Innovative Real-World Experience Generation: Supplementing Registry Data with Patient Community Input for In-Depth Patient Understanding

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INTRODUCTION

- Exocrine pancreatic insufficiency (EPI) is caused by a deficiency of functional pancreatic enzymes resulting in maldigestion and malnutrition, commonly secondary to chronic pancreatitis (CP).
- The EPI in CP patient experience is not well understood, making the diagnosis and treatment challenging.
- To address this unmet need, a patient-centric registry and online patient community were formed.

OBJECTIVES

- To outline an innovative dual methodology for obtaining in-depth patient-reported insights in addition to real-world clinical data.
- To describe how registry data and patient community insights can provide a complete picture of the patient experience.
- To define a methodology used to obtain quantitative, qualitative, clinical, and patient-reported data related to EPI due to CP.

METHODS

- An innovative methodology that combines a disease registry and an online patient community is being used to understand the patient experience in individuals living with EPI due to CP *(figure 1)*.
  - The disease registry is collecting insights into the clinical journey of these patients, as well as Patient-Reported Outcome (PRO) data *(figure 2)*.
  - The community is supplementing this data with patient experience insights that may not always be shared with healthcare providers.
  - Posts and replies in the community are moderated by a CP non-profit organization.
- Prior to protocol and community development, market research was conducted to determine appropriate messages for communicating value and identify initial topics for community discussions.
- A scientific advisory board was formed to inform registry design, optimize data collection logistics, and provide guidance on community activities.
- In addition to statistical methods used to analyze registry data, thematic analysis is applied to online community discussions.

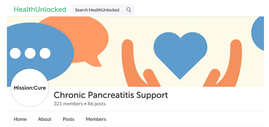
Figure 1: Purpose of Registry and Community

Clinical Registry:
Qualitative Insights, Clinical Journey

PACT-CP
PAtient-CenTric Chronic Pancreatitis Registry

- Unmet needs
- Therapeutic burden
- How treatment decisions are made
- Prescribing patterns of Pancreatic Enzyme Replacement Therapy (PERT)

Community:
Qualitative Insights, Emotional Journey



- Patient experience insights that may not always be shared with healthcare providers
- Patient journey exploration
- Online research activity output
- An environment for peer-to-peer disease related discussions

Figure 2: Summary of key variables collected in the PACT-CP Registry

Demographics	Age Gender Height Weight	Education Body Mass Index (BMI) Work status Insurance type	Smoking Status Alcohol use Cannabis use
Treatment History	Prior Medication Treatment initiation (dose and frequency)		Over the counter medication use Nutrition/Diet Changes
Disease Characteristics	Year of onset and year of diagnosis, clinical diagnosis TIGAR-O Checklist EPI due to CP-related pancreatic manifestations Clinical Manifestations		Social History CP-related surgeries History of comorbidities, infections
Patient Reported Outcomes	Healthcare utilization Treatment Satisfaction Questionnaire for Medication (TSQM-9) Hospital Anxiety and Depression Scale (HADS) Short Form Survey (SF-12) Bristol Stool Chart		
Relevant Lab Abnormalities	CBC ESR, CRP, renal function, hematology, LFTs HDL, LDL, Triglyceride, Total cholesterol Vitamin panel		Fecal elastase, Fecal fat CT, MRI Capsule endoscopy, Endoscopy
Adverse Events	Serious Infection, Malignancy, Cardiovascular, Neurologic, Hepatic, General Serious, Anaphylaxis, Autoimmune, Gastrointestinal, Pregnancy Event		

