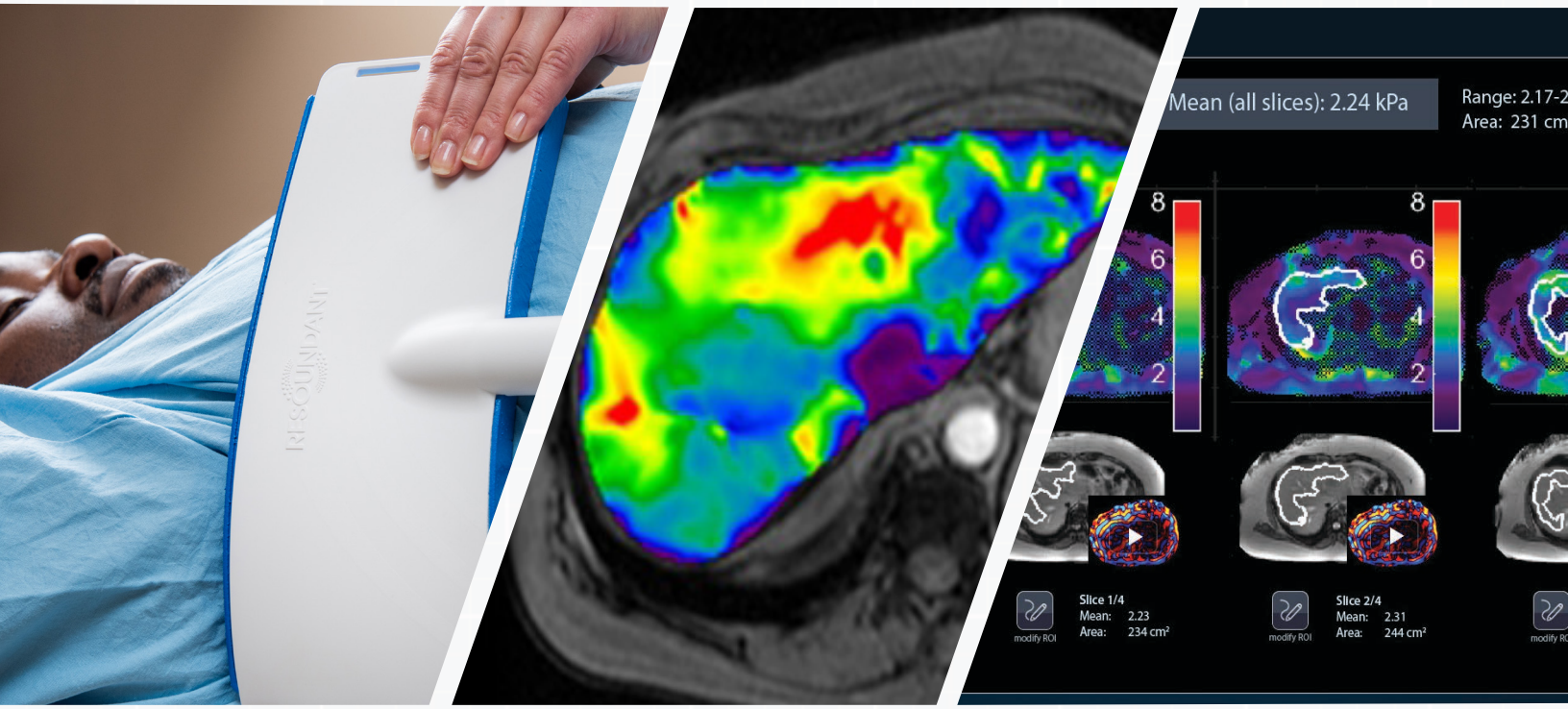


Clinical Trial Imaging Solutions

Detecting and staging liver fibrosis can often be one of the most critical, yet challenging, aspects of a clinical trial.

See how our expertise with **MR Elastography** can make a difference.

