

# Exploring Barriers and Perceptions of Cystic Fibrosis (CF) Clinical Trial Participation Among Racial and Ethnic Minoritized Populations in the United States

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## Action-Oriented Qualitative Data Report



## Background and Significance

Cystic fibrosis (CF) is a progressive and multisystem disease that affects approximately 40,000 individuals in the United States (1). Although advances in therapeutics and clinical care have significantly improved survival, there are still racial and ethnic disparities that persist in CF outcomes (2). Black and Hispanic individuals with CF in particular experience higher morbidity and mortality due to, reduced access to cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapies, social determinants of health, and structural inequities rooted in racism (3).

Despite the critical role that clinical trials play in shaping CF treatment, Black and Hispanic patients remain underrepresented in CF research (4). Prior research indicates that participants in CF trials are more likely to be White and privately insured with barriers to enrollment including logistical challenges such as time commitment, financial constraints, poor quality of communication, language and cultural barriers, and medical mistrust rooted in systemic racism (5, 6). Lack of diverse participation in CF trials threatens equitable access to emerging therapies and limits the generalizability of clinical research findings.

This data report addresses crucial gaps in CF research and explores factors that influence clinical trial participation among minoritized individuals with CF. By identifying structural barriers, patient perceptions and systemic inequalities this report aims to provide strategies for improving representation in CF clinical trials and advance health equity in CF care.

## Objective

1. To explore the perceptions of barriers to clinical trial participation at 4 large CF centers using a race-conscious adaption of the Behavioral Model for Vulnerable Populations and semi-structured, in-depth qualitative interviews of minoritized people with CF.

## Methodology

A critical approach will be used to account for the complex multilevel systems of inequity. The Public Health Critical Race Praxis (PHCRP) which is a pragmatic form of the Critical Race Theory will be implemented to inform the process and bring a critical race conscious approach to the work (7).

Table 1: Integrating Public Health Critical Race Praxis (PHCRP) into our research process

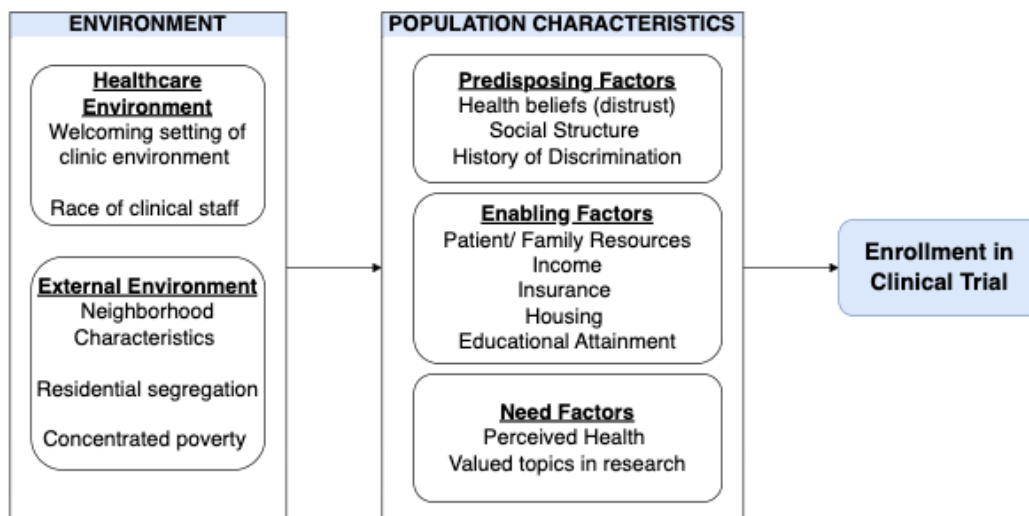
PHCRP Focus and Affiliated Principles	Affiliated Principles	Application in the Proposed Research
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Race consciousness		Awareness of researchers' racial position, present in all four focus areas
<b>Focus 1:</b> Contemporary race relations: Understand how racialization has been operationalized over time, how current events influence patients and their perspectives.	<ul style="list-style-type: none"> <li>- Primacy of racialization</li> <li>- Race as social construct</li> <li>- Ordinarity of racism</li> <li>- Structural determinism</li> </ul>	<ul style="list-style-type: none"> <li>- Include characteristics that reflect ongoing systemic racism (<i>primacy of racialization</i>)</li> <li>- Understand how race is routinely operationalized in medical and research settings (<i>ordinariness</i>)</li> <li>- Study macrolevel forces that reinforce low enrollment of minoritized patients in clinical trials (<i>structural determinism</i>)</li> </ul>
<b>Focus 2:</b> Knowledge production: Understand how racialization has shaped CF research and has reinforced beliefs about racial groups that perpetuate bias or stigma.	<ul style="list-style-type: none"> <li>- Social construction of knowledge</li> <li>- Critical approaches</li> <li>- Voice</li> </ul>	<ul style="list-style-type: none"> <li>- Consider alternative reasons for low enrollment in clinical trials (<i>critical approaches</i>)</li> <li>- Prioritize patient perspectives that are marginalized or othered (<i>voice</i>)</li> </ul>
<b>Focus 3:</b> Conceptualization and Measurement: Defining race and racism related constructs and relationships between them.	<ul style="list-style-type: none"> <li>- Race as a social construct</li> <li>- Intersectionality</li> </ul>	<ul style="list-style-type: none"> <li>- Elicit multiple marginalized identities, shapes, and views of clinical trial participation (<i>intersectionality</i>)</li> </ul>
<b>Focus 4:</b> Action: Using knowledge obtained in this study to disrupt inequities.	<ul style="list-style-type: none"> <li>- Critical approaches</li> <li>- Disciplinary self-critique</li> <li>- Intersectionality</li> <li>- Voice</li> </ul>	<ul style="list-style-type: none"> <li>- Directly apply findings to develop a program to pilot in future K23 to improve enrollment of racially minoritized patients in CF trials (<i>disciplinary self-critique</i>)</li> <li>- Include patient perspective in development of future intervention (<i>voice</i>)</li> </ul>

Adapted from Ford and Airihenbuwa (7,8)

In addition, for the conceptual framework the Behavioral Model for Vulnerable Populations (BMVP) will be used (9). The BMVP summarizes multi-level factors that contribute to health behaviors and outcomes with racism informing each level of this model. The BMVP has been adapted to stress that it is not race but racism that influences health outcomes and other variables that inform health behaviors.

**Figure 1: The Behavioral Model for Vulnerable Populations**



## Qualitative Study Design

A qualitative approach will be used to explore barriers to participation. Semi-structured in-depth interviews have been conducted with 12 participants from 4 large CF Centers (University of Washington, University of California Los Angeles, John Hopkins and University of Miami). Participants were over 18 and identified as a minoritized racial / ethnic group. Individuals were included regardless of if they did or did not previously participate in a CF clinical trial. Participants were ineligible if  $FEV_1 < 25\%$  predicted, which is typical exclusion criteria from CF clinical trials.

The interviews were conducted on zoom and recorded and transcribed. An interview guide was developed based on the BMVP and reviewed by a focus group of CF patients from CF Foundation Community Voice. The interviews explored patient experiences with CF clinical trial participation and focused on population characteristics (predisposing, enabling and need factors) as well as interactions with healthcare environments, social barriers and solutions.

Transcripts were coded using Dedoose and a draft codebook was created based on initial reviews by the research team. Regular team meetings ensured consistency in coding and member checking was conducted with the focus group to validate findings. Emergent themes and categories were refined throughout the coding process and illustrative quotes identified to support each theme. The final codebook was created and quotes representing each codes identified.

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## Key Findings (Preliminary Themes)

Using the BMVP our overall codes can be categorized into the 4 large categories from the BMVP Model. Enabling factors that enable patients to participate in clinical trials or research such as patient / family resources, income, insurance, housing and educational attainment



# 1. Enabling Factors

## 1.1 Familial Influence / Community Support

### *Key Findings:*

A patient's family, caregivers or broader community influence their decision to participate in clinical trials or research. Familial influence / community support can be either positive, negative or neutral. Some people's families want them to participate in research while others are concerned about the risks and therefore influence the patient to not participate. Lack of family support can also create barriers to research participation because they do not provide emotional, logistical or financial support for the patient managing their condition. Finally, there can also be additional strain on patients who are primary caregivers for others which makes research participation more challenging due to time, energy and emotional demands.

