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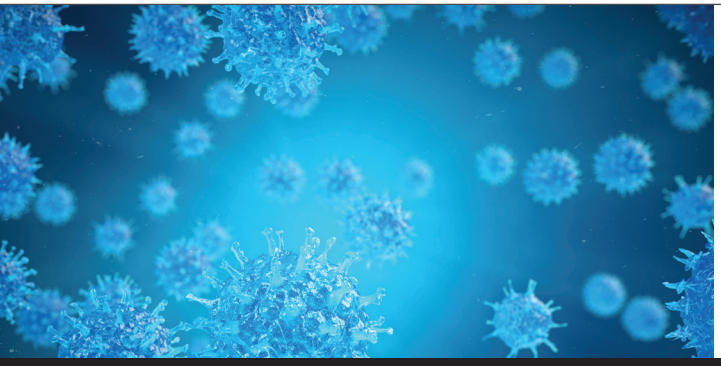

HEPATITIS B

Experts. Experience. Execution.

Deep Dive: Hepatitis B Clinical Research

Accelerate your next Hepatitis B study with Medpace's noted medical and regulatory experts, highly experienced clinical trial management teams, central labs, and a Cardiovascular Core Lab and Clinical Pharmacology Unit for TQT studies.

As a therapeutically-focused CRO, Medpace specializes in the design and conduct of global trials in Infectious Disease, including Hepatitis B virus (HBV). We bring a global footprint, strategic medical, regulatory and operational leadership, as well as fully integrated Central Labs and safety services to enhance and expedite development.

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Experience

The complex nature of conducting chronic hepatitis studies demands a deep understanding of the issues and challenges surrounding the geography, epidemiology, current standard of care, virology, endpoints, and prevalence of the disease. Medpace and its team of therapeutic experts has extensive experience managing clinical studies in viral infections and in liver diseases and understand the nuances of chronic hepatitis.

Featured Medical Expert – Hervé Momméja-Marin, MD

Hervé Momméja-Marin, MD, one of the principal physicians in Medpace's anti-viral/anti-infectives team, brings his extensive knowledge and experience in HBV to your project. Prior to joining Medpace, Dr. Momméja-Marin was a Director of Clinical Research at a large pharmaceutical firm where he served as project lead for their HBV program, and was responsible for the overall development program including two worldwide phase III studies and two phase II studies. (See biography below.)

Medpace is unique in its approach to clinical research and Dr. Momméja-Marin will be deeply embedded and an active participant in your project team. In his role, he is able to participate in the careful discussions with regulatory agencies with respect to design (combination therapy), comparator, endpoints and duration of treatment - always a challenge for HBV studies.

Background Biography - Hervé Momméja-Marin, MD
Senior Medical Director, Infectious Diseases and Vaccines

Dr. Hervé Momméja-Marin is an internal medicine and infectious disease specialist, trained in Paris, France. Hervé has more than 15 years of clinical research experience working for both the pharmaceutical industry and Contract Research Organizations. During his tenure at Gilead Sciences, i3 Research, and Chimerix, Hervé acted as project leader for numerous antiviral (including compounds targeting HIV, hepatitis B, hepatitis C, smallpox, double stranded DNA infections in transplant recipients, and other immunocompromised patients), and vaccine, in patient populations ranging from neonates to the elderly. He has designed and conducted numerous global clinical trials from Phase I through IV, including expanded access, leading the regulatory interactions with FDA, EMA, and multiple competent authorities/reimbursement bodies globally. He has contributed to multiple NDAs, MAAs, and INDs.

Dr. Momméja-Marin has led collaborative projects with BARDA, NIAID, NIH, ACTG, ANRS, CDC, MSF, and multiple disease networks. He has authored numerous publications including the New England Journal of Medicine, and presented at scientific conferences worldwide as an invited speaker. Hervé has extensive experience and relationships in Asia pacific and with leading hepatologists globally. In addition to his medical degree, Dr. Momméja-Marin holds degrees in biostatistics and epidemiology. As Senior Medical Director at Medpace, Dr. Momméja-Marin brings his breadth of experience as a drug developer to support the development of novel anti-infective agents from study design through study report, with a particular emphasis on a collaborative relationship with stakeholders, including site personnel.

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Recruitment and Global Site Relationships

Identifying treatment-naïve patients in the era of multiple available therapies can be challenging. Medpace is able to navigate the complex world of patient recruitment and retention by employing our multi-dimensional recruitment model that enables us to implement customized strategies that identify, recruit, and retain infected patients. Our productive network of key clinical sites and KOLs who specialize in anti-virals and liver disease ensures study timelines and key milestones are achieved. In addition, our strong site and KOL relationships and strategies keep PIs engaged and can lead to greater success in collecting liver biopsies at the end of treatment, if necessary. In addition, Medpace has a strong presence in Asia-Pac countries which are critical to successful recruitment.

Medpace Global Labs Provide Safety and Biomarker Analysis

Medpace's labs provide the safety testing, HBV DNA and HBsAg quantitation, and other serology testing (e.g. HBV, HIV, HAV, HCV) associated with hepatitis B studies (see table below). Just as important, we can help you determine what testing is necessary based on your endpoints.

Medpace Labs provide consistency in methods and instrumentation across wholly-owned and purpose-built laboratories located in the US, Europe, China and Singapore. We offer a wide range of relevant biomarker assays and have the ability to rapidly establish and validate novel assays as needed.

Key tests for Hepatitis B supported by Medpace Central Laboratories

Assay	Method	Medpace Validated Assays	Medpace Lab Partner Network*
Hepatitis B core Antibody, IgM (Qualitative)	ECLIA	✓	
Hepatitis B core Antibody, Total (Qualitative)	ECLIA	✓	
Hepatitis B DNA	RT-PCR	✓	
Hepatitis B Envelope Antibody	ECLIA	✓	
Hepatitis B Envelope Antigen (Qualitative)	ECLIA	✓	
Hepatitis B Envelope Antigen (Quantitative)	ECLIA	✓	
Hepatitis B Surface Antibody (Qualitative)	ECLIA	✓	
Hepatitis B Surface Antigen (Qualitative)	ECLIA	✓	
Hepatitis B Surface Antigen (Quantitative)	ECLIA	✓	
Hepatitis B Genotyping	PCR/Sequencing		✓

**There may be some tests / biomarkers requested that are not on the central lab test menu. Although those biomarkers may not currently be on Medpace's validated menu, they are available via Medpace's laboratory partners. These assays may be candidates as new validations to the Medpace in house test menu. Each year Medpace validates over 70 new assays based on guidelines from the Clinical and Laboratory Standards Institute (CLSI) and in accordance with CAP and CLIA regulations.*

Thorough QT/QTc (TQT) Studies: CPU and Cardiovascular Core Lab

TQT studies are needed for HBV prior to Phase 3. With our state-of-the-art Clinical Pharmacology Unit (CPU), Cardiovascular Core Lab, and cardiac safety experts all housed on the same clinical research campus in Cincinnati, OH, we are able to take total control of the testing environment and manage the rigors of TQT studies.

About Medpace

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. Headquartered in Cincinnati, Ohio, Medpace employs approximately 2,600 people across 35 countries.