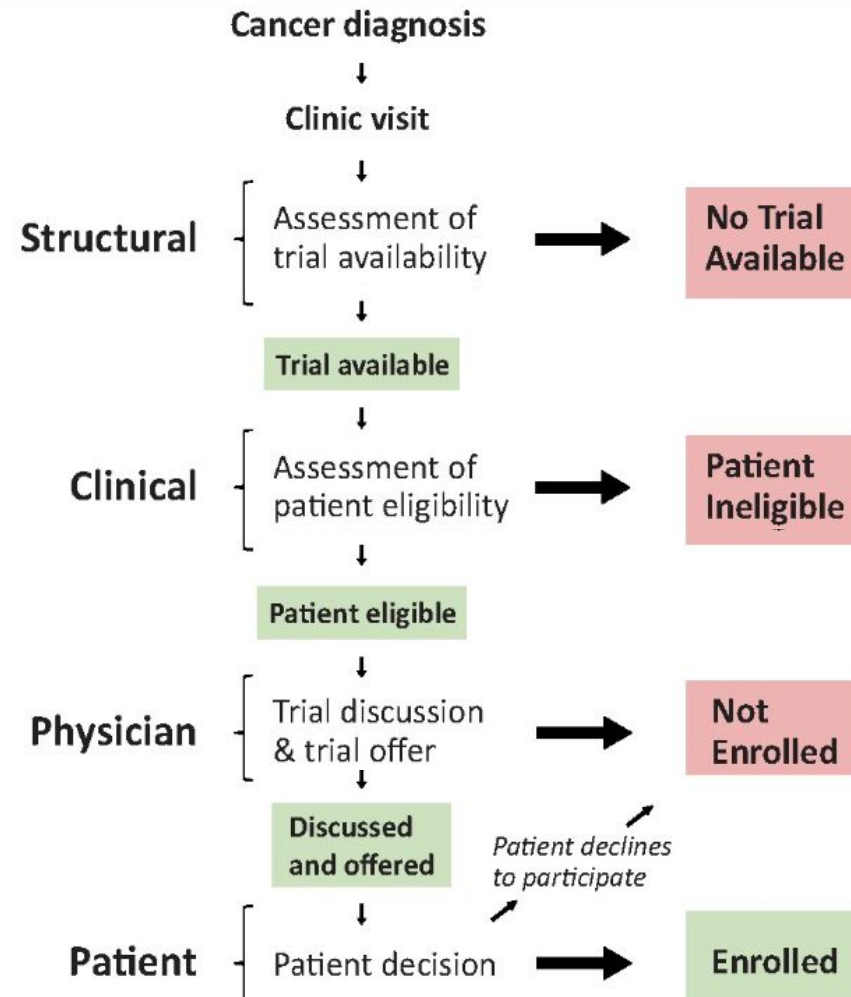
- ▶ **Results from CCTs are not generalizable**
- ▶ **Lack of minority recruitment means slower progress**
- ▶ **CCTs represent access to the newest and most advanced treatments**

Causes of CCT Disparities

- ▶ **Limited access**
- ▶ **Limited knowledge**
- ▶ **Distrust of healthcare system and providers**
 - Tuskegee syphilis study
 - Henrietta Lacks
- ▶ **Out of pocket costs**
 - Financial toxicity