### *Supporting Quotes:*

"Here I am with these two kids and a husband and a house, and I'm like you want me to participate for three hours for \$15?... I have life going on. In addition to my -- so that compounded by my already thinking of I'm healthy, what do you want me for?" [PID9]

"That's funny because that's when my mom starts worrying, "What's going to happen? Are you going to be okay? Why are you doing this? You sure you have that? Why even -- why put yourself at risk? Why do this? Why do that?" [PID6]

"Everyone else does not in my family. They just think it's... I don't know what they think, but every time that I'm in the hospital it becomes blatantly aware that they have no idea what it is. And my family cares about me, and I love them, and they just think of me as a sick person, but they don't really understand the disease or that they can pass me things, and I'm 26 years old now." [PID11]

"My mom was like, if there's anything we can do to help if it's you participating in this and it'll help you in the long run get on a new medicine or something, why not?" [PID8]"

## 1.2 Logistics

### *Key Findings:*

Logistics include practical factors that affect a patient's ability to participate in clinical trials or research such as scheduling, coordination of study visits and availability of resources. Patients find that time commitment and travel to be the largest barrier when it comes to logistical barriers and financial / incentives to give the greatest reason to participate in clinical trials or research. Other things that affect a patient's ability to participate in clinical trials involves insurance, other responsibilities and digital literacy.

### *Supporting Quotes:*

"If it was something that was going to take a really a big-time commitment, I feel like that I was always like I don't know, especially the older I got, just because I got busier with school and extracurriculars and stuff." [PID9]

"But I would say that. It's not fun to drive over to Seattle to do a nearly three-hour drive and then sit there at UW for another three hours, or maybe even four hours sometimes if I have to get X-rays and blood work, and then have another three hour drive back. " [PID10]

"The only thing I'm having an issue with, I would say, is the lack of knowledge when it comes to insurance because I'm still not able to get some things that I need because the person over my case doesn't know anything about CF." [PID2]

"Yeah, I think what would help them maybe consider it more is – even if they go to the hospital and do something maybe really long, it's like, hey we can – kind of like what you guys do, we'll give you a gift card for gas, or a lunch at the hospital." [PID7]

## Figures:



Figure 1. Packed Code Cloud Enabling Factors

This code cloud highlights the most mentioned themes in enabling factors which is time commitment, financial / incentives and transportation / travel.

Codes	Enabling Factors	Family influence / community support	Caregiving and burden of CF	Family concerned about risks	Family unaware about disease	Family wants them to participate	Feeling of isolation from family	Lack of family support	Neutral influence	Logistics	Digital literacy	Financial / incentives	Insurance	Lining up appointments	Responsibilities	Time commitment	Transportation / travel	Virtual Study Visits	Totals
Enabling Factors																			
Family influence / community support				1								1					1		3
Caregiving and burden of CF						1													1
Family concerned about risks																			1
Family unaware about disease		1																	1
Family wants them to participate			1									1							2
Feeling of isolation from family																			
Lack of family support																			
Neutral influence																			
Logistics																			
Digital literacy																		1	1
Financial / incentives																	3		5
Insurance																			
Lining up appointments																	1	1	2
Responsibilities																	1		1
Time commitment												3		1		3			7
Transportation / travel													1		3		3		7
Virtual Study Visits																	2		4
Totals		3	1	1	2						1	5	2	1	7	7	4		

Figure 2. Code Co-Occurrence for Enabling Factors

Applying code co-occurrences shows the themes more correlated with each other are:

- 1) Tied
  - a. Time commitment x financial / incentives
  - b. Time commitment x transportation / travel
- 2) Virtual study visits x transportation / travel

Media	Codes																		Totals
	Enabling Factors	Familial influence / community	Caring and burden of CF	Family concerned about risks	Family unaware about disease	Family wants them to	Feeling of isolation from family	Lack of family support	Neutral influence	Logistics	Digital literacy	Financial / Incentives	Insurance	Lining up appointments	Responsibilities	Time commitment	Transportation / travel	Virtual Study visits	
Participant9_9.16.2024.docx		1	1									2				3		1	8
Participant8_9.16.24.docx		1				3					1			1		2	2	3	13
Participant7_9.9.24.docx		1				1						2	2		2	3			11
Participant6_9.4.24 (1).docx		1		1											1	2			5
Participant5_9.3.24.docx			3										1						4
Participant4_8.27.24.docx		1	3				1					1					5		11
Participant3_8.26.26_2pm.docx						1	3					14	1			5	4		28
Participant2_8.26.24_1pm.docx		2	1									4	3			4			14
Participant1_8.22.24.docx		1								3		2	5	3		5	11	2	32
Participant12_10.4.24.doc				1	1			1	2										5
Participant11_9.20.24.doc			3		1	1					2	2							9
Participant10_9.18.24 (1).doc							1					3	1		1	2	2		10
Totals	1	16	3	4	1	9	1	2	3		3	30	13	4	4	31	19	6	

Figure 3. Code Applications for Enabling Factors

Code application for enabling factors reveals that the top three most mentioned codes are

- 1) Time commitment
- 2) Financial / Incentives
- 3) Transportation / travel

Overall time commitment, financial incentives and transportation are key enabling factors that influence participation in clinical research. The strong correlation between time commitment and both financial incentives and transportation suggests that logistical and economic barriers are closely intertwined and individuals considering participation weight the feasibility of travel and time investment against potential compensation. The relationship between virtual study visits and transportation indicates the remote participation could be a potential solution to transportation barriers. Overall, these results shows that there needs to be a reduction in logistical burdens through financial support, flexible scheduling and virtual participation options to enhance inclusivity and engagement. Negative and racialized experiences are the largest contributor to a loss in trust in healthcare but advocacy weather from the patients themselves of healthcare teams have the potential to serve as an alleviating factor. The strong correlation between negative experiences, racialized experiences and losing trust suggest that systemic and interpersonal factors erode confidence in the healthcare environment particularly for minoritized patients.

## 2. Healthcare Environment

The healthcare environment refers to the physical, social and systemic aspects of medical settings. This includes provider interactions accessibility, atmosphere and staff diversity which all affect patient engagement and research participation.

### 2.1 Experience of racism / discrimination

#### *Key Findings:*

The presence or absence of discriminatory practices in healthcare settings can affect the quality of care provided and influence a patient's willingness to engage in research or clinical trials. Patients have found that experiences of racism

or discrimination in healthcare settings can impact trust in healthcare and willingness to participate in research and their overall health outcomes. Biased medical guidelines can be harmful if they do not account for racial or ethnic differences and can lead to disparities in care. In addition, if patients don't fit the 'general image' of a CF patient it can lead to misdiagnosis, delayed treatments or even feelings of exclusion if healthcare staff are quick to point that out. Racialized experiences make up a large portion of this theme and the sense of emotional or social disconnection is often experienced by patients due to factors such as health conditions, lack of support or not seeing others who share similar identities.