RESOUNDANT
CLINICAL TRIALS

MRE for Clinical Trials

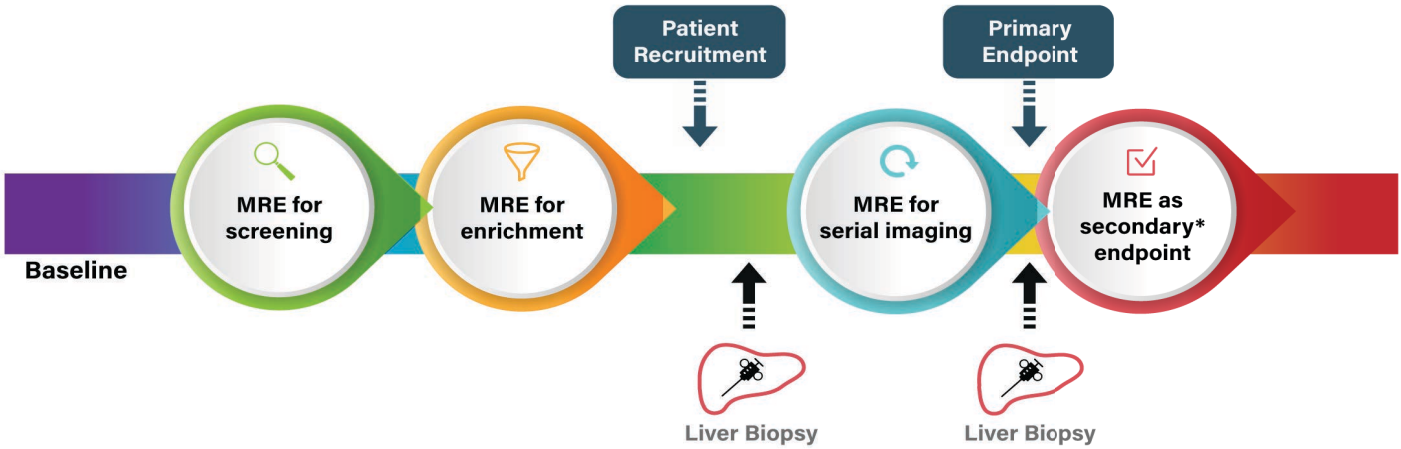
Many clinical trials focused on liver diseases, such as non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), require detection and staging of liver fibrosis. Liver biopsy with histopathologic analysis has been the traditional tool for this purpose but is not ideal due to cost, invasiveness, and sampling error. There is a widely-recognized need for non-invasive approaches to reliably assess liver fibrosis at a significantly lower cost and with greater technical capacity.

MR Elastography (MRE) is an MRI-based technique for quantitatively assessing liver fibrosis, with high diagnostic performance that has been extensively documented in the literature and recognized by the US Centers for Medicare and Medicaid Services.

With over 1,500 installations worldwide (including 600+ in the United States), MRE is widely available and provides a more comfortable, more accurate, and less costly alternative to liver biopsy for assessing hepatic fibrosis.

The combination of MRE and PDFF in a single, rapid exam for steatosis and fibrosis staging - as well as the use of advanced in-house tools - provide a comprehensive assessment of liver health by helping to distinguish NAFLD/NASH phenotypes. For longitudinal research, MRE can also be used to assess disease progression, regression, and treatment response. Together, our powerful tools can bring promising therapies closer to realization more rapidly, more confidently, and at far less cost than ever before.

Optimize Your Trial Design with MRE



*MRE is also being actively investigated as a surrogate endpoint

Why Resoundant

Resoundant offers Clinical Trial services in collaboration with the Mayo Clinic scientists and medical professionals who invented MR Elastography over 20 years ago.

Today, Resoundant and Mayo Clinic continue to support the ongoing advancement of MRE through joint research and development activities. Resoundant Clinical Trial personnel also hold joint appointments in Mayo's MRE laboratory, and are recognized as experts in the field of MRE. The MRE laboratory at Mayo Clinic has held continuous grant support from the National Institutes of Health since 1995.

