PCOR Challenges & Solutions

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CCEB

Potential Conflict of Interest

Consulting (since 2014)

- Nestle Health Science
- Dark Canyon Laboratories
- Merck
- Celgene / BMS
- Janssen Pharmaceuticals
- Bridge Biotherapeutics, Inc
- Pfizer (DSMB)
- Gilead (DSMB)
- Arena Pharmaceuticals (DSMB)
- Protagonist Therapeutics (DSMB)
- Entasis Therapeutics

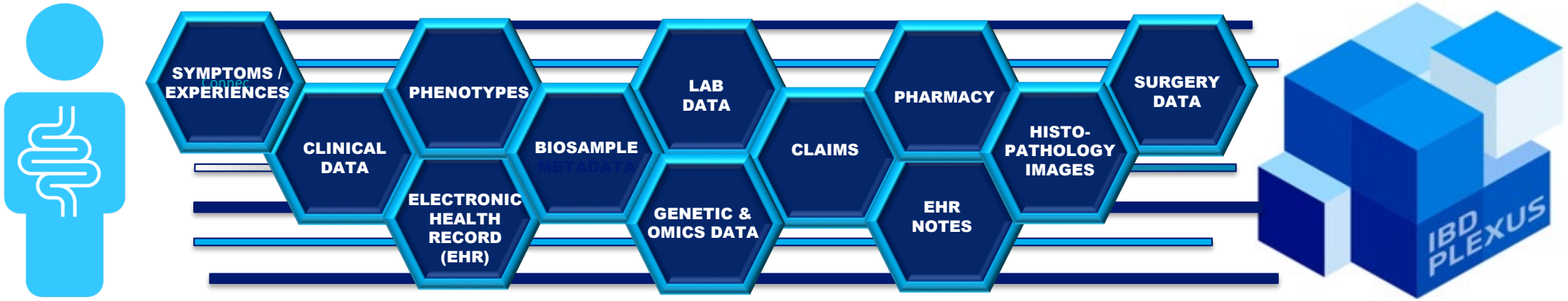
Research Support (since 2014)

- Takeda
- Janssen
- AbbVie
- Nestle Health Science
- Bayer

Barriers to PCOR

- PC = Patient Centered
  - Hard to be patient centered without patient engagement
  - PC research is expensive and time consuming
  - Most patients do not desire to be active research subjects
  - Some patients have concern about safety of their data
- OR = Outcomes Research
  - Routinely measure processes or clinical outcomes
  - Patients may have different priorities

Connecting fragmented health data to advance patient-centric research and understand disease holistically



Enriching the medical record to standardize collection of disease-specific data

IBD SmartForm embedded into EHR system

Phenotyping Quality Control Study

Centralization of patients' medical records from all study sites into IBD Plexus platform to enable research

The Impact of Introducing Patient-Reported Inflammatory Bowel Disease Symptoms via Electronic Survey on Clinic Visit Length, Patient and Provider Satisfaction, and the Environment Microbiome