### *Supporting Quotes:*

"But and even when it comes to our FEV, I was switched by accident on -- did it -- there it goes -- I was switched by accident in the computer. They put it as Caucasian and not Black. But when I blew, I was still at 80 percent versus me blowing as African American, I was at 100. " [PID2]

"I think what makes it hard is not -- feeling as if you don't have support or that you don't feel inclusive. It's not inclusive to you or to us. I think that's really it. Make me feel as if it's here to help me, not hurt me." [PID1]

"A lot of it is -- majority is I'm Hispanic. "You're a person of color. You're Hispanic. It's White people's disease. I've only seen White people have it. And I'm just like -- and the funny thing is, back in the day, I was so sick throughout, so it never crossed my mind." [PID6]

"And even until this day when I had kidney stones, I went into the hospital, and there was a nurse. She was like, "You're the first patient I ever had that ever had CF and that was Black." I was like, "Oh, okay." It's like there are a few of us. There are a few of us" [PID2]

"I'm being seen as very young and very small. And yeah, I think that is racism baked into this idea of Black people being less intelligent, less knowledgeable. The inverse complexing of adultifying Black children, and infantilizing Black adults, I think, is part of it. Yeah." [PID3]

## 2.2 Feelings of Isolation

### *Key Findings:*

Feelings of isolation relate to the sense of emotional or social disconnection often experienced by patients due to factors such as health condition or not seeking others who share similar identities to them. The patients often feel especially the impact of the absence of racial and ethnic diversity in clinical settings, research studies or CF communities.

### *Supporting Quotes:*

" And that's like the loneliest I've ever felt. I really thought that... I mean, I got treated bad, like hours of waiting. They didn't care that I had CF. They had me waiting with other people, which, I never wait with other people. They always put me in a separate room." [PID11]

"Yeah. Definitely alone in that. It's the same when you see you're surrounded by people who are Caucasian or just not even Caucasian, just around about anyone else who's not African American, it's like, okay, well, cool. I'm the only one that's African American here, so. [PID4]

"I think my experience as a child maybe I would say that—I mean, because I haven't been to every CF clinic in the country—but I think it would be nice to see, in CF clinics, pictures of different ethnicities having the disease, because they'd be like oh, that's like me, okay, I see it. Because I never saw that at all. I saw just regular anatomy, but it didn't say this is a Hispanic person, this is a Black person, this is a white person. And like I said, in my own personal experience it just said European disease, and I was like oh, okay. And I think if kids saw...because we can't see each other, if kids saw on the boards, on the wall and everything pictures that looked like them, they'd feel less alone. I know I would have. " [PID11]

## 2.3 Previous Experiences in the Healthcare Environment

### *Key Findings:*

Previous experiences in the healthcare environment refers to a patient's past interactions with healthcare systems include experiences with healthcare providers, clinics and treatment settings. In this theme, the patients often mentioned experiences they had when changing care teams from pediatric CF care to adult CF care and how these experiences have differed for them including changes in their treatment approaches, support systems and provider interactions. Patients also mentioned that they sometimes felt they had a lack of information or understanding due to limited knowledge about CF, clinical trials or options because their provider gave them insufficient knowledge or patient education. Finally, patients spoke about their previous experience with research and how prior participation in clinical trials or research studies have shaped their attitudes towards future participation.

### *Supporting Quotes:*

"No. Honestly, I had a great experience at the children's hospital. I loved the children's hospital when I think about it. Also, I was really healthy, really, really healthy until I was 23. So yeah, I honestly can't say that I felt that way at the children's hospital. I had a -- I loved Doernbecher. It was awesome. I wish I could go back. When I came to the adult side, I feel like my quality of care dropped from being at Doernbecher immediately. [PID3]

"That one was good up until I was a teenager. Then it went downhill real fast because the peds doctor... They're very focused on numbers, numbers, numbers, numbers, numbers and not focused on your mental status....My relationship with my adult care team is amazing right now. I can't complain. They actually listen to what you want in life. " [PID4]

"But if I feel like if it's not right, if something doesn't sit right with me, if it's not enough information, I'm not going to do it. I don't want to expose myself and put myself at risk of something that I don't know about. If I don't have enough research about it, I will pull it up myself and look." [PID2]

"I did participate in one study to where it had the opposite effects. I ended up developing erythema nodosum from one of them... we participated in one study where it would help me grow, and I enjoyed it. I hated needles. I had to give myself a shot. I think it was twice a day or once a day, but I hated the shots. But it did, it did help me grow, but I developed erythema nodosum from it, so that was -- we ended up stopping it, of course, because I could no longer tolerate it." [PID2]

## 2.4 Interactions and experiences with healthcare staff and CF Care Team

### *Key Findings:*

Interactions and experiences with healthcare staff and CF Care Team are the positive or negative experiences patients have had with doctors, nurses or other healthcare providers which may influence their participation in CF clinical trials or research. In this theme, patients report on instances where they have had either positive or negative experiences



with their healthcare providers, instances where the patient or their healthcare team had to advocate for the patients' health or experiences where patients felt their appointments were being hurried and therefore gave them insufficient care. Overall, how a patient has felt in their previous interactions will largely shape if in the future they chose to participate in clinical trials or not.

### *Supporting Quotes:*

"Overall, I've had -- I've had -- overall, I think I've generally had positive medical experiences. I feel very -- despite often feeling infantilized, I feel very equipped. I feel very knowledgeable. I feel very comfortable in medical settings. I feel very empowered, in control of my own healthcare. And I feel comfortable with the doctors that I have who I see more regularly. [PID3]

"Well, my relationship with my CF doctor made me not want to even do it. I think I was sad. I was so focused on doing the opposite of what he wanted me to do that I was neglecting my own health at the expense of it because I was so focused on doing the opposite of what he wanted me to do because I had so much hatred towards him. " [PID4]

So it's -- I think the one I stayed the longest with is my endocrinologist on the team. She apologizes to me every single time, "I'm sorry it's taking forever. We've been here for three hours." And I'm just like, "You're one of the only few that will advocate for me," so I'm like, "I'm happy to sit here for however long I need to for you to help me out." I'm like, "I appreciate you more than you know." [PID6]

"Sometimes I feel like my appointments are rushed a bit. I just wish there was a little bit more standard of care. I know over time, since I've been in the Clinton Clinic -- and I go quarterly -- I don't even get visits from certain people. I used to see the nutritionists, don't do that anymore. I don't even know where my social worker's at, to be honest. And it's kind of slipped through the wayside." [PID6]

## 2.5 Trust in CF Care Team

### *Key Findings:*

Trust in CF Care Team is the level of confidence a patient has in healthcare providers and researchers including the impact on willingness to engage in research. This theme looks at building trust which are experiences, behaviors or interactions that strengthen a patient's confidence in their CF care team as well as losing trust. Personal biases are also explored in this theme which are how a patient's preexisting beliefs, past experiences of societal influences shape their level of trust in their CF healthcare providers and researchers.

### *Supporting Quotes:*

"I stated earlier, too, that it's the way I'm approached when asked certain things, and the conversation that I'm having with you right now is a positive one, and the way you're speaking to me, the way we're interacting right now it's like okay, cool, we're talking like we've met before, and so that definitely allows me to, like anything, kind of open up a little more and tell you certain things that I wouldn't tell to a stranger. I think that's really what it comes down to, is just how people interact with each other." [PID10]

"And they canceled it on me because even though everything else was fine, my BMI was just slightly over, and so they were just like yeah, we're going to have to cancel. And he's now saying that you need to transfer care to this other place they see CF. I'm like all right. Now I feel like he's just abandoning me." [PID6]

"In any of these things it's interesting, if I really think about it. In any of these things, there are these biases that come into play. For instance, my primary care physician is a young Indian,-- I make myself sound like an old lady. I was going to say she's a young Indian girl, but she's about -- she could be 30ish. I'm going to say 30 to 30, no, 29 to 33, approximately. And part of me is like, gosh, she's kind of young. Does she have the experience for this? So that's a bias in terms of age. " [PID 9]

## Figures:

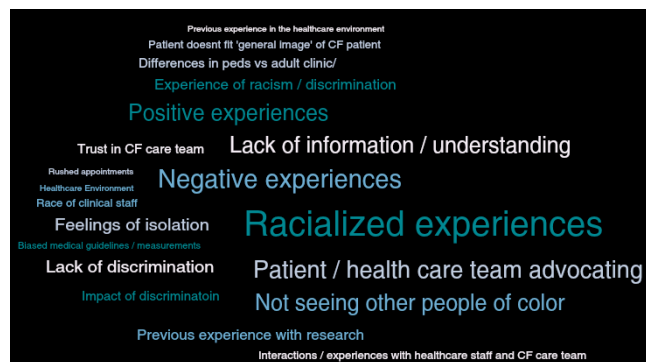


Figure 4. Code Cloud for Healthcare Environment

This code cloud highlights the themes of racialized experiences, negative experiences, patient / health care team advocating and not seeing other people of color as impacting their ability to participate in clinical trials / research the most when it comes to healthcare environment.

