

RESEARCH STRATEGY 2023-2028

Defining our five year strategy, priorities and approach to maintain momentum for progression of coeliac disease research.

Executive Summary

Our 2023-2028 Research Strategy follows on from the successes of the previous research strategy, which was the first Coeliac UK strategy to incorporate the ten research priorities chosen by people living with coeliac disease, alongside those who care for them and healthcare professionals. It defines a clear approach for how Coeliac UK will maintain momentum in contributing to the progression of coeliac disease research.

We have a vision for no life to be limited by gluten and ultimately a world without coeliac disease!

We will...

Continue to strive for research to be of maximum benefit to those affected and ensure that research is relevant and impactful by a variety of means including, but not limited to, fostering relationships with relevant institutions and professional bodies, considering the involvement and engagement of patients and the public, facilitating the work of both early career and well-established researchers and promoting the priorities of the coeliac disease community.

Fund and support research that aligns with our research agenda that seeks to improve the understanding, diagnosis, treatment and care of those living with coeliac disease and other gluten related conditions, whilst actively seeking national and international collaborations that may help to expedite progress.

Look towards established organisations to ensure that research is conducted according to best practice and due diligence and that the involvement of our membership and the wider coeliac community in research is valued and appreciated.

Introduction

Coeliac UK is the only charity within the UK dedicated to supporting people living with coeliac disease and those who care for them, representing a population of over one million. The charity is a global leader in funding and supporting research into coeliac disease and provides a strong collective voice for the coeliac community at a national and international level.

Throughout this strategy, the term “coeliac disease” is to include dermatitis herpetiformis (DH), the skin manifestation of coeliac disease and other gluten related autoimmune conditions such as gluten ataxia, peripheral neuropathy and encephalopathy.

Coeliac UK was founded in 1968 to create a voice and provide support for the challenges facing the coeliac community. At the time there was a notable lack of awareness of coeliac disease, a lack of support and a lack of quality gluten free food, despite a gluten free diet being the only treatment. While the priority was to find safe gluten free food to support the management of the condition, research was at the charity’s core and that remains the case today.

Since the publication of our previous research strategy in 2018, much has happened. Globally we have experienced a pandemic which saw a halt to all but essential research and healthcare. We witnessed how, with the right funding, resources and dedicated expert minds, medical science advanced at lightning speed.

In spring 2022, Coeliac UK held its postponed Research Summit from 2020, and although it was two years late, it did not disappoint. Attended by internationally renowned experts in coeliac disease research, and researchers exploring other autoimmune

conditions, they helped identify the ongoing evidence gaps to underpin the charity’s research priorities.

Some researchers believe that if coeliac disease was funded as generously as some other autoimmune conditions, combined with a concentrated approach, (as applied to COVID-19 research), we could achieve a breakthrough in coeliac disease research. This would make a step change in the management of the condition, eventually leading to a world without coeliac disease.

Looking back, not only at the last five years but the last 30 years, some researchers suggest that significant progress has been made in coeliac disease research, despite relatively limited funding, compared to the spend on other autoimmune conditions.^[1]

Unlike other autoimmune conditions, where much is still to be discovered about the pathogenesis, in coeliac disease we are ahead. We already know the antigen (gluten), the genetics (HLA DQ2.5, HLA DQ8, HLA DQ2.2) so now need to discover the remaining missing factors to complete our understanding.

Screening studies in the UK show that the prevalence of coeliac disease is estimated to be 1 in 100 people.^[2,3] Over the years, the blood tests, the first step in the diagnosis of coeliac disease have improved significantly and research has advanced such that an endoscopy and biopsy is no longer required in all cases to confirm a diagnosis. Despite this, still only 36% of people living with coeliac disease in the UK, currently have a medical diagnosis.^[4]

To date there is still only one treatment, strict adherence to a lifelong gluten free diet, and there is a significant unmet need for alternative treatments.^[5] We know from surveys of the coeliac community that only approximately half of respondents hadn't had any symptoms associated with their coeliac disease in the past four weeks.^[6]

