



**CELIAC DISEASE  
FOUNDATION®**  
ADVOCACY. BREAKTHROUGHS. CURE.



# Pioneering Precision in Clinical Trial Recruitment for Celiac Disease

Redefining Patient Engagement and Trial Efficiency, One Study at a Time.



**iQualifyCeliac**  
STUDY SCREENING



**iCureCeliac®**  
PATIENT REGISTRY

## Success at a Glance...

### **iQualifyCeliac™ Platform**

Revolutionary iQualifyCeliac platform centralizes data from all recruitment initiatives, providing real-time statistics, detailed ROI analysis, and complete transparency.

### **Exceptional Enrollment Rates**

Achieved enrollment rates of 30%-100% through hyper-targeted digital marketing strategies and live, in-house secondary screening, significantly reducing site burden by assuring only high-quality referrals.

### **37,000+ Patients Screened**

Successfully screened more than 37,000 patients across 14 studies with restrictive inclusion/exclusion criteria in the United States and Canada.

## **iRecruitCeliac Case Study: Leading the Way in Clinical Trial Recruitment**

At the Celiac Disease Foundation, we pride ourselves on **connecting patients** with critical **clinical trials** to advance celiac disease treatment. This case study series highlights the success of iRecruitCeliac, our dedicated patient recruitment initiative, in utilizing our innovative iQualifyCeliac platform to ensure efficient and transparent patient enrollment.

Through our **strategic marketing**, comprehensive **screening processes**, and **patient-centric approach**, we have achieved unparalleled recruitment and retention outcomes across multiple clinical trials.



# Case Study 1: Phase 1 Clinical Trial with 3-Day Gluten Challenge

## Background

This nationwide phase 1 clinical trial aimed to enroll 36 patients with biopsy-confirmed celiac disease across 14 sites. This 2-month study required 5-7 visits. Despite the COVID-19 pandemic, we completed recruitment in just 14 months, **referring 60% of completed patients.**



## Challenges for Patients

- COVID-19 pandemic
- Study site response times
- Gluten challenge in Part B

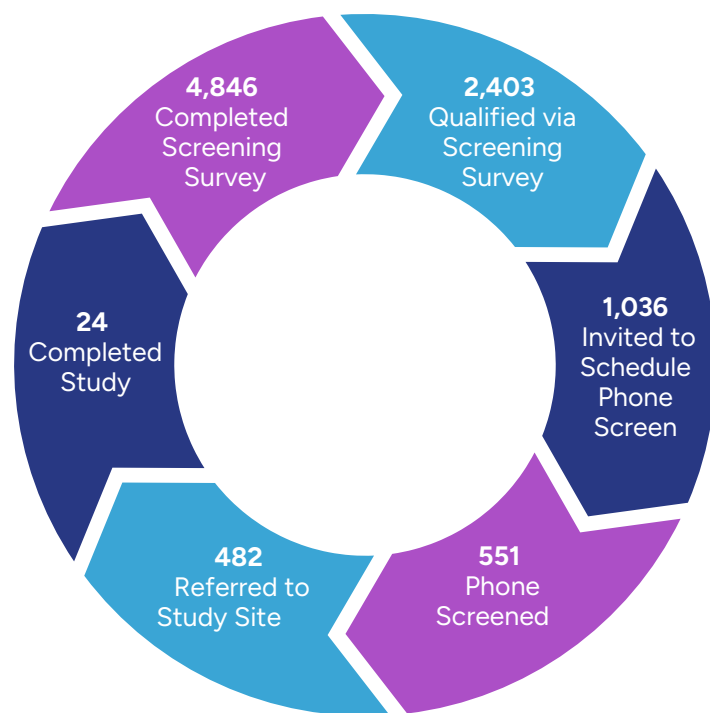
## Advantages for Patients

- Short participation duration
- Fewer visits
- No gluten challenge in Part A
- No endoscopies

## Execution

We launched a comprehensive **digital marketing campaign** including website ads, email, and social media posts. These directed patients to our hosted **study microsite**. This microsite linked to the **iQualifyCeliac™** platform featuring a **customized online screening survey**. Qualified patients were phone-screened by our **in-house call center team** and assigned to study sites through the iQualifyCeliac platform.

**60% of Completed Patients Were Referred By Our Process.**



## Case Study 2: Phase 1b Clinical Trial with Multi-Week Gluten Challenge

### Background

This international phase 1b clinical trial aimed to enroll 18 patients across Europe and the US. Despite a multi-week gluten challenge, we completed recruitment in just 7 months, **referring 56% of completed patients.**



### Challenges for Patients

- Long participation duration
- Extensive gluten challenge
- Few study sites

### Advantages for Patients

- Remote visit option
- Single dose of study drug
- Improved study site response times

### Execution

We ensured study success through an **in-depth protocol review** and the establishment of a **patient advisory panel**.