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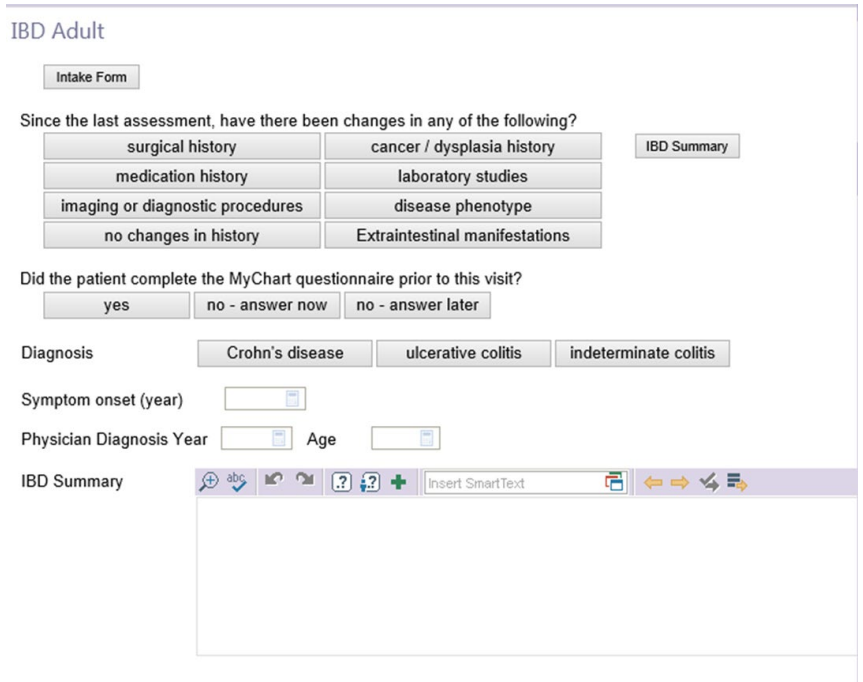
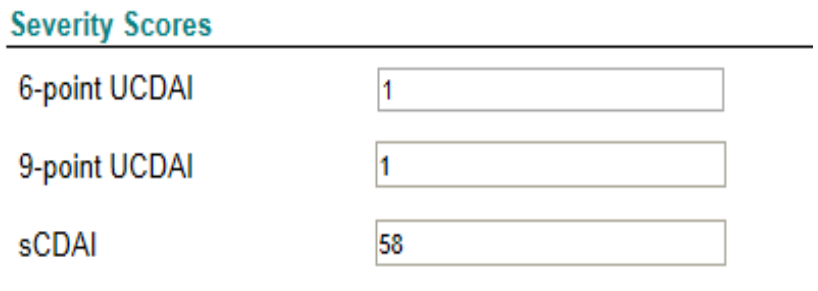
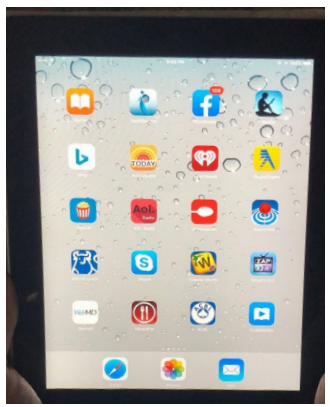
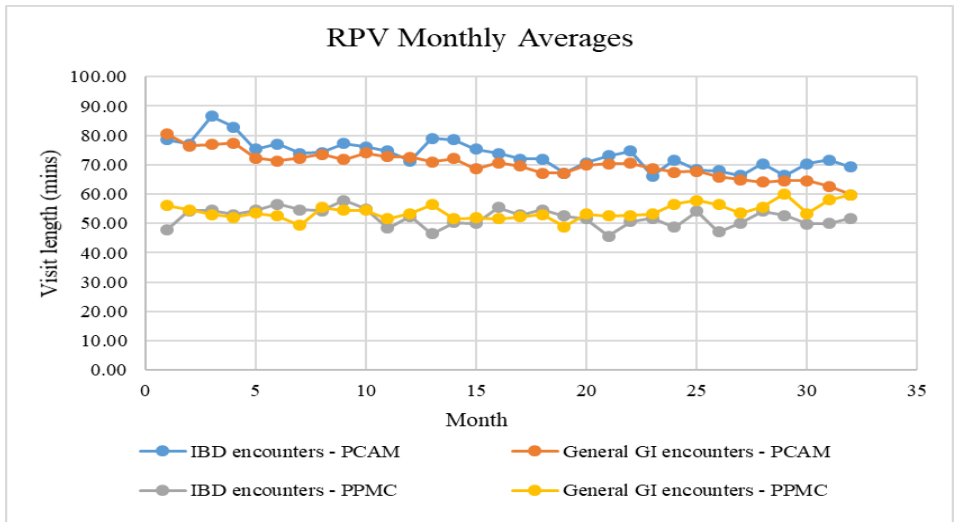
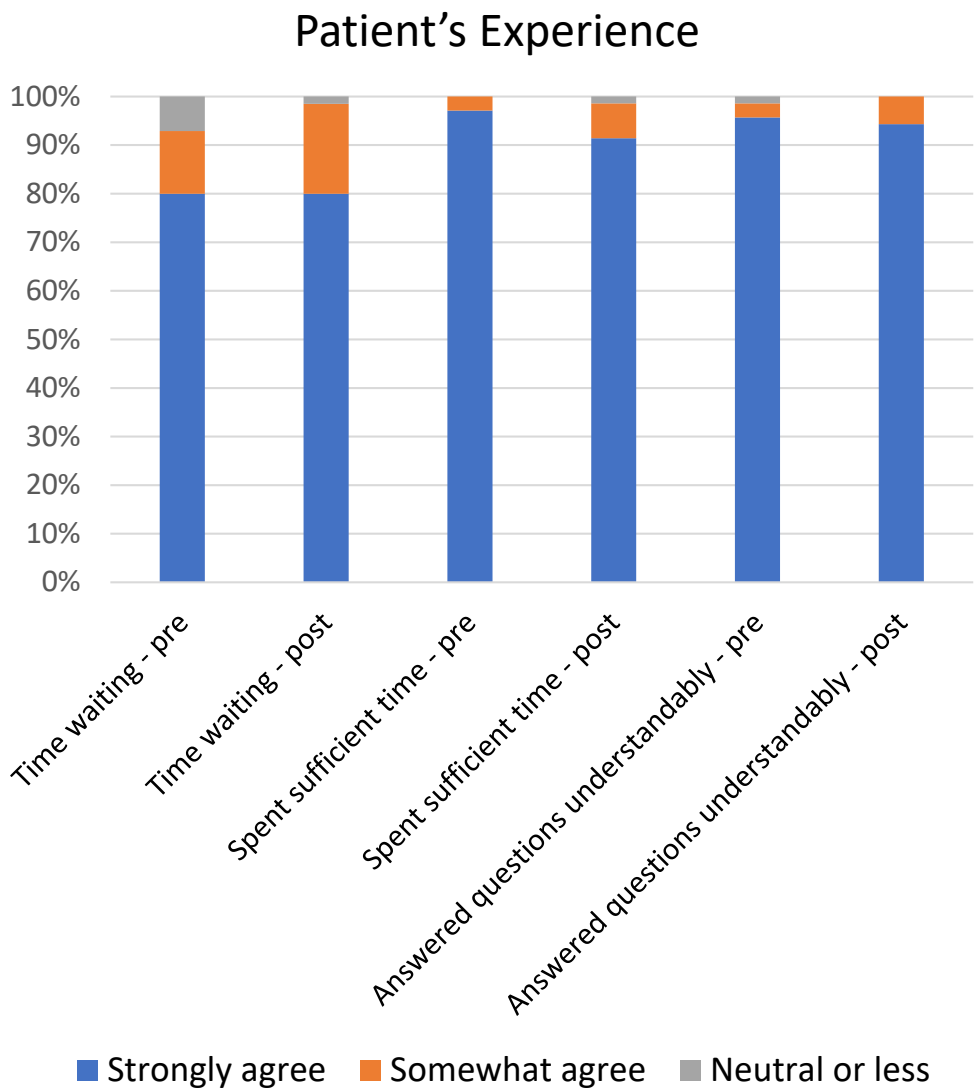