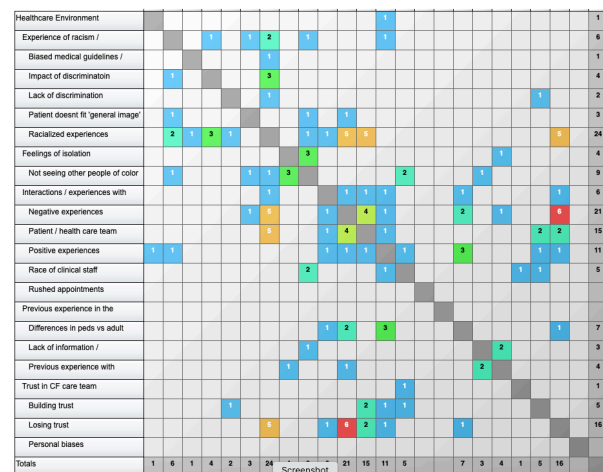


Figure 4. Co-Occurrence Codes for Healthcare Environment

Looking at codes the co-occur most with each other, we can see the most correlated themes are

- 1) Negative experiences x losing trust
- 2) Tied

- a. Racialized experiences x losing trust
  - b. Racialized experiences x patient / healthcare team advocating
  - c. Negative experiences x racialized experiences
- 3) Tied
- a. Patient / health care team advocating and negative experiences

Media	Codes														Totals
	Healthcare Environment	Experience of racism /	Biased medical guidelines /	Impact of discrimination	Lack of discrimination	Patient doesn't fit general	Racialized experiences	Feelings of isolation	Not seeing other people of	Interactions / experiences with	Negative experiences	Patient / health care team	Positive experiences	Race of clinical staff	
Participant9_9.16.2024.docx			1				8	1	1	1	1	1	1	1	17
Participant8_9.16.24.docx				2				1			4			1	8
Participant7_9.9.24.docx				2						1	3				6
Participant6_9.4.24 (1).docx		3	1	1	1	1	2	6	4	4	1			2	26
Participant5_9.3.24.docx	1		1	1	1	7	1	3	2	7	4				24
Participant4_8.27.24.docx				2			3	2	1	5	2	3		3	25
Participant3_8.26.26_2pm.docx	2	3				17	6	6	3	4	4			1	54
Participant2_8.26.24_1pm.docx	5	2	4	3	9	3	8	1	10	11				2	81
Participant1_8.22.24.docx	1			7	4			1			2			2	18
Participant12_10.4.24.doc	1	1		1		2		2	1						10
Participant11_9.20.24.doc				1	1	1	3	4	1	2	2			1	17
Participant10_9.18.24 (1).doc	1			2	1	2						1		1	8
Totals	2	13	3	9	18	6	48	18	25	6	31	28	25	7	1

Figure 5. Code Application for Healthcare Environment

The topmost occurring codes for Healthcare Environment are:

- 1) Racialized experiences
- 2) Patient / health care team advocacy
- 3) Tied
  - a. Positive experiences
  - b. Not seeing other people of color
  - c. Lack of information / understanding

These findings highlight the critical role of patient-provider relationships and structural interventions in addressing these disparities. Efforts to improve trust in healthcare for minoritized patients should focus on reducing negative experiences, addressing racialized discrimination and strengthening advocacy mechanisms within clinical settings. Finally, the presence of positive experiences being among the top occurring codes suggests that not all interactions in the healthcare environment are negative but “not seeing other people of color” and “lack of information / understanding” also indicates that representation and accessible clear information should be key concerns in the healthcare settings. Trust building efforts are critical as well as advocacy for both patient and healthcare teams as well as increasing diversity in healthcare spaces and improving access to culturally competent information can help address concerns related to representation and understanding of clinical trial information.

### 3. Need Factors

Need factors are factors related to a patient’s perceived health status and topics they value in research. Need factors can influence a patient’s need for medical care and their motivation to participate in clinical trials or research.

### 3.1 Perceived Health or Health Status

#### *Key Findings:*

Perceived health or health status is how a patient perceives their current health status and how it influences their willingness to participate in clinical trials or other healthcare activities. In this theme, patients explore how their view or accept their current health status which influences their decisions about treatment or research participation. Patient's also talk about the availability and affordability of CF treatments, feeling like they have no other choice but to participate in research and medications and clinical trial interventions. One thing that came up was that CF is a specialized disease, and the complexity and rarity of CF can affect treatment options, research participation and care availability. Patients also would sometimes avoid clinical trials due to concerns about the potential negative effects on their current health stability or when severe illness discourages research participation due to concerns about added burden or risks. However, some patients were motivated to contribute to research despite experiencing poor health. Mutation requirements also proved to be a barrier as having certain mutations could change a patient's eligibility for treatments or research studies. Finally, some patients reported that they desired to live a typical life without CF defining their identity or choices.

#### *Supporting Quotes:*

"So guess what? See, I've accept that, accept this in my life. I've learned to accept things. So that's the biggest part. So today, that's why I tell a person like I'm telling you now, as long as I accept this, but I have accept things in my life, there's nothing else more can really go on more to in, in and that I really couldn't deal with." [PID5]

"In a medical context? I feel excluded in a broader sense on a research level. I feel excluded because I know that people of color are less likely to have the more common mutations, and that is the reason why we have -- and that's why less of us are on Trikafta or medications like that. And I feel excluded in that way." [PID3]

"It's just really hard because it's just knowing that I'm on decline and instead of being eligible for any of the modulators, it's just we can just add more to your treatment to get you to survive longer, I guess, would be the key word. [PID6]

"Yeah. Going and you see how it's all the whole team, and it's the nutritionist, the respiratory therapist, it is so specialized. And it's like okay, I will listen to you guys because it's -- obviously it's a team effort." [PID8]

"Yeah. What are they going to -- and then for the drug trials, I'm like hey, hey, hey, the soup is seasoned well. I'm not putting something different in here and changing anything up. And that's very seriously been my thinking when I've been approached about the drug trials that I'm just barely here, probably, right. I don't want to mess it up. And it wasn't even inquiring more about what it was, what it could do, possible side effects. It was just no thanks. [PID9] "

"So at this point it doesn't feel -- I don't personally feel like I have a ton of choice. I don't feel pressured by doctors or researchers or anybody. I just personally don't feel like I have a huge sense of autonomy around my -- around whether or not I should be participating in something that's going to help develop medication that's going to improve my health, because I do have rare mutations." [PID3]

So in that case, my health at that moment made me like, I don't want to do it. Just because of the fact, I just want to get this out of my system. It's already been a week and a half of just suffering. I was like, I just want to get it over with. In that sense, that's one of the ways it affected my health with the study. [PID1]

"Well, first I started off because I was very sick, and none of the medications were really working... So when they told me that there was an opportunity for a whole new drug and something that could help my lung function get better and potentially keep me out of the hospital every other month, I was like absolutely." [PID4]

"I guess I just always, as a kid I know that I wanted to be normal. Like I never...there was nobody else in my community that had that, and no one in my family, either. My mom and dad are just carriers. So I wanted to be as normal as possible, and because CF, at least for me, because I know there's much more severe cases, I think I have it mild, it was easy for me to pretend like it didn't exist because it was internal, and I would just tell people I had asthma or something because I just didn't want them to know that I had that. " [PID11]

## 3.2 Valued Topics in CF Research

### *Key Findings:*

Valued topics in CF research encompass specific areas of CF research that patients prioritize or find most relevant to their health needs. This theme found that patients feel topics such as airway clearance, lung transplants, medications, eating disorders, and weight are critical to improving their quality of life and disease management.