We designed a robust **marketing campaign** and developed a hosted **study microsite**. We designed **site materials** for both US and international audiences.

A **targeted recruitment campaign** was launched, linked to the iQualifyCeliac™ platform with a **customized online screening survey**.

Qualified patients were **phone-screened** by our **in-house call center** team and assigned to study sites via the iQualifyCeliac platform.

**56% of  
Completed  
Patients Were  
Referred By  
Our Process.**

**1,400**  
Completed  
Screening  
Survey

**1,007**  
Qualified via  
Screening  
Survey

**170**  
Invited to  
Schedule  
Phone Screen

**109**  
Phone  
Screened

**63**  
Referred to  
Study Site

**10**  
Completed  
Study



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# Case Study 3: Phase 2 Clinical Trial With No Gluten Challenge

## Background

This phase 2 clinical trial sought to enroll 220 patients across 36 sites in the US and Canada. The 9-month study involved multiple doses, two endoscopies, and up to 17 in-person visits. Despite the COVID-19 pandemic and the slow rollout of responsive sites, we completed recruitment in 36 months, referring 30% of the completed patients.



## Challenges for Patients

- COVID-19 pandemic
- Long participation duration
- Two endoscopies
- Stool and urine samples

## Advantages for Patients

- No gluten challenge
- Phase 2 trial
- Option for remote visits
- Improved accessibility with additional trial sites added over time

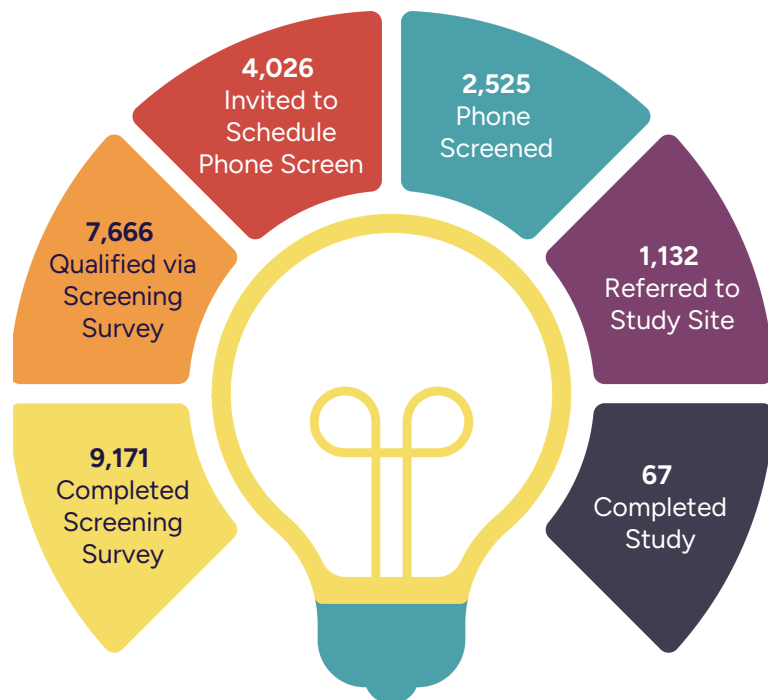
## Execution

We implemented several key services, including the design of a robust **marketing campaign** and the development of a hosted **study microsite**.

A **targeted recruitment campaign** was launched, linked to the **iQualifyCeliac™ platform** with a **customized online screening survey**.

Qualified patients were phone-screened by our **in-house call center** team and assigned to study sites via the **iQualifyCeliac** platform.

**30% of Completed Patients Were Referred By Our Process.**



# Case Study 4: Phase 2 Clinical Trial With Multi-Week Gluten Challenge

## Background

This international phase 2 clinical trial aimed to enroll 50 patients across the U.S., Europe, and Australia. Despite a multi-week daily gluten challenge, we completed recruitment in just 8 months, **referring 36% of randomized patients.**



## Challenges for Patients

- Long participation duration
- Extensive gluten challenge
- Prolonged period of daily questionnaires
- Two endoscopies
- Long study visits

## Advantages for Patients

- Single dose of study drug
- Phase 2 trial
- Remote visit option
- Well-spaced study visits
- Highly responsive sites