Although 60% are satisfied or very satisfied with the gluten free diet, three quarters think it very or extremely important to have an alternative therapeutic to the gluten free diet and 90% feel the same about a potential adjunct to the gluten free diet.^[7]

We have committed around £3.5 million to research in the past 20 years; research to understand the genetic basis^[8] and immune processes involved in the disease, identifying the major toxic fragments of gluten^[9], as well as the impact of gluten on the nervous system.^[10] We have also committed funds to improving diagnosis, post diagnosis care and understanding the challenges of managing the condition.

We plan to increase momentum in coeliac disease research by both strengthening the research base in the UK, and further initiating stronger international collaborations and partnerships to advance knowledge and understanding that may be translated to benefit the coeliac community. Research

of this nature is expensive, requiring innovative approaches to funding, on a national and international scale. Increasingly, researchers and international or national research organisations, including, but not exclusively, the National Institute for Health and Care Research (NIHR) are recognising that patient and public involvement and engagement (PPIE) is essential to producing high quality, impactful research.

Additionally, Coeliac UK members, volunteers and the wider coeliac community have an important role in research. Our charity has the largest register of patients with the condition in the UK, a valuable resource for the research community. The employees within the charity are an important source of expertise and as such, they can provide a strategic view and representation of the community at large, and are involved as active members of research teams, facilitating an outreach to the wider research community.

Our mission is to improve the lives of people living without gluten. By investing in research into the nature and effects of gluten, as well as the pathogenesis of coeliac disease, we hope to overcome coeliac disease one day. Our vision is for no life to be limited by gluten.

Our Goal

Our Research Strategy aligns with the charity's overarching strategy.

Our vision is no life limited by gluten, ultimately, we would like to see a world without coeliac disease.

It is important to acknowledge that when a 'cure' for coeliac disease is referenced, it means different things to different people; for some it means preventing coeliac disease from ever developing, for those already diagnosed it is no longer needing to have a gluten free diet and for some, it is successful management of their condition, maintaining health and wellbeing. We remain conscious of these different views and that for all, a 'cure' means no longer living a life that is limited by gluten.

To achieve this, we have identified four key areas for research:

- **Understand the cause** – identifying risk factors and triggers involved in the cause, risk or development of disease
- **Advance diagnosis** – discovering and developing better diagnostic processes and predictive markers and technologies
- **Find new treatments** - discovering new targets for treatment and working with industry and the NHS to develop treatments and measure their effectiveness
- **Improve care** - research into the individual care needs and management of the disease and associated conditions, including provision and delivery of health and social care services

We will work to identify gaps in the evidence base and, where appropriate, commission work to fill those gaps.

We want to grow the number of researchers and research organisations who specialise in the study of coeliac disease. By promoting and funding research in this area, we hope to establish the field of coeliac science as a recognised academic research speciality.

Our Approach

There are key pillars on the path to achieving our goal

- Ensure that people affected by coeliac disease and other gluten related immune conditions have the opportunity to have their say.
 - We have a policy outlining our expectations with regard to PPIE in research.^[11]
- Encourage and support early career researchers to choose coeliac disease as their speciality.
 - We offer small grants of up to £5000 to early career researchers.
- Seek collaborations, nationally and internationally and across disciplines and diseases.
 - In 2021 Coeliac UK became a member of the Connect Immune Research (CIR) alliance^[12], a group of autoimmune disease patient charities with a common goal to see a world without autoimmune disease. The CIR encourages and promotes the sharing of knowledge to accelerate understanding and make those leaps in research that are needed.
 - Since 2013, Coeliac UK has been a member of the International Society for the Study of Celiac Disease.^[13]
 - In the UK, we actively collaborate with other relevant patient organisations and have jointly funded research.
- Diversify funding streams and work towards an international fund with other likeminded patient organisations so that we make the most of our valuable resources and avoid unnecessary repetition, siloed thinking and working.
- Communicate and disseminate evidence.
 - Our research marketing strategy will ensure that we are held accountable for sharing research.
- Review our research strategy on an annual basis with our Research Strategy Board.