Invented by

MAYO CLINIC

This unique relationship offers clinical trial sponsors the ability to tap into sophisticated products and tools developed through rigorous Mayo Clinic academic research, but in a nimble, low-cost, and industry-friendly manner. These services include image central reading, protocol development, scientific advisory services, site training, and site qualification.

Our specialization, at your service

We strive to specialize in a single, powerful marker that can quickly assess fibrosis stage.

For trials of chronic liver diseases, MRE can reliably enrich study populations and support more rapid go/no-go decision making for the sponsor - all at a low cost and in an extremely short amount of scanner time for the patient.

Technology-assisted analysis of MRE and PDFF data, which can greatly reduce inter-reader variability and analysis time.

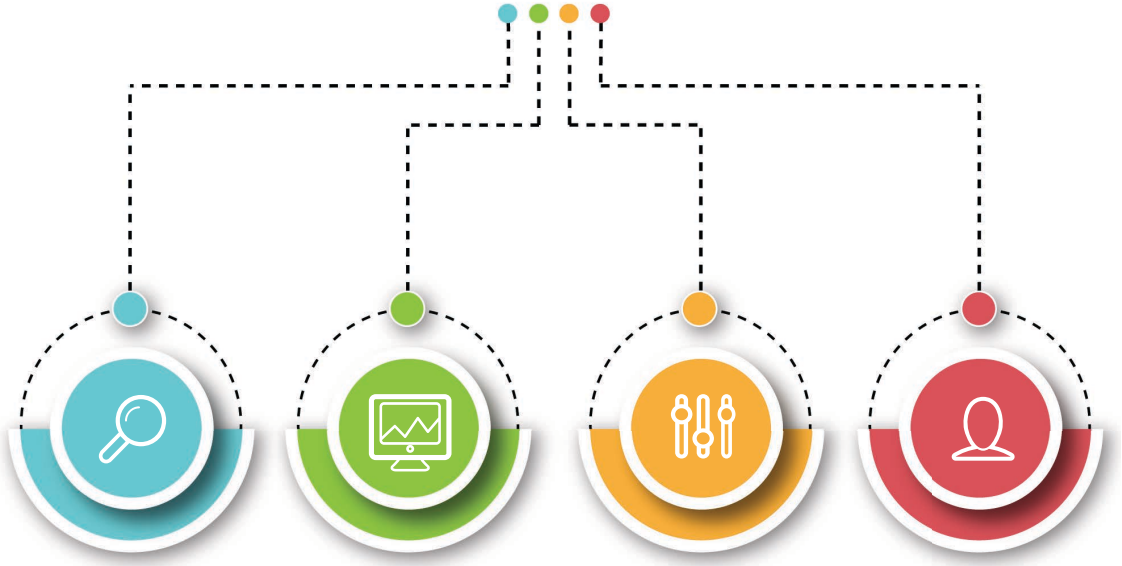
Experience matters

Our staff has extensive experience in the use of quantitative imaging in clinical trials and can deliver a rapid, accurate, and quantitative assessment of liver health from MRE+PDFF expert central analysis. Our goal is to streamline the image analysis process for drug development clinical trials in order to provide an accurate, rapid, and biologically relevant evaluation of liver health for trial enrollment, safety, monitoring, and endpoints.

Resoundant personnel are recognized leaders in the field, with deep experience in the acquisition and post-processing of key MR-based biomarkers - notably MRE and PDFF. Collaboration with our team offers you access to the technology's inventors, unparalleled experience, and state of the art technology and post-processing tools.

Altogether, our staff have served as consultants on completed and ongoing trials, as well as international consortia. These roles have included protocol development, scientific advisory services, imaging central reading, site training, and site qualification.