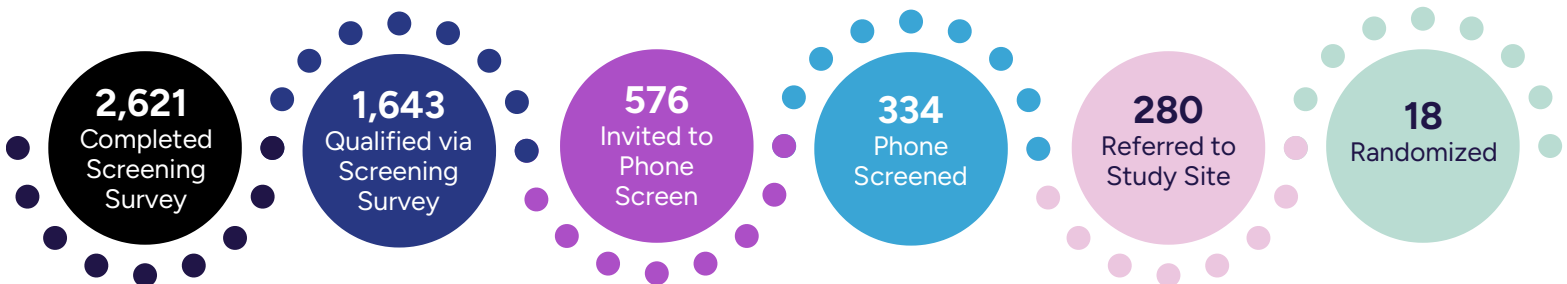
## Execution

We designed a robust **marketing campaign**, **study microsite**, and **site materials** for both US and international audiences.

We supported **site selection** by identifying and recommending high-performing sites using data from **iQualifyCeliac™**. We ensured site readiness through a dedicated **investigator meeting presentation**, walking through the study protocol and sharing **patient-informed retention strategies**.

A **targeted recruitment campaign** was launched, linked to the iQualifyCeliac platform with a **customized online screening survey**. Qualified patients were **phone-screened** by our **in-house call center** team and assigned to study sites via the **iQualifyCeliac** platform.

**36% of  
randomized  
patients were  
referred by our  
process.**



## Case Study 5: Observational Study

### Background

This nationwide US observational study aimed to enroll 300 adult and 100 adolescent patients with celiac disease to assess symptom patterns, quality of life, and psychometric properties of the Celiac Disease Symptom Diary (CDSO). The 90-day study was fully remote, with no in-person visits required. We completed recruitment in two months, **referring 100% of completed patients** and **surpassing the initial enrollment goal by 20%**.



### Challenges for Patients

- Commitment to complete daily, weekly, and monthly ePRO for 90 days

### Advantages for Patients

- Fully remote
- No gluten challenge
- No biopsy confirmation required
- No medical records required

### Execution

To ensure success, we designed a robust **marketing campaign** and **study microsite**. A **targeted recruitment campaign** linked to the **iQualifyCeliac™** platform featured a **customized online screening survey**.

To monitor participant performance and provide compensation, we integrated **patient data capture** with an ePRO vendor software into iQualifyCeliac. Our **in-house call center** was utilized for patient reminders to complete questionnaires and notifications of failure to meet payment milestones.

**Virtual ClinCard milestone compensation** was implemented through our Greenphire integration to ensure seamless monitoring and participant engagement.

**100% of  
Completed  
Patients Were  
Referred By  
Our Process.**

Completed  
Screening  
Survey:  
**1,326**

Qualified via  
Screening  
Survey:  
**973**

Enrolled  
in Study:  
**577**

Completed  
Study:  
**480**  
338 adults  
142 adolescents





## About iRecruitCeliac

iRecruitCeliac is revolutionizing the patient recruitment landscape for celiac disease through its innovative use of technology and patient-centric strategies. Our iQualifyCeliac™ platform centralizes data from all recruitment initiatives, providing real-time statistics, detailed ROI analysis, and complete transparency. We specialize in targeted digital marketing, comprehensive screening processes, and seamless patient engagement to connect patients with critical trials and studies, advancing the treatment of celiac disease.

### Our Services Include:

**Guided Study Design:** Expert guidance to address barriers and optimize efficiency from screening to study completion.

**Patient Advisory Panels:** Curated panels to improve satisfaction and retention through a patient-centric approach.

**Impactful Study Branding and Marketing:** Compelling digital and print campaigns to ensure maximum reach and engagement.

**High-Performing Study Site Selection:** Leveraging a database of high-performing, geo-targeted study sites to maximize successful outcomes and accelerate recruitment.

**Targeted Patient Reach:** Utilizing unmatched celiac disease patient databases and extensive digital reach to connect qualified patients to study opportunities.

**Seamless Collaboration:** Secure, compliant cloud-based solutions to connect patients, call center specialists, coordinators, and sponsors, streamlining the screening and tracking process.

**Enhanced Efficiency:** Patient data capture through eConsent, eCOA, ePRO, eDiary, and wearable devices, alongside virtual patient compensation, optimizing success and information transfer.

### Our Impact:

iRecruitCeliac's strategic approach has resulted in successful recruitment and retention across multiple trials and studies, setting a new standard in patient recruitment. Our commitment to innovation, efficiency, and patient engagement makes us the leading choice for advancing celiac disease research.

**For more information, visit [iRecruitCeliac.org](https://iRecruitCeliac.org)**



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**iRecruitCeliac**  
**PATIENT RECRUITMENT**

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