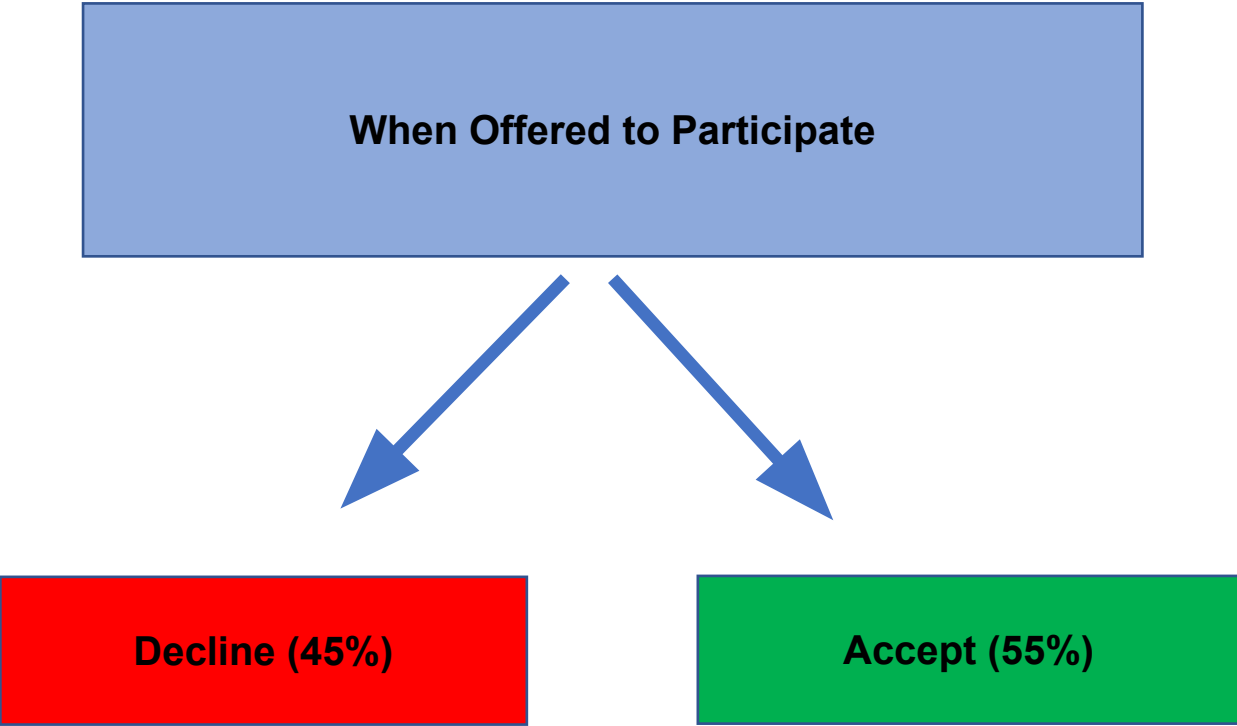


Barriers to CCT Participation

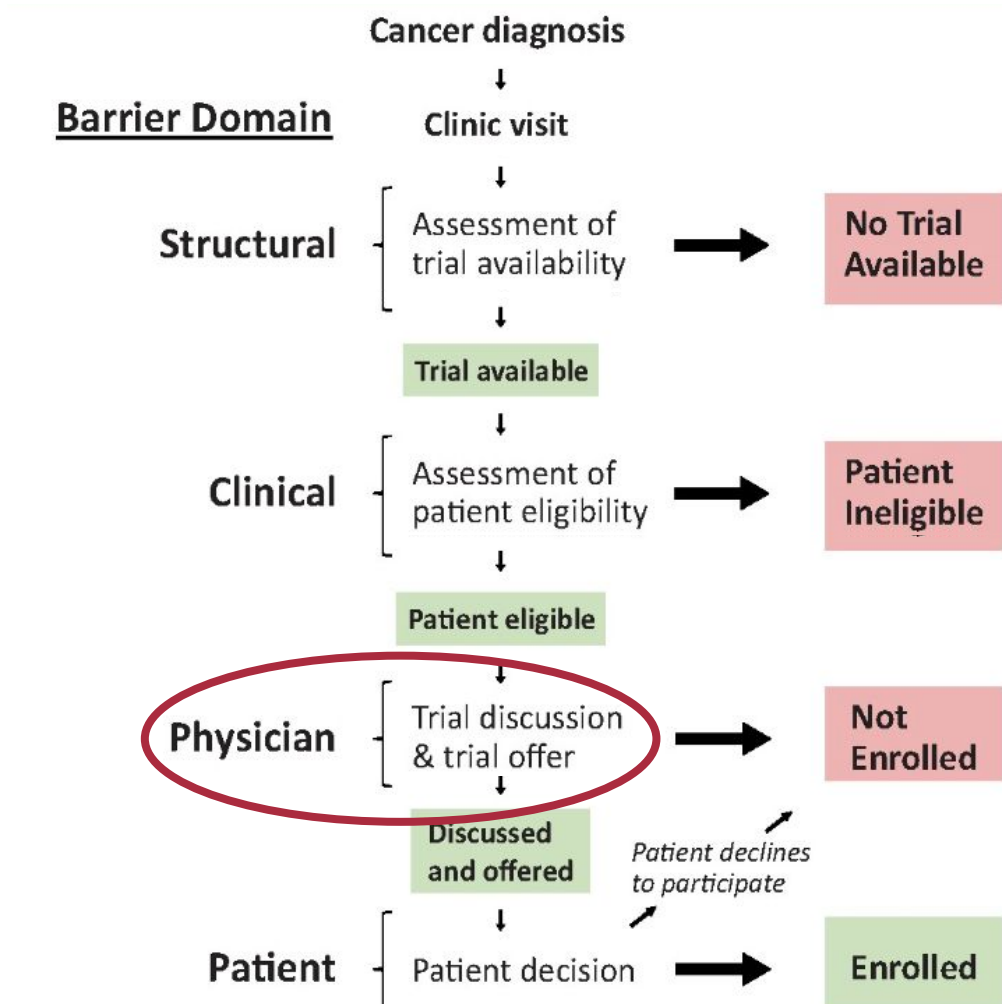


Source: Unger et al., *JNCI* 2019

Why Do Patients Not Participate in CCTs?

