Data Warehousing & Sharing
Learnings from IBD Plexus

Oct 16, 2018
Angela Dobes, MPH
Senior Director, 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
Collaborative Exchange Network

Bringing together diverse stakeholders and breaking data silos

- Patients
- Academic Researchers
- Clinicians
- Industry

Stakeholders

- Data / Biosamples
- Genetic & ‘Omics
- Health Record
- Patient-reported
- Metadata
- Samples

Exchange

IBD PLEXUS
Propelling Research

- Over 60 participating sites
- 7 Industry members
- 4 Research study cohorts
- Tens of thousands of patients
- Tens of thousands of samples
- Millions of data points
Propelling Research

- Over 60 contributing sites
- 7 Industry members
- 4 Research study cohorts
- Tens of thousands of patients
- Tens of thousands of samples
- Millions of data points

**IBD Plexus Founding Premier Members**

- Abbvie
- Allergan
- Boehringer Ingelheim
- Celgene (Committed to improving the lives of patients worldwide)
- Janssen
- Lilly
- Takeda
Diverse research programs for cutting edge research

- **SPARC IBD**
  - Adult
  - Longitudinal
  - Precision medicine
  - 17 sites

- **PEDIATRIC RISK**
  - Pediatric
  - Longitudinal
  - Surgical complication risk factors
  - 28 sites

- **IBD QORUS**
  - Adult
  - Longitudinal
  - Quality of care
  - 30 sites

- **IBD PARTNERS**
  - Adult & pediatric
  - Longitudinal
  - Patient-driven research
  - Online registry
Real world data integrated and linked within and across research programs

- **Electronic case report forms**
  - Longitudinal phenotypic and clinical data
  - Disease severity scores
  - Endoscopy / colonoscopy results

- **Patient surveys**
  - IBD symptoms
  - Hospitalization
  - Medications
  - Experiences

- **Medical record**
  - In-patient and out-patient health record data

- **Molecular data**
  - Genetics
  - Genomics
  - Transcriptomics
  - Metabolomics
  - Proteomics
  - Microbiome
Exchange Platform
Components

- Patient & Clinician Engagement Platform
- Biobank & Lab Information Management System
- Central Reference Molecular Service Labs
- Data & Analytic Platforms
- High Performance Computing
- Researcher Portal
Welcome to IBD Plexus Researcher Portal

IBD Plexus® is a first-of-its-kind research information exchange platform designed to centralize data and biosamples from diverse research initiatives to advance science, accelerate progress toward precision medicine, and transform the care of inflammatory bowel disease (IBD) patients.

Getting Started
Getting started is easy. To begin exploring the database just create a query to find a population of interest. Explore Cohorts  Quick Start Steps

Research Initiatives High Level Details

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Population</th>
<th>Research Intent</th>
<th>Clinical Data</th>
<th>Patient Reported Data</th>
<th>Molecular Data</th>
<th>DNA</th>
<th>RNA</th>
<th>Proteins</th>
<th>PBMCs</th>
<th>Blood</th>
<th>Tissue Biopsies</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPARC IBD</td>
<td>Adult IBD Patients</td>
<td>Biomarker discovery</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>IBD</td>
<td>Nearly Diagnosed CD Pediatric Patients</td>
<td>IBD Stratiﬁcation</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>IBD-Qorus</td>
<td>Adult IBD Patients</td>
<td>Quality Improvement</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>IBDPartners</td>
<td>Adult and pediatric IBD Patients</td>
<td>Natural history of disease</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
</tbody>
</table>

Protocol Summaries

[Images of protocol summaries for SPARC IBD, Pediatric Risk, IBD Qorus, and IBD Partners]
Data Provisioning

- Explore
  - Query database
  - Generate / validate hypothesis

- Refine
  - Visualize Data
  - Refine criteria

- Request
  - Data Request
  - Approval

- Delivery
  - Automated de-identified data delivery
  - Limited data set requires IRB approval

- Share
  - Raw data deposited back to IBD Plexus
    - Non-targeted data = 6 months exclusivity
    - Targeted data = 18 months exclusivity

- Non-targeted data = 6 months exclusivity
- Targeted data = 18 months exclusivity
Data Provisioning

- **Explore**
  - Query database
  - Generate / validate hypothesis

- **Refine**
  - Visualize Data
  - Refine criteria

- **Request**
  - Data Request
  - Approval

- **Delivery**
  - Automated de-identified data delivery
  - *Limited data set requires IRB approval*

- **Share**
  - Raw data deposited back to IBD Plexus
  - Non-targeted data = 6 months exclusivity
  - Targeted data = 18 months exclusivity

---

**Prep-to-research tools**
Partnering to Accelerate Science
IBD Plexus is designed to support

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
- Label expansion / revisions

Commercialization
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization

Mucosal healing biomarker validation project leveraging IBD Plexus clinical and patient-reported data, stool and blood biosamples
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization

**Acceleration of early stage clinical studies leveraging SPARC IBD Study Network – Infrastructure, Sites and PIs**
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization

FDA Catalyst project leveraging FDA My Studies App to support collection of patient reported data for real world evidence
IBD Plexus is designed to support

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
- Label expansion / revisions

Commercialization
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization
IBD Plexus is designed to support

**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
- Label expansion / revisions

**Commercialization**
- Comparative effectiveness
- Outcomes Research
- Healthcare utilization

**Partnerships to Conduct Research award - Comparative Effectiveness Study of Biologic and Small Molecules Therapies in IBD**
The Power of Plexus

- Scale & size of data can't be achieved at any one institution or company
- Near real-time capture & transmission of reliable, rigorous data
- Vehicle to conduct ancillary studies
  - Discovery, pre-clinical, clinical, post-approval, commercialization
- Rapid data exchange environment
  - Novel data-sharing guidelines: requires raw project-specific generated data to go back into Plexus to enrich database