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Mobile Phlebotomy in MASLD / MASH Clinical Trials: Enhancing Recruitment, Retention, and Data Integrity

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Abstract: ***Background: Metabolic dysfunction–associated steatotic liver disease (MASLD, formerly NAFLD) and metabolic dysfunction–associated steatohepatitis (MASH, formerly NASH) represents a growing global health burden, affecting an estimated 25–30% of adults worldwide. Despite high prevalence, no pharmacologic therapies have yet received regulatory approval. Clinical development programs in MASLD/MASH are challenged by complex eligibility criteria, reliance on biomarker-driven endpoints, and substantial participant burden, resulting in high screen-failure and attrition rates. Decentralized trial approaches, including home-based blood collection via mobile phlebotomy, have been proposed as mechanisms to improve trial accessibility and efficiency. Methods: This article is a narrative review with applied operational modeling. We synthesize peer-reviewed literature, regulatory guidance (including FDA guidance on decentralized clinical trials, Good Clinical Practice, HIPAA, and CLIA/CAP standards), and published evaluations of home-based phlebotomy in clinical research. Operational considerations, equity implications, and quantitative enrollment and retention modeling were examined. Results: Incorporation of mobile phlebotomy into clinical trial workflows has been associated with reduced logistical barriers to participation and improved retention. Decentralized trials have reported enrollment timelines up to 50% faster than traditional site-centric models[7] and retention rates approaching 96% compared with approximately 70% in conventional designs[8]. Applied modeling demonstrates that increasing retention from 70% to 85% can reduce required enrollment by approximately 17% to achieve the same number of completed participants. Evidence indicates that, when standardized protocols are followed, home-collected biospecimens meet laboratory quality benchmarks, preserving biomarker integrity critical to MASLD/MASH endpoints[9]. Conclusions: Mobile phlebotomy offers a patient-centered, operationally scalable adjunct to site-based trial models in MASLD/MASH research. When implemented with appropriate oversight, training, and documentation, it aligns with contemporary regulatory expectations for decentralized trial elements. While not a replacement for all in-clinic procedures, mobile phlebotomy can meaningfully improve recruitment efficiency, retention, and data completeness in hepatology trials.***

Keywords: fatty liver disease, mobile blood testing, decentralized clinical trials, patient recruitment, trial retention

1. Introduction

Metabolic dysfunction–associated steatotic liver disease (MASLD) and metabolic dysfunction–associated steatohepatitis (MASH), formerly known as NAFLD and NASH, are among the most common chronic liver conditions globally. These disorders are closely linked to obesity, type 2 diabetes, and cardiovascular disease and are projected to become leading indications for liver transplantation in coming decades.[1,2] Despite their growing prevalence and clinical impact, therapeutic development has progressed slowly, underscoring the importance of efficient and inclusive clinical trial designs.[3]

MASLD/MASH trials are uniquely complex. Eligibility determination frequently requires sequential noninvasive tests, advanced imaging, and confirmatory liver biopsy, contributing to high screen-failure rates and prolonged enrollment timelines.[4–5] Repeated fasting laboratory assessments and frequent site visits further increase participant burden, which contributes to attrition and limits demographic diversity.[6] These challenges have prompted increased interest in decentralized trial elements that reduce travel demands while maintaining scientific rigor.

Home-based blood collection via mobile phlebotomy represents one such strategy. By shifting routine laboratory procedures from research sites to participants' homes, mobile phlebotomy aims to improve accessibility and convenience while preserving specimen quality through standardized protocols. This approach is consistent with evolving regulatory perspectives that support decentralized trial components when appropriate controls are in place.[15]

Recruitment and Retention Barriers in MASLD/MASH Trials

Recruitment and retention challenges in MASLD/MASH studies arise from several interrelated factors:

1) **Multistep screening requirements**, including serial laboratory tests and imaging, extend enrolment timelines and increase participant burden.
2) **High rates of futile screening**, in which participants undergo multiple procedures before being deemed ineligible, reduce efficiency and increase dropout.[4]
3) **Visit intensity**, particularly repeated fasting laboratory assessments, complicates participation for individuals managing metabolic comorbidities.[2]
4) **Geographic access limitations**, which disproportionately affect rural and underserved populations and reduce trial representativeness.[6]
5) **Pre-analytical variability risks**, where inconsistent collection or transport conditions may compromise biomarker reliability.[16]

Together, these barriers contribute to prolonged timelines, increased costs, and limited generalizability of trial outcomes.