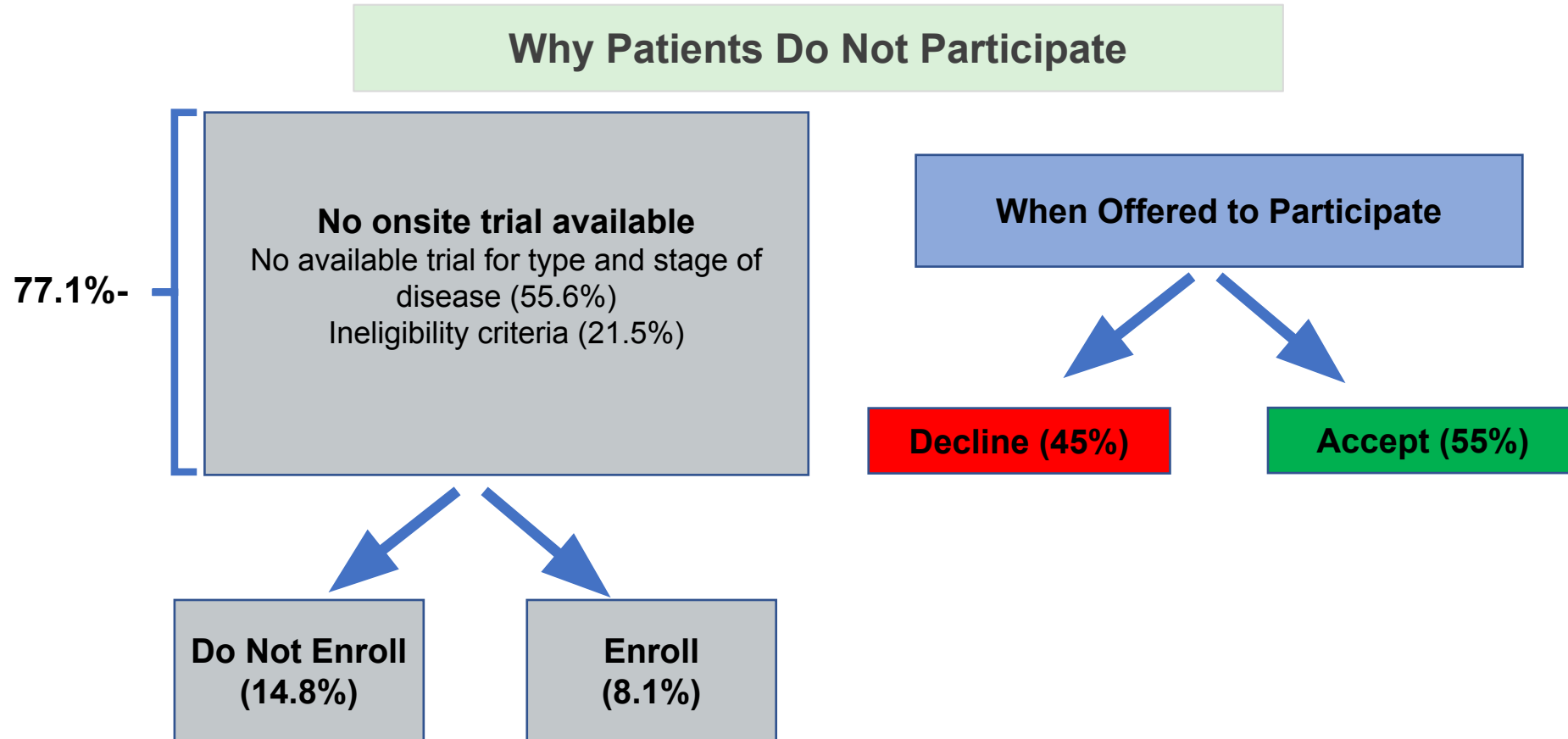


Barriers to CCT Participation



Source: Unger et al., *JNCI* 2019

Barriers to CCT Participation



>85% of patients are prevented from participating by structural and clinical barriers outside their control
Unger, JNCI, 2019

55% of asked say "Yes" and there no statistically significant difference in acceptance rates by race
Unger, JNCI, 2020

Recent policy changes

- ▶ **In 2022, the FDA developed draft guidance for industry to develop minority accrual plans**
- ▶ **In Jan, 2023, a federal law began to require diversity action plans for the clinical trials used by the FDA to decide whether drugs are safe and effective**

ACC Minority Accrual Toolbox

TABLE OF CONTENTS

Clinical trial development

- ❖ Obtaining input from patient and community focus groups for clinical trial development, design and recruitment
 - [Abramson Cancer Center Patient and Family Advisory Board Council](#)
 - [Abramson Cancer Center Community Advisory Board](#)
 - [Community Outreach and Engagement within the Abramson Cancer Center](#)
 - [Cancer Clinical Trials Community Ambassador Training Program](#)
 - [Additional organizations](#)
 - [Organizations focused on the Latinx community](#)
 - [Organizations focused on Black women](#)
- ❖ Translation resources
 - [Translated IRB short forms.](#)
 - [Real time interpreter access at UPHS](#)
 - [Translation of documents, and consent forms](#)
- ❖ Training and resources for research staff
 - [Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials Training](#)
 - [The ASCO-ACCC “Just Ask” Increasing Diversity in Cancer Clinical Research training](#)
 - [The ASCO-ACCC Equity, Diversity and Inclusion Research Site Self-Assessment](#)