### *Supporting Quotes:*

"I definitely think airway clearance for sure... there are patients on the lung transplant list, I know sometimes that can take forever, so I would love to be able to see what could be done to get that a little more organized, you know what I mean? Basically more categorized and organized, as compared to like who has the hardest case of it, and then kind of go from there.... So it would be really nice if the patients who need these things quickly and their parents have a lot more resources, so that they're not scrambling to try to get a lung transplant for their loved one. " [PID7]

"But yet I do struggle when it comes to the lung part of it. So I have the lung thing, but the pancreas and the liver and all that kind of stuff... And he was like yeah, I just had a lung transplant. And I'm like oh my gosh, like that's...yeah. And so about a year later he ended up passing away." [PID10]

"I think an equity issue in CF is eating, like I was talking about, eating disturbances, eating disorders. I think that's something that's really not looked at, especially for women of color. With CF, eating disorders are already, again, something that where most of the research is about White people. And in CF, there's so many ways and reasons that you can experience an eating disturbance because of the caloric needs and because of information messaging from doctors conflicting with messaging from the outside world in terms of what you should be eating, and fluctuating body issues. So that's something I'm passionate about is more research and screening and understanding of how eating issues might come up for people with CF, specifically women and women of color" [PID3]

"The Trikafta obviously was a big one that definitely helped, you could notice it helped get stuff out. If you have any phlegm, it definitely works on loosening it and getting it out. So it's definitely important. It's like anything, any advancement possible." [PID1]

## Figures:

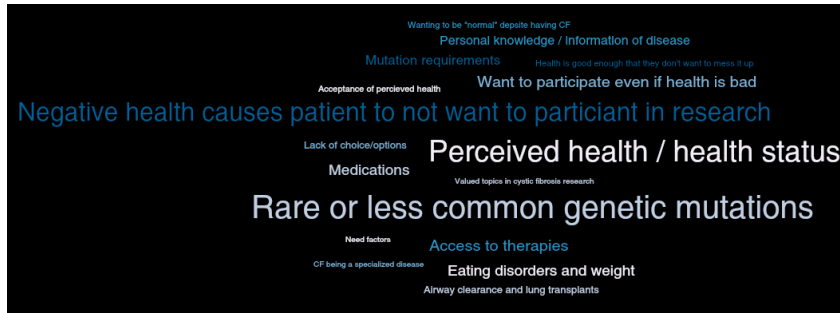


Figure 10. Code Cloud for Need Factors

Codes	Need factors	Perceived health / health status	Acceptance of perceived health	Access to therapies	CF being a specialized disease	Health is good enough that they	Lack of choice/options	Mutation requirements	Negative health causes patient	Personal knowledge /	Rare or less common genetic	Want to participate even if health	Wanting to be "normal" despite	Valued topics in cystic fibrosis	Airway clearance and lung	Eating disorders and weight	Medications	Totals
Need factors																		
Perceived health / health status									5									5
Acceptance of perceived health																		
Access to therapies								1			1							2
CF being a specialized disease																		
Health is good enough that they																		
Lack of choice/options											1							1
Mutation requirements			1							4								5
Negative health causes patient	5																	5
Personal knowledge /																		
Rare or less common genetic			1				1	4										6
Want to participate even if health																		
Wanting to be "normal" despite																		
Valued topics in cystic fibrosis																1		1
Airway clearance and lung																1		1
Eating disorders and weight													1	1				2
Medications																		

Figure 11. Code Co-Occurrence

Code occurrence for Need Factors are as follows:

- 1) Negative health causes patient to not want to participate in research x Perceived Health / Health Status
- 2) Rare or less common genetic mutations x Mutation requirements

Media	Codes																	Totals															
	Need factors	Perceived health /health status		Acceptance of perceived health		Access to therapies		CF being a specialized disease		Health is good enough that		Lack of choices/options		Mutation requirements		Negative health causes patient			Personal knowledge /		Rare or less common genetic		Want to participate even if		Wanting to be "normal" despite		Valued topics in cystic fibrosis		Airway clearance and lung		Eating disorders and weight		Medications
Participant9_9.16.2024.docx		4						2								1	4															11	
Participant8_9.16.24.docx								1													1											2	
Participant7_9.9.24.docx																					1						3	1	1			6	
Participant6_9.4.24 (1).docx													5							7												13	
Participant5_9.3.24.docx		2	2	1																	2									4	11		
Participant4_8.27.24.docx	1	5													1						5											12	
Participant3_8.26.26_2pm.docx		6		6						4	1	13	2	6							6								3			41	
Participant2_8.26.24_1pm.docx		1		1																	3											5	
Participant1_8.22.24.docx		1													3												1		4	2		11	
Participant12_10.4.24.doc														1	1					3												5	
Participant11_9.20.24.doc			1																						2						1	6	
Participant10_9.18.24 (1).doc		2																		1	1							1				5	
Totals	1	22	2	9	1	2	4	7	18	6	24	9	2	1	4	8	8																

Figure 12. Code Application for Need Factors

The code application for Need Factors shows that the most commonly occurring themes are:

- 1) Rare or less common genetic mutations
- 2) Perceived health / health status
- 3) Negative health causes patient to not want to participant in research

Overall, the key themes within Need Factors emphasize relationships between perceived health status, genetic mutations and research participation. The code co-occurrences highlight that negative health status often discourage participation in research and having rare or less common genetic mutations can lead to not meeting mutation requirements which limit access to treatments and trials. The findings from this theme suggest that both personal health perceptions and structural barriers (such as genetic eligibility criteria) are large drivers to shape patient's decision regarding clinical research involvement. Therefore, there should be increased research inclusivity for rare mutations as well as addressing perceived health concerns for patients and reducing the burden of research participation for patients with declining health.

## 4. Predisposing Factors

Predisposing factors are factors that influence an individual's predisposition to participate in research or clinical trials including their beliefs, attitudes, motivations and personal history.

### 4.1 Altruism

#### *Key Findings:*

Altruism is a patient's desire to participate in research to benefit future patients, advance science or contribute to the CF community. Altruism may be influenced by past experiences with CF care, relationships with the medical community or a broader commitment to improving health outcomes for others. Some patients view participation as a way to give back and others may see it as an opportunity to leave a lasting impact on CF treatment and research advancements.

### *Supporting Quotes:*

"And it could maybe help somebody else, too. I think that's probably the biggest thing. I don't want to be selfish with it, which sounds kind of weird. But I would love to be able to, if there's something in me that helps you determine what somebody else might need to get them help, I'm all for it." [PID10]

"So I think what makes it easier is just knowing that I'm helping. And I'm making a difference, even if it's just a little portion. I think more people would contribute just a little bit to research, even if they're not comfortable doing a certain thing, maybe another thing, we would come really far. So it makes it easier knowing I'm helping. In some way." [PID7]

I'm very open to clinical trials because if they can help the younger generation or the newer generation based off of research for me, that's all we want. We just want to keep progressing so that people that come after us don't have to go through what we went through. " [PID4]

## 4.2 General Perceptions of Clinical Research & Trials

### *Key Findings:*

General perceptions of clinical research and trials encompass patient's perceptions of risks and benefits and trust in the overall process. Many patients reported that they had concerns about being "Guinea pigs" where they are just being experimented on rather than receiving treatments that directly benefit them. Other concerns are worries about potential risks, side effects or unknown outcomes of clinical trials. Patients were also aware of past unethical research practices particularly among marginalized communities and there was a sense of general distrust in research due to systemic issues in medicine. Finally, misinformation about clinical trials also influenced decisions to participate.

