MEASURE WHAT MATTERS

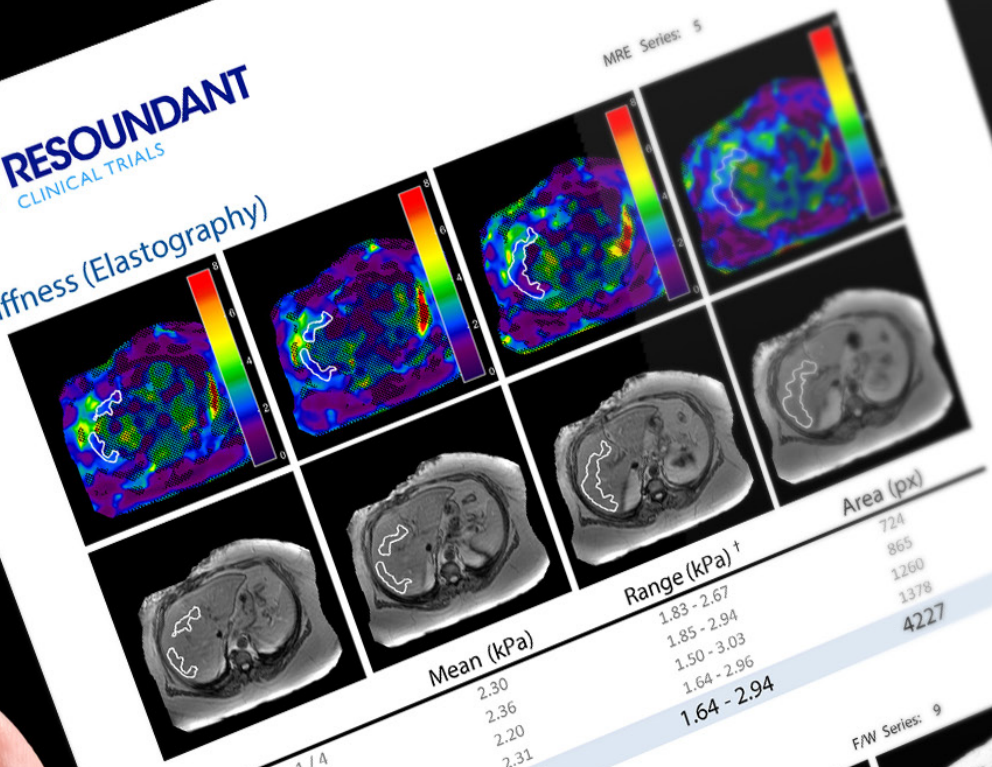
MR Elastography for
Clinical Trials

RESOUNDANT
CLINICAL TRIALS

RESOUNDANT
CLINICAL TRIALS

Stiffness (Elastography)

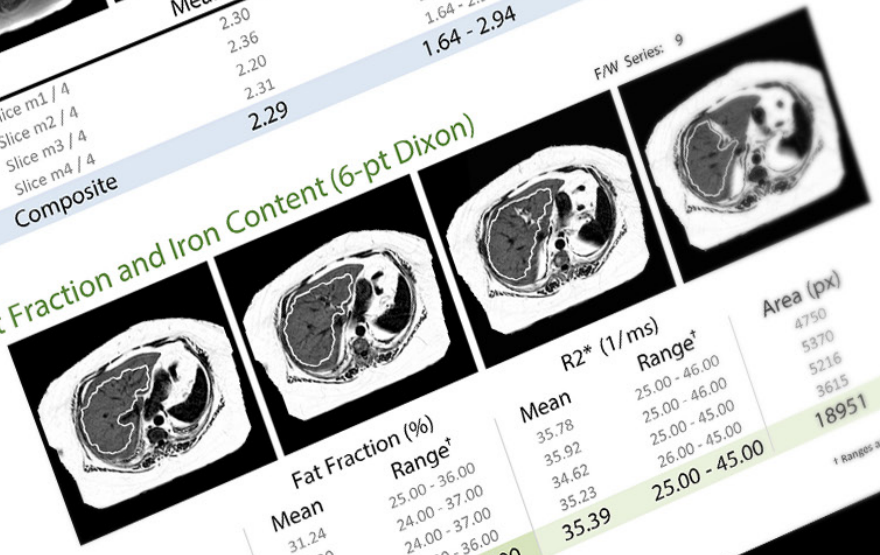
MRE Series: 5



	Mean (kPa)	Range (kPa)†	Area (px)
Slice m1 / 4	2.30	1.83 - 2.67	724
Slice m2 / 4	2.36	1.85 - 2.94	865
Slice m3 / 4	2.20	1.50 - 3.03	1260
Slice m4 / 4	2.31	1.64 - 2.96	1378
Composite	2.29	1.64 - 2.94	4227

Fat Fraction and Iron Content (6-pt Dixon)

F/W Series: 9



	Fat Fraction (%)		R2* (1/ms)		Area (px)
	Mean	Range†	Mean	Range†	
Slice f1 / 60	31.24	25.00 - 36.00	35.78	25.00 - 46.00	4750
Slice f2 / 60	31.00	24.00 - 37.00	35.92	25.00 - 46.00	5370
Slice f3 / 60	31.47	24.00 - 37.00	34.62	25.00 - 45.00	5216
Slice f4 / 60	30.39	24.00 - 36.00	35.23	26.00 - 45.00	3615
Composite	31.07	24.00 - 36.00	35.39	25.00 - 45.00	18951

† Ranges are 10%-90%

EXECUTIVE SUMMARY

Expert analysis from Resoundant-trained analysts gives a snapshot of the most important liver metrics.