Tool utilized	Available tools	Overview
PATIENT AND COMMUNITY FOCUS GROUPS FOR CLINICAL TRIAL DEVELOPMENT, DESIGN AND RECRUITMENT		
<input type="checkbox"/> Yes <input type="checkbox"/> No	ACC Patient and Family Advisory Council	This group includes ACC patients and caregivers. It can provide feedback and guidance that can be incorporated in protocol development, including recruitment strategies and dissemination of results
<input type="checkbox"/> Yes <input type="checkbox"/> No	ACC Community Advisory Board	The membership of the ACC CAB consists of community leaders and representatives of community organizations that share our goal of reducing the burden of cancer, especially in racial ethnic minorities. The goals of the advisory board are: <ul style="list-style-type: none"> ● Identify and develop new community-engaged research initiatives ● Disseminate research findings and evidence-based cancer prevention strategies in the diverse communities Identify and ● Inform new strategies for reducing cancer disparities

Research Questions

- ▶ Is the ACC Minority Accrual Toolbox an acceptable resource for the creation or enhancement of minority accrual plans for CCTs? (**Acceptability**)
- ▶ What are the barriers and facilitators to utilizing the ACC Minority Accrual Toolbox? (**Preliminary Feasibility**)
- ▶ What additional resources would be helpful for creating minority accrual plans? (**Improvement**)

Methods

▶ Study Design

- Qualitative

▶ Participants

- Oncology researchers at ACC

▶ Data Collection

- Demographic questionnaire and informed consent
- Dissemination of toolbox
- Semi-structured, in-depth virtual interviews

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Data Collection and Analysis