Characteristic	Pre Tablet Implementation (n=70)	Post Tablet Implementation (n=70)	P value
Female, n (%)	38 (54.3)	25 (35.7)	0.03
Age, y (SD)	41.6 (±14.9)	40.6 (±15.2)	
Age Group, n (%)			0.06
18-29	20 (28.6)	21 (30.0)	
30-39	16 (22.9)	20 (28.6)	
40-49	7 (10.0)	10 (14.3)	
50-59	19 (27.1)	6 (8.6)	
60-69	5 (7.1)	12 (17.1)	
70-79	2 (2.9)	1 (1.4)	
80-89	1 (1.4)	0 (0.0)	
Race, n (%)			0.50
Asian	1 (1.4)	1 (1.4)	
Black or African American	8 (11.4)	6 (8.6)	
White	59 (84.3)	62 (88.6)	
Multi-racial	2 (2.9)	0 (0.0)	
Prefer not to answer	0 (0.0)	1 (1.4)	
Ethnicity, Hispanic or Latino/a, n (%)	2 (2.9)	1 (1.4)	0.56
Highest education, n (%)			0.17
Less than or equal to high school diploma	10 (14.3)	10 (14.3)	
Some college	12 (17.1)	16 (22.9)	
Bachelor's degree	25 (35.7)	21 (30.0)	
Technical / associates degree	9 (12.9)	2 (2.9)	
Graduate degree	14 (20.0)	20 (28.5)	
Prefer not to answer	0 (0.0)	1 (1.4)	
Clinic Location, n (%)			0.87
PCAM	35 (50.0)	36 (51.4)	
PPMC	35 (50.0)	34 (48.6)	



