DEMYSTIFYING THE PATIENT'S EXPERIENCE: USE OF PATIENT JOURNEY STUDIES TO GATHER VALUABLE QUALITATIVE INSIGHT INTO THE PATIENT EXPERIENCE

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INTRODUCTION

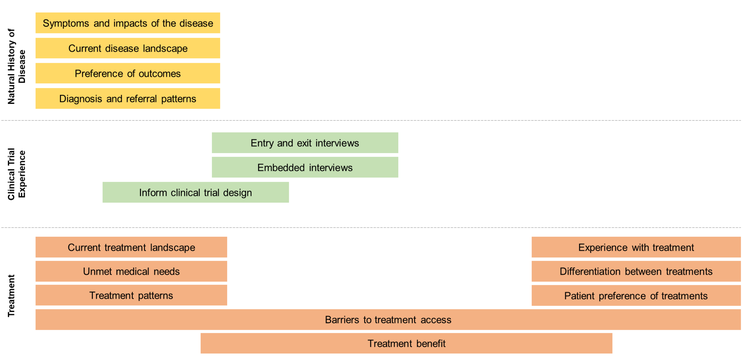
- Obtaining first-hand accounts of patient experiences through patient journey studies provides valuable insight for patient stakeholders, clinicians, drug development researchers, regulatory agencies, and payers.[1]
- Qualitative interview data from patient journey studies can expose the burdens of living with a disease/condition and highlight unmet medical needs, support hypothesis generation and study design, and inform participant recruitment and retention in clinical trials.[2]
- Patient-centered data can inform the development of meaningful patient-relevant outcome measurement and regulatory endpoints for drug decision-making throughout the product life-cycle.[3]
- This poster details key characteristics of patient journey studies, which is an emerging research approach that leverages qualitative methods to understand a patient's "lived" experience and to inform improvements in drug adherence and clinical trial design, improve efficacy, and reduce treatment barriers.[2]

METHODOLOGICAL FRAMEWORK & APPROACH

Background

- Patient journey studies utilize qualitative interviews to explore/confirm hypotheses, establish essential context, and provide perspectives to the disease/condition and medical product.
  - These studies can help us further understand the experiences, perspectives, needs, and priorities related to the natural history of the disease (e.g., symptoms, quality of life, outcomes), clinical trials, and treatments.[2]
- Patient journey study findings are utilized throughout the medical product development process (**Figure 1**).
  - Engaging patients early and throughout the development process is pivotal and can help improve rates of trial enrollment and increase applicability to the patients.[4]
  - The specific objectives of the study will influence the most appropriate time to collect the patient data.

Figure 1: Utilization of Patient Journey Studies across the Clinical Trial Continuum



Data Collection

- Patient journey data is collected via semi-structured, in-depth interviews with the patients, caregivers, and/or clinical care providers.
- Interview guides are developed using results from literature review and feedback from clinicians with experience in the therapeutic area.
- **Table 1** provides examples of questions that are used for this type of study.

Table 1: Interview Approach

Types of Question and Purpose	Examples
Open-ended questions: Elicits spontaneous patient/care provider experience	Q: What has it been like for you since you were diagnosed with the condition? Q: How was it decided to start your treatment? Q: What symptoms have you experience due to your condition?
Follow-up questions: Explores individual symptoms and impacts; confirms and authenticates patient's unbiased response	Q: Who diagnosed you? Q: Who chose the treatment? You, your doctor, or was it a collaboration? Q: How frequently do you experience pain?
Example questions: Elicits patients to give examples and scenarios for their disease/condition or treatment	Q: What is a good night like with your condition? Q: When you said daily chores, what specific activities were you thinking of? Q: Could you describe any activities that you had to stop during your treatment?
Experience questions: Explores the patient's experience with the treatment	Q: Can you describe your experience with the drug? Q: What would you say is the most positive feature of the treatment? Q: How did this treatment affect your quality of life, if at all?