▶ Data Collection

- Survey: REDCap
- Interview transcripts: Microsoft Teams

▶ Analysis

- Coding for themes and subthemes: Nvivo

Results

Participant demographics

Measure	Count (n = 8)
Age (mean, SD)	47.3 (6.3)
Gender (n, %)	
Male	5 (62.5)
Female	3 (37.5)
Ethnicity (n, %)	
Hispanic/Latino	1 (12.5)
Non-Hispanic/Latino	7 (87.5)
Race (n, %)	
White	4 (50.0)
Asian	4 (50.0)

Results

Participant demographics

- ▶ **All Penn faculty**
- ▶ **Majority have worked in cancer research for ten or more years**
- ▶ **Span across multiple departments**
 - Radiology
 - Hematology
 - Urology
 - ...and more!

Measure	Count (n = 8)
Track (n, %)	
Tenure	1 (12.5)
Clinician-Educator	4 (50.0)
Academic Clinician	3 (37.5)
Rank (n, %)	
Assistant Professor	3 (37.5)
Associate Professor	2 (25.0)
Full Professor	3 (37.5)

Results

Overall use of toolbox

- ▶ **Participants spent 31 minutes on average reviewing**
 - SD: 19
- ▶ **Described as a quick scan of the whole document**
 - “I read through the whole thing and clicked on a few links”
 - “A fact finding mission”

Prevalent Themes

Helpful sections

Theme Coded	Definition	Interviews Mentioned	Total References
Helpful sections	Sections of the toolbox that were noted to be particularly relevant or useful for any reason	6	19
Previously unknown resource	Components or sections which a participant noted they had never heard of / thought about before	4	7
For use in future	Components that participant noted will be particularly helpful in their future work	3	5

▶ **“I really love the table of contents, I thought that was amazing. I quickly understood the landscape.”**

Prevalent Themes

Suggestions for improvement

- ▶ **Additional sections or resources to include in later versions**
- ▶ **Structural changes**



Prevalent Themes

For use in future: added credibility

“You’re trying to persuade grant reviewers that there's an infrastructure that supports your aims. And I mean, this represents months if not years of work and something that competing institutions and grant applications might not be able to boast or have. So I think this can only help.”

Prevalent Themes

Suggestions for improvement

Theme Coded	Theme Definition	Interviews Mentioned	Total References
Additional sections or resources (alone, agg.)	Sections or resources to be added to the toolbox to expand its scope	7	31
Increased resources for staff	Making sure staff is educated on diversity and also diverse themselves	5	16
Financial assistance	Assistance with expenses incurred during or before and because of the trial (e.g. transport / housing / food)	4	6

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▶ **“You list some patient support groups, and it's very breast cancer specific and heavy. Obviously that's very important, but you should look for others too.”**

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▶ **“I’ll be honest, a lot of that set up for trials and budgets is done by staff. PI’s get involved very minimally at that stage.”**

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- ▶ **“If you look at clinical trials there are these massive, massive budgets... you can't really even get into the game for under \$100,000... and yet a \$5 toll to come over the bridge is going to be a barrier? It's just stupid.**
- ▶ **I would love to see it more than just, ‘you paid \$5 for the toll, and we're gonna give you \$5 back... we should be giving them \$20 back for all of their inconvenience.’”**

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Ad and social media assistance	Additional help navigating advertisements and social media presences	2	9
Measure for recruitment progress	Some sort of measure from which to base recruitment goals and gauge progress	3	5

▶ **“I’m a sort of an idiot when it comes to social media. I know about it, but I just don't engage in it myself... so I need people to help me.”**

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- ▶ **“Why don't you give us an enrollment table that includes the proportion of underrepresented minorities in our catchment area? Investigators can use that as a goal they have to meet.”**

Prevalent Themes

Suggestions for improvement

Theme Coded	Theme Definition	Interviews Coded	Total References
Structural changes (alone, agg.)	Suggestions involving reorganization or reformatting of the toolbox or its content	2 (3)	7 (27)
Grouping or organization of sections	Changes to the order/clustering of sections and components	3	6
Problems with resources	Mentions of broken links, outdated or incorrect resources, etc.	2	4
Improving clarity	Clearer and more concise explanations for components	2	10

