IBD Plexus®
SRA Information Session

2020

IBD PLEXUS®
CROHN'S & COLITIS FOUNDATION

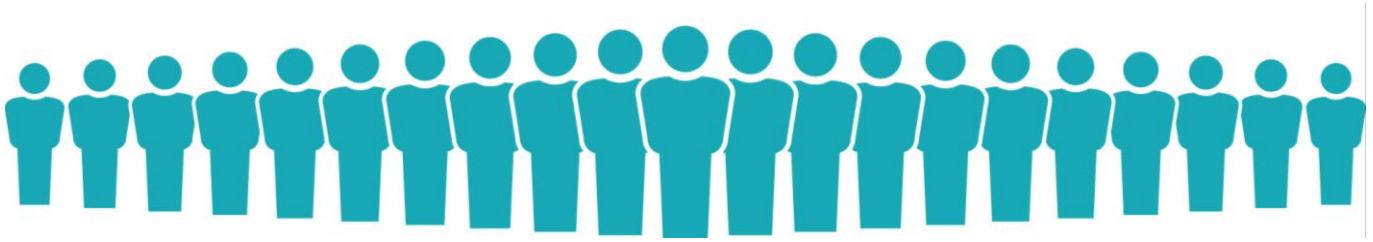
IBD Plexus® is the largest US registry with biosamples in the IBD field

8 pharmaceutical company members

1 biotechnology member

85 academic and medical centers

Over **24,000** patients participating in IBD Plexus cohorts



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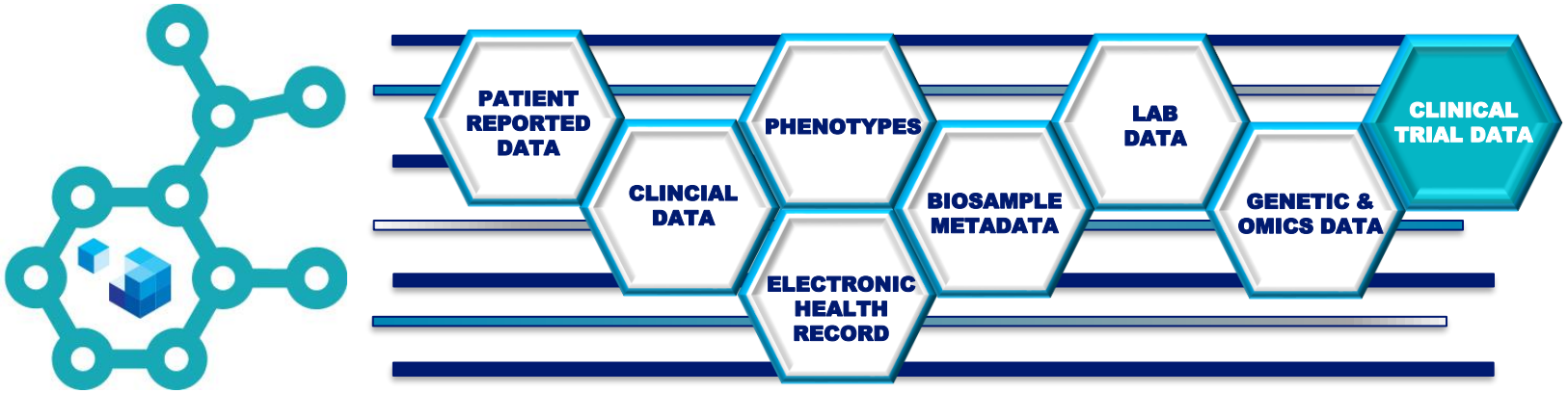
A national scale, integrated, real-world data platform designed to achieve the full picture of a patient's disease journey



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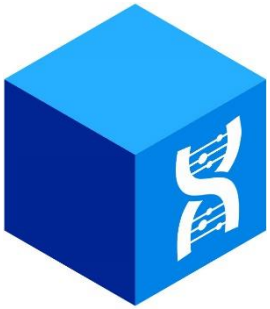
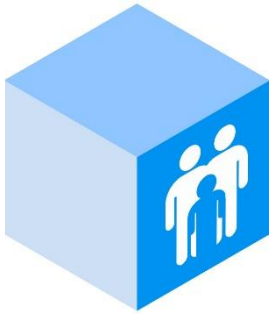
Acceleration of activities across the drug development lifecycle