Mobile Phlebotomy as a Recruitment and Retention Enabler

Streamlined Pre-Screening
At-home blood collection enables early assessment of screening biomarkers such as FIB-4 and ELF, allowing investigators to triage potential participants before referral for more invasive or resource-intensive procedures. This approach can reduce unnecessary imaging and biopsy evaluations while improving screening efficiency.[4–5]

Improved Participant Convenience
Conducting fasting blood draws in participants' homes reduces travel demands and scheduling conflicts. This flexibility may improve protocol adherence and decrease attrition, particularly in long-duration studies requiring repeated laboratory assessments.[2]

Expanding Reach and Diversity
By removing geographic barriers, mobile phlebotomy facilitates participation by individuals who live far from major research centers or lack reliable transportation. This expanded reach supports efforts to improve equity and diversity in clinical research populations.[7]

Data Integrity Through Standardized Collection
MASLD/MASH trials rely heavily on biomarker-based endpoints, including CK-18, PRO-C3, and ELF. Professional mobile phlebotomy programs employ standardized collection techniques, temperature-controlled transport, and documented chain-of-custody procedures to minimize pre-analytical variability. Immediate sample stabilization and backup aliquoting further protect data integrity.[10]

In practice, some service providers—for example, organizations offering integrated phlebotomy and logistics support—have demonstrated that decentralized blood collection can meet regulatory-grade quality standards when appropriately implemented.

Regulatory and Compliance Considerations

Recent FDA guidance on decentralized clinical trials supports the use of home-based specimen collection when conducted under defined oversight, documentation, and quality assurance frameworks.[12] Rather than prescribing specific operational models, the guidance emphasizes risk-based approaches that ensure participant safety, data reliability, and traceability.

Key considerations include:
- **Good Clinical Practice (GCP):** Mobile phlebotomists must be trained on protocol-specific procedures and documentation requirements.
- **HIPAA Compliance:** Protected health information must be safeguarded throughout scheduling, collection, and data transfer processes.
- **Audit-Ready Documentation:** Time-stamped records of collection, transport, and laboratory receipt are essential for inspection readiness.
- **Participant Choice:** Home-based collection should remain optional to respect participant preferences and clinical needs.

Integration into MASLD/MASH Trial Designs

Mobile phlebotomy can be incorporated across multiple study models, including natural history cohorts, biopsy-enriched Phase 2 trials, and non-invasive test–based Phase 2b/3 studies. Its role is particularly valuable for longitudinal safety monitoring, metabolic laboratory assessments, and early screening evaluations, where consistency and participant convenience are paramount.

Table 1: Mobile Phlebotomy Integration Across Trial Models

Trial Model	Key Laboratory Requirements	Mobile Phlebotomy Contribution
Natural history cohorts	Longitudinal NITs and metabolic labs	Improves follow-up adherence and minimizes dropout
Biopsy-enriched Phase 2	Screening biomarkers, safety labs, PK samples	Reduces futile screens and ensures PK accuracy through timed home draws
NIT-based Phase 2b/3	Serial safety and efficacy biomarkers	Enhances data completeness and quality through consistent sample handling
Metabolic comorbidity arms	HbA1c, fasting glucose, lipid panels	Facilitates fasting compliance in real-world schedules

Quantitative Impact on Trial Performance
Operational modeling highlights the potential efficiency gains associated with improved retention. For a trial requiring 100 completed participants, a historical retention rate of 70% necessitates enrolment of approximately 143 individuals. Increasing retention to 85% reduces required enrolment to 118 participants, representing a 17.4% reduction. This improvement translates into lower recruitment costs and shorter timelines while preserving statistical power.

Evidence from decentralized trial evaluations further suggests that, with appropriate controls, home-collected specimens achieve quality metrics comparable to site-based collection.[9]

2. Limitations

Mobile phlebotomy is not a universal substitute for site-based visits. Procedures such as advanced imaging, liver biopsy, and certain pharmacokinetic assessments will continue to require in-clinic infrastructure. Additionally, the feasibility and effectiveness of mobile phlebotomy may vary based on regional workforce availability, courier networks, and local regulatory requirements. Careful planning and site-specific risk assessment remain essential to ensure consistent implementation across geographies.

3. Conclusion

MASLD and MASH clinical trials face persistent operational challenges related to complex eligibility criteria, participant burden, and geographic access. Mobile phlebotomy offers a practical decentralized solution that can reduce logistical barriers while maintaining biospecimen quality through standardized collection and transport protocols.

When integrated thoughtfully and supported by appropriate training and oversight, home-based blood collection aligns

patient-centered trial conduct with regulatory expectations. Although not a replacement for all site-based procedures, mobile phlebotomy represents a scalable adjunct that can enhance recruitment efficiency, retention, and data completeness—contributing to more inclusive and effective hepatology trials.

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