Data Analysis

- A coding scheme is developed from verbatim words of patients and refined until team consensus is reached, keeping in mind the themes and concepts presented in the interview guide.
- Codes eventually become concepts through merging of conceptually equivalent codes and are developed into broader code categories.
- The adequacy of the sample size is based on achieving evidence of concept saturation.[5-7]

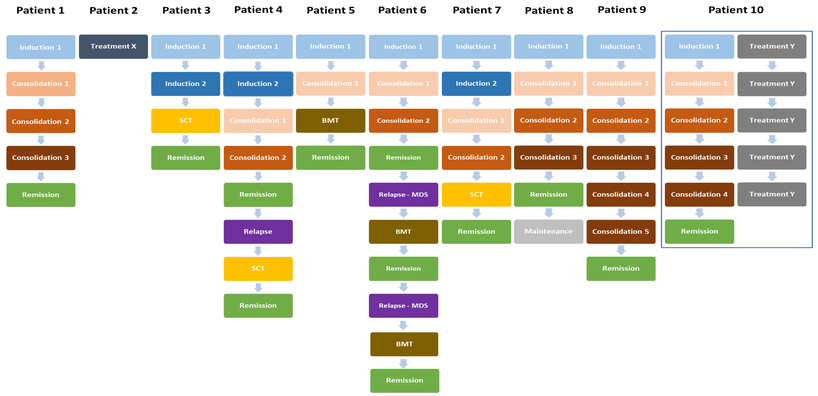
Reporting

- Once the data has been analyzed, detailed tables are developed to show the concept codes, concept frequency, and exemplary verbatim quotes associated with the themes and concepts.
  - **Table 2** demonstrates the various burdens, risks, and barriers that can emerge from patient journey studies.
- Researchers should consider using tables and figures to present the data so that the audience can easily visualize the patterns and grasp the key messages of the study.
  - **Figure 2** demonstrates one of the many ways that the patient journey data can be visually presented.

Table 2: Capturing Unmet Needs and Barriers

Benefits and Risks	Disease Experience	Barriers	Unmet Needs
Cancer Treatment Risks "There was a relatively high likelihood that I would experience some side effects afterward, but to what extent, they couldn't say. There was a relatively high risk that I might develop other forms of cancer afterward, but which types, they couldn't say either."	Gastroparesis Experience "If I sit down to eat like, you know, you'll have a salad, you'll have a vegetable and you'll have a meat and a drink. If I combined all of that together and I eat all of that, then say like 20 minutes or something like that, I am miserable."	Financial Barrier of New Cancer Treatments "I was just told that the treatment was expensive. So I thought, maybe 100,000 yen? I am carrying 150,000 yen in cash with me. I was just told that it was expensive…The doctor may not know the details of the cost…We don't talk about details like that. It is so expensive that I am shocked."	Unmet Needs of Rare Urinary Disease "What bothers me, one doctor said yesterday, 'you got no urinary infection. Nothing else seems to be the matter with you. Let it go…' I poke at the doctor's mind, and it come to a point a lot of doctors say, we don't know, because they don't ….nobody seems to have a good solution."

Figure 2: Example of Patient Journey Mapping



Note: The objective of this study was to understand the similarities and differences in treatment pathways experienced by oncology patients. This mapping indicated the variability of treatment pathways between patients.

DISCUSSION

- Qualitative interviews reveal patients' symptoms and impacts, and characterize the barriers that impede patients from receiving the most effective, comprehensive prescribed care.
- The FDA has a preference for patient-derived and patient-reported endpoints wherever feasible, as those help them understand how patients "feel and function."[3]
- Patient journey studies can provide insight into the best way to create and select patient-reported endpoints.
- Particularly important, when collecting qualitative patient data, is the approach and consideration of representativeness and how to incorporate interview data by using concurrent interviews and exit interviews from clinical trials.
- Exit interviews focus on patients' clinical trial experiences with emphasis on what symptoms, impacts and side effects the patient may have experienced during trial. Patient journey data collection can also entail pre-trial interviews to obtain a holistic experience and gather baseline health data.

CONCLUSIONS[8-10]

- Patient journey studies incorporate specific qualitative methods to gather robust empirical evidence that provides richer insights into the patient experience with illness and treatment.
- These studies help researchers obtain a thorough understanding of what is effective and ineffective for patients, contributing invaluable knowledge for researchers seeking to develop sensitive efficacy assessment strategies in drug development programs.
- Documenting and disseminating patient-centered data on the daily experiences of specific diseases and therapeutic agents can identify unmet need and barriers to treatment, increase adherence, and provide valuable data for policy makers and practitioners striving to expand options for health interventions.
- Information collection and dissemination are pivotal to a holistic understanding of disease treatment impacts and promote improvements in drug adherence, health status, improved quality of life, life expectancy and reduce adverse events.

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DISCLOSURES

All Author(s) of this presentation are employees of Pharmerit International. None of the authors have additional disclosures concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Angela Stroupe[1], Caroline Seo[2], Alyssa Uzumcu[1], Kelly McCarrier[2]: Nothing to disclose
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