Clinical trials in liver disease have a strong need to diagnose and stratify patients based on fibrosis stage and to monitor trial participants for treatment response. The current gold standard – liver biopsy – is expensive and prone to variability and sampling error. There exists a critical need for a non-invasive way to diagnose fibrosis with high accuracy and low variability.

MR Elastography (MRE) is an MRI-based technique for quantitatively assessing liver stage. In this capacity, MRE is recommended for routine clinical use by several multidisciplinary medical societies. With over 1,600 installations worldwide (700+ in the United States), MRE is widely available and provides a more comfortable and less costly alternative to liver biopsy for assessing hepatic fibrosis, while simultaneously improving accuracy and precision. In chronic liver disease clinical research, MRE may also be used to assess disease progression, regression, and treatment response. The combination of MRE and proton density fat fraction (PDFF) in a single rapid exam for steatosis and fibrosis staging provides a comprehensive and rapid assessment of liver health. Emerging advanced multiparametric 3D-MRE technology will add new capabilities beyond liver stiffness for fibrosis assessment, including more advanced mechanical properties to assess inflammation.

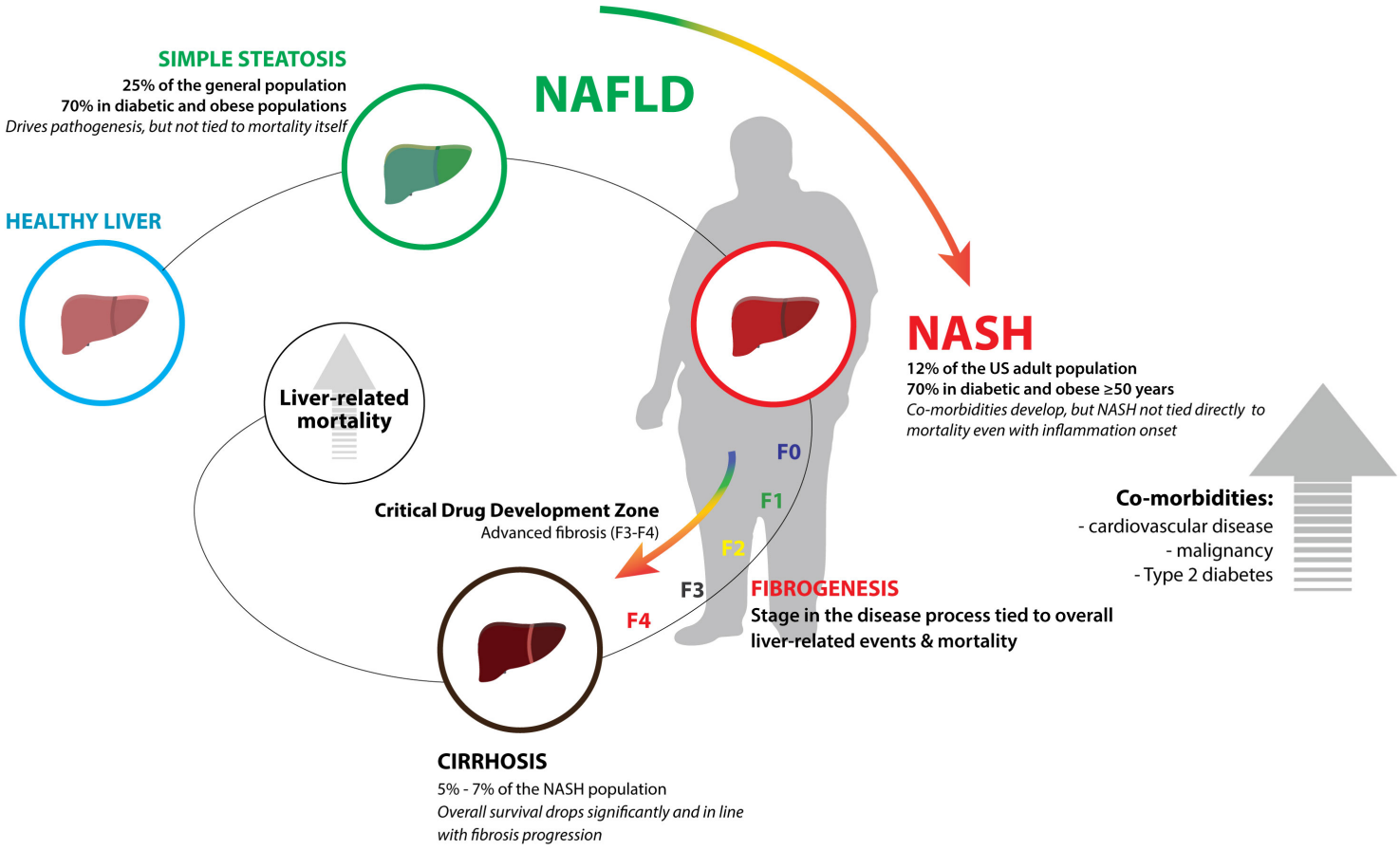
CHALLENGES FOR SPONSORS

Non-alcoholic steatohepatitis (NASH) is projected to become the leading cause of liver transplantation in the United States within the next five years [1]. While pharmaceutical companies are actively researching potential therapies, the clinical trial landscape for NASH has presented unique challenges. These range from questions regarding pathogenesis and the interplay between the underlying mechanisms of disease (lipogenesis and inflammation) to a reliance on liver biopsy, which is widely recognized as both costly and prone to high levels of variability [2].

