The AIOS Mission All hepatology research is not created equal. AIOS knows this, and aims to provide its clients with comprehensive, integrated solutions to their product-development needs. Our mission is to help clients answer important hepatology research and development questions in the most efficient, meaningful, and ethical ways possible. We achieve our mission by leveraging the expertise of our affiliated thought leaders and operations specialists around the globe. We believe that inclusion of multiple perspectives results in the best product possible for our clients. At the same time, our streamlined structure translates into maximum flexibility and responsiveness. WE STAND READY TO ASSIST YOU WITH PRODUCT DEVELOPMENT FOR THE FOLLOWING INDICATIONS: HEPATITIS B LIVER CANCER HEPATITIS C SUPPORTIVE CARE

HEPATOTOXCITY

LIVER DEVICES

■ HIV/HEPATITIS COINFECTION

FIBROSIS

CIRRHOSIS



"Hepatitis B and C represent an enormous burden and challenge for the research community and the public, affecting five times as many Americans as AIDS/HIV..."

Nezam Afdhal, MD, cofounder, AIOS

The AIOS Difference Unlike most clinical development groups, AIOS offers access to the expertise of specialists with proven track records in both clinical practice and clinical and translational research. As a result, we can provide our clients with: IN-DEPTH UNDERSTANDING OF SUCCESSFUL TRIAL DESIGNS FOR HEPATOLOGY RESEARCH PRACTICAL, REAL-WORLD KNOWLEDGE OF MODERN MEDICAL PRACTICE ACCESS TO NETWORKS OF EXPERIENCED **CLINICAL INVESTIGATORS AND THOUGHT LEADERS AROUND THE WORLD** SKILLED GUIDANCE IN NAVIGATING THE REGULATORY PROCESS FOR PRODUCT DEVELOPMENT THOROUGH AWARENESS OF THE CURRENT MARKET FOR HEPATOLOGY PRODUCTS APPROPRIATE PATIENT POPULATIONS, FOR RAPID **ENROLLMENT OF QUALIFIED CANDIDATES** AIOS can offer the winning combination of research operations expertise, thought leadership, and customer-service focus that ensures our clients' satisfaction. How can we help you achieve your goals?

AIOS Clinical Leadership



Nezam H. Afdhal, MD

Director, Liver Center, Beth Israel Deaconess Medical Center

Associate Professor of Medicine, Harvard Medical School

Dr. Afdhal received his specialty training in gastroenterology and hepatology at the Boston University School of Medicine and St. Vincent's Hospital and University College, Dublin. He directs one of the largest hepatology divisions in the U.S., with major NIH-funded basic and clinical research programs and 20+ industry-sponsored trials. The Center has expertise in immunology, fibrosis, biliary diseases, genomics, and proteomics. Dr. Afdhal is widely published in biliary and liver diseases with numerous original articles and several books. He has served on editorial boards for several peer-reviewed journals, including *Gastroenterology*, and on many AASLD and AGA committees. He has been involved with numerous clinical trials as a local, regional, national, and global Pl. A special area of expertise has been in interactions with FDA and industry in development of new devices for the diagnosis and treatment of liver diseases.

Dr. Afdhal's clinical and research interests span all elements of liver disease, with a special focus on Phase I–III studies of HBV and HCV therapeutics.



John G. McHutchison, MD

Director, Gastroenterology and Hepatology Research, Duke Clinical Research Institute (DCRI)
Professor of Medicine, Duke University Medical Center

Dr. McHutchison is a distinguished GI and liver disease researcher. After leaving his native Australia, he served as assistant professor of medicine at the University of Southern California and as medical director for liver transplantation at the Scripps Clinic before joining Duke in 2002. The DCRI's GI-Hepatology research program, which has conducted over 250 clinical studies, is home to a large hepatology database, which includes demographic, treatment, and outcomes data for over 1500 patients with chronic HCV treated at one center. Dr. McHutchison has served on many advisory committees and on the editorial boards of the peer-reviewed liver journals *Hepatology* and *Journal of Hepatology*. He also has published extensively in the hepatology field.

Dr. McHutchison's clinical and research interests are broad; the GI-Hepatology research program includes hepatitis B and C viruses in relationship to treatment, disease progression, immunopathogenesis and genetic factors, ascites, noninvasive markers of fibrosis, and steatosis. He is often asked to advise and consult with industry and for regulatory authorities.

AIOS Services

Our range of professional services — whether performed directly by AIOS or accomplished through our strategic relationships with other thought leaders and operational experts — encompasses all of your potential hepatology research and development needs:

- STRATEGIC PLANNING
- KEY OPINION LEADER (KOL) DEVELOPMENT
- CLINICAL DEVELOPMENT PLANNING
- MEETING ADVOCACY: INDS/NDAS, END OF PHASE II, ADVISORY PANELS, INVESTIGATORS, INVESTORS, VENTURE CAPITALISTS
- REGULATORY SERVICES
- ☐ INVESTIGATOR/SITE RECRUITMENT AND TRAINING
- STUDY MATERIALS DEVELOPMENT: PROTOCOLS, CRFS, EDUCATIONAL MATERIALS, PROMOTIONAL AIDS
- □ ACCESS TO PATIENT SUPPORT GROUPS
- DATA ANALYSIS AND INTERPRETATION
- EVALUATION OF HEPATOTOXICITY OF NEW AGENTS
- PUBLICATIONS SUPPORT AND STRATEGIES
- INTEGRATION WITH LEADING BASIC-RESEARCH
 GROUPS IN IMMUNOLOGY, VIROLOGY, AND
 LIVER FIBROSIS