

# IBD Plexus® High-Level Overview for CDA Applicants

2021



**IBD  
PLEXUS®**

**CROHN'S & COLITIS  
FOUNDATION**



# IBD Plexus® is the largest US registry with biosamples in the IBD field



**9** pharmaceutical  
company members



**4** biotechnology  
member

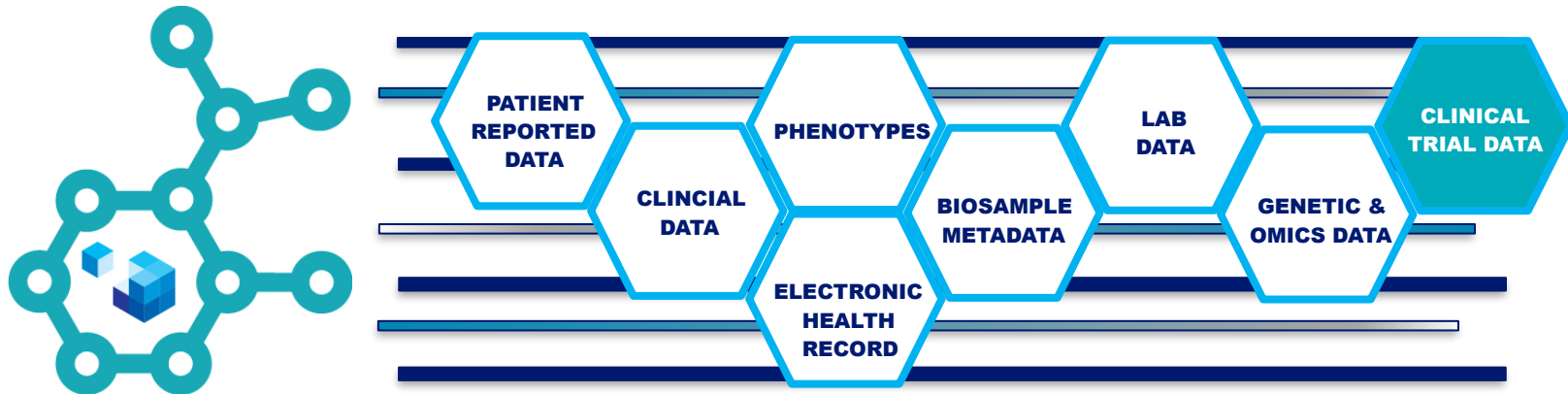


**90** academic and  
medical centers

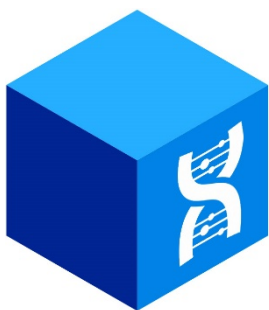
Over **25,000** patients participating in IBD Plexus cohorts



A national scale, **integrated**, real-world data platform designed to achieve the **full picture** of a patient's disease journey

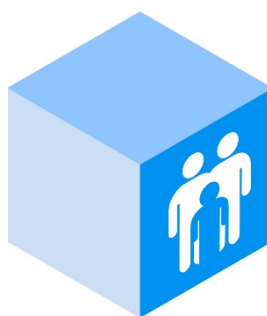


# Acceleration of activities across the drug development lifecycle



## Discovery

- Hypothesis testing
- Drug target discovery
- Biomarker identification



## Clinical development

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



## Real-world evidence

- Product differentiation
- Outcomes research
- Health systems research
- Post-marketing commitments
- Regulatory application support
- Formulary support

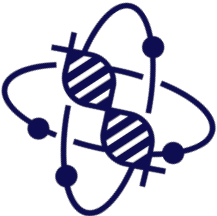
# The fastest-growing IBD real-world database and biobank



- Over 8,800 adult IBD patients enrolled through provider sites
- Over 1,400 pediatric IBD patients enrolled through provider sites
- Over 15,200 IBD patients self-enrolled through online platform



- Over 3,500 adult IBD patients with biosamples
- Over 1,300 pediatric IBD patients with biosamples



