



A Mission-Driven, Multidisciplinary & Multi-Stakeholder Workshop

MOSAIC brings together cardiology, hepatology, nephrology and endocrinology clinical trialists, industry leaders, regulatory experts, payers, patients, patient representatives, journal editors, and other stakeholders to advance collective intelligence and foster collaboration about MASLD/MASH clinical trials through cross-organ dialogue.

5TH EDITION

26 – 27 October, 2026
Washington, D.C., USA

◆ A defining moment for MASH and multi-organ medicine

For decades, MASH was considered one of biopharma's most intractable challenges. That era is over. The approval of the first MASH therapies, the expansion of established metabolic drugs into liver disease, and a wave of strategic acquisitions have transformed the landscape.

But the real paradigm shift runs deeper. A new cross-organ thinking is emerging - formalized in the Cardiovascular–Kidney–Liver–Metabolic (CKLM) framework championed by the MOSAIC consortium and now published as a peer-reviewed roadmap. MASLD and MASH are no longer understood as isolated liver conditions: they sit at the center of an interconnected syndrome where cardiovascular events remain the leading cause of death and where kidney, metabolic, and hepatic pathways converge. This demands a fundamentally different approach to clinical trial design.

New classes of therapeutic agents are entering late-stage development, with every major program now built around combination strategies. Noninvasive diagnostics are gaining regulatory traction as potential surrogate endpoints for MASH, opening the door to larger, faster, and more representative trials that no longer depend on liver biopsy.

◆ What this moment means – And why MOSAIC matters

Now in its fifth edition, MOSAIC is the only global, mission-driven forum where the boundaries between hepatology, cardiology, nephrology, and endocrinology dissolve - replaced by a shared commitment to advancing MASLD/MASH science across organ systems. What distinguishes MOSAIC is not its size, but its composition: trialists, regulators, patients, journal editors, payers, and industry leaders - every voice in the room shapes the outcome.

- Regulatory milestones are accelerating. The first MASH therapies have been approved, and the first-ever non-invasive biomarker has been accepted into formal regulatory qualification. MOSAIC offers a unique opportunity to engage in in-depth, multistakeholder discussions with regulators on surrogate endpoint qualification and approval pathways.
- The CKLM framework is being operationalized. The MOSAIC consortium is drafting template protocols for integrated multi-organ trials that keep MASLD/MASH at their center while capturing cardiovascular, kidney, and metabolic endpoints. This work is setting new standards for how liver disease is studied in a systemic context.
- Combination therapy demands new trial architectures. Master protocols, basket trials, platform designs, and novel endpoint frameworks are being shaped in real time at MOSAIC - in a setting that values scientific rigor and multidisciplinary exchange.
- Noninvasive diagnostics are approaching regulatory acceptance. MOSAIC addresses the tools that will replace liver biopsy in MASH trial design - and the validation pathways required to get there.
- Cross-specialty alignment is no longer optional. Hepatologists, cardiologists, nephrologists, endocrinologists, regulators, patients, and journal editors must converge on endpoints and substudies - or risk perpetuating the data gaps that have slowed the field. MOSAIC is the one place where this convergence happens.

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◆ What Industry Partners Gain at MOSAIC

- **Be part of the conversation that shapes the CKLM trial playbook.** Enrollment criteria, endpoint strategies, biomarker frameworks, and substudies are being defined now. Partners at the table contribute to that process as it unfolds.
- **Work alongside regulatory authorities.** The FDA participates in open working sessions as a committed partner - a format unique to MOSAIC that enables genuine dialogue on accelerated approval pathways and surrogate qualification for MASH.
- **Anticipate trial design innovation.** Master protocols, DOOR frameworks, hierarchic composites, embedded substudies - the methodological innovations shaped here will define how the next wave of MASH and metabolic therapies is evaluated.
- **Navigate combination strategies.** With the field converging on multi-mechanism portfolios, MOSAIC is where competing and complementary approaches are examined across organ systems with scientific rigor.
- **Advance noninvasive diagnostics for MASH.** From screening algorithms to imaging biomarkers and circulating panels - MOSAIC addresses the validation pathways required for regulatory acceptance and the elimination of liver biopsy from trial design.

◆ Be Part of What Comes Next

The convergence of new therapeutic options, regulatory innovation, and cross-organ science is reshaping MASH and metabolic medicine. Over five editions, MOSAIC has grown from a pioneering initiative into an established, mission-driven institution - distinguished by the quality of its participants, the depth of its regulatory partnerships, and the multidisciplinary nature of its scientific output.

We invite you to join the conversation and contribute to this defining moment.

Industry Relations & Global Sponsorship

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