Further, many patients have severe co-morbidities such as obesity, which can confound other non-invasive screening technologies [3]. This can result in high levels of false positives – leading to costly and unnecessary liver biopsies and high levels of screen failure rates (as high as >90% when using traditional study screening).

Although NAFLD and NASH are driven by lipogenesis and inflammatory pathways, there are no diagnostic criteria for predicting which patients with NAFLD will progress to NASH. Therefore, the US Food and Drug Administration (FDA) encourages trial sponsors to focus on developing treatments for NASH with liver fibrosis [4]. This matches a growing body of outcomes-focused literature, which shows that the onset and progression of fibrosis remains the only aspect of pathogenesis that is correlated with higher liver-related mortality [5-8].

Fortunately, MRE is well poised to address this part of trial design due to its superior accuracy, wide availability, and high technical success for staging fibrosis in NAFLD cohorts [9-14]. Depending on the trial design, MRE can accurately stage fibrosis, enrich study populations, or monitor response to treatment.



MRE LINKED WITH OUTCOMES

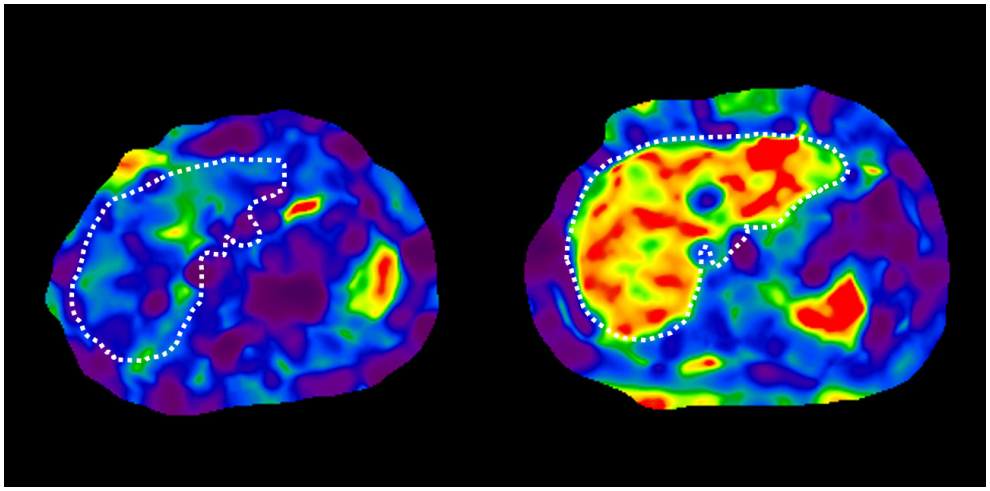
Of the various pathogenetic factors involved in NAFLD/NASH development, the onset of fibrosis is the only known factor of the disease process tied to liver-related events and mortality. Elevated liver stiffness assessed by MRE has also been shown to correlate with histologic events in NAFLD patients, including decompensation. A recent study showed that NAFLD increased liver stiffness was associated with ascites, hepatic encephalopathy, esophageal variceal bleeding, and mortality [15]. Fibrosis stage as determined by MRE is also associated with increased risk of cardiovascular disease [16].

BIOMARKER FOR LIVER FIBROSIS

A large body of evidence demonstrates that MRE is very effective for distinguishing normal liver tissue from fibrotic liver tissue with high sensitivity and specificity. Decades of research into MRE have validated that normal liver parenchyma has a shear stiffness less than 3 kPa. However, as liver disease progresses, liver stiffening accelerates and MRE has been shown to be highly accurate in characterizing this progression on a continuous, quantitative scale [9-14, 17].

Given the current absence of clear diagnostic criteria for identifying patients who are likely to progress from NAFLD to NASH, the FDA encourages drug developers to focus on treatment of NASH patients with advanced fibrosis or cirrhosis. Therefore, one of the most important applications of MRE in clinical trials is to screen potential participants to accurately identify subjects who have stage 2-4 fibrosis prior to confirmatory biopsy.

A pooled analysis of data from 12 studies and 697 patients found that MRE has a high diagnostic accuracy for the diagnosis of significant or advanced fibrosis, independent of BMI and etiology of chronic liver disease [17]. The mean area under the receiver-operating curve for the diagnosis of fibrosis were: 0.84 for any stage (stage >=1), 0.88 for significant (stage >=2), 0.93 for advanced (stage >=3) and 0.94 for cirrhosis.



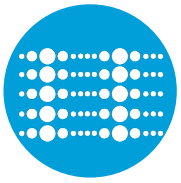
MRE image of the liver, showing areas of soft healthy tissue (blue) and areas of increased stiffness (red). MRE software calculates the mean stiffness across the entire liver, helping to decrease the variability and sampling error that can occur with liver biopsy and ultrasound elastography.

VALIDATED & ACCEPTED

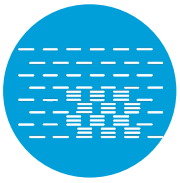
MRE measures the mechanical properties of tissue by using the physical principle that the propagation of mechanical waves in a material are directly related to the stiffness of that material. MRE is an add-on option available for most new MR scanner purchases, or MRE can be added to nearly any existing 1.5T or 3T MR scanners from one of our partners (GE, Philips, Siemens, or United Imaging). MRE upgrades consist of both a hardware and software component.