WORK TO DATE



Number trials	Number of exams	Phases	Indications
8	1,500+	IIa-IIb	NAFLD NASH HCV HBC PBC

Clinical Trial Services

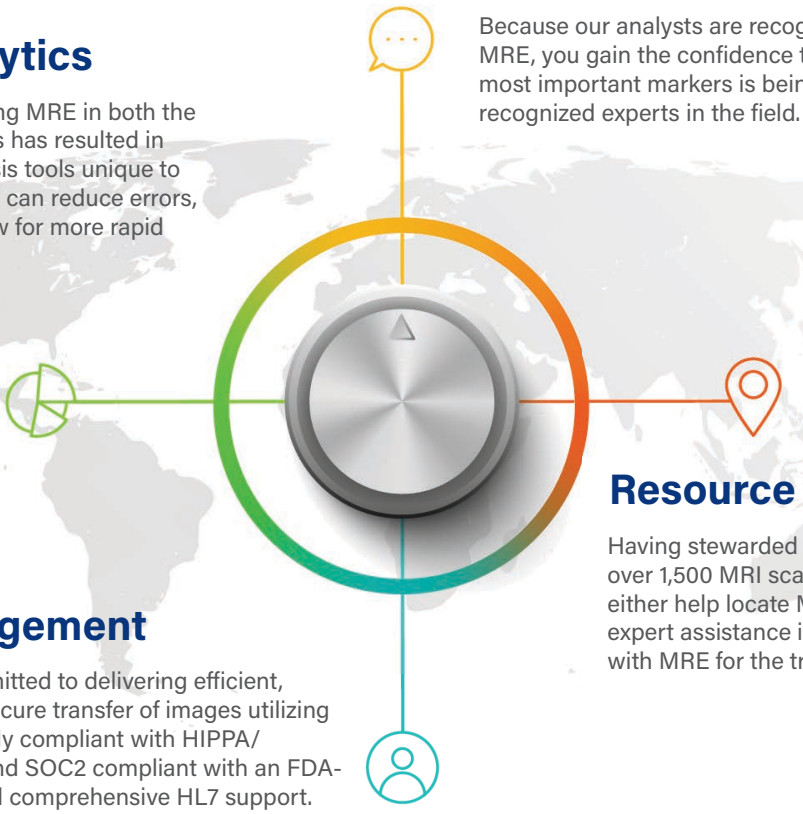
Dial in just the amount of support you need.

Expert Image Reading

Because our analysts are recognized leaders in MRE, you gain the confidence that one of your trial's most important markers is being evaluated by the recognized experts in the field.

Advanced Analytics

Our commitment to advancing MRE in both the clinical and research settings has resulted in proprietary, advanced analysis tools unique to Resoundant. These analytics can reduce errors, decrease variability and allow for more rapid turnaround.



Resource Allocation

Having stewarded the installation of MRE on over 1,500 MRI scanners worldwide, we can either help locate MRE capabilities or provide expert assistance in outfitting imaging sites with MRE for the trial.

Data Management

Resoundant is committed to delivering efficient, HIPPA-compliant, secure transfer of images utilizing solutions that are fully compliant with HIPPA/ HITECH HITRUST and SOC2 compliant with an FDA-approved viewer and comprehensive HL7 support.

Study Start-Up

From governing documents to eCRF, imaging manuals and charters, our experts can help create high-impact study documentation.

Regulatory Support

Building upon our own work on MRE biomarker qualification, we can advise on MRE for submission to regulatory authorities.

Quality Control

Our validated QC infrastructure ensures high quality data with rapid turnaround, while working with sites directly on any quality issues that may arise.

Site Support

Resoundant's experts are always available via our dedicated hotline and other timely support resources to ensure each acquisition is optimal.

Study Design Consultation

No matter the context of use, you can engage our team at any point in your design process to ensure accurate, precise, and reproducible MRE results.

