

Forty thousand patients, researchers, and healthcare providers come together to create \$40 million new initiative

IBD Plexus[®] is the largest and most innovative research and information exchange platform ever created. It will transform how IBD research is being conducted.

IBD Plexus involves every IBD stakeholder, including academic and industry researchers, patients of all ages, and clinicians and other healthcare providers. It is designed to form and nurture collaboration and cooperation among them -- powered by their common drive toward better care, treatments and cures.

Currently in development, this initiative incorporates data from existing Foundation programs, and from a new, prospective cohort: SPARC IBD. IBD Plexus is designed to speed progress toward precision medicine by enabling novel research, leading to better diagnostics, treatments and, ultimately, cures for Crohn's disease and ulcerative colitis.

IBD Plexus is the result of the leadership and expertise of a small group of IBD researchers, combined with the vision of generous funders, most notably The Leona M. and Harry B. Helmsley Charitable Trust. The Helmsley Charitable Trust has provided \$2 million for planning the initiative, and has committed \$17.5 million to build it out over the next three years, from 2015-2018. Additional support has also been received from industry for key components of the project.

Shifting the Research Paradigm

Convened by the Crohn's & Colitis Foundation over the years, leading IBD researchers have wanted a centralized, IBD-focused "research exchange." They envisioned a powerful resource that would house, organize and share vast amounts of de-identified patient based data that would grow as participating researchers incorporated their own findings for utilization by other researchers.

Huge amounts of data and information critical to better understanding and treating IBD is produced every day from a variety of sources, including scientific and industry research, patient care clinics, and, increasingly, patients themselves. The problem is, data-gathering activities currently occur sporadically and are uncoordinated and un-sustained. The data itself most often lies in separate silos that are inaccessible to outsiders.

In isolation -- when not linked to each other -- these various data types are of limited value in helping our understanding of IBD. However, when brought together in an organized and comprehensive way, and analyzed using sophisticated bioinformatics technology, this pool of data has the potential to yield extraordinary new opportunities for IBD research as well as for patient disease management and care.

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How It Works

IBD Plexus[®] utilizes new technology that enables scientists, researchers, clinicians and patients to capture, organize, and share large amounts of data, and to link and mine this data for new insights into Crohn's disease and ulcerative colitis.

This initiative centralizes patient registries to capture clinical, patient-reported, and derived biosample data, housed in a biobank. It will utilize a centralized analytics lab to conduct omics and expression analysis, a large data management platform to house, organize, link, and disseminate data, and a researcher portal that provides access to aggregate de-identified data sets. The prep-to-research tools enable hypothesis generation and cohort search and selection capabilities, submission of research proposals, and access to high performance cloud computing to conduct data analysis and analytics activities.

Large Data Management (LDM) Platform

The initiative's critical data storage and coordinating element is an extremely powerful large data management (LDM) platform capable of safely storing longitudinal-derived biosample and other scientific data, as well as patient self-reported, clinical, and metadata from tens of thousands of de-identified IBD patients. It will have the capacity to organize, track, and integrate this data for access by IBD researchers, caregivers, and patients.

Functionally, the LDM platform will serve as the link between all information in IBD Plexus. Its architecture will support several "classes" of interfaces to the system features and data, which will allow capture, query, and/or retrieval of information for analytics or viewing and extraction. Dedicated interfaces are also being created for patients, clinicians, researchers, and the centralized biobank collaborating with IBD Plexus. To support and facilitate research studies, the LDM platform will also develop and incorporate automated analysis tools, a library of template analysis codes, and a collection of standard queries.

The LDM platform for IBD Plexus is being developed in collaboration with Deloitte Consulting LLP.

Biobank

Academic and industry scientists have identified the lack of high-quality, well-documented biosamples as one of the biggest challenges in advancing the development of new therapeutic targets. IBD Plexus will fill this need through its biobank. The biobank will have the capacity to receive and manage tens of thousands of biosamples from IBD patients, and provide to researchers genomic and microbial profiles on adult and pediatric patients who will be followed over time. The biobank will also provide the foundation for integrative serial analysis of a range of biosamples (i.e., blood, intestinal tissue, and stool) linked to clinical, patient-reported, and metadata from other IBD Plexus cohorts.