Standalone MRE can also be requested (not as part of full abdominal MRI) and can be completed in under 15 minutes (CPT code 76391).

A simple, drum-like driver generates acoustic waves within .the tissue of interest



A special MRI technique images tiny displacements of the tissue that result from wave propagation.



An advanced mathematical algorithm generates maps of tissue stiffness, known as "elastograms."

Reproducibility and standardization

The implementation of MRE is consistent across MRI manufacturers and field strengths [18-19]. All the FDA-cleared and CE mark implementations of MRE use standardized acquisition techniques, driver technology, and processing algorithms. Several studies have demonstrated reproducibility of stiffness measurements across different vendor platforms and field strengths [9], [10].

Further, under standards developed by the **Quantitative Imaging Biomarkers Alliance (QIBA)**, a change of 19% or greater in measured stiffness can be attributed to a true biological change with at least 95% confidence in any individual [20].

ROUTINE CLINICAL MRE

Due to its accuracy, precision, and high technical success rate, MRE is recommended by several multidisciplinary societies for routine clinical evaluation of liver fibrosis.

"In adults with NAFLD and a higher risk of cirrhosis, MRE is suggested, rather than VCTE, for detection of cirrhosis."

American Gastroenterological Association Institute Guideline on the Role of Elastography in the Evaluation of Liver Fibrosis (2017) [21]

"MRE is excellent for identifying varying degrees of fibrosis in patients with NAFLD. VCTE or MRE are clinically useful tools for identifying advanced fibrosis in patients with NAFLD."

The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance From the American Association for the Study of Liver Diseases (2017) [22]

"MR elastography is the most accurate method for diagnosing liver fibrosis non-invasively because it assesses the whole liver and can stage liver fibrosis."

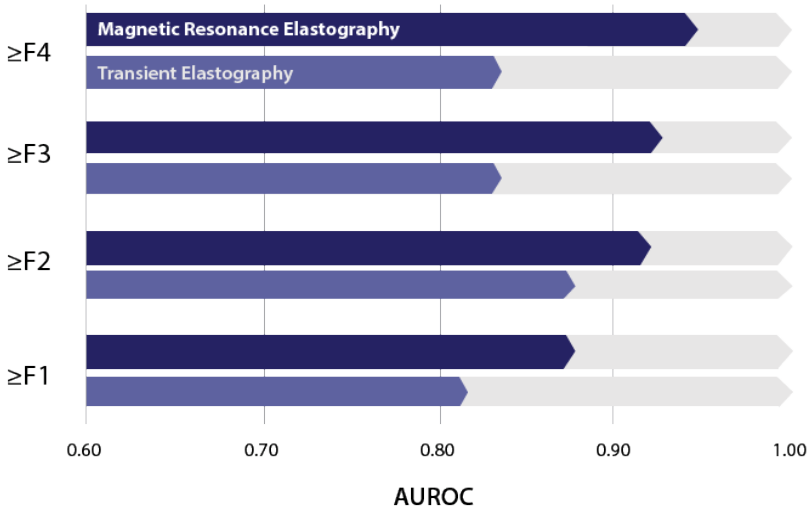
American College of Radiology Appropriateness Criteria® Chronic Liver Disease (2017) [23]

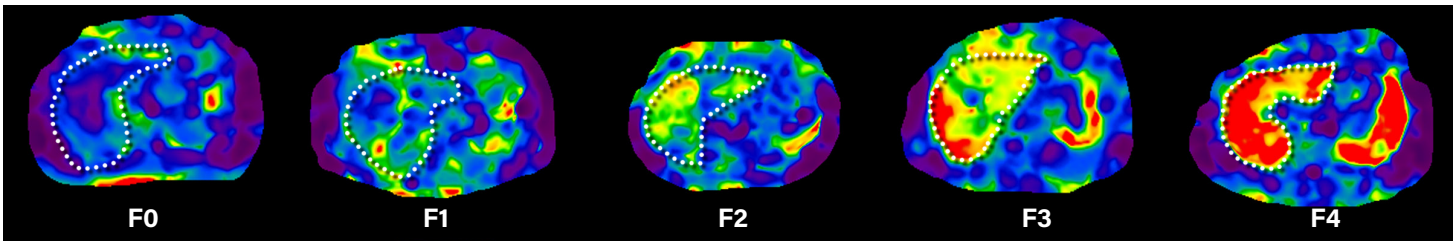
Highest diagnostic accuracy among noninvasive tests

Liver MRE is a robust imaging technique for the quantification of liver stiffness and is currently the most accurate noninvasive imaging technology for the evaluation of liver fibrosis [9-14]. In a pooled analysis of data from individual participants with NAFLD in three independent studies, MRE demonstrated a significantly higher diagnostic accuracy than TE for the detection of individual stages of fibrosis using liver biopsy as a reference [24].

Additionally, MRE has excellent diagnostic performance and a high technical success rate in obese patients (95.5%) when compared to VCTE (81.4%), and may be a better alternative in this population.

