



Focus on: **RISK Stratification Study**

There is an urgent need for a prognostic test to predict disease complications very early in the disease in pediatric Crohn's patients. Such a test would help caregivers and clinicians make critical therapeutic decisions at the time of diagnosis. The groundbreaking RISK Stratification Study has demonstrated a combined approach to detect the risk factors present in children with Crohn's disease, which play a role in disease progression, and is paving the way for future drug discovery and therapies.

About the RISK Stratification Study

Some children diagnosed with Crohn's disease manifest mild disease course and do well with first-line medication. Inexplicably, others may develop complicated disease which may require surgery. The Crohn's & Colitis Foundation's **RISK Stratification Study**, a 10-year, \$10+ million investment, and the largest new-onset study ever completed on pediatric Crohn's disease patients, enrolled 1,800 newly-diagnosed pediatric patients at 28 clinics. Focus was put on 913 children with Crohn's disease who were complication-free 90 days after diagnosis. Researchers collected biosamples (blood, stools, biopsies) in addition to clinical, demographic, immunological, and genetic data, with the goal of identifying—at the onset of disease—signatures to predict which patients would develop the two most common complications, stricturing and penetrating disease, that typically require surgery.



Study Outcomes

Significantly, the RISK Stratification Study found that early anti-TNF therapy reduces the rate of penetrating, but not stricturing, complications, and successfully identified unique biological markers that are predictive of complications later in life. These discoveries reveal a potential new approach to precision medicine—tailoring of a medical treatment to the individual characteristics of each patient to deliver the right drug, to the right patient, at the right time—for pediatric IBD patients.

Since the publication of the RISK study results in 2017, the Crohn's & Colitis Foundation research team, in collaboration with Genedata, a leading bioinformatics company, has used artificial intelligence methods for data analysis and has identified optimized biological signatures—with improved accuracy to predict complications—with which to start the next phase of development toward a prognostic test.

Next Steps



The Crohn's & Colitis Foundation's research team has initiated a partnership with LifeArc, a nonprofit organization dedicated to advancing novel diagnostic tests to address unmet needs of patients. LifeArc has extensive experience in diagnostics development and will develop and evaluate a prototype test in close collaboration with the Foundation.

The development of a prognostic test is the culmination of years of intense focus, bringing us closer than ever to helping clinicians and caregivers determine the right treatment course at the time of diagnosis.