Training Needs

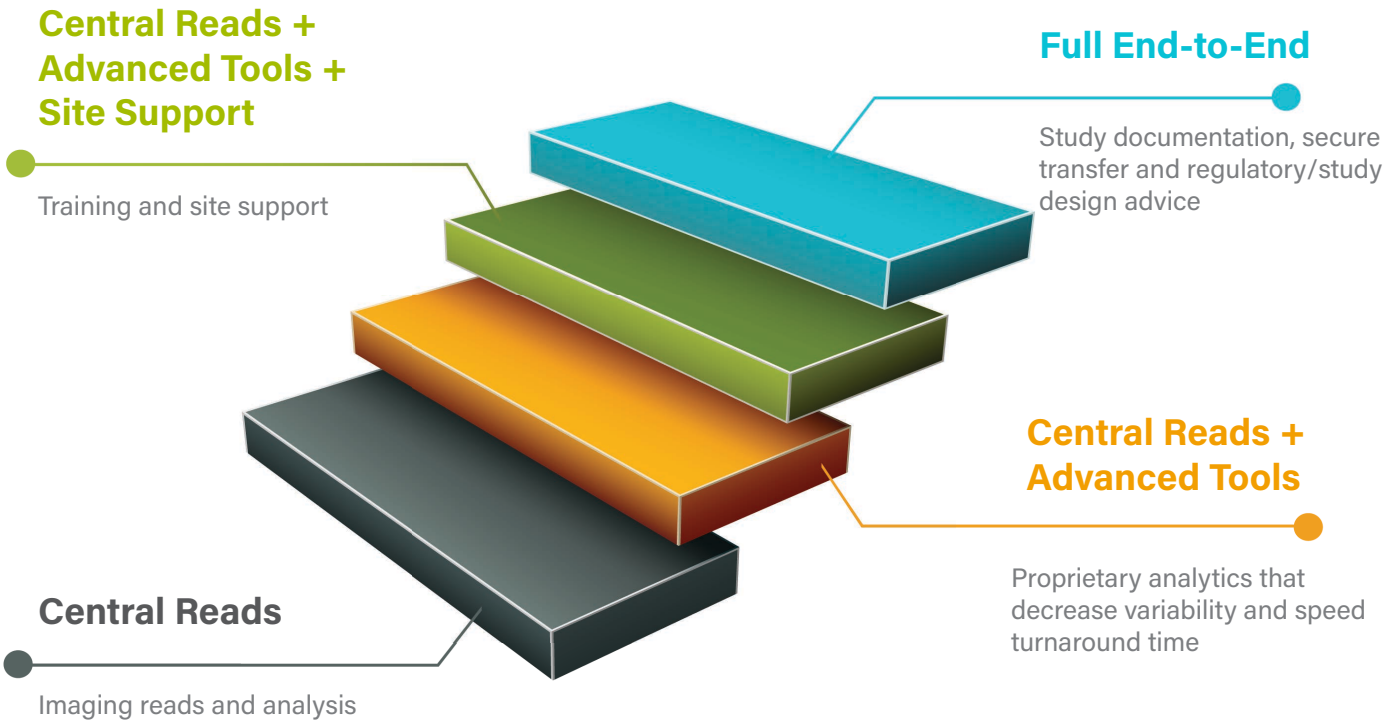
Whether through online courses, live webinars, or onsite training, we ensure that each site meets our standards.

Tailored Solutions

Our goal is to fit seamlessly into your existing architecture and workflow.

Whether you need end-to-end support for imaging of fibrosis and steatosis, or you simply need more tailored levels of support that fit into your current workflow, we are here to support you and your sponsors along the drug development journey.

Levels of service that fit your need



THE RIGHT TEAM FOR THE RIGHT TECHNOLOGY

Resoundant, Inc.

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Rochester, MN
55902, United States

clinicaltrials@resoundant.com

Resoundant, Inc. was founded by Mayo Clinic and is the developer and manufacturer of Magnetic Resonance Elastography (MRE).

MRE has been commercially-available as an FDA-cleared diagnostic technology since 2009 and is used in clinical practice on over 1,500 MRI systems around the world.

R1-MKT-REC-134, Rev 2