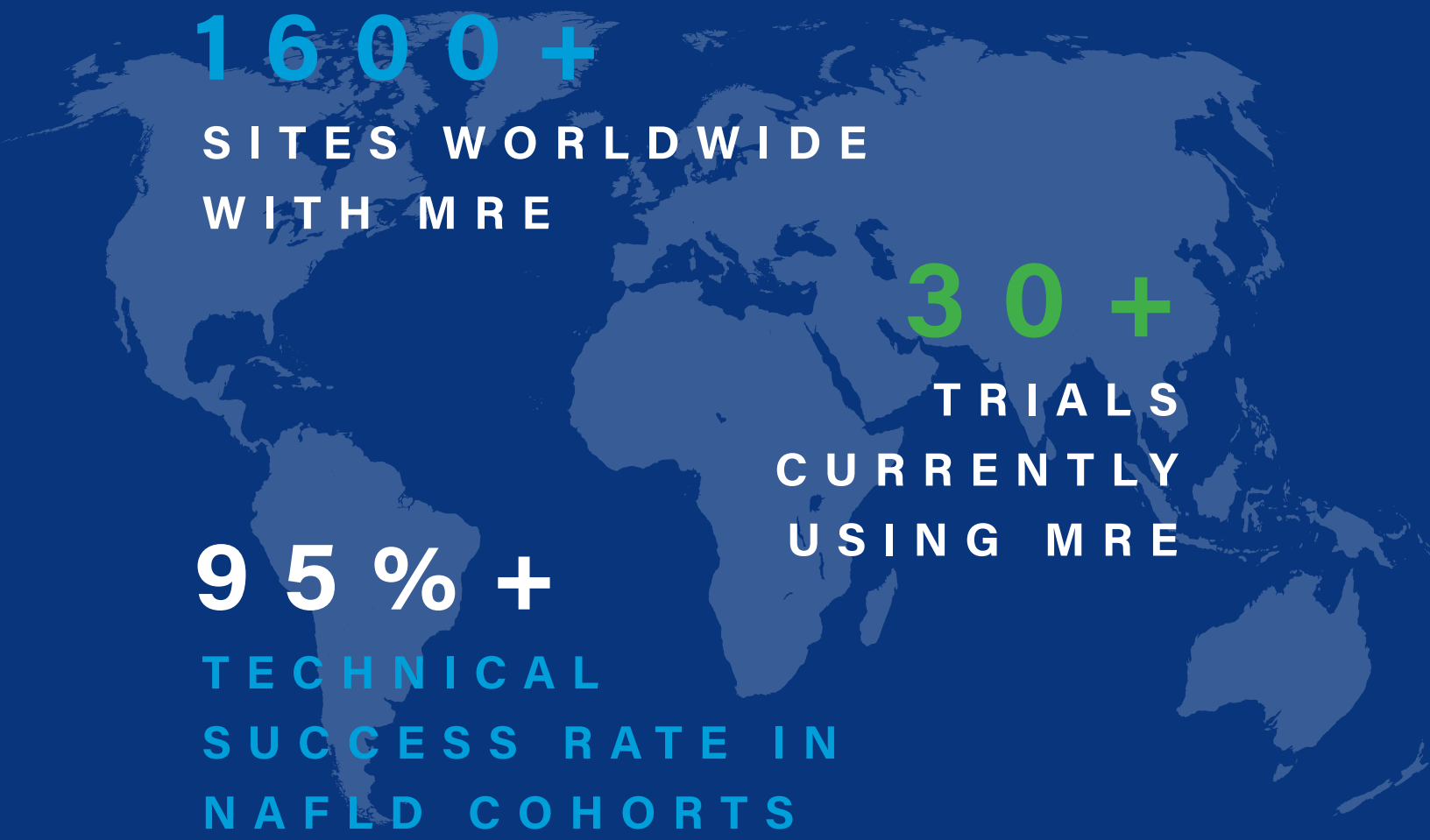
When compared with other imaging and laboratory tests, MRE is reported to have one of the highest diagnostic accuracies for staging fibrosis in NAFLD patients [25].





TRIAL DESIGN WITH MRE

MRE can be incorporated into nearly any study design at multiple points in the clinical trial pathway. Given its high accuracy for diagnosing and staging fibrosis, it can greatly reduce screen failure rates at the point of confirmatory biopsy. MRE can also be used to monitor treatment effect with a high degree of sensitivity, repeatability and confidence.