Research Priorities

In 2017, we completed a James Lind Alliance Priority Setting Partnership. We identified a list of research priorities from consulting individuals affected by coeliac disease and/or other gluten related immune conditions and healthcare professionals:

- **What are the risk factors or triggers** (e.g. environmental, lifestyle, dietary, additional genetics) involved in the development of coeliac disease in people who are genetically predisposed to the condition i.e. HLA-DQ positive? Do they determine when someone will develop coeliac disease and/or predict how severe disease-associated symptoms and complications will be?
- How can **healthcare professionals be best supported** to accurately diagnose and manage coeliac disease and other gluten related autoimmune conditions to achieve **earlier diagnosis and improve patient care**?
- What is the **spectrum of neurological forms** of coeliac disease and how does neurological dysfunction develop? How are they best diagnosed and managed?
- Are there **less invasive tests** (apart from gastroscopy and duodenal biopsy) for recognising coeliac disease and is it possible to accurately test for coeliac disease once gluten has been excluded from the diet?
- What are the **associations between coeliac disease and other conditions** e.g. Type 1 diabetes, autoimmune thyroid disease, and what factors influence the risk of developing such conditions?
- What is the **best means of follow up management** of people with coeliac disease and/or other gluten related autoimmune diseases, including help with sticking to the gluten free diet and prevention of long term health complications? *(taking into consideration things like other conditions, age, education, socioeconomic status, mental health, no symptoms)*
- What are the **best ways to educate people working in the catering/hospitality industry** about the gluten free diet to improve safety for people with coeliac disease when eating out?
- How can coeliac disease be **cured** so that consideration for a gluten free diet is no longer necessary?
- How can **coeliac disease and associated complications be prevented** in genetically vulnerable individuals (e.g. using drugs, vaccinations or modification of diet)?
- How can a greater **understanding of the causes of refractory coeliac disease** Types I and II be used to develop and improve diagnosis and treatment of the conditions?

In preparing this research strategy we revisited these priorities and engaged with key stakeholders (people with coeliac disease, those who care for them and healthcare professionals). We asked if they still recognised these research priorities as relevant to them and the wider community and if there were any new, unanswered, research questions. Without exception, all priorities remain relevant. There is ongoing work with the research community to identify the evidence gaps to underpin the priorities.

We do not intend to exclusively restrict our funding to these priorities. However,

applications for research that specifically address any of these priorities will be considered more favourably. In any case, exceptional proposals of novel research must demonstrate how the research will further the understanding of coeliac disease and the potential to improve the lives of people affected by the condition. Where appropriate, we will also consider funding research that provides evidence to bridge gaps and underpin our organisation activities in support of the coeliac community.

Key Principles

Research governance: a robust framework will be maintained to call for research proposals, undertake scientific peer review, award funding, manage grants and ensure maximum impact of research findings through dissemination and publication, always looking to best practice.

Integrity: All research proposals must have a statement of originality. Replication of work carried out elsewhere will not generally be accepted, although there may be exceptions where the same research question may have a different outcome e.g. depending on the cultural environment.

Only appropriately qualified individuals, with the necessary skills and facilities, as determined during the peer review process, may receive research funding. Applicants must be contracted to work in an appropriate institution which has the necessary networks to support education, training, ethical standards and professional development.

Funding: We will fund research that makes significant contributions to the long term research agenda in understanding, diagnosing, managing and treating coeliac disease and we will also consider funding research that may provide a crucial short term improvement for the coeliac community. Funded research will be assessed for intellectual property to ensure appropriate recognition and any appropriate return on investment.

Collaboration and PPIE: We invite applicants from national and international institutions to apply for research grants. Research outcomes must be translatable to the UK coeliac community. International applicants are encouraged to collaborate with UK researchers, but this is not mandatory.