### *Supporting Quotes:*

"So when I think about clinical research, I guess I think of it in two ways. I'm thinking of it from the perspective of clinical trials and medications and research to improve health and well-being. Then I also think of it -- so on the other hand, I think of it from a building a body of knowledge about a specific thing. So I guess one is more body of knowledge; the other one is more tangible instead of a drug or some kind of treatment via medication." [PID9]

"It's usually just a medicine. I feel like I think of a medicine being tested out on people, but I feel like the older I get, the more I learn it's not. It's stuff like this. I remember maybe three years ago or something, I did another Zoom one, and it was about birth control and people with cystic fibrosis. So I feel like the older I get, the more I realize it's not physical like testing out a medicine or a pill or something, but it's more just talking about stuff. " [PID8]

"I think maybe the outside world thinks of, when you say clinical trials they think oh, we're the guinea pigs, right, let's test something on somebody. I think that's just society in general." [PID10]

" Honestly, you want to know what -- if you get the drug, what's in it, what could possibly -- whatever's in it, these side effects that it has on other or potentially could have on the rest of your body. And that's just the fear of the unknown because you don't know how your body's going to react. And some people, it's not worth the risk for them to even try it out. That would be the only deterring factor, the time and the fear of the unknown. " [PID4]



"There are urban legends about, especially in Baltimore, in the Johns Hopkins area, about people going in for X treatment and Y happened or they died or if you really want to get extreme people missing from that area, et cetera. And the whole thing is they were used for some experimentation. " [PID9]

"I think there's a lot of skepticism for people of color about the medical field generally. [PID3]

"Oh, yeah. I heard about -- before I started Trikafta, I did hear a potential negative when people were on clinical trials for it. I would just read up on the research for it. I definitely heard potential negative about how it could destroy your liver or I'm like -- or they said it really messed -- it could really mess up you mentally. So that was -- those were negative things that I had already read from people that were on clinical trials with that drug." [PID4]

### 4.3 Intersectional Identities

#### *Key Findings:*

Intersectional identities encompasses how individuals with CF navigate multiple intersecting social identities such as race, gender and chronic illness and how these identities shape their experiences in healthcare and clinical research. Patients report on experiences of discrimination in other areas of life that may still influence healthcare perceptions and decisions as well as the strengths derived from having to navigate multiple identities. Finally, patients also talk about unique challenges and perspectives that are face by women of color in CF care and research.

#### *Supporting Quotes:*

"Sure. I noticed at different places -- whether this is racial profiling or not, I really don't know -- at certain places, a couple of times I was in line for something, and I'd be waiting, and someone who was obviously blatantly Caucasian was waiting too, and they got helped first. And once they were done, they helped someone else. And I noticed the people that were being helped were Caucasian, and I was there like -- am I going to get helped? I just had to wait. The same thing has happened to my dad, he's full Hispanic, so. People just start assuming, you know what I mean?" [PID7]

"I think in a good way, honestly, because I think when we're doing these different studies and even any different opportunities that I had through CF, being African American with CF is rare. There's not that many. And so I think that when they happen to stumble upon someone who is African American and has CF, it helps with definitely diversity in studies and helps them to get broader perspective and not just on predominantly Caucasian people. Because definitely Caucasian people have CF, but then you have, like I said, there's a few African Americans, a few Hispanics. So I think it is -- truthfully, I would think that I probably got a few more opportunities because there's not as much of us in the CF world, so they need representation from different races in that matter. " [PID4]

"For women of color there's already -- well, for Black women specifically, there's already -- I know a lot of Black women already experience doctors just not knowing how to work with them because they don't work with any other Black people. And having different body image expectations as Black people, having a different standard of beauty than White people do, and then contrasting that with what happens to your body when you have CF, which is being very thin, being bloated. And I think that's -- and just from research, I know that's a specific -- that issue is more specific to Black women as opposed to where the standard is more just being thin." [PID3]

## 4.4 Language, Communication and Culture

### Key Findings:

This theme encompasses how language, cultural norms and communication shape individuals' experiences in healthcare and clinical research. Topics cover the role of religious or spiritual beliefs in health, challenges in accessing healthcare or research due to limited English proficiency and cultural stigmas or beliefs about CF, medical research or chronic illness that influence participation in clinical trials.

### Supporting Quotes:

"Some days I'm just like -- I just -- I'm very spiritual. So I pretty much give it to God. He provides for me. It carries me through this because when I get to thinking, I get kind of weak-minded, kind of depressed. But when I give it to God, he keeps me lifted up and let me live my life one day at a time. [PID5]

"I feel like there's just more resources. I think, especially, I think about language barriers. I think if you live in a more culturally diverse place, more people speak different languages. I speak Spanish, too. That was my first language, so I'm bilingual. So I -- but when I go to the hospital, to doctor's appointments, I will choose to speak in English just because I know it's probably easier for them, for my doctors and stuff. But I feel like there's just more resources. And I'll notice when you check in or something, there's a -- they'll randomly have if you've traveled outside the country, whatever, they'll have it in English and in Spanish. And so I feel like it's just a lot more, way more resources compared to if I lived maybe in the Midwest or something, but. [PID8]"

"Because in Latino families we've been brought up to not share personal information or be careful what you say in front of professionals because they could take you away, or they could... And not that they were doing anything crazy, just because my family is immigrant, so they were scared that, like, kids would say like oh, my mom doesn't have these papers or my mom—you know, kids say everything. [PID11]

"My family still doesn't believe that I have CF. There's a lot of taboo, especially within the Hispanic community, regarding diseases like this and autoimmune disorders. Even my own mom is just like, "No. Maybe you have this. Watch this on YouTube." So I -- not only having to deal with doctors and facilities and battling them, I have to battle my own family. And I'm not the only one, which is good. [PID6]

### Figures:



Figure 13. Code Cloud

This code cloud shows the most reported codes in this theme. General perceptions of clinical research & trials is reported the most but this is also largely due to the structure of the interview guide and beginning the interview with, "When you think of clinical research what comes in mind?" Altruism is the second most mentioned along with intersectional identities and discrimination no in healthcare.

Codes	Codes													
	Predisposing Factors	Altruism	General perceptions of clinical	Being 'guinea' pigs	Fear / apprehension	History of injustice in trials	Inherently feeling skeptical	Myths & misconceptions	Intersectional identities	Discrimination not in healthcare	Positives to having intersectional	Specific experience of woman of	Language / Communication /	Faith
Predisposing Factors			1											
Altruism													1	
General perceptions of clinical	1				1									
Being 'guinea' pigs														
Fear / apprehension			1				1	1						
History of injustice in trials														
Inherently feeling skeptical					1			1						
Myths & misconceptions					1		1							
Intersectional identities											1	1		
Discrimination not in healthcare														
Positives to having intersectional									1					
Specific experience of woman of									1					
Language / Communication /														
Faith		1												
Language barrier														
Taboo within Hispanic														
Totals	1	1	2	3			2	2	2		1	1	1	

Figure 14. Code co-occurrence

The code-co occurrence matrix shows that unlike in other themes there are actually no overlap in codes occurring with each other.

Media	Codes													
	Predisposing Factors	Altruism	General perceptions of clinical	Being 'guinea' pigs	Fear / apprehension	History of injustice in trials	Inherently feeling skeptical	Myths & misconceptions	Intersectional identities	Discrimination not in healthcare	Positives to having	Specific experience of woman	Language / Communication /	Faith
Participant9_9.16.2024.docx			7			4	3	1	3		1			
Participant8_9.16.24.docx			3		2		1	2		2				1
Participant7_9.9.24.docx		4	3						1	2	3			
Participant6_9.4.24 (1).docx			3		1					1				2
Participant5_9.3.24.docx		9	3					1	1					3
Participant4_8.27.24.docx		2	4		3			2	1		1			
Participant3_8.26.26_2pm.docx		6	1		1		2		6		1	3		
Participant2_8.26.24_1pm.docx			3		3				2					
Participant1_8.22.24.docx			1						1	2				1
Participant12_10.4.24.doc			2				2							
Participant11_9.20.24.doc			1											1
Participant10_9.18.24 (1).doc	1	1	3	1				1		1				1
Totals	1	22	34	1	10	4	8	7	15	8	6	3		3

Figure 15 Code Application

The code application for this theme show that the most common occurring themes are

- 1) General perceptions of clinical trials and research (Due to structure of interview guide)
- 2) Altruism
- 3) Intersectional identities
- 4) Fear / apprehension

The findings of predisposing factors find that key factors such as altruism, general perceptions of clinical research, intersectional identities, and language, communication and culture play a significant role in shaping patients' decisions and attitudes toward clinical trial participation. Patients with CF view participation in clinical trials to contribute to the broader community and are often driven by a sense of altruism. However, despite having positive motivations there is a strong undercurrent of fear and apprehension that stem from concerns about risks, misinformation and past ethical breaches in medical research. Intersectional identities such as race and gender also influence the experiences and perceptions of patients in healthcare settings. Finally, language barriers and cultural stigmas play a pivotal role in shaping access and engagement with clinical research.

