

Accelerating clinical trials in celiac disease by addressing major patient barriers



# Beyond Celiac Coalition Objectives

Identify significant roadblocks to the diagnosis and treatment of celiac disease.

Address major patient barriers to accelerate clinical trials for celiac disease.

### Join us in breaking down barriers

Since 2003, Beyond Celiac has been the leading patient advocacy and research-driven celiac disease organization working to drive diagnosis, advance research and accelerate the discovery of new treatments and a cure.

Now, Beyond Celiac has brought together members of academia, key opinion leaders, government agencies, and pharmaceutical, biotech and diagnostic companies to identify and address significant roadblocks to the diagnosis and treatment of celiac disease.

You are invited to join the Beyond Celiac Coalition, a partnership focused on accelerating clinical trials in celiac disease. Our concentration on major barriers to trial participation will propel clinical development and increase patient involvement.

Coalition members are supporting meaningful research in a collaborative setting.



## Goals

- · Increase and accelerate patient enrollment
- Address the value of histology in clinical trial development
- · Standardize the gluten challenge
- · Expand clinical trials network
- · Validate prognostic and diagnostic biomarkers
- · Develop best practices to increase clinical trial diversity
- Increase pediatric opportunities
- Better utilize real-world evidence
- · Provide enhanced testing for non-celiac gluten sensitivity

## **Current Priorities**

The Coalition has identified two priority projects for 2023-2024.

The Coalition's unique composition and precompetitive nature lends itself well to hosting a biannual meeting among stakeholders committed to accelerating a cure for celiac disease. Primary objectives would be the following:

- Focus on priority topics of drug development for celiac disease such as symptoms, histology, biomarkers, endpoints.
- Highlight differences between approach to celiac vs. other chronic immune-mediated GI disorders (e.g., IBD).
- Engage with the FDA & NIH.
- Determine best patient selection for trials.

Conduct a gluten exposure study utilizing the "Go Beyond Celiac" Symptom Tracker to collect real world data on accidental gluten exposure and related celiac disease symptoms to gain a better and more accurate understanding of the patient experience. This project would be valuable in increasing knowledge and generating compelling evidence that the glutenfree diet is not sufficient treatment for people with celiac disease. In addition, the data collected would help to inform the design of clinical trials.





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#### **Structure and funding**

Our Coalition structure includes an Executive Board to set the vision, strategic priorities and oversee the use of funds, plus a Steering Committee to provide recommendations on project priorities and plans.

The Beyond Celiac Coalition is operated and funded by annual membership dues, with projects funded from supplemental funds members provide. Membership benefits include seats on the Executive Board and/or Steering Committee. Participation in project funding is based on the discretion of each potential project participant, with project funding opportunities offered to all members.



#### **Member benefits**

- Play a role in shaping best practices and accelerating celiac disease clinical trials
- Gain knowledge and insights that will help advance business decisions
- Leverage resources in a pre-competitive environment
- · Gain access to shared data
- Contribute to celiac disease science and the expansion of the clinical trials network
- Have the opportunity to work collaboratively, both in person and remotely, with other members of the Beyond Celiac Coalition
- Receive frequent communications on the latest science/trends



# Membership Opportunities

Our Coalition members participate in meetings and collaborations while supporting activities and projects.

Members contribute directly to the acceleration of clinical trials in celiac disease by engaging in extensive dialogue.

- \$40,000 Executive Membership: Allows 2 seats on the Coalition's Executive Board that sets the vision and strategic priorities while overseeing the use of funds of the partnership, plus 2 seats on Steering Committee that recommends project priorities.
- \$20,000 Steering Membership: 2 seats on Coalition's Steering Committee that recommends projects and plans.
- <u>Academic Membership</u>: Allows for participation in Coalition projects. No fee.
- <u>Government Agency Membership</u>: Allows for participation in Coalition projects. No fee.



Discounts available with multi-year commitments



# Contact

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