Research must consider ways to involve and engage people living with coeliac disease throughout all stages of design, planning, executing and disseminating research and we will actively support those who consider and participate in research. Research must implement effective patient and public involvement and engagement (PPIE).

Translation: We will promote clinical translation to the benefit of people living with coeliac disease. It's recognised that to underpin the charity's research priorities, research may need to be clinical or basic science, both will be considered for funding.

All research funded by Coeliac UK must aim to benefit people with coeliac disease. Researchers must understand and appreciate the importance of translating their research into practice for the benefit of people with coeliac disease.

Dissemination: We will actively support the dissemination of research outcomes to all stakeholders including the coeliac disease and research communities and healthcare professionals.

Funding - types of grants

Calls for research are ultimately approved by Coeliac UK's Board of Trustees. The research call and application process will be clearly advertised on the Coeliac UK website and networks, with relevant professional bodies and via national research call networks. There are several different types of research grant that may be awarded:

Research Programmes

The charity aims to award programme grants designed to answer a single question or a small group of related questions, which must be directed at the charity's research priorities. It is expected that programmes will establish a network of researchers and that research will consider patient and public involvement and engagement, not just participation. Many research questions require funding beyond an individual organisation's capability and so it is important that the charity recognises this and actively seeks opportunities to contribute to research programmes that seek to pool funds to increase the impact of research.

The programme should aim to create a virtual network of excellence in research into coeliac disease, with the foundation for longevity and for further research into the condition, beyond the original research programme grant.

Collaborations across countries, disciplines and conditions, where appropriate, are encouraged, as is securing additional funding from organisations other than Coeliac UK.

Project Grants

The charity will award research project grants to proposals that underpin our research priorities and those affected by coeliac disease. These projects must aim to involve and engage with those affected by the research and

collaborations across autoimmune conditions, are considered. Coeliac UK supports additional funders contributing to the project and encourages applicants to demonstrate how this research might lead to a possible programme grant in the future, potentially attracting funding from elsewhere increasing the value of the original investment in research.

Innovative Grants

The charity will award grants to provide support for innovative short term, small scale pilot or proof of concept projects.

Research Fellows

In the past, although research fellowships have been offered in collaboration with the Medical Research Council, they have attracted little interest. However, many of our previous project grants have supported early career researchers and we are keen to continue to nurture.

The objective of the fellowship (clinical or non-clinical) is to build capacity in research into coeliac disease and the impacts of gluten, where there is currently a deficit, by encouraging the best graduates to embark on an early career in this field.

Sponsored Dissertations

The charity may provide a grant (max. £5000 per student) to encourage postgraduates (including but not limited to dietitians, immunologists, food

technologists, epidemiologists, social scientists, psychologists, medical students) studying at UK institutions or working in the NHS, to focus on coeliac disease and the impact of gluten in their project work.

The primary objective is to place coeliac disease on the research agenda of UK academic institutions, whilst commissioning research that supports the charity's research priorities. It is also intended to ignite enthusiasm in coeliac

disease research and encourage early career researchers to take a long term interest in coeliac disease.

Lab Placements

These grants are to enable researchers to visit other research institutions to share and benefit from each other's skills, knowledge and experience. Placements within institutions exploring other autoimmune conditions are encouraged to advance understanding.

Research governance

We will ensure we meet the Association of Medical Research Charities (AMRC) standards of best practice in research governance.

Good governance is important in ensuring that we fund high quality and relevant research that has an impact on people living with coeliac disease.

Our Research Awards Panel comprises expert researchers working in relevant/associated fields. Grant applications will be screened and subject to peer review by our Research Awards Panel. Applications will be reviewed by both external peers and our lay Member Review Panel. All applications will be scored and judged on the quality of science, PPIE and relevance to coeliac disease. Our Research Awards Panel will make recommendations for funding to

our Board of Trustees based on the results of the review process.

Progress, annual and final reports from funded research will also be reviewed by our Research Awards Panel.

