Panel Discussion: Strategies to Overcome Recruitment and Retention Challenges in Metabolic Associated Steatotic Liver Disease

Monday, May 5 @ 3:20 to 4:05 PT at DDW Theatre 2

We hope you will attend our panel discussion: We will review recruitment and retention strategies in fatty liver disease trials with expertise from Parexel (CRO), distinguished investigators in the field of MASH, patient advocates, and more!

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Background

Recruitment and retention are becoming more and more challenging in clinical trials[1].

- >90% of clinical studies experience delays due to challenges in patient enrollment or retention
- 80% of clinical trials do not meet their enrollment timelines
- Between 6% and 29% of clinical trials are terminated due to insufficient participant recruitment
- ~25% of participants withdraw from clinical trials after providing informed consent
- Over the past 2 decades, trial recruitment rates have declined by 16% and participant retention rates have decreased by 21%

Root Causes of Low Recruitment

- Risk of placebo arm
- Length of trial participation
- Liver biopsy and safety risk
- Concern for side effects from the study drug
- Requirement for multiple procedures: blood collections, imaging
- Clinic visits resulting in time away from family, work, school
- Screen Fail Rate: 75-85% in recent MASH studies [2]

Building a Patient Engagement Strategy

- Understand potential referral pathways: Insights into symptom onset or condition discovery, diagnostic process, healthcare utilization patterns, and typical referral pathways. Use of site and patient heat mapping utilizing real-world data assets
- Patient panel review: Help ensure that the trials are designed in a way that is acceptable and feasible for participants, which can improve recruitment and retention rates
- Establish connections with Patient Advocacy Groups within the MASH community

Patient Insight

- **Participant concerns**: what if I get placebo, what are the side effects, what if my disease gets worse?
- **Trusted advocates and resources:** I trust my doctor to recommend what's best for me
- **Patient needs**: clear explanation of study, potential benefit, possible side effects, reassurance surrounding underlying conditions, travel support and reimbursement

Promoting study awareness at the sites by providing robust education, addressing placebo arm and biopsy concerns, utilizing enhanced digital storytelling with anecdotes and stories support the participant and boost retention

What's it like for me?

Symptoms & Daily Challenges

- *I noticed that I was often very tired and had less appetite.*
- *Sometimes I felt pain in my upper right abdomen.*

Current Treatment & Care Options

- *I was told I need to continue trying to lose weight, exercise, and manage my blood sugar levels.*
- *There is a new medication available, but I've not tried it yet.*
- *I've never thought about being in a clinical trial before. I'm not sure what the benefit would be for me. My doctor has not spoken to me about trials.*

Diagnosis Experience

- *A couple years ago, my doctor said that I just had some fat on my liver, but I didn't think it was serious. I focused more on my diabetes and trying to adjust to new medicine and lifestyle.*
- *I had some blood tests done to check my liver functioning and the levels of fat in my blood. I also had an ultrasound of my liver. My doctor told me I had moderate fatty liver disease.*

Strategies for Improving Retention

- **Site Selection and Start-up:** Front-loading tasks where possible with draft protocol (early start of site contract negotiation with finalized assessment schedule)
- **Site Engagement:** Close follow-up on non-enrolling sites and activating back-up countries where needed. In-person Investigator Meetings. Utilization of CRAs, Clinical Enrollment Managers, and newsletters to keep engagement high
- **Vendor Logistics:** Ensure that the vendors provide clear lead time for providing equipment, devices, central reviews
- **Side Effects:** Counsel patients on the possibility of side effects pre- and post-enrollment. Design methods to address and alleviate GI symptoms, provide dietary and physical activity counseling to optimize weight loss, permit slower infusions if a participant demonstrates a mild infusion-related reaction
- **Biopsies:** Utilize sites experienced in biopsies but also to ensure all sites are fully trained on the biopsy expectations and requirements. Long-term goal of minimizing the need for liver biopsy and utilizing non-invasive tests
- Many of the recruitment tactics are intended to support overall retention – if the **participant is well-informed at enrollment** about their responsibilities as a subject and what will be asked of them, they will be less likely to drop out when multiple procedures and/or biopsies become reality
- Level of care patients receive is much higher than standard of care in terms of frequent assessments of liver function and overall health assessments

REFERENCES

[1] Changes in key recruitment performance metrics from 2008–2019 in industry-sponsored phase III clinical trials registered at ClinicalTrials.gov - PMC (nih.gov) Strategies for participant retention in long term clinical trials: A participant –centric approaches - PMC (nih.gov)

[2] Harrison SA et al. Nature Med. 2023 Mar;29(3):562-573)