

IBD PLEXUS OVERVIEW



**IBD
PLEXUS**



IBD Plexus maximizes opportunities for IBD research

A national-scale research exchange platform designed to:

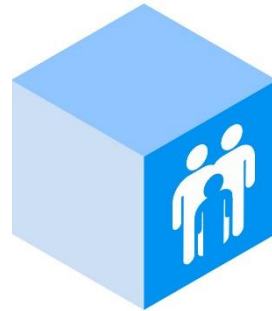
- Centralize data & biosamples from diverse research cohorts, clinical care settings and patients' experiences
- Enrich patient datasets through researcher-initiated data generation projects
- Advance science and accelerate progress towards precision medicine
- Transform the care of IBD patients

IBD Plexus is designed to support activities across the research continuum.



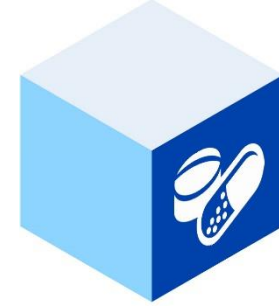
Discovery

- Drug target discovery
- Biomarker identification
- Hypothesis validation



Clinical development

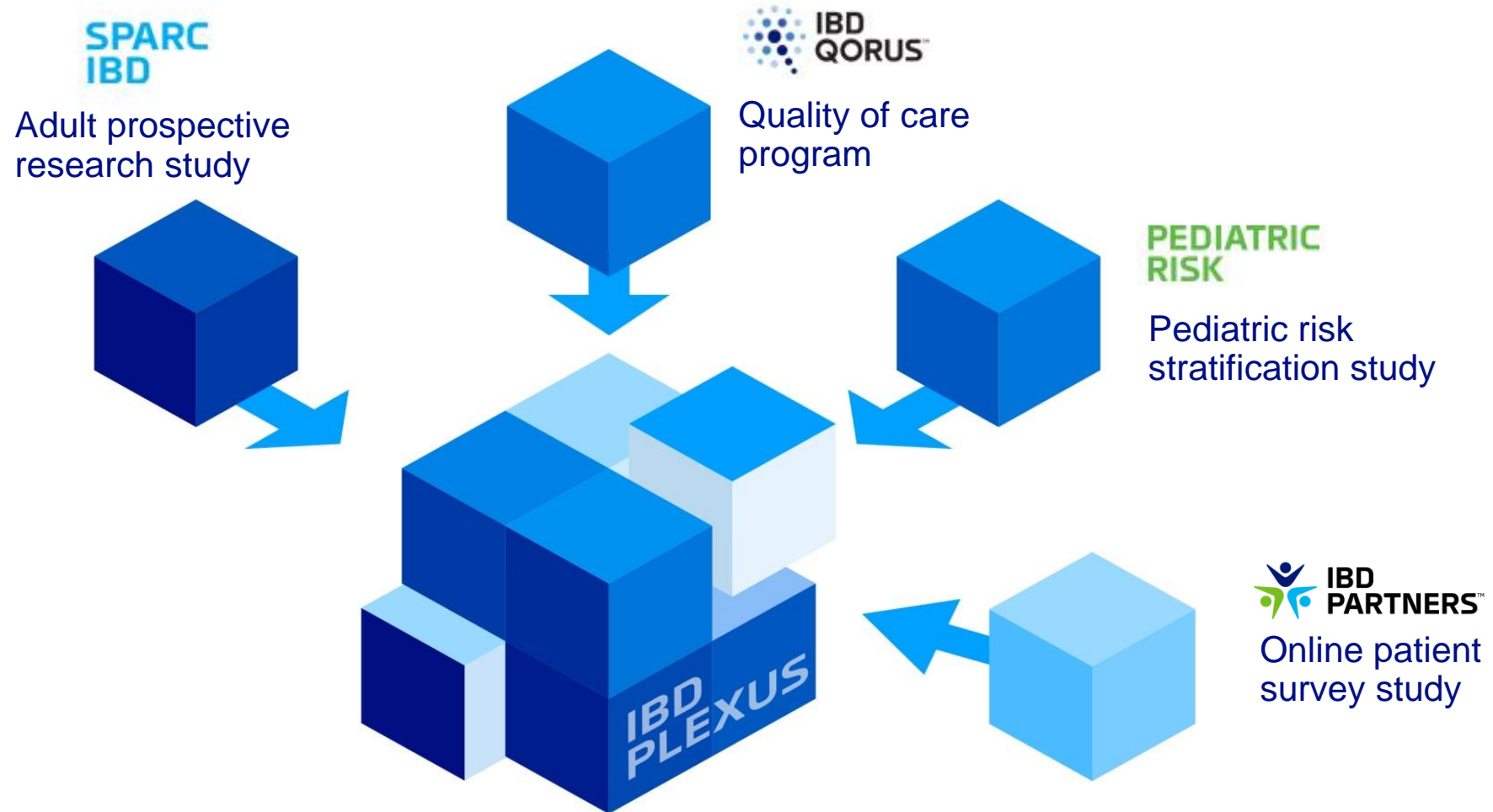
- Study feasibility
- Protocol development & refinement
- Clinical trial support



Post approval

- Safety surveillance
- Post-marketing commitments
- Comparative effectiveness
- Outcomes research
- Healthcare utilization

