Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR)

consortiapedia.fastercures.org/consortia/cegir/

<table>
<thead>
<tr>
<th>Research Areas</th>
<th>At a Glance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tool Development</strong></td>
<td>• Status: <strong>Active Consortium</strong></td>
</tr>
<tr>
<td>Resource</td>
<td>• Year Launched: <strong>2014</strong></td>
</tr>
<tr>
<td><strong>Biomarker Research</strong></td>
<td>• Initiating Organization: <strong>NIH Rare Disease Clinical Research Network</strong></td>
</tr>
<tr>
<td>Drug</td>
<td>• Initiator Type: <strong>Government</strong></td>
</tr>
<tr>
<td></td>
<td>• Rare disease</td>
</tr>
<tr>
<td></td>
<td>• Location: <strong>North America</strong></td>
</tr>
</tbody>
</table>

Abstract

The Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR) is dedicated to improving the lives of individuals with eosinophilic gastrointestinal disorders through innovative research, clinical expertise, and education via collaborations between scientists, healthcare providers, patients, and professional organizations. CEGIR focuses on eosinophilic esophagitis (EoE), eosinophilic gastritis (EG), and eosinophilic colitis (EC). The team has a multidisciplinary approach and integrates expertise in pediatric and adult clinical specialties, including gastroenterology, allergy, immunology, and pathology. Funded by the National Institutes of Health (NIH), CEGIR is part of the Rare Diseases Clinical Research Network (RDCRN).

Mission

The mission of CEGIR is to improve the lives of individuals with eosinophilic gastrointestinal disorders through innovative research, clinical expertise, and education via collaborations between scientists, healthcare providers, patients, and professional organizations.
CEGIR’s overall goals are as follows:

Structure & Governance

This consortium is part of the Rare Diseases Clinical Research Network (RDCRN), an initiative of the Office of Rare Diseases Research, National Center for Advancing Translational Sciences (NCATS). The RDCRN is designed to advance medical research on rare diseases by providing support for clinical studies and facilitating collaboration, study enrollment, and data sharing. Through the RDCRN consortia, physician scientists and their multidisciplinary teams work together with patient advocacy groups to study more than 200 rare diseases at sites across the nation.

Funding and scientific oversight for the RDCRN are provided by NCATS and 10 NIH components: Eunice Kennedy Shriver National Institute of Child Health and Human Development; National Cancer Institute; National Heart, Lung and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis and Musculoskeletal and Skin Diseases; National Institute of Dental and Craniofacial Research; National Institute of Diabetes and Digestive and Kidney Diseases; National Institute of Mental Health; National Institute of Neurological Disorders and Stroke; and Office of the Director. In addition, patient advocacy groups provide funds for many of the projects.

Patent Engagement

The RDCRN CEGIR Contact Registry is a way for patients with eosinophilic gastrointestinal diseases and their family members to learn about CEGIR research studies they may be able to join. Participation is completely voluntary, and participants can withdraw at any time. There is no cost to join the Contact Registry.

Impact/Accomplishment

CEGIR has four primary cores: Clinical Research Projects 1 and 2, a Pilot/Demonstration Clinical Research Program, and the Training (Career Development) Program. There is also an Administrative Core that directs and coordinates the activities of these endeavors.
Clinical Research Project 1, called the OMEGA Trial (Outcome Measures for Eosinophilic Gastrointestinal Diseases Across Ages), is a multicenter, longitudinal study of children and adults with EoE, EG, and EC focused on two aims. Aim 1 is to determine the correlation of COMs, including PROs, with the histological disease activity as measured by mucosal eosinophil counts. It will also test a series of related hypotheses concerning secondary histological parameters that may correlate with clinical and phenotypic measurements, potentially leading to a new gold standard for EoE, EG, and/or EC diagnosis and monitoring. Aim 2 is to determine the correlation of the molecular profile for EoE, EG, and EC with COMs and mucosal eosinophilia. It will identify biopsy-based messenger ribonucleic acid (mRNA) expression profiles of children and adults with EoE, EG, and EC from Aim 1 to identify disease-specific molecular diagnostic criteria, provide key insight into disease pathogenesis, and answer questions concerning the molecular basis of distinct clinical phenotypes.

