AllerGen Asthma&AllergicRhinitis

Evaluating Potential New Drugs

last updated: March 2015

Asthma presently affects 8.1% of the Canadian population, or 2.8 million people, and one in three Canadians will be diagnosed with asthma during their lifetime. The risk of developing asthma is comparable to that of diabetes or cancer, but while these chronic diseases tend to develop in older people, asthma is more likely to develop in the young and last a lifetime. In Ontario alone, the healthcare costs associated with asthma have reached $1.8 billion annually and without innovative disease management strategies, the cost could reach more than $96 billion in 30 years. The incidence of allergic rhinitis (AR), or hayfever, is even higher than asthma, with lifetime prevalence between 30-50%.

CLINICAL INVESTIGATOR COLLABORATIVE (CIC)

- **Conducted 20 clinical trials**
- **Established research sites in Canada and Sweden**
- **Exploring new international sites in the United Kingdom and the Netherlands**
- **Attracted over $21.5 million in new R&D investment**
- **Created 40 new jobs in the health and private sector**

An AllerGen Investment Priority

AllerGen's *Clinical Investigator Collaborative (CIC)* Legacy Project is a multi-centre Canadian-based Phase II clinical trials group enhancing drug discovery for allergic diseases, including allergic asthma, severe asthma and allergic rhinitis.

The CIC is dedicated to studying the pathobiology of these allergic illnesses and fast-tracking early stage drug candidates from proof-of-concept to use in Phase II trials with patient populations. The CIC has placed Canada at the forefront of related diagnostics and therapeutics, leading the discovery, development and commercialization of new tests and treatments for the benefit of Canadians suffering from allergic airways diseases.

Established in 2005, this consortium is globally unique in its ability to undertake early stage clinical trials to evaluate the efficacy of new molecules and compounds that treat inflammation in the lung, using well validated methods, with proprietary Standard Operating Procedures (SOPs).

AllerGen's CIC Projects

CIC-Allergic Asthma (AA)

The CIC-AA is a highly-networked project with six centres in Canada (at McMaster University, Université Laval, University of Saskatchewan, University of Alberta, The University of British Columbia and the University of Calgary) and one international site—the Karolinska Institute in Stockholm, Sweden—that have established ongoing partnerships with biopharmaceutical and biotechnology companies.

The CIC-AA ensures that each centre uses identical, well-validated research methods employing proprietary SOPs, including an allergen challenge SOP with a long-standing track record, and stringent quality assurance measures. In partnership with global pharmaceutical companies and small Canadian biotechnology companies, the CIC-AA fast-tracks potential drug candidates for allergic asthma based on the internal capabilities of the group and ready access to a well-phenotyped patient population.

CIC-AA Fast Facts

Number of clinical trials: 20

Revenue: $21.5 million

CIC members on Global Initiative for Asthma (GINA) Board of Directors: 3

The CIC-AA is now recognized as the place to study new drugs for asthma, where Canadian research excellence contributes to global pharmaceutical innovation. Each year, the CIC-AA receives many more requests for Phase II studies than it can accept.

In 2012, the CIC added the capacity to study new compounds to treat allergic rhinitis and severe asthma. This expansion positions Canada at the forefront of allergic disease therapeutics, and helps biopharmaceutical and biotechnology industries to achieve international competitiveness in the arenas of allergic and respiratory disease.

CIC-Allergic Rhinitis (AR)

Allergic rhinitis (AR), or 'hay fever' is a common condition, affecting up to 50% of the Canadian population over their lifetime. Many, if not all of the new compounds evaluated by the CIC-AA, also have a biologic rationale for efficacy in AR.

CIC-AR is a new network of allergic rhinitis researchers across Canada with expertise in conducting hay fever studies. This group has collaborated to develop a consensus protocol for nasal allergen challenge (*i.e.,* delivering allergens such as ragweed, cat allergen, *etc.* directly into a participant's nasal passage) to induce symptoms of allergic rhinitis. This team follows recently piloted and refined SOPs in the conduct of future clinical trials studying new treatments for allergic rhinitis.

CIC-AR Objectives

Provide a national platform and Standard Operating Procedures (SOPs) for industry-partnered clinical trials of novel therapeutics in allergic rhinitis

Identify and validate novel 'patient centred' biomarkers of allergic airways diseases, including rhinitis and asthma

With multiple sites across Canada, including centres in Kingston, Hamilton, Edmonton and Quebec City, the CIC-AR can evaluate new treatments for allergic rhinitis more efficiently than a single-centre study. In each CIC-AR site, biological samples are collected prior to the treatment phase, allowing for the study of allergic responses at the cellular level, thereby enhancing an understanding of this common, yet complex condition. Partnered funding from industry has been secured to help validate the revised pilot protocol, and the CIC-AR is well poised to conduct clinical investigations of allergic rhinitis across the country.

CIC-Severe Asthma (SA)

Although only 5-10% of asthmatics have severe asthma (SA), this condition accounts for over 50% of the costs related to asthma care, due in part, to a lack of understanding of the mechanisms of this disease. This knowledge gap results in inappropriate management of the condition and a paucity of new treatment strategies. Therapies currently available to treat severe asthma do not effectively address the needs of this patient group and there is an urgent need to identify new targets, and to develop and evaluate new therapies for severe asthma.

CIC-SA Objectives

Develop novel biomarkers for severe asthma and automate current diagnostic methods

Understand the mechanisms of specific types of bronchitis in severe asthma

Evaluate new therapies for specific types of bronchitis

Within the AllerGen CIC, a platform for SA studies has been developed that facilitates the evaluation of new therapies. This team is unique in its access to a well-characterized cohort of patients with severe asthma, and to specialized clinical and laboratory methods, including airway inflammometry, required to evaluate these patients available through a collaborative network for the evaluation of new treatments.

Over the next five years, the CIC-SA aims to deepen its understanding of the mechanisms of specific types of bronchitis, and to develop and apply biomarkers in sputum to treat patients with severe obstructive airway diseases.

To explore opportunities for partnership or collaboration, contact the AllerGen Administrative Centre

AllerGen NCE Inc. | McMaster University | Michael DeGroote Centre for Learning and Discovery, #3120 |
| 1280 Main Street West | Hamilton, ON | L8S 4K1 | 905-525-9140 ext. 26502 | www.allergen-nce.ca |