IBD Plexus biobanking services are being provided by BioStorage Technologies, a leader in critical biologic material management.

Cloud Hosting and Analyzing

IBM SoftLayer has been selected to host the IBD Plexus solution. SoftLayer's hybrid cloud infrastructure approach accommodates the strict patient health information security and regulatory demands while also providing the necessary scalable infrastructure capabilities to accommodate storage of large amounts of data derived from high-throughput technologies, in addition to the ability to provision on-demand high performance cloud clusters to allow researchers to conduct extensive analysis.

IBD Plexus incorporates and integrates existing Foundation initiatives including CCFA Partners, the Pediatric RISK Stratification Project, IBD Qorus (a quality of care cohort), and SPARC IBD, a prospective adult clinical cohort.

CCFA Partners

Since 2011, the Crohn's & Colitis Foundation has collaborated with the University of North Carolina School of Medicine (UNC) to create CCFA Partners, a "patient-powered research network" for IBD. CCFA Partners uses state-of-the-art bioinformatics to engage and gather information from patients that researchers then study and analyze along with clinical and other patient-generated data (e.g., biosample and derived data) from IBD Plexus[®]. This expanding program is the patient-facing aspect of IBD Plexus, providing self-reported and other data for over 14,000 patients. CCFA Partners also provides participants with tools to better manage their disease and help shape the research agenda by proposing and evaluating research questions.

Register as a researcher at: <https://cgibd.med.unc.edu/ccfapartners/forresearchers.php>.

Pediatric Risk Stratification Initiative

In 2005, the foremost Pediatric IBD basic and clinical researchers met with the medical leadership of the Crohn's & Colitis Foundation to set priorities in pediatric science and further pediatric IBD treatment and research. Today, every major pediatric IBD center in America is touched by the work or funding of the Foundation.

The Pediatric Risk Stratification Initiative is working to "crack the code" of disease prognosis by identifying measurable risk factors for the complications of severe disease. The Foundation's Pediatric Resource Organization for Kids with Inflammatory Intestinal Diseases (PRO-KIIDS) is committed to identifying the genetic, microbiological, and immunological factors that are predictive of more severe disease. The resulting knowledge will translate into new protocols for individualized approaches to treating IBD in children and the prevention of severe disease and its lifelong consequences.

Member sites include:

- Cedars Sinai Medical Center
- Children's Healthcare of Atlanta
- Connecticut Children's
- Goryeb Children's /Atlantic Heath
- Harvard Children's Boston
- IWK Health Centre
- John Hopkins Children's
- Medical College of Wisconsin
- Nationwide Children's Hospital
- University of Chicago
- Women's & Children's Hospital Buffalo

- University of California San Francisco
- Primary Children's Medical Center Utah
- BCM Texas Children's Hospital Houston
- Children's Hospital Philadelphia CHOP
- UNC Chapel Hill
- Cincinnati Children's
- Children's Center for Digestive Health Care
- Cohen Children's
- Riley Children's Hospital Indiana
- Rhode Island Hospital
- Children's Hospital of Pittsburgh
- Monroe Carell Jr Children's at Vanderbilt
- University of Texas Southwestern Dallas
- Nemours Children's Clinic Jacksonville

IBD Qorus™

IBD Plexus will incorporate and manage data resulting from the Crohn's & Colitis Foundation's expanding Quality of Care Program for adult IBD practices. Ten academic, clinical sites will be enrolled in the program by next year, yielding clinical and care data of all types on individual patients.

As a key component of IBD Plexus, IBD Qorus will afford many synergies across the spectrum of IBD research. It will provide patient clinical data that can be analyzed with other cohorts to enable additional research and early discoveries, particularly related to clinical questions, and complementing the extensive basic and translational research efforts to be supported by IBD Plexus.