Diverse research programs for cutting-edge research



Real world data integrated and linked within and across research programs



Patient surveys

- IBD symptoms
- Hospitalization
- Medications
- Experiences



Electronic case report forms

- IBD SmartForm*
 - Longitudinal phenotypic and clinical data
 - Disease severity scores
- Endoscopy / colonoscopy results

* Embedded in medical record for sites with Epic



Lab

- Fecal calprotectin
- High-sensitivity CRP



Molecular data

- Genetics
- Genomics
- Transcriptomics
- Metabolomics
- Proteomics
- Microbiome

Biosamples

- Blood
- Intestinal tissue
- Stool



Medical record

- In-patient and out-patient health record data (*Dx, history, problems, procedures, labs, medications, observations*)

Patient enrollment as of February 01, 2020

**SPARC
IBD**

3,149 adults

- 66% CD
- 32% UC
- 2% IBD-U

**PEDIATRIC
RISK**

**1,812 pediatric
patients**

- 62% CD
- 8% UC
- 10% IBD-U
- 20% Non-IBD

**IBD
QORUS™**

3,893 adults

- 61% CD
- 36% UC
- 3% IBD-U

**IBD
PARTNERS™**

16,000 adults

- 62% CD
- 35% UC
- 3% IBD-U



Research Cohorts Overview

Objective: to identify predictors of response to IBD therapies and predictors of disease relapse among responders to therapies

Characteristics: Adult, CD, UC, IBD-unclassified (IBDU), longitudinal data & samples

Study Profile	Data & Biosamples	Study Features
<ul style="list-style-type: none">• Prospective• Longitudinal• 17 US sites	<ul style="list-style-type: none">• Clinical data• Patient-reported data• EHR data• Biosamples:<ul style="list-style-type: none">• Blood• Intestinal tissue• Stool• Molecular data:<ul style="list-style-type: none">• Genotyping• Transcriptomics• Metagenomics• Additional lab data:<ul style="list-style-type: none">• Calprotectin	<ul style="list-style-type: none">• Standard data & biosample collection & molecular data generation processes• Improved tracking of patient's phenotypic data within EMR system through use of IBD SmartForm

Objective: to improve the quality of care delivered to patients by defining standards of care for IBD, measuring, and improving the impact on patient outcomes

Characteristics: Adult, CD, UC, IBDU, longitudinal data

Study Profile	Data	Study Features
<ul style="list-style-type: none">• Nationwide, learning health collaborative• 40 sites; academic, community & private practices• Tracking outcome and process measures	<ul style="list-style-type: none">• Clinical data• Patient-reported data• EHR data	<ul style="list-style-type: none">• Improved patient engagement• Population management• Improved urgent care vs ER visits• Development of clinical care pathways• Strengthened patient/provider relationship

PEDIATRIC RISK

Objective: to identify, at diagnosis, measurable risk factors for developing complications and severe course of disease in pediatric patients

Characteristics: Pediatric, Crohn's, longitudinal, 5-year follow-up

Study Profile	Data & Biosamples	Study Features
<ul style="list-style-type: none">• Enrollment: 1,812<ul style="list-style-type: none">• 1,134 Crohn's disease pediatric patients<ul style="list-style-type: none">• UC = 142• IBDU = 179• Non-IBD = 357• Inception cohort (treatment-naïve)• 25 sites in US; 3 in Canada	<ul style="list-style-type: none">• Clinical data• Molecular data:<ul style="list-style-type: none">• Genotyping• Transcriptomics• Metagenomics• Biosamples:<ul style="list-style-type: none">• Blood<ul style="list-style-type: none">• DNA, Plasma• Intestinal Tissue• Extracted DNA• Extracted RNA• Stool	<ul style="list-style-type: none">• Model for risk stratification at diagnosis

Objective: to empower IBD patients, researchers, and providers to partner in finding answers to research questions patients care about and ultimately improve the health and lives of patients living with these conditions

Characteristics: Online survey, patient-reported outcomes & patient-generated data

Study Profile	Data	Study Features
<ul style="list-style-type: none">• Internet-based (any patient globally can sign up)	<ul style="list-style-type: none">• Patient-reported data• Patient-generated data (wearables; apps)• Baseline & 6-month longitudinal follow-up surveys• Ancillary surveys	<ul style="list-style-type: none">• Understanding issues facing IBD patients• Vehicle for additional ancillary studies• Over 48 manuscripts

IBD Plexus Molecular data: RISK & SPARC

Service	RISK		SPARC IBD	
	Samples	Patients	Samples	Patients
ImmunoChip <i>(genotyping)</i>	1,456 blood DNA	1,456		
Global screening array <i>(genotyping)</i>	1,000 blood DNA	982	2,000 blood DNA	2,000 CD & UC
Whole exome sequencing <i>(genomics)</i>			2,000 blood DNA	2,000 CD & UC
RNAseq - 10 M reads <i>(transcriptomics)</i>	778 baseline tissue 10 follow-up tissue	565		
RNAseq – 30 M reads <i>(transcriptomics)</i>	850 baseline tissue 44 follow-up tissue	540 63	1,089 baseline tissue 116 follow-up tissue	350 CD
16S <i>(rDNA sequencing)</i>	888 (tissue and stool)	625		
WGS - bacteria and fungi <i>(metagenomics)</i>	295 baseline stool	295	400 baseline stool CD	400 CD
WGS viruses <i>(metagenomics)</i>	100 baseline stool	100	100 baseline stool CD	100 CD
Methylation <i>(epigenetics)</i>	402 baseline and follow-up blood DNA	238		