Paladhi UR. Inflamm Bowel Dis. 2021

Challenges with EMR-embedded tools

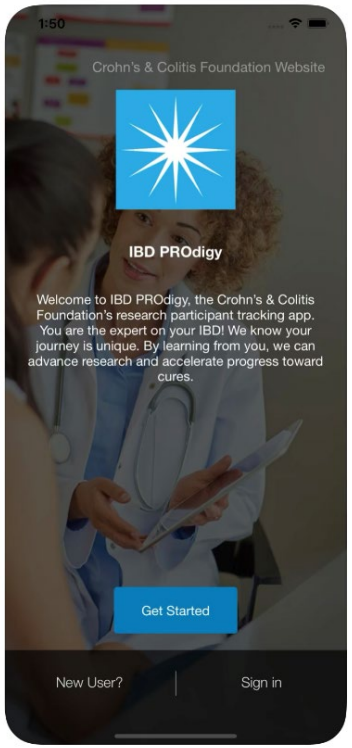
- Difficult to teach an old dog new tricks
- Garbage in = garbage out

Reaching patients where they are

Patient Journey: For chronic, episodic diseases, like IBD, the feedback loop between treatment and effect is hard to capture leveraging just RWD

Consideration: Leverage direct-to-patient technology to fill data gaps and capture the patient experience beyond the clinical delivery system

FDA MY STUDIES



Why do clinicians tolerate inaccurate and incomplete clinical data?

- EHRs consume half of physicians workday
  - Lots of unpaid labor
- ~25% of physicians considered retirement in past year
- New CMS rules may be user friendly for clinicians but a threat to researchers
- Need EHR solutions to facilitate accurate and completed collection of clinical data

Filling the Data Gaps

Leverage partnerships to maximize value of existing data

Generation of unique person-specific identifier

One-way hash algorithm resulting in "tokens" that cannot be decrypted

Installed on site at The Foundation

Use of Natural Language Processing

Processing of text to extract key phrases, entities, and sentiment for further analysis

Installed on site at The Foundation

Enriching IBD Plexus platform data with linked care and treatment data to increase visibility into the patient journey

IQVIA

Better understanding of treatment utilization

Capture of data across healthcare settings

More comprehensive picture of comorbidities

Barriers and Solutions to EHR – Claims Linkage: Trust

- Knowledge, priorities, laws and fear influence our ability to make linkages
  - Patients fear loss of confidentiality
  - Corporations and research centers are risk averse
- Lack of single payer system
- Potential solutions
  - National neutral broker
    - Link the major EHRs and claims data
    - Provide researchers with de-identified linked data
  - Standardization of data structure

Embrace the multidisciplinary nature of PCOR

- Clinician-scientists
- Patients
- Domain specialists
- Biostatisticians
- Bioinformaticians
- Biomedical informaticians
- Epidemiologists
- Insurance specialists