GETTING TO BETTER TREATMENTS THAT MATTER TO PATIENTS THROUGH BUILD OF A COLLABORATIVE RESEARCH PLATFORM

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Answering the most important questions in IBD

Guided by the patient voice
Laying the groundwork for better treatments

65% to 80% of IBD patients do not experience full remission\(^1\)

Why?

- Biology and environmental triggers not well understood
- Need novel treatments
- Lack of optimal endpoints and biomarkers
- Access to care issues

\(^1\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4969780/
A solution to problems too big or complex to solve alone

High impact research infrastructure & ecosystem

- Enroll a large and diverse patient population
- Collect the right longitudinal data and biosamples
- Capture a holistic view of the patient experience
- Improve data sharing & utilization and return value to participants
- Access to a network of IBD experts & unmatched partnering opportunities
Data collection done the right way

Research opportunities designed to fit the patient journey

DIRECT-TO-PATIENT
- Web-based portal
- Mobile app

ROUTINE CARE
- Telehealth visit
- Office visit

DISEASE EVENTS
- Endoscopy
- Surgery
- Infusions
No more research silos. Unlocking the full value of data.
Better Data for Better Outcomes

Unparalleled, comprehensive data to better understand the complete picture of disease and patient journey

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Programs</th>
<th>EHRs from Participating Sites</th>
<th>Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBD diagnosis</td>
<td>✔</td>
<td>All local</td>
<td>All billed</td>
</tr>
<tr>
<td>Phenotype</td>
<td>✔</td>
<td>Free text</td>
<td>-</td>
</tr>
<tr>
<td>PROs / symptoms</td>
<td>✔</td>
<td>Mostly free text, some structured</td>
<td>-</td>
</tr>
<tr>
<td>QoL / experience</td>
<td>✔</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Medications</td>
<td>Prescribed for IBD</td>
<td>Prescribed + OTC</td>
<td>Filled Rx</td>
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<tr>
<td>Labs</td>
<td>Selected IBD-related results</td>
<td>Most results</td>
<td>Performed w/out results</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>IBD-related comorbidities</td>
<td>All local</td>
<td>All billed</td>
</tr>
<tr>
<td>Procedures / imaging</td>
<td>Selected results</td>
<td>Most results</td>
<td>Performed w/out results</td>
</tr>
<tr>
<td>Surgical complications</td>
<td>✔</td>
<td>Mostly free text</td>
<td></td>
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<tr>
<td>Demographics</td>
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<tr>
<td>Social history &amp; SDOH</td>
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<td>Present, but often incomplete</td>
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<tr>
<td>Genetics &amp; ‘omics</td>
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<td>-</td>
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</tbody>
</table>
There remains a high unmet medical need for IBD patients with progressive disease despite treatment with available therapies that utilize varied mechanisms of action.

Established a pre-competitive, multi-stakeholder working group to:

- Develop a definition of progressive disease
- Create a RWD disease progression composite score
- Build a model to identify risk factors associated with development of progressive disease
Precision medicine value chain simplified

Use Case: Development of a prognostic biomarker of disease progression

- **Research & discovery**
  - Biomarker discovery & validation

- **Clinical development**
  - I / E selection criteria
  - Endpoint development

- **Approvals & market access**
  - Labels and formulary design

- **Post market safety & surveillance**
  - Monitor pharmacovigilance and safety
  - Treatment sequencing

Use Case: Development of a prognostic biomarker of disease progression
A new paradigm for IBD research

possible research robust modern biorepository
improve metadata molecular best
scientific provided models best
samples accelerate depth
Novel access ambitious
treatment patients
study microbiome effective risk
discovery clinical significant
symptoms pediatric
data characterized
quality unique
investigators original
partner
Igniting great science for a brighter future

Over 200 research projects across life science companies and academic institutions

IBD Plexus Members*

Academic Institutions

*Current and former members
A path to improve the lives of IBD patients

Understanding biology of human disease

- Identified genetic variants in 10 new CD genes

Advancing Rx/Dx

- Redefining treatment value

Increasing access

- Microbiome-based signature to predict 5-ASAs failure

Precision medicine

- Landmark real-world urgency paper

Improving outcomes

- https://www.nature.com/articles/s41588-022-01156-2
- https://www.nature.com/articles/s41591-023-02217-7
- doi.org/10.1093/crocol/otab046