Participating IBD Qorus Centers:

- Baylor College of Medicine, Houston, TX
- Cedars-Sinai Medical Center, Los Angeles, CA
- Dartmouth-Hitchcock Medical Center, Lebanon, NH
- Gastro-1, Memphis, TN
- Gastroenterology Associates, Providence, RI
- Georgetown University Hospital, Washington, DC
- Henry Ford Hospital, Detroit, MI
- Midwest Gastroenterology, Omaha, NE
- Northwestern University, Chicago, IL
- Oregon Clinic, Portland, OR
- Penn State, Hershey, PA
- Physicians Group Gastroenterology, Oklahoma City, OK

- Saratoga-Schenectady Gastroenterology Associates, Saratoga Springs, NY
- Shreveport Gastrointestinal Specialists, Shreveport, LA
- UC San Diego School of Medicine, San Diego, CA
- University of Chicago, Chicago, IL
- University of North Carolina, Chapel Hill, NC
- University of Southern California, Los Angeles, CA
- University of Washington Medical Center, Seattle, WA
- Winthrop Gastroenterology, Mineola, NY

For more information, [contact Alandra Weaver](#).

SPARC IBD

The Study of a Prospective Adult Research Cohort with Inflammatory Bowel Disease (SPARC IBD) is a multi-centered longitudinal study of adult IBD patients which will collect and link clinical data, self-reported outcome data, and serial biosamples through the course of the patients' disease. Data and samples will then be used for basic, clinical, and translational research that will lead to precision medicine strategies and new therapeutic targets that will improve the quality of life of patients with IBD. The specific aims for the initial phase of the study are:

- Enroll and follow 7,000 well-phenotyped adult IBD patients aged 18 years or older (CD, UC, or IBD unspecified)
- Identify predictors of response to IBD therapies from clinical, patient reported, genetic, genomic, transcriptomic, metabolomics, and microbiomic data
- Identify predictors of disease relapse among responders to therapies for IBD from clinical, patient reported, genetic, genomic, transcriptomic, metabolomics, and microbiomic data

Participating SPARC IBD sites:

- Brigham & Women's Hospital
- Cedars-Sinai Medical Center
- Mayo Clinic
- University of Maryland
- University of Michigan
- University of Pennsylvania
- University of Pittsburgh
- University of Wisconsin

For more information, [contact Cecile Norris, CCRC, Research Program Manager](#).

Leadership Team

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The IBD Plexus[®] Leadership Team is accountable for ensuring that IBD Plexus is built and carried out in accordance with its mission. The team will oversee the day-to-day conduct of IBD Plexus and will lead development and implementation of all policies and guidelines. They are responsible for the governance and quality of biosamples, data, and derived data. Additionally the team will consult and support the development of associated studies using the IBD Plexus infrastructure and monitor the use of distributed samples and data that are approved by the project selection committee.

Chief Scientist

James Lewis, MD, MSCE

**Professor of Medicine and Clinical Epidemiology
University of Pennsylvania**

James Lewis, MD, MSCE, is Professor of Medicine and Epidemiology and Senior Scholar in the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania's Perelman School of Medicine in Philadelphia, PA. Dr. Lewis has been actively involved in clinical research related to inflammatory bowel diseases, medication safety, and optimizing medical therapies for more than 15 years. During the last five years, he has additionally focused on the impact of diet on the gut microbiome and the course of inflammatory bowel disease. He has employed a various research methods to address these questions, ranging from mathematical modeling to placebo-controlled randomized trials. His work has been funded by the NIH, AHRQ, PCORI, and numerous foundations and corporate sponsors. Dr. Lewis previously served as the Chair of the National Scientific Advisory Committee for the Crohn's & Colitis Foundation and as associate editor for *Gastroenterology* and *Pharmacoepidemiology and Drug Safety*.