1600+

SITES WORLDWIDE WITH MRE

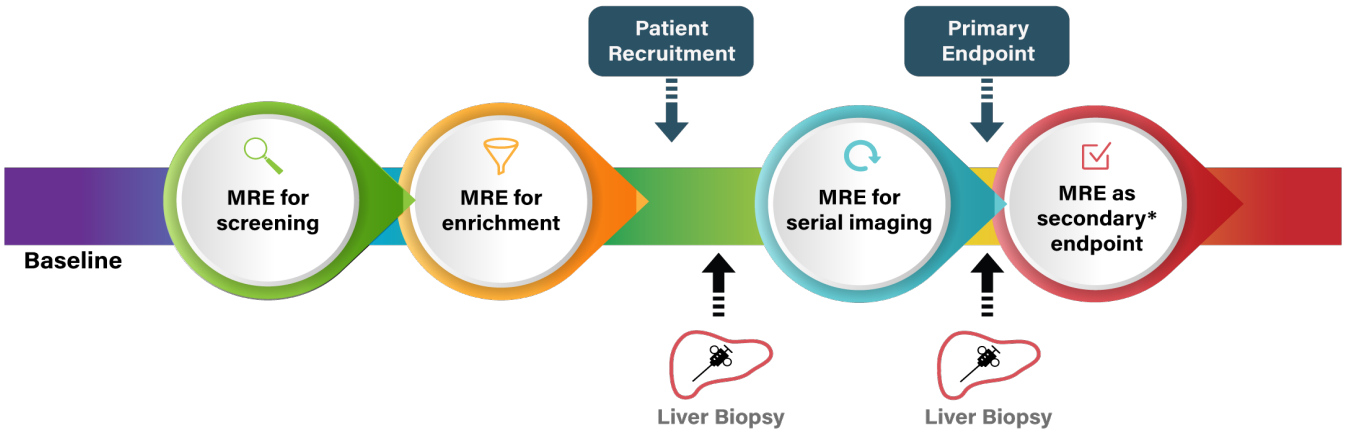
30+

TRIALS CURRENTLY USING MRE

95%+

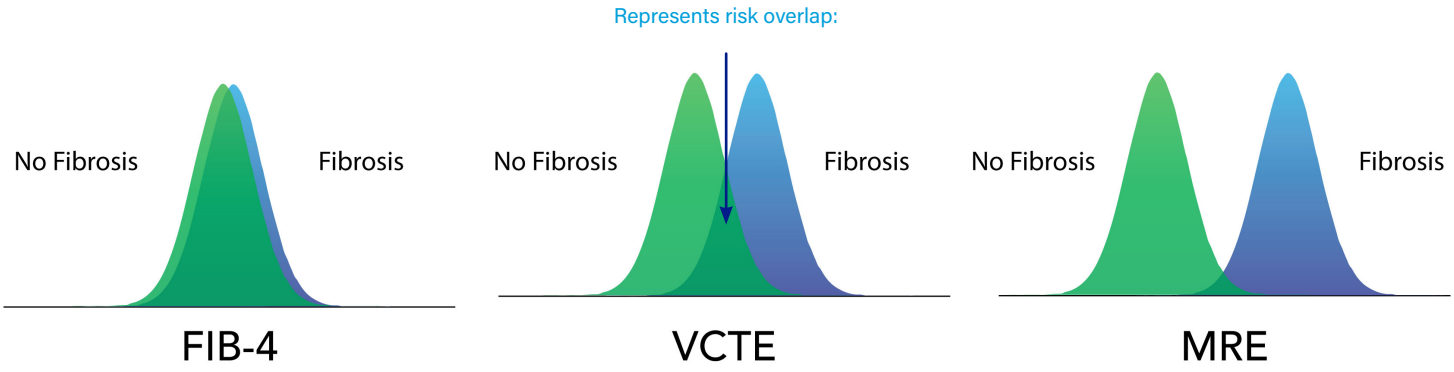
TECHNICAL SUCCESS RATE IN NAFLD COHORTS

Snapshot: potential Contexts of Use



De-risking early phase trials

One of the most important characteristics of a diagnostic biomarker is its ability to **stratify between disease classes with a high level of precision.** MRE's excellent diagnostic accuracy and high technical success results in lower class overlap. This allows sponsors to assign a high level of confidence to early trial data and make more confident go/no-go decisions regarding later phase studies.



*MRE is also being actively explored as a surrogate endpoint

Diagnostic

MRE's ability to diagnose and stage liver fibrosis is well validated in the literature. The specific biomarker is **liver stiffness**, obtained by measuring the magnitude of the complex shear modulus |G*|.

This biomarker and Context of Use has been accepted into the FDA Biomarker Qualification Process [26] and is currently being used in dozens of clinical trials around the world. Additional work into combination approaches has further shown that FIB-4 plus MRE has a 0.97 positive predictive value (PPV) to "rule-in patients with ≥stage 2 fibrosis without needing a liver biopsy assessment." [27] This powerful approach can greatly reduce screen fail rates when compared to a diagnostic pathway using FIB-4 and vibration-controlled transient elastography (VCTE), which only has a PPV of .62 for ruling-in advanced fibrosis. [28]

To rule in NASH, MRE can be combined with proton density fat fraction (PDFF) to distinguish biopsy-confirmed NASH from NAFLD with an excellent 0.87 AUROC [29].

Powerful combination approaches

To confirm underlying etiology:

MRE + PDFF

0.87

AUROC for distinguishing NASH from NAFLD

To rule in for study enrollment:

FIB-4 + MRE

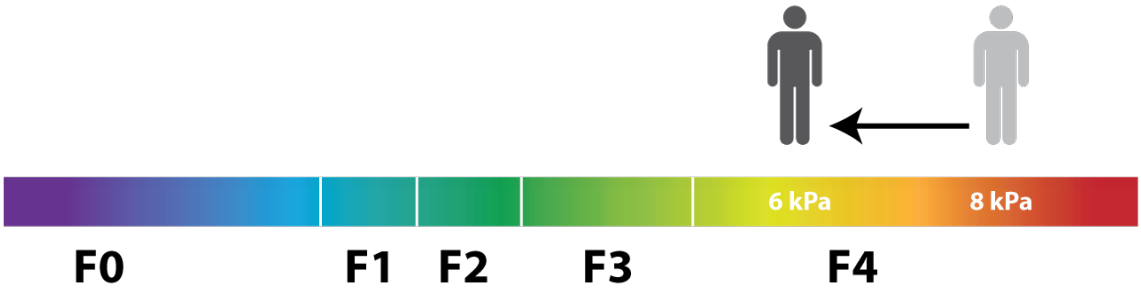
0.97

PPV for confirming NASH with fibrosis

Pharmacodynamic/Treatment Response

As a quantitative exam, MRE is also highly sensitive to changes in liver stiffness longitudinally. This is important, as outcomes-driven studies show that meaningful clinical benefit can potentially occur intra-stage.