Figure 3: Registry Enrollment to Date

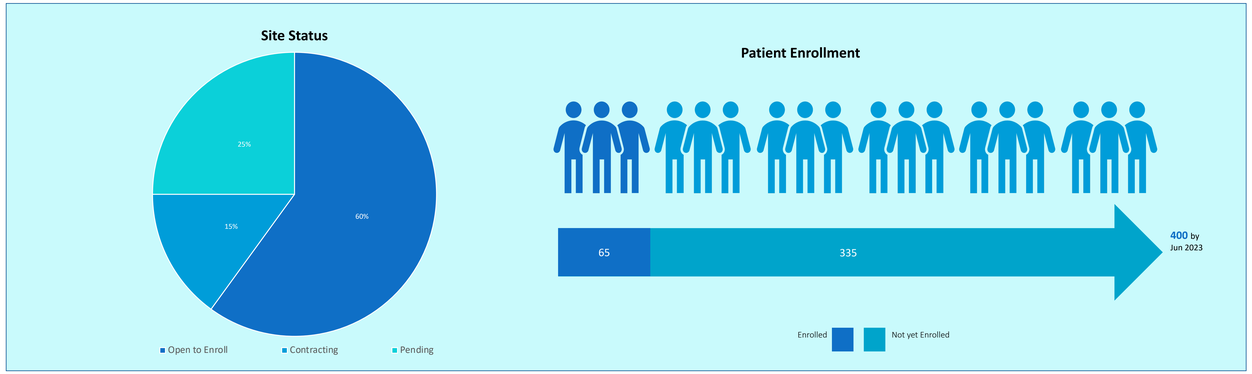


Figure 4: Community Growth to Date

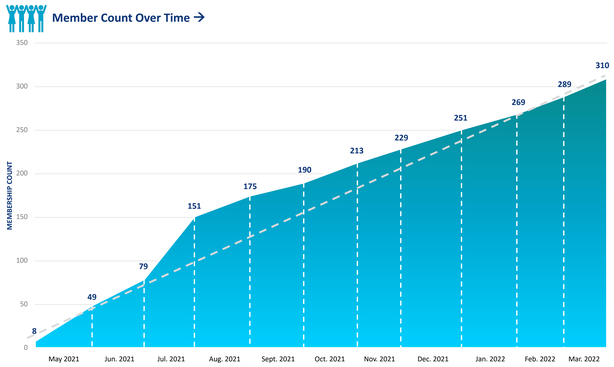
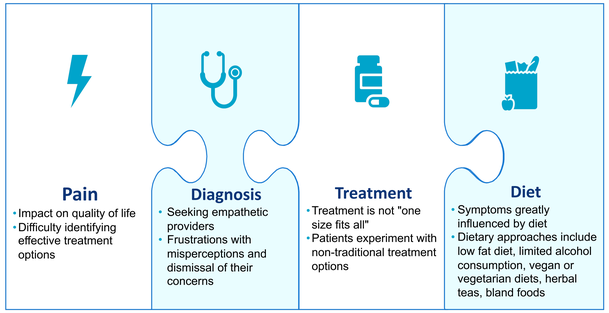


Figure 5: Thematic Analysis Results, Jan 2021 – Feb 2022



RESULTS

- The registry is actively recruiting and enrolling patients. As of 31 March 2022:
  - 12 of 20 sites are open to enroll.
  - 65 of 400 patients have been enrolled *(figure 3)*.
- 309 participants are currently registered in the online community *(figure 4)*.
  - A total of 442 comments have been made, with average replies per post = 7 (average for a community of this size ~ 2).
  - Community members have participated in 10 online research events to date.
- An initial thematic analysis revealed four key themes from online community discussions: pain, diagnosis, treatment, and diet *(figure 5)*.
- Data from both methodologies will be analyzed and shared in peer-reviewed journals and conferences.
- Analysis of these two modalities together is anticipated to provide a more holistic view of the patient experience.

CONCLUSION

The addition of the online community to this broader research project has several advantages. Patients and care partners can openly discuss their condition in ways they may not with healthcare providers, adding patient experience insights to the clinically relevant registry data.

Once both registry and online community are fully realized, the combined data will provide a more comprehensive picture of the EPI due to CP patient experience to describe a more complete, real-world patient journey.

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PACT-CP
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