When supporting external research projects, we will do so in line with best practice and account for this as an extension of our own work. We will support researchers and research projects that align with our research strategy and research priorities.

We will look to the Association of British Pharmaceutical Industry (ABPI) guidelines when working with industry that is seeking to develop alternative treatments for people with coeliac disease and to meet the current unmet need.

Supporting Researchers

In addition to funding research, when possible, we will support researchers by:

Providing expertise and advice on the history and current state of coeliac disease research, the healthcare system, prevalence, diagnosis, challenges and unmet needs of people with coeliac disease, their carers and healthcare professionals.

Steering researchers to work with best practice and research governance.

Supporting grant applications and being a member of the research team, where appropriate.

Advocating for the patient voice by advising researchers on the patient

perspectives that we have gained from experience and close connections with the community over an extended period of time.

Facilitating patient and public involvement and engagement

Conducting surveys

Assisting with recruitment for research.

Assisting with dissemination of research. Introducing researchers to relevant organisations or individuals that can help with or impact their work.

Collaborations

NHS

Continue to foster relations with both established and new healthcare professionals in the field (in the NHS) to ensure that the people providing care to patients are aware of the most up to date research.

We will maintain active communication with key contacts within the NHS to ensure that we are acting as advocates for the needs of people with coeliac disease but also so that we are aware of challenges within the NHS. This will allow identification of areas where research might be needed.

Industry

Further develop relationships with pharmaceutical and biotech companies to ensure that we advocate for patients' needs. We will also help researchers to meet and connect with relevant companies and stakeholders, jointly and appropriately supporting education of the unmet needs of patients and possible solutions. Working to codes of best practice such as the ABPI, where appropriate we will inform the coeliac community of the potential new therapeutic pipelines and when relevant any associated clinical trials.

International Connections

We will continue to attend international events to network on a global scale and to understand the ongoing research and strengths of other countries. We will also use these opportunities to share our research and highlight the UK's strengths, including the robust research culture in the UK, inviting other countries to draw on our strengths and drawing on theirs as appropriate.

We will continue to build and maintain strong relationships with coeliac patient associations around the world as well as maintaining our voice within international research organisations by attending meetings and promoting our research but also offering our support to international projects.

We understand that for research to progress optimally, knowledge and expertise should be shared, and that collaboration is a must. We will seek to help large scale, global projects whenever possible.

Involving people affected by coeliac disease

Patient and Public Involvement and Engagement (PPIE)

Our members and their carers/families play a vital role in research and their participation in the past has advanced the understanding of coeliac disease and the impact of gluten. We will continue to advise anyone from the coeliac community interested in research, to make informed decisions about taking part and will support participants throughout their involvement.

We will strive to ensure that research is carried out with effective PPIE so the needs of those living with coeliac disease are met. We will ask that research involves those that are affected by coeliac disease at every stage of the research process; planning, managing, designing and disseminating research. This aims to ensure research is relevant and impactful.

We will continue to engage the coeliac community and others in understanding the aims of our research and supporting our need for further funding through our communication channels, including social media, our website and printed publications. We will encourage researchers to engage with anyone impacted by research in a two way process.

In 2014, we introduced the Member Review Panel to give our members the opportunity to have their say. Members of the panel review lay summaries of research grant applications and score them. The feedback from the panel influences what research we fund. We will provide participants of the panel with the support they need to be most effective.

Equality Diversity and Inclusion (EDI)

We will...

- strive to ensure that the research we carry out and the research we support considers best practice on equality, diversity and inclusion
- aim to provide equal opportunities and support for researchers from a diverse spectrum of backgrounds
- actively encourage the involvement of people from different backgrounds to ensure that we represent the diversity of the coeliac disease population, and we will seek to identify and overcome barriers that may exclude people from being involved in research
- aim to address issues with accessibility and under-representation

Advocacy

We will use evidence from research to underpin our campaigns, advocating for the coeliac community. Together we will provide a strong collective voice.