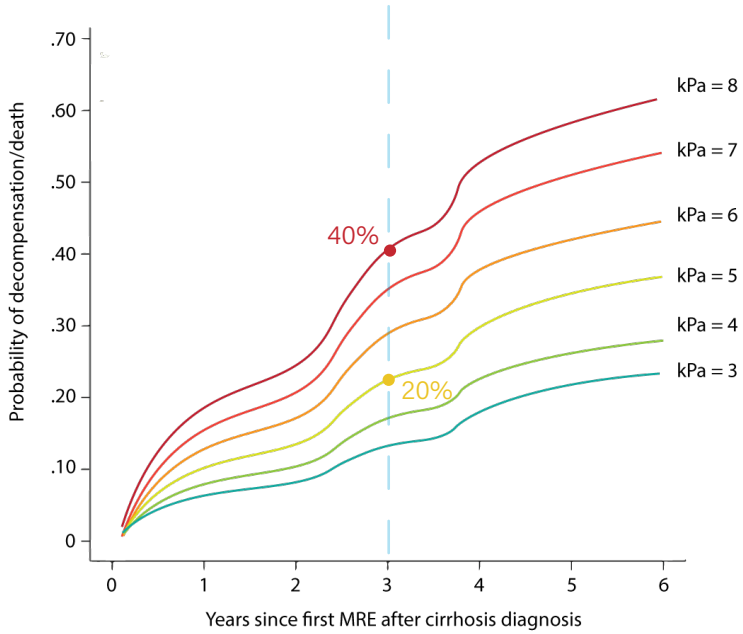
MRE has been utilized in this capacity with high degrees of sensitivity, either for a specific mechanism of action [30] or non-therapeutic interventions (i.e., weight loss or bariatric surgery) [31-33]



Prognostic

MRE has also been shown to correlate well with outcomes, predicting the probability of an adverse event with greater sensitivity than biopsy [34].

In a 2020 study, patients who had a liver stiffness of 5 kPa had half the risk of decompensation or death as patients with a liver stiffness value of 8 kPa - though both would be scored as F4 via liver biopsy alone [35]. This demonstrates the value of being able to quantitatively assess fibrosis on a continuous scale, allowing clinicians the ability to better predict risk of a decompensation event at a level of sensitivity not possible with liver biopsy.



COST EFFECTIVE

As a basic screening and enrichment marker, MRE can provide greater enrollment fidelity (fewer false positives) at a lower overall cost. Fewer false positives are highly desirable, as they reduce the potential for unintended placebo effects.

