BARRIERS AND STRATEGIES FOR RECRUITMENT AND RETENTION IN CELIAC DISEASE CLINICAL TRIALS: INSIGHTS FROM A MIXED-METHODS ANALYSIS OF U.S. RESEARCH SITES

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Introduction

- Celiac disease affects ~1% of the global population and requires lifelong adherence to a gluten-free diet[1], yet many patients experience persistent symptoms, reduced quality of life[2], and ongoing intestinal damage[3]
- Over the past decade, the number of investigational agents targeting CeD has grown[4]; however, clinical trial execution in this population remains challenging
- Strict dietary management motivating a reluctance to undergo gluten challenges, variable provider awareness, and site infrastructure may limit efficient enrollment
- Widespread use of the CDF's iQualifyCeliac™ platform (which provides centralized recruitment and referral tracking) across several CeD trials created an opportunity to assess enrollment impact and site-level experiences

Objectives

The study aimed to characterize barriers and strategies influencing recruitment and retention at US sites in CeD clinical trials, and to develop actionable strategies to enhance trial execution.

Methods

- Semi-structured virtual interviews were conducted individually with PIs (n=10) and SCs (n=10) from U.S. research sites with CeD trial and iQualifyCeliac™ platform experience
- Quantitative and qualitative content analysis confirmed sample heterogeneity and identified recurrent and unique experiences related to recruitment strategies, participant engagement, and trial execution

Results

- Across 10 geographically diverse US sites, the interviewed PIs and SCs reported a wide range of professional experience **(Table 1a-b)**

Table 1a. Research and CeD Clinical Trial Experience of Interview Participants, Principal Investigators

Participant Demographics	Total N=10*
Experience at Current Site, years	
Mean (SD)	14.5 (11.3)
Min-Max	2-30
Clinical Specialty, n (%)	
Gastroenterology	4 (40.0)
Endocrinology	2 (20.0)
Internal Medicine	2 (20.0)
Emergency	1 (10.0)
Family Medicine	1 (10.0)
CeD Studies Over Career	
Mean (SD)	3.8 (3.1)
Min-Max	1-10
CeD Studies Conducted at Current Site	
Mean (SD)	3.6 (3.1)

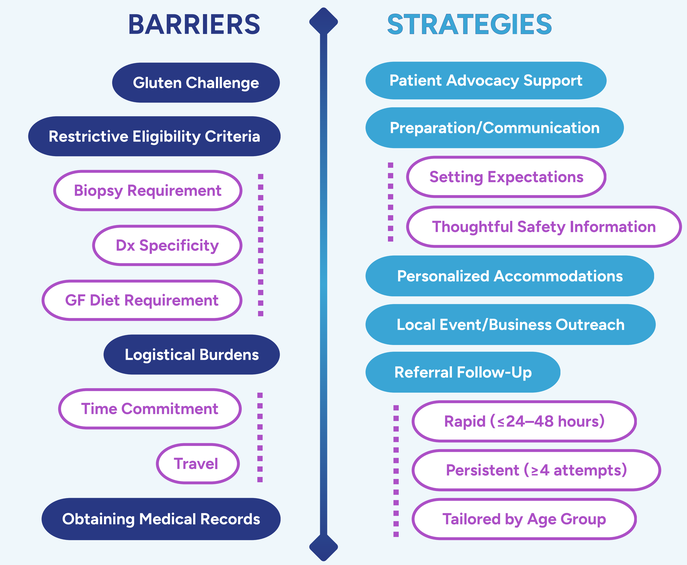
*Included one Sub-Investigator who was closely involved with the study, in place of the Principal Investigator

Table 1b. Research and CeD Clinical Trial Experience of Interview Participants, Site Coordinators

Participant Demographics	Total N=10
Experience at Current Site, years	
Mean (SD)	7 (5.5)
Min-Max	2-20
Recruitment Involvement, n (%)	
Directly performs recruitment tasks	5 (50.0)
Oversees recruitment	2 (20.0)
Combination, oversees and contributes	3 (30.0)
CeD Studies Over Career	
Mean (SD)	2 (1.3)
Min-Max	1-5
CeD Studies Conducted at Current Site	
Mean (SD)	2.2 (1.0)

- PIs most frequently reported the gluten challenge among a variety of recruitment barriers **(Figure 1)**
- SCs emphasized that rapid and persistent outreach **(Figure 1)** improved referral conversion, and that adapting contact methods to accommodate individual preferences (e.g., call, SMS, email) can increase success
- PIs and SCs reported that retention challenges were infrequent, citing AEs or reactions to the gluten challenge as the main motivators for discontinuation
- Both PIs and SCs rated CDF referrals as highly valuable, citing greater awareness, increased trust, higher enrollment yield, and stronger completion rates than other recruitment methods
- All 10 PIs indicated they would recommend using CDF's recruitment efforts to other sites

Figure 1. PI & SC Reported Barriers and Strategies for Recruitment in CeD Clinical Trials



Conclusions

- Targeted operational strategies, including rapid and diversified outreach, proactive expectation-setting, and collaboration with patient advocacy organizations enhance CeD trial recruitment and retention
- The best practices toolkit derived from these findings offers practical, adaptable recommendations to accelerate therapeutic development in CeD
- Future work should incorporate patient perspectives to further refine recruitment and retention strategies

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Abbreviations: **AE**, adverse event; **CeD**, celiac disease; **CDF**, Celiac Disease Foundation; **Dx**, diagnosis, **GF**, gluten-free; **PI**, principal investigator; **SC**, site coordinator; **SD**, standard deviation

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Celiac Disease Clinical Trials Best Practices Toolkit:
celiac.org/trial-toolkit