folia
HEALTH
HOME-REPORTED OUTCOMES

CASE STUDY

Improving Life Sciences Research with Patient Involvement

Objective

When a study sponsor needed a broader and more detailed dataset than could be gathered with in-clinic research, they approached Folia Health. This organization required real-world data documenting changes in symptoms and treatment while individuals living with cystic fibrosis began a new therapy. This data, provided totally by the patient or their caregiver using a web- and mobile-based app, would provide the sponsor with keen insights to assess this new therapy's effectiveness given average circumstances on an individual level and illustrate the range of outcomes, particularly focusing on the therapy's ability to reduce the need for chronic daily treatments.

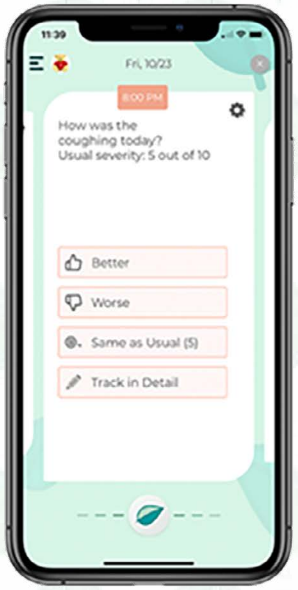
They partnered with Folia Health to gather home-reported outcomes (HROs), gauge patient and caregiver desire for tracking outcomes at home via a mobile app, assess the quality of their dataset, and their ability to match records with their registry.

Between the ease and speed of enrollment, the level of participant involvement, and the usefulness of the data collected, this study clearly outlined the value of HROs in clinical research.

Approach

The initial study's 63 participants were recruited from Folia's existing user base and four partnered clinics. We succeeded with total enrollment in just 29 days by leveraging referral and recruitment sites and social media. All participants were over 12 years old, had never had a lung or liver transplant, could communicate in English, had access to the necessary technology to use the Folia app, and were treated for cystic fibrosis using the novel therapy.

Did you finish your Wake Up Treatments?
1. Hypertonic saline solution
2. Pulmozyme
3. Orange pill trikafta
4. Vest treatment



How was the coughing today?
Usual severity: 5 out of 10

Bowel movement number count:

Using the Folia Health App, participants selected symptom and treatment use questions pertinent to their treatment plan and tracked their progress weekly for six weeks. The data collected was systematically organized, and participants could supplement it with qualitative observations for their benefit.

Once we collected the relevant data, Folia matched the participants with the registry and analyzed the dataset. Upon reviewing the results, the sponsor decided to collaborate with Folia for a nationwide implementation of this study, focusing more on treatment effectiveness over an extended collection period of 12 months.

The Results

This noteworthy study was the first of its kind, designed as a real-world research study conducted with no research visits, entirely online, that used social media as an independent recruitment tool. It also gleaned valuable numerical insights into the value of HROs to both researchers and patients or caregivers.

By the Numbers

29	DAYS TO COMPLETE ENROLLMENT	24,630	NOVEL & STRUCTURED DATA POINTS TRACKED
90%	OF PARTICIPANTS SAID PARTICIPATION WAS EASIER THAN TRADITIONAL STUDIES	80%	OF PARTICIPANTS WERE WILLING TO ENROLL IN A SIMILAR, YEAR-LONG STUDY
83%	FOUND PERSONAL VALUE IN TRACKING	94%	MATCH ACHIEVED BETWEEN STUDY PARTICIPANTS & PATIENT REGISTRY

Conclusions

There were several significant conclusions to come from the valuable research provided by the Folia Health app. The first was that almost 40% of those who participated stopped at least one of their chronic daily therapies while using the novel therapy. The second important takeaway was that this study demonstrated the viability of using HROs, community-based recruitment, and a web-based application to gain consent and adequately collect and use patient-reported data. Between the ease and speed of enrollment, the level of participant involvement, and the usefulness of the data collected, this study clearly outlined the value of HROs in clinical research.

Improving Life Science Research Research with Patient Involvement

Historically, healthcare systems have prioritized clinician assessments and device measurements over patient feedback to understand outcomes, particularly in research settings. This approach relies on periodic checkups and information from other conventional sources, overlooking the day-to-day experiences of living with a chronic condition and resulting in gaps in the data.

HROs gather a vast amount of personal knowledge, placing the most critical needs and opinions at the forefront of decision-making at every stage of the process. As demonstrated by this study using the Folia Health app, patient-generated data provides valuable depth, which can provide comprehensive disease burden and therapy impact insights and positive health outcomes.

Folia Health is the founder of home-reported outcomes (HROs), the next generation of patient health data that transforms lived experiences outside the clinic into valuable insights for better research and care. Through an innovative platform backed by expert analysis and support from a compassionate team, we help life science partners develop effective therapies with demonstrated, real-world value for complex, chronic conditions.

Contact us today to bridge gaps in patient health data and expand the possibilities of healthcare research.

folia
HEALTH
HOME-REPORTED OUTCOMES

foliahealth.com | (617) 306-1282
partnerships@foliahealth.com | in