Associate Chief Scientist, Patient-Powered Research

Mike Kappelman, MD, MPH

**Associate Professor
University of North Carolina
Scientific Director of CCFA Partners**

Michael D. Kappelman, MD, MPH is a pediatric gastroenterologist at the University of North Carolina at Chapel Hill with an interest in the clinical care of children and young adults with inflammatory bowel diseases. He also devotes considerable effort to quality improvement and epidemiological and outcomes research in this area. This includes studies of the prevalence, natural history, costs, and utilization of resources by children and adults with IBD, as well patient-centered outcomes research and comparative effectiveness and safety research. His research is funded through the NIH, the Crohn's & Colitis Foundation, AHRQ, PCORI, and industry.



Dr. Kappelman is an Associate Professor at the University of North Carolina at Chapel Hill, Director of Data Management for the ImproveCareNow pediatric IBD network, and currently serves as Chair of the Foundation's Pediatric Affairs Committee.

Associate Chief Scientist, Translational Research

Richard H. Duerr, MD

University of Pittsburgh

Richard H. Duerr, MD, is the Inflammatory Bowel Disease Genetic Research Chair, Professor of Medicine, Human Genetics, and Clinical and Translational Science, and Co-Director and Scientific Director at the University of Pittsburgh Medical Center Inflammatory Bowel Disease Center. Dr. Duerr has been involved in research related to inflammatory bowel diseases throughout his career. He leads one of six genetic research centers that comprise the NIH/NIDDK Inflammatory Bowel Disease Genetics Consortium. His research program has had uninterrupted funding from the NIH, the Crohn's & Colitis Foundation, and other foundations since 1995.

Dr. Duerr is a member of the American Gastroenterological Association, the American Society of Human Genetics, and the Crohn's & Colitis Foundation. He has been an invited lecturer in local, national and international venues, and he has published original inflammatory bowel disease genetics research articles in journals such as *Nature*, *Science*, *Nature Genetics*, *American Journal of Human Genetics*, and *Human Molecular Genetics*. He has served on grants review committees for the NIH and the Foundation.

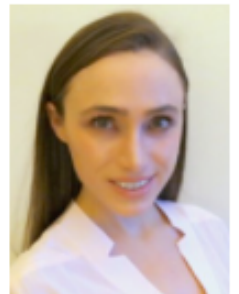


IBD Plexus Director

Angela Dobes, MPH

Angela Dobes is the IBD Plexus program Director at the Crohn's & Colitis Foundation. Angela has more than 10 years of experience in the health care industry. In addition to her experience at the Foundation, Angela has previously worked for clinical technology and pharmaceutical organizations, where she has led implementation of various technology solutions focused on accelerating the delivery of new therapies to patients safely. Angela has also conducted research in the fields of managed care and patient engagement and is a member of the CCFA Partners Research Team.

Angela holds an undergraduate degree in Chemical Engineering from Lehigh University and she earned her graduate degree in Public Health from the Icahn School of Medicine at Mount Sinai.



What is IBD Plexus?

IBD Plexus is the largest and most innovative research and information exchange platform ever created. IBD Plexus has the capacity to aggregate and analyze various types of data and information critical to understanding, treating and curing Crohn's disease and ulcerative colitis (together known as inflammatory bowel diseases, or IBD). Named for its intricate network of parts, this initiative is designed to accelerate research and transform the care of the estimated 1.6 million Americans living with IBD.

How will IBD Plexus work?

IBD Plexus will utilize new technology that enables scientists, researchers, clinicians, and patients to capture, organize, and share large amounts of patient data, and to link and mine this data for new insights into IBD. When fully operational in 2018, IBD Plexus will combine or build databases with clinical information and self-reported data on more than 40,000 IBD patients, along with genomic and microbial profiles patients who will be followed over time.

The various components of IBD Plexus will provide the infrastructure and capacities to dramatically shift the IBD research paradigm by facilitating novel, potentially groundbreaking studies into the causes and treatments of IBD.

What is the significance of IBD Plexus?