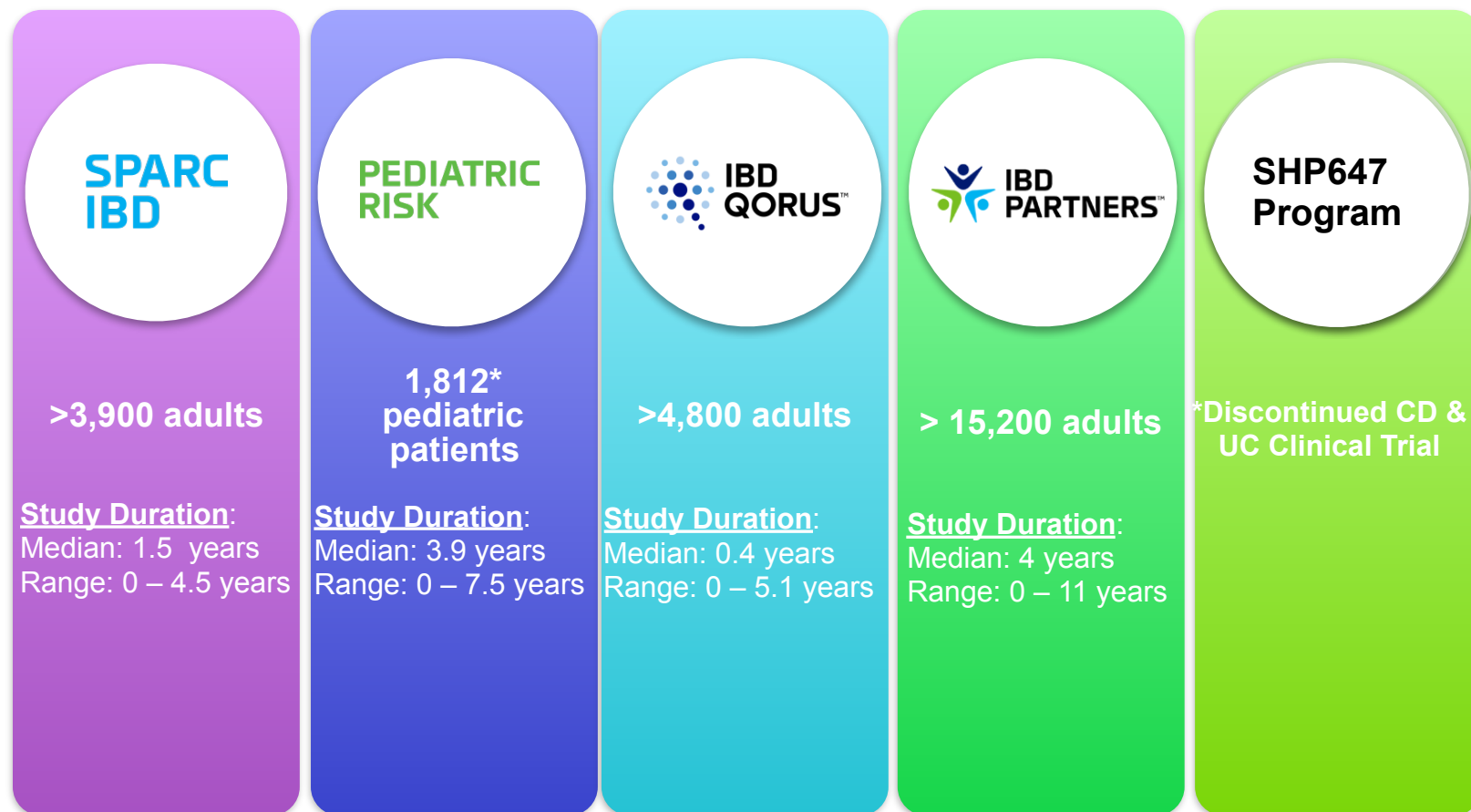
- Over \$4 million dollars of molecular data generated:
  - Over 2,300 adult IBD patients with molecular data
  - Over 1,300 pediatric IBD patients with molecular data



- Over 5,900 adult IBD patients with electronic health record data
- Medium of 10 years of electronic health record data per patient

# Study Programs

# Diverse research programs integrated for cutting edge research



\* Enrollment has stopped

\* More details to come

# Program Characteristics

Characteristics	RISK	SPARC IBD	IBD Qorus	IBD Partners
<b>Gender</b>				
Female	42%	55%	56%	72%
Male	58%	45%	44%	28%
<b>Age at enrollment</b>				
< 21	100%	24%	24%	4%
21 - 40	n/a	37%	35%	45%
41 - 60	n/a	30%	30%	38%
> 60	n/a	9%	11%	13%
<b>Diagnosis at enrollment</b>				
Crohn's Disease	63%	66%	57%	62%
Ulcerative Colitis	8%	32%	40%	35%
IBD-U	10%	2%	3%	2%
Not IBD	20%	n/a	n/a	n/a
<b>Medications</b>				
5-ASAs	43%	25%	26%	48%
Antibiotics	35%	9%	6%	12%
Biologics	44%	71%	75%	44%
Immunomodulators	51%	32%	37%	33%
Steroid therapies	61%	16%	12%	30%
<b>Biologics breakdown</b>				
Adalimumab	13%	27%	12%	20%
Certolizumab	1%	3%	2%	5%
Golimumab	n/a	0.8%	1%	0.6%
Infliximab	40%	35%	48%	21%
Natalizumab	0.2%	0.1%	0.5%	0.9%
Ustekinumab	n/a	16%	8%	2%
Vedolizumab	n/a	19%	28%	5%