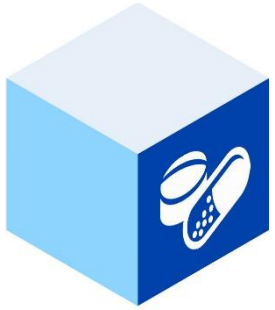
Discovery

- 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

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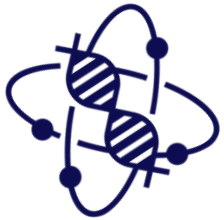
The fastest-growing IBD real-world database and biobank

- Over 7,600 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 3,000 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 4,900 adult IBD patients with electronic health record data
- Medium of 11 years of electronic health record data per patient

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Study Programs

IBD Plexus Study Programs

SPARC IBD

>3,300 adults

Study Duration:
Median: 14 months
Range: 0 – 42 months

PEDIATRIC RISK

1,812* pediatric patients

Study Duration:
Median: 48 months
Range: 0 – 60 months

** Enrollment has stopped*

IBD QORUS™

>4,300 adults

Study Duration:
Median: 13 months
Range: 0 – 51 months

IBD PARTNERS™

> 15,200 adults

Study Duration:
Median: 60 months
Range: 12 – 84 months

SHP647 Program

***Discontinued CD & UC Clinical Trial**

** Data & biosamples available Q1 2021*

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Program Characteristics

Characteristics	RISK	SPARC IBD	IBD Qorus	IBD Partners
Gender				
Female	42%	55%	56%	72%
Male	58%	45%	44%	28%
Age at enrollment				
< 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%
Diagnosis at enrollment				
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
Medications				
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%
Biologics breakdown				
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%

SPARC IBD

Objective: to identify predicators 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 20 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

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PEDIATRIC RISK

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

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

Study Profile

- Inception cohort (treatment-naïve)
- 25 sites in US; 3 in Canada

Data & Biosamples

- Clinical data
- Molecular data:
  - Genotyping
  - Transcriptomics
  - Metagenomics
- Biosamples:
  - Blood
    - DNA, Plasma
  - Intestinal Tissue
    - Extracted DNA
    - Extracted RNA
  - Stool

Study Features

- Model for risk stratification at diagnosis

IBD Plexus Molecular data: RISK & SPARC IBD

Service	RISK		SPARC IBD	
	Samples	Patients	Samples	Patients
Immunochip *(genotyping)*	1,456 blood DNA	**1,456**		
Global screening array *(genotyping)*	1,000 blood DNA	**982**	2,188 blood DNA	**2,188 CD & UC**
Whole exome sequencing) *(genomics)*			2,187 blood DNA	**2,187 CD & UC**
RNAseq @ 10 M reads *(transcriptomics)*	778 baseline tissue 10 (longitudinal tissue)	**565** **10 (longitudinal)**		
RISK: RNAseq @ 30 M reads **SPARC: Total RNAseq @ 50M reads** *(transcriptomics)*	850 baseline tissue 44 (longitudinal tissue)	**567** **29 (longitudinal)**	1,141 baseline tissue 129 follow-up tissue	**369 CD** **35 CD** **48 CD (longitudinal)** **204 UC** **23 UC (longitudinal)** **14 IBDU**
16S *(rDNA sequencing)*	888 (tissue and stool)	**625**		
WGS - bacteria and fungi *(metagenomics)*	295 baseline stool	**295**	909 baseline stool	**402 CD** **63 CD** **444 UC**
WGS viruses *(metagenomics)*	100 baseline stool	**100**	247 baseline stool	**100 CD** **147 UC**
Methylation *(epigenetics)*	402 baseline and follow-up blood DNA	**238**		

Available in January 2021

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IBD QORUS™

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)*

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IBD PARTNERS™

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

- Internet-based (any patient globally can sign up)

Data

- Patient-reported data
- Patient-generated data (wearables; apps)
- Baseline & 6-month longitudinal follow-up surveys
- Ancillary surveys

Study Features

- Understanding issues facing IBD patients
- Vehicle for additional ancillary studies
- Over 52 abstracts & 41 manuscripts

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