Huge amounts of data and information, which are critical to better understanding and treating IBD, is produced every day from a variety of sources -- including scientific and industry research, patient care clinics, and patients themselves. The problem is, data gathering activities currently occur sporadically and are uncoordinated and un-sustained. The data itself most often lies in a separate silo that is inaccessible to outsiders. When not linked to each other, these various data types are of limited value in helping us develop better treatments and cures for IBD. However, brought together in an organized and comprehensive way, and analyzed using sophisticated bioinformatics technology, this pool of data has the potential to yield extraordinary new opportunities for IBD research as well as for patient disease management and care.

IBD Plexus will create the largest registry of IBD patients of all ages in the world. Access to patient's genetic, biological, clinical, and self-reported information – with the capacity to compare and analyze each data type as it relates to the others – has the potential to shift the paradigm in IBD research. Ultimately, IBD Plexus will enable healthcare providers to practice what is known as precision medicine, in which they are providing treatment that is laser tailored to the needs of a unique patient.

What are the components of IBD Plexus?

The structure of IBD Plexus includes a large data management platform, a biobank, and a cloud hosting and analyzing tool.

- **Large Data Management (LDM) Platform**

IBD Plexus' critical data storage and coordinating element is an extremely powerful large data management (LDM) platform capable of safely storing longitudinal derived biosamples and other scientific data, as well as patient self-reported, clinical, and meta data, from tens of thousands of de-identified IBD patients. It will have the capacity to organize, track, and integrate this data for access by IBD researchers, caregivers, and patients. The LDM platform will serve as the link between all information in IBD Plexus. Its architecture will support several "classes" of interfaces to the system features and data, which will allow capture, query, and/or retrieval of information for analytics or viewing and extraction. Dedicated interfaces are being created for patients, clinicians, researchers, and the centralized biobank collaborating with IBD Plexus. To support and facilitate research studies, the LDM platform will also develop

and incorporate automated analysis tools, a "library" of template analysis codes and a collection of standard queries. IBD Plexus' LDM platform is being developed in collaboration with Deloitte Consulting LLP.

- **Biobank**

The IBD Plexus biobank will have the capacity to receive and manage tens of thousands of biosamples from IBD patients and provide to researchers genomic and microbial profiles on adult and pediatric patients, who will be followed over time. The biobank will also provide the foundation for integrative serial analysis of a range of biosamples (i.e. blood, intestinal tissue, and stool) linked to clinical, patient-reported, and metadata from other IBD Plexus cohorts.

IBD Plexus biobanking services are being provided by BioStorage Technologies, a leader in critical biologic material management.

- **Cloud Hosting and Analyzing**

IBM SoftLayer has been selected to host the IBD Plexus application. SoftLayer's hybrid cloud infrastructure approach accommodates the strict patient health information security and regulatory demands while also providing the necessary scalable infrastructure capabilities to accommodate storage of large amounts of data derived from high-throughput technologies, in addition to the ability to provision on-demand high performance cloud clusters to allow researchers to conduct extensive analysis.

How will the patient registry be created?

IBD Plexus will create the largest registry of IBD patients of all ages in the world. Patients will come from existing Foundation initiatives, including CCFA Partners, Pediatric RISK Stratification Study, IBD Qorus (a quality of care cohort), and SPARC IBD (a prospective adult clinical cohort).

Who will benefit from IBD Plexus?

IBD Plexus will engage and involve every IBD stakeholder, including the IBD community (i.e., patients of all ages, their families, and caregivers), academic and industry researchers, and clinicians and other healthcare providers. It is being designed to form and nurture collaboration and cooperation among them – powered by their common drive toward better care, treatments, and cures for IBD.

- **IBD Patients**

IBD Plexus will deliver new therapies that will keep IBD in remission; provide better tools to help select the right therapy for the right patient (personalized medicine); and identify practical ways to reduce variability in the quality of care for individual patients.

- **Researchers**

IBD researchers need access to research-quality, linked, longitudinal clinical data, and biosamples from carefully characterized (i.e. phenotyped and genotyped) patients, and the computing and bioinformatics resources and expertise to most efficiently and effectively analyze these data to discover new treatment targets, and biomarkers to guide optimal use of existing therapies. IBD Plexus will meet these needs.