Clinical Research Project 2, called the SOFEED Trial (Six Versus One Food Eosinophilic Esophagitis Diet), is a multicenter study with two aims. Aim 1 is to conduct a randomized diet trial that eliminates one food (milk) vs. six foods (milk, egg, wheat, soy, nuts, and fish) to evaluate the efficacy of less-restricted diets and determine whether patients who experience diet failure remain responsive to SGC therapy if they fail the 6FED and remain responsive to 6FED when they fail 1FED. Aim 2 is to develop a personalized medicine approach based on biomarker analysis that can predict the best treatment for individual patients. Clinical Research Project 2 addresses a topic of direct interest to PAGs and their constituents—the rapid development of practical solutions for individuals living with EoE. It aims to optimize treatment with readily available therapies (diet and SGCs) and develop a personalized medicine approach, based on cutting-edge biomarker analysis, to optimize response rates and reduce unnecessary treatments and procedures.

The Pilot/Demonstration Clinical Research Program supports new ideas that have potential to create and/or change paradigms concerning EoE, EG, and EC. Two Pilot/Demonstration Clinical Research Projects are supported each year. The projects last up to two years and ideally take maximum advantage of new clinical research opportunities in investigating EoE, EG, and EC. The projects are collaborative among investigators within one or more CEGIR sites or with investigators outside the CEGIR environment. Projects are selected by their likelihood to develop new models and ideas that will improve the way researchers, healthcare providers, and patients understand these diseases and to develop better treatments.

The Training (Career Development) Program trains new investigators in clinical and translational research, enhancing the likelihood of academic success for the investigators in training. The program’s specific goals are to (a) enable CEGIR trainees to become independent clinical and/or
translational investigators; (b) aid CEGIR trainees in developing a broad understanding of the basic, translational, and clinical science pertinent to the immunobiology, pathogenesis, and genetics of EoE, EG, and EC via didactic instruction; and (c) facilitate CEGIR trainee networking and integration in the EoE, EG, and EC research community. The consortium believes that increasing the number and quality of clinician researchers studying EoE, EG, and EC will improve current and future patient care.

Patient Advocacy Groups (PAGs) are an important part of the CEGIR team. PAGs contribute numerous resources to the consortium, including, but not limited to, efficient pathways to communicate the latest clinical and research developments to patients and their families (via conferences, websites, newsletters, contact registries); a forum for the collection and dissemination of patient and family perspectives and priorities; public educational initiatives to raise awareness of and quality of care for eosinophilic gastrointestinal diseases; and financial support for important research and clinical efforts.

Links/Social Media Feed

Homepage  http://www.rarediseasesnetwork.org/cms/CEGIR

Points of Contact

Melody Hess, M.S.
Clinical Research Coordinator, Coordinating Center
Cincinnati Children’s Hospital Medical Center (CCHMC)
phone: 513-636-5540
e-mail: Melody.Hess@cchmc.org

Josh Rosenfeld, M.B.A.
Senior Research Administrative Coordinator
Children’s Hospital Colorado
University of Colorado School of Medicine
phone: 303-724-3211
e-mail: Josh.Rosenfeld@childrenscolorado.org

Sponsors & Partners
Ann & Robert H. Lurie Children’s Hospital of Chicago
Cincinnati Children’s Hospital Medical Center (CCHMC)
Northwestern University Feinberg School of Medicine
Riley Hospital for Children, Indiana University Health
Swiss EoE Clinic (Schweiz, Switzerland)
Tufts Medical Center
University of California, San Diego
University of Colorado School of Medicine (CU SOM) & Children’s Hospital Colorado (CHCO)
University of North Carolina School of Medicine (UNC)
University of Pennsylvania Perelman School of Medicine & The Children’s Hospital of Philadelphia

Updated: 04/14/2016