Impact

We will continue to evaluate the impact of research that we fund and support to ensure that we are making a positive contribution to the progression of coeliac disease research. We will continue to monitor that research is impacting the right people and ensure that

research is relevant and will track our impact; monitoring publications, project outcomes, any increased funding as a result of our initial investment in research, patient feedback, product or policy development.

Dissemination

We will strive to ensure the evidence we generate and that of others is used to its full capacity. We will communicate and disseminate the outcomes of research, both positive and negative to both the research community and people affected by coeliac disease. The results of our research can underpin our policy positions and campaigning, as well as influence the research agenda of others.

We will offer a supporting role in the dissemination and publication of research and will ask to be recognised for this where relevant.

Professional engagement

We will aim to hold an annual research symposium for healthcare professional members of the charity and researchers. This will provide the opportunity for researchers, including those funded by Coeliac UK, to share their research findings and best practice with healthcare professionals in the NHS, whilst also contributing to their continuing professional development.

This is to increase awareness and knowledge about the latest discoveries in coeliac disease and to ensure the achievements and the implications of the research Coeliac UK has funded are recorded and communicated. This information allows us to determine if the research has been carried out in accordance with the grant conditions and objectives of the charity. It also helps with the reporting to our members and for our future planning and strategy development.

Our staff

Our staff have a wealth of experience, expertise and knowledge of coeliac disease and the impact of gluten. Where appropriate we will support researchers in the preparation of their research proposals and/or applications for funding. Where resource allows and the expertise is available, we contribute to steering committees, collaborate on projects and facilitate an outreach to the wider research network.

As a not-for-profit organisation, researchers should factor in the costs associated with the charity providing support with external research, on a case by case basis, ensuring that there is no dilution of the charity's efforts in other areas of its work. We will consider the support provided by our staff when measuring our research impact.

Your views

If you have any comments or questions about our 2023-2028 Research Strategy please contact research@coeliac.org.uk.

References


- [1] Coeliac UK's Research Summit 24 March, 2022
- [2] West J, Logan RFA, Hill PG et al. (2003) Seroprevalence, correlates, and characteristics of undetected coeliac disease in England. *Gut* 52:960–965
- [3] Bingley PJ, Williams AJ, Norcross AJ et al. (2004) Undiagnosed coeliac disease at age seven: population based prospective birth cohort study. *BMJ* Feb 7;328(7435):322-3
- [4] Nartey Y, Crooks CJ, Card TR et al. (2021) Incidence and prevalence of coeliac disease across the United Kingdom (Internal report; as yet unpublished)
- [5] Alhassan E, Yadav A, Kelly CP et al. (2019) *Novel non dietary therapies in coeliac disease*. *Cell Mol Gastroenterol Hepatol* 8(3):335-345 doi:10.1016/j.jcmgh.2019.04.017
- [6] Coeliac UK Dietary preferences survey (2021); unpublished
- [7] Coeliac UK Clinical trials and therapeutics survey (2021); unpublished
- [8] van Heel DA, Franke L, Hunt KA et al. (2007) *A genome-wide association study for celiac disease identifies risk variants in the region harboring IL2 and IL21*. *Nat Genet* Jul; 39(7): 827-9. doi: 10.1038/ng2058.
- [9] Anderson RP, van Heel DA, Tye Din JA et al. (2006) Antagonists and non-toxic variants of the dominant wheat gliadin T cell epitope in coeliac disease. *Gut* Apr;55(4):485-91. doi: 10.1136/gut.2005.064550.
- [10] Croall ID, Tooth C, Venneri A et al. (2020) Cognitive impairment in coeliac disease with respect to disease duration and gluten free diet adherence: A pilot study. *Nutrients* Jul 8; 12(7): 2028. doi: 10.3390/nu12072028.
- [11] PPIE policy – currently in writing
- [12] Connect Immune Research alliance <https://jdrf.org.uk/connect-immune-research/>
- [13] International Society for the Study of Celiac Disease (ISSCD) <https://www.isscd-global.org/home/>

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