- **Clinicians**

The Crohn's & Colitis Foundation's focus on patient quality of care aligns with the country's shift to "value-based care," a critical aspect of today's healthcare reform. The expanding network of IBD clinics participating in IBD Qorus -- the Foundation's Quality of Care initiative -- will track and report clinical and patient outcomes data that will be analyzed through IBD Plexus to help codify and disseminate the best treatment, administered properly. This will result in increased time in remission for IBD patients, and the forestalling or prevention of ongoing intestinal inflammation.

How was IBD Plexus created?

Leading IBD researchers, convened by the Crohn's & Colitis Foundation over the years, have repeatedly pointed to the potential of a centralized, IBD-focused "research exchange" to meet the demand from both the medical and patient communities for new therapies; better tools to help select the right therapy for the right patient; and practical ways to reduce variability in the quality of care for individual patients. The researchers envisioned a powerful resource that would house, organize, and share vast amounts of de-identified patient-based data -- a resource, moreover, that would grow as researchers who used its information incorporated their own findings for utilization by future researchers.

With seed money provided by The Leona M. and Harry B. Helmsley Charitable Trust, the Foundation embarked on a two-year discovery and planning process to conceptualize and design IBD Plexus. Dr. James Lewis, professor of medicine and clinical epidemiology at the University of Pennsylvania and Chief Scientist for IBD Plexus, led a small group of IBD researchers who developed the plans to create this game-changing resource. At the end of this planning process in early 2015, the Helmsley Charitable Trust awarded the Foundation an additional \$17.5 million to support the development and implementation of IBD Plexus. The initiative has already made significant progress in its build out phase.

What are the key partnerships that enable IBD Plexus?

There are several key IBD Plexus partnerships, including the Helmsley Charitable Trust, Deloitte Inc., BioStorage Technologies, and IBM. We have also established an Industry Affairs workgroup where we brought together representatives from seven leading pharmaceutical and nutrition companies to help inform the design and operations of IBD Plexus and guide roadmap development. We leveraged our Patient Powered Research Network Patient Governance Committee to improve the patient experience for CCFA Partners and find ways to better reach patients who are interested in research and self-monitoring. In addition, we are engaging academia, industry, and lay stakeholders in development of key policies for IBD Plexus including data and biosample sharing strategies and publication policies.

How is IBD Plexus going to be different than the numerous other registries / biobanks that exist in this space?

IBD Plexus will provide numerous benefits that do not exist in standalone efforts. Researchers will have access to large amounts of uniform longitudinally-collected data and samples across multiple distinct study cohorts. Through directly accessing data found in electronic medical records (EMR), IBD Plexus will allow clinicians participating in the program to continue their routine care regimen with minimal disruption. Use of EMR will also enhance the completeness of data collected.

IBD Plexus will also allow researchers to share knowledge more rapidly through data deposition prior to manuscript publication, where a critical success factor for IBD Plexus will be ensuring end users trust that the data. Accordingly, a central analytical lab(s) will be selected to optimize use of these samples and assure that derived data is of high quality and reusable. Finally, IBD Plexus is the first ever partnership of patients, caregivers, healthcare providers, scientists, private supporters, and industry all coming together with a common goal: to accelerate research and transform the care of patients.

How can I get involved in IBD Plexus?

If you are a patient, a great way to support IBD Plexus is to enroll in CCFA Partners. It only takes 20 minutes of your time twice a year. By enrolling in CCFA Partners, you can make a valuable contribution to the research process and gain access to tools to better manage your disease and help shape the research agenda by proposing and evaluating research questions. This expanding program is the patient-facing aspect of IBD Plexus, providing self-reported and other data over 14,000 patients.

If you are a researcher or a healthcare provider, we encourage you to learn more by continuing to visit ccfa.org for updates. You can also reach out to Angela Dobes, the Foundation's IBD Plexus Director, at adobes@ccfa.org.