## 5. Solutions

Solutions is an important theme that includes strategies or interventions about overcoming barriers to healthcare access and research participation in CF clinical trials.

### 5.1 Information Needs

#### *Key Findings:*

Information needs is how language, cultural norms and communication styles shape an individuals' experience in healthcare and clinical research. Patients say that they need clear information a more time spent explaining the risks and benefits of a study and how the benefits impact both the patients and their community. Patients also ask for easily understandable and transparent explanations about research participation. In this theme, patients stress how important doctor recommendation is as well as having interactive questionnaires, personalized clinical trial 'sales pitches', being able to provide feedback, technology and translation services.

#### *Supporting Quotes:*

"I would say giving in more detail about what it is they're going to be doing. Like if they were to study my mutation, what type of test would they need to run and what each result would mean. And then what type of, I would say, what type of antibiotics that they would need to create based off the tests, and just how the whole process goes." [PID12]

"How is it going to be beneficial? What are the long-term aspects of me taking it or exactly what is it going to do? Give me the option to say yes to it or no to it. But I've got to have the details." [PID2]

"If my doctor says it's okay, I'm like okay. I feel like I just really trust them. So I'm just like sure, if you want me to take it, I'll take it. If they say it's safe, I'm like why not? " [PID8]

"So, for us, for, I guess, Gen Z, we like online things. Like if this was an interactive questionnaire, but like not boring, key word "interactive," we would actually do it. It's just the talking on the phone and Zoom meetings that we do not like. It's just...I don't know what it is, but we don't like it, and we're just more prone to doing things if it's super quick and online. [PID11]

"I think it's the same for the solicitation, for lack of a better word, to participate. This is what you will get. This is how it could benefit you and why and how. Now, I don't know -- again, the language has to be made -- there are some things that cannot be made into -- in a way that can be summarized or changed in a way that every man understands. I know that. But when it comes to the benefits of or the check boxes that will be checked for person A, B, or C, we can easily crosswalk that. " [PID9]

" I think it's important to let doctors know, this was great I had a good experience, or not. I think a lot of people are scared to speak up and say -- you just have to word it right and be comfortable. I don't like it when I have to see people come to the clinic to a doctor, they're really not comfortable with. Or don't feel like they're really getting what they need out of it." [PID7]

"She understands English, but definitely when it comes to something like this that's more in depth, more likely to hear things you may not know in not your native tongue, it definitely would be better and preferable in Spanish. I know it took them a while, like I already did the whole study by the time they were getting to the point of, oh we've got it translated to where she could do it. So, in that sense, it takes time for them to get things translated over." [PID1]

## 5.2 Specifically Focusing on Minorities in Research

### *Key Findings:*

Specifically focusing on minorities in research is the need for more inclusive research efforts in addressing topics pertinent to communities of color and lived experiences of people of color with CF. The key findings of this theme encompass how to approach different communities, and the importance of research targeted towards people of color.

### *Supporting Quotes:*

" I have this issue also when people approach me and say, oh you're Brown, or Hispanic or Mexican. It doesn't really offend me, but it's like, oh that caught me off guard. Because there's not a way to say skin color without it feeling racial profiling. Such as when an African American comes up and they say Black, or dark-skinned or whatever color, it's hard because you don't know what they're comfortable with. But you know basically what they're uncomfortable with, so you want to make sure that that's addressed. I think it would really help if questions like that were asked -- kind of like when people say what your gender pronouns are. The same thing with skin color, would you be more comfortable being addressed as darker-skinned, or Hispanic, Latino? Something like that. Skin color-wise. [PID7] "

"Outside of, say, these smaller research pools where it's just like okay, we're looking for specific people of color, which makes a huge difference because that piques my interest. I'm like yeah, I want to do that. I want to get involved because now I'm getting my voice heard. So if they would put that in there as like, "Hey, we're looking for specific people of color, especially those that has a nonsense, unknown, rare mutation. This is what we're looking for," just to include us more." [PID6]

"There needs to be way more research that's targeted towards people of color and towards their lived experience. And I think, yeah, I think, yeah, there could be a lot of benefit from more qualitative studies about people of color, just like letting them share, yeah, what their experiences are in these settings to just learn more about what, yeah, what it looks like to treat people of color versus White people in a more comprehensive way and what their preferences are and what makes them feel more comfortable in a medical setting. There's just a huge dearth of research in that area. [PID3]

"We have to include because if it's not talked about, nothing's ever going to get done anyway. How are you going to know to change or something to change when this group of minorities have no idea, no clue about it? " [PID2]

## 5.3 Support Needs

### *Key Findings:*

Support needs covered the various support that participants or patients seek when engaging in clinical research. Different support needs mentioned have been having 24/7 support line or clinical staff support, activities to do while waiting, providing emotional support, guarantee confidentiality and privacy, providing resources that are not monetary and patients feeling that they have a sense of autonomy or choice when it comes to decision making in research participation.

### *Supporting Quotes:*

"And even if even they're -- even if you can have somebody, there like a social worker there. They say oh, this person can stay with you the entire time. This person can talk to you, have conversation with you. You'd have to have somebody on the team that can really just do that, be there by your side and support you -- especially if -- I'm grateful that I have people that can come with me, but some people don't." [PID4]

"Maybe finding alternative ways. For example, before I would just do my treatments and I'd just sit there super bored, and just upset. I remember this one respiratory therapist told me it doesn't have to be that way. You could put a movie on while you're doing your treatment, or you can listen to music, or you could play some type of board game while doing your treatment, which is, it's nice." [PID12]

"Yeah. Maybe having more people available in studies that relate to things like CF which are hard to talk about, more often having people available who are like I'm here to talk about things after, people who are there to support the mental health aspect after the fact. " [PID3]

"I would say if there was like a guarantee that it would be confidential and private, because I know a lot of immigrant communities fear for their lives of doing anything because of their status... And like 100% that it's a Spanish speaker doing that. That also reassures them that they're okay here, that nothing is going to happen." [PID11]

"I think just practical things like...like a lot of immigrant communities, especially now, in this economy, are struggling a lot, and I think food vouchers, diapers and stuff, like if they join the study that they will get stuff that is helpful. School supplies are really hard to get around when school is coming. A lot of us growing up wore the same shoes every year. So very practical things like that I think would make families feel like okay, this is worth it. " [PID11]

"No, not really. I feel like maybe being able to back out at any time and not having to fully -- yeah, I feel like that, in case you just get really busy or something and you just can't do it anymore. Because then I feel like I would feel bad having to back out. But if they're like you can before, I'd be like okay. I feel like just stuff like that, but no, not really. " [PID8]

## Figures:

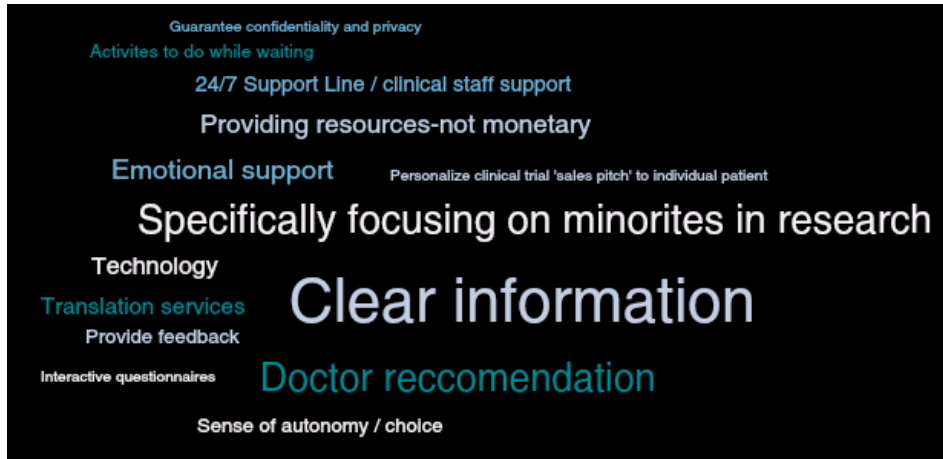


Figure 16. Code Cloud for Solutions

This code cloud shows that clear information, doctor recommendation and specifically focusing on minorities in research are mentioned the most.