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▶ **“A web interface is gonna eliminate a lot of investigator fatigue and that feeling of chaos like, ‘oh my god, where do I start?’ I think [the ability to scroll] is gonna be really key.”**

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- ▶ **“What may be easier is a limited number of links in the front... Use it more like an application rather than an outline.”**
- ▶ **“The more scrolling you have, the less elements at the bottom of the list are going to get used, and they may be just as important as the ones on top.”**

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- ▶ **“We need [translations] to be not only word for word, but someone who actually knows the language to translate it appropriately.”**

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▶ **“It sounds nice that you have this resource that promotes accrual, but we need to know the mechanisms.”**

Prevalent Themes

Implications for oncology research

Theme Coded	Theme Definition	Interviews Mentioned	Total References
Implications for oncology research (alone, agg.)	How the toolbox will impact cancer clinical trial research development and practices	7	40
Change in culture and practice	Potential for the toolbox to change the way researchers think about minority accrual and its importance	5	16
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▶ **“As somebody with a different background... I’m always thinking how can I do better. Reading this gave me happiness to be able to do this.”**

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► **“We often think about minority accrual as an afterthought... after the trial is open or if the grant is awarded. I thought this toolkit actually has the potential to shift our practice.”**

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▶ **“A lot of times people just give what I would say is lip service to what they're going to do, but the plans aren't really fleshed out. So the overall toolbox is interesting to me from that standpoint because it's a little bit more concrete than these vague plans.”**

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► **“It will save me hours if not days of Googling for resources... this is just a massive time saver.”**

Prevalent Themes

Change in Culture and Practice

- ▶ **“I have yet to see a PI say that they think there are barriers to recruitment. And I'm guilty of it, too. It's easier to say that than to say I need to do something.”**
- ▶ **“A lot of times people just give what I would say is lip service to what they're going to do, but the plans aren't really fleshed out. So the overall toolbox is interesting to me from that standpoint because it's a little bit more concrete than these vague plans.”**
- ▶ **“I will tell you that whenever this question comes up in any venue, it's like ‘I'll just reach out to Carmen.’ That's the reflex answer for anything.”**
- ▶ **“We need to work with our study teams and say, it IS part of your job to make sure people can get on the trial. And I know it's inconvenient, but it's also inconvenient to go bankrupt because you have cancer.”**

Conclusions

- ▶ **The toolbox is an acceptable resource for individuals who are writing protocols with minority accrual plans**
 - Unanimously positive feedback
- ▶ **Barriers to using this toolbox are...**
 - The large scope of resources (can be overwhelming)
 - Lack of knowledge of how to properly utilize
- ▶ **Facilitators to using this toolbox are...**
 - Simple, to-the-point structure
 - Examples as guidelines for usage of resources
- ▶ **Improvements to be made**
 - Expansion of the toolbox to include more resources
 - Some slight re-formatting

Limitations

- ▶ **Small sample size**
- ▶ **Single institution**
 - Only at ACC
- ▶ **No efficacy or effectiveness data**
- ▶ **Single coder**
- ▶ **Selection bias**
 - Participants were all very enthusiastic
 - What happens if they aren't?

“People have very short attention spans and this is gonna be unfortunately low in terms of the things that they need to accomplish before the submission of a protocol... I'm gonna get a lot of complaints when I start telling people that they have to use this... So you want to make the process as easy as possible.”

Future Directions

- ▶ **Double coding**
- ▶ **Continue with interviews to collect feedback for improvement and determine feasibility**
- ▶ **Efficacy study to evaluate whether minority accrual plans are more robust with the use of the toolbox**
- ▶ **Effectiveness study to evaluate enrollment of underrepresented minorities into CCTs**

“The most urgent question of all is when will this launch officially?”



Lessons Learned

- ▶ **Minority accrual is highly complex!**
- ▶ **Researchers are very busy!**
- ▶ **Qualitative data collection and analysis**
 - Conducted interviews
 - Created a codebook
 - Learned to use Nvivo
- ▶ **Still enthusiastic about this research!**
 - More interviews scheduled into next week
 - Will continue to do as much as I can remotely!

Acknowledgements

- ▶ LDI SUMR
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 - Dr. Brenda Castillo
 - Our participating ACC oncologists

Questions?

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