**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 collected across 17 US sites



Patient  
surveys

- IBD symptoms
- Hospitalization
- Medications
- Experiences
  - Pain
  - Fatigue
  - Social Isolation



Electronic case  
report forms

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



Lab

- Fecal calprotectin
- High-sensitivity CRP



Medical  
record

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



Molecular  
data

- Genotyping
- Whole exome sequencing
- Transcriptomics
- Proteomics
- Microbiome

Biosamples

- Blood
- Intestinal tissue
- Stool

\* Embedded in medical record for sites with Epic

# Molecular data: SPARC IBD

Service	SPARC IBD		
	Samples	Patients	
Global screening array (genotyping)	2,950 blood DNA	Collection Time Period: Anytime CD: 1,949 UC: 948 IBD-U: 53	
Whole exome sequencing (genomics)	2,949 blood DNA	Collection Time Period: Anytime CD: 1,947 UC: 949 IBD-U: 53	
Total RNAseq @ 50M reads (transcriptomics)	1,780 enrollment tissue 207 follow-up tissue	Collection Time Period: Enrollment CD: 369, 35, 211 UC: 204, 110 IBD-U: 14	Collection Time Period: Follow-up CD: 48, 22 UC: 23, 17
FFPE digitization	1,342 enrollment tissue	Collection Time Period: Enrollment CD: 396 UC: 204 IBD-U:14	Collection Time Period: Follow-up CD: 48 UC: 23
WGS - bacteria and fungi (metagenomics)	1,433 enrollment stool 367 follow-up stool	Collection Time Period: Enrollment CD: 913 UC: 192 IBD-U: 26	Collection Time Period: Follow-up CD: 150 UC: 103 IBD-U: 5
WGS viruses (metagenomics)	247 enrollment stool	Collection Time Period: Enrollment CD: 100 UC: 148	

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

Study Profile	Data & Biosamples	Study Features
<ul style="list-style-type: none"><li>• Inception cohort (treatment-naïve)</li><li>• 25 sites in US; 3 in Canada</li></ul>	<ul style="list-style-type: none"><li>• Clinical data</li><li>• Molecular data:<ul style="list-style-type: none"><li>• Genotyping</li><li>• Transcriptomics</li><li>• Metagenomics</li></ul></li><li>• Biosamples:<ul style="list-style-type: none"><li>• Blood<ul style="list-style-type: none"><li>• DNA, Plasma</li></ul></li><li>• Intestinal Tissue<ul style="list-style-type: none"><li>• Extracted DNA</li><li>• Extracted RNA</li></ul></li><li>• Stool</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Model for risk stratification at diagnosis</li></ul>

# Molecular data: RISK

Service	RISK	
	Samples	Patients
Immunochip ( <i>genotyping</i> )	1,456 blood DNA	1,456
Global screening array ( <i>genotyping</i> )	1,000 blood DNA	982
Protein expression ( <i>proteomics</i> ) 13 Olink Panels, 1196 proteins	250 plasma	250
RNAseq @ 10 M reads ( <i>transcriptomics</i> )	778 (baseline tissue) 10 (longitudinal tissue)	565 10 (longitudinal)
RNAseq @ 30 M reads( <i>transcriptomics</i> )	850 baseline tissue 44 longitudinal tissue	567 29 (longitudinal)
RNAseq from FFPE slides	188 baseline FFPE slides 281 longitudinal FFPE slides 24 unknown timepoint FFPE slides	183 (baseline) 169 (longitudinal) 24 (unknown timepoint)
16S ( <i>rDNA sequencing</i> )	888 tissue and stool	625
WGS - bacteria and fungi ( <i>metagenomics</i> )	295 baseline stool	295
WGS viruses ( <i>metagenomics</i> )	100 baseline stool	100
Methylation ( <i>epigenetics</i> )	402 baseline and follow-up blood DNA	238

**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, IBD-unclassified (IBDU), longitudinal data collected across 40 US sites



Patient  
surveys

- IBD symptoms
- Hospitalization
- Medications



Electronic case  
report forms

- Longitudinal  
phenotypic and  
clinical data



Medical  
record

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

**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"><li>• Internet-based (any patient globally can sign up)</li></ul>	<ul style="list-style-type: none"><li>• Patient-reported data</li><li>• Patient-generated data (wearables; apps)</li><li>• Baseline &amp; 6-month longitudinal follow-up surveys</li><li>• Ancillary surveys</li></ul>	<ul style="list-style-type: none"><li>• Understanding issues facing IBD patients</li><li>• Vehicle for additional ancillary studies</li><li>• Over 52 abstracts &amp; 41 manuscripts</li></ul>