Codes	Codes																	Totals
	Solutions	Information needs	Clear information	Doctor recommendation	Interactive questionnaires	Personalize clinical trial 'sales	Provide feedback	Technology	Translation services	Specifically focusing on minorities	Support	24/7 Support Line / clinical staff	Activities to do while waiting	Emotional support	Guarantee confidentiality and	Providing resources-not	Sense of autonomy / choice	
Solutions																		
Information needs																		
Clear information				3				2		1							1	7
Doctor recommendation			3															3
Interactive questionnaires																		
Personalize clinical trial 'sales																		
Provide feedback														1				1
Technology			2															2
Translation services										1								1
Specifically focusing on minorities			1						1									2
Support																		
24/7 Support Line / clinical staff													1			1		2
Activities to do while waiting												1						1
Emotional support							1									1		2
Guarantee confidentiality and																		
Providing resources-not												1		1				2
Sense of autonomy / choice			1															1

Figure 17. Code co-occurrence rate for Solutions

Code that co-occur together are:

- 1) Doctor recommendation X Clear information
- 2) Technology X Clear Information

Media	Codes																	Totals
	Solutions	Information needs	Clear information	Doctor recommendation	Interactive questionnaires	Personalize clinical trial /sales	Provide feedback	Technology	Translation services	Specificity focusing on minorities	Support	24/7 Support Line / clinical staff	Activities to do while waiting	Emotional support	Guarantee confidentiality and	Providing resources-not	Sense of autonomy / choice	
Participant9_9.16.2024.docx			3			2	1			1								7
Participant8_9.16.24.docx			3	4								1		1		1	1	11
Participant7_9.9.24.docx			4	1			2			4				1				12
Participant6_9.4.24 (1).docx			3					4	1	3				1		3		15
Participant5_9.3.24.docx														1				1
Participant4_8.27.24.docx			5	1								3	4	5				18
Participant3_8.26.26_2pm.docx			9	4			1			6		1		3		3	2	29
Participant2_8.26.24_1pm.docx			6	2			2			4				1				15
Participant1_8.22.24.docx			5	9				5	7	1							2	29
Participant12_10.4.24.docx			4					1				2	1			1		9
Participant11_9.20.24.doc					1										2	2		5
Participant10_9.18.24 (1).doc			1	1						5						2	1	10
Totals			43	22	1	2	6	10	8	24		7	5	13	2	12	6	

Figure 18. Code applications for Solutions

The most mentioned codes for this theme are:

- 1) Clear information
- 2) Specifically focusing on minorities in research
- 3) Doctor recommendation

The findings from solutions highlight that key factors are essential for improving participation and accessibility in CF clinical trials particularly for underserved and minority communities. Key conclusions from this data include clear and transparent information is crucial, doctor recommendation plays a key role, research should focus on minorities and inclusive research, support systems are essential and technology and interactive tools and engage younger populations.

## Actionable Recommendations

### Address Logistical Barriers to Participation

**Recommendation 1:** Implement flexible scheduling and virtual participation options to accommodate patients with transportation challenges. Virtual study visits should be promoted as they provide an effective solution for overcoming transportation barriers.

**Recommendation 2:** Offer financial incentives or reimbursements that cover transportation costs and time investments. This can help alleviate economic burdens and improve participation rates especially for patients considering participation based on feasibility.



## Improve Trust through Advocacy and Representation

**Recommendation 3:** Foster strong patient-provider relationships by incorporating advocacy mechanisms into clinical settings. It is important that both healthcare teams and patients are equipped with tools to advocate for one another, and this will help to strengthen and rebuild trust.

**Recommendation 4:** Address racialized discrimination within healthcare environments by training healthcare providers on cultural competence, diversity and anti-racism. By incorporating diverse patient care teams and advocates that reflect the communities they serve this can help reduce systemic barriers.

**Recommendation 5:** Increase efforts to create a culturally inclusive healthcare environment that addresses the lack of representation. Encourage recruitment of healthcare professionals from diverse backgrounds and that are multilingual to better present patient's identities and build trust.

## Enhance Inclusivity in Clinical Research

**Recommendation 6:** Expand eligibility criteria to include patients with rare or less common genetic mutations. This can increase access to clinical trials for broader patient population and allow patients with diverse genetic profiles to participate

**Recommendation 7:** Develop more inclusive research study designs that do not exclude individuals with declining health status or negative health perceptions. Be conscious when approaching patients for studies especially if they have recently been hospitalized and address their concerns by offering additional support, clear information and flexible participation options.

**Recommendation 8:** Proactively target minority and underserved communities in research efforts. Reach out through culturally relevant channels and engage in partnerships with community-based organizations to build trust and facilitate participation.

## Improve Communication and Reduce Fear and Misinformation

**Recommendation 9:** Provide clear, transparent and culturally competent information about clinical trials. Translate materials into various languages and formats to ensure accessibility and develop communication strategies that address cultural stigmas that surround clinical research.

**Recommendation 10:** Combat fear and apprehension regarding clinical trials by focusing on risk minimization strategies, ethnical transparency and the history of past ethical breaches. Educational campaigns can be created to emphasize positive contributions of clinical research while making sure that patients understand their rights and ability to withdrawal from the study whenever they would like to.

## Leverage Technology and Support Systems

**Recommendation 11:** Use technology and interactive tools to engage populations and make participation more convenient. Consider creating user-friendly apps or platforms for patient engagement and communication about clinical trials and use digital tools for real-time updates and feedback.

**Recommendation 12:** Build strong support systems, both pre- and post-trial to ensure patients feel supported throughout the clinical research process. This includes providing activities to do while waiting during participation in

clinical trials, providing emotional support, guidance on logistics, having multilingual staff and access to peer networks that can reduce apprehension.

## Foster Altruism and Community Involvement

**Recommendation 13:** Utilize the altruistic motivations of patients by highlighting the community impact of clinical trial participation and how it can benefit not only them but the larger population. Encourage patients to share stories and experiences to build a collective purpose.

**Recommendation 14:** Leverage doctor recommendations as a critical factor for increasing participation. Healthcare professionals should understand the studies and benefits and be able to actively encourage eligible patients to participate while emphasizing personal and societal value.

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## Conclusion

Addressing racial and ethnic disparities in cystic fibrosis (CF) clinical trials is critical for ensuring equitable access to emerging therapies and improving health outcomes for minoritized populations. This report highlights structural barriers, patient perceptions and systematic inequities that contribute to underrepresentation of Black and Hispanic individuals in CF research. By applying race-conscious framework and integrating patient voices, the findings provide a roadmap for fostering inclusivity in CF clinical trial participation.

The actionable recommendations outlined in the qualitative data analysis report emphasize both immediate practical solutions and long-term systemic changes. Short term strategies focus on removing logistical barriers, enhancing communication and improving trust while long term initiatives aim to restructure clinical research eligibility, expand diversity in healthcare and develop sustainable community partnerships. Implementing these changes require commitment from researchers, healthcare institutions and policymakers in order to work collaboratively and remove inequities to build a more inclusive research environment. By taking these next steps, the CF research community can ensure that clinical trials reflect the diversity of the CF population and lead to improved health outcomes for all individuals affected by this disease.

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