Biopsy Pathway

Total Biopsies
100

Total Enrollment: 28

True Enrichment: 15
Identified 83% of original prevalence

False positives: 13/28
46% of sample not staged correctly

Total cost: $500,000

MRE Pathway

Total Biopsies
15

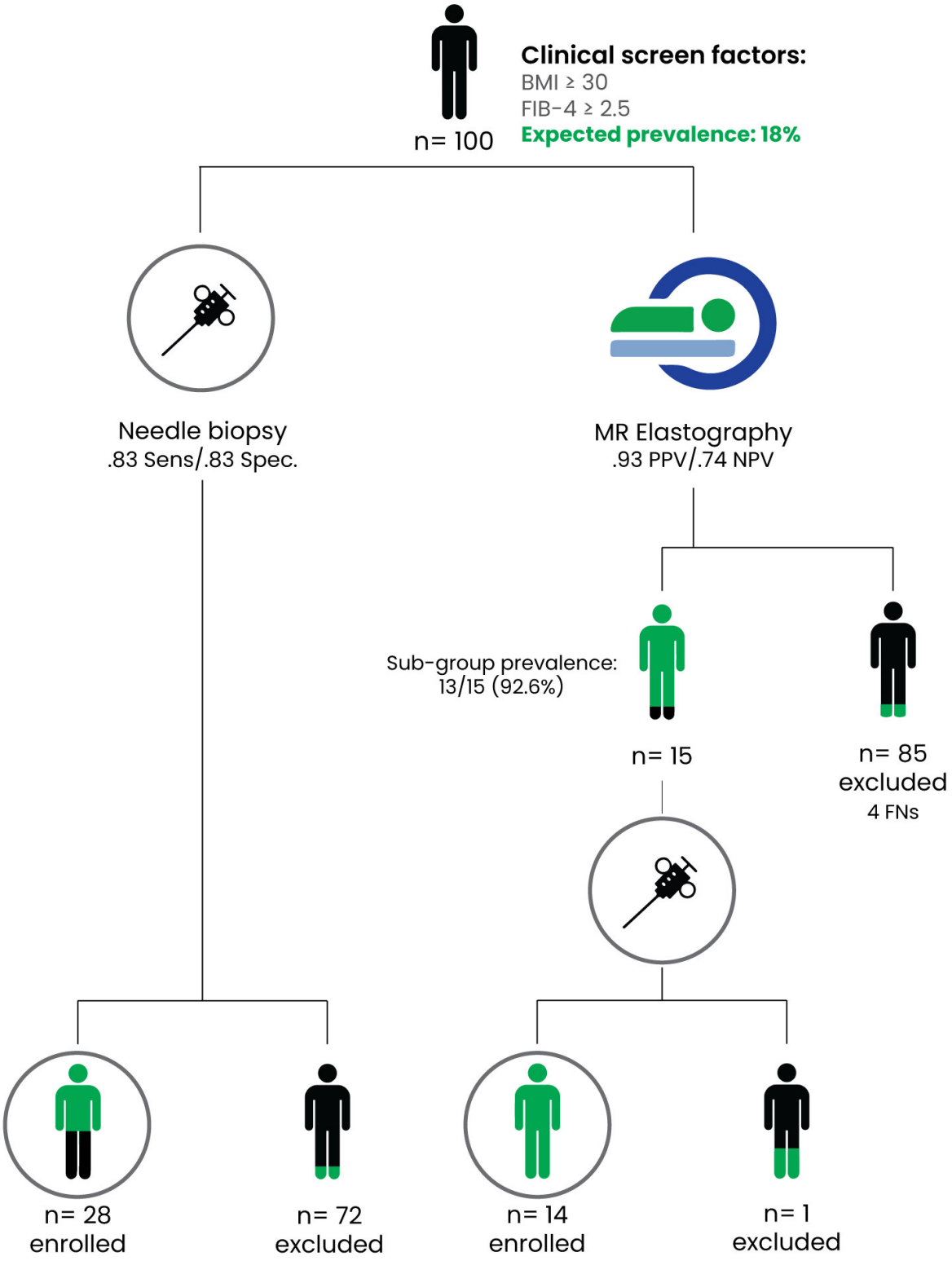
Total Enrollment: 14

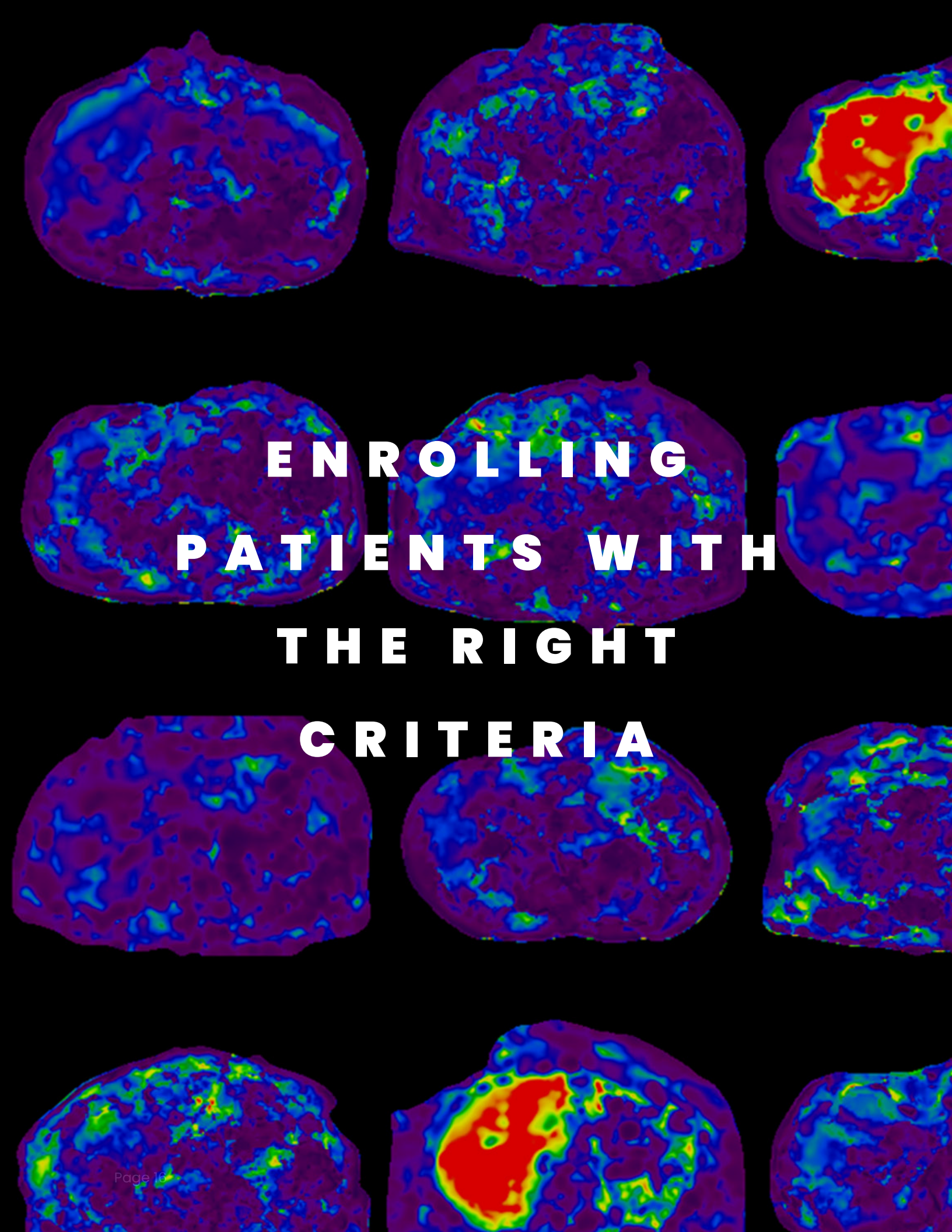
True Enrichment: 14
Identified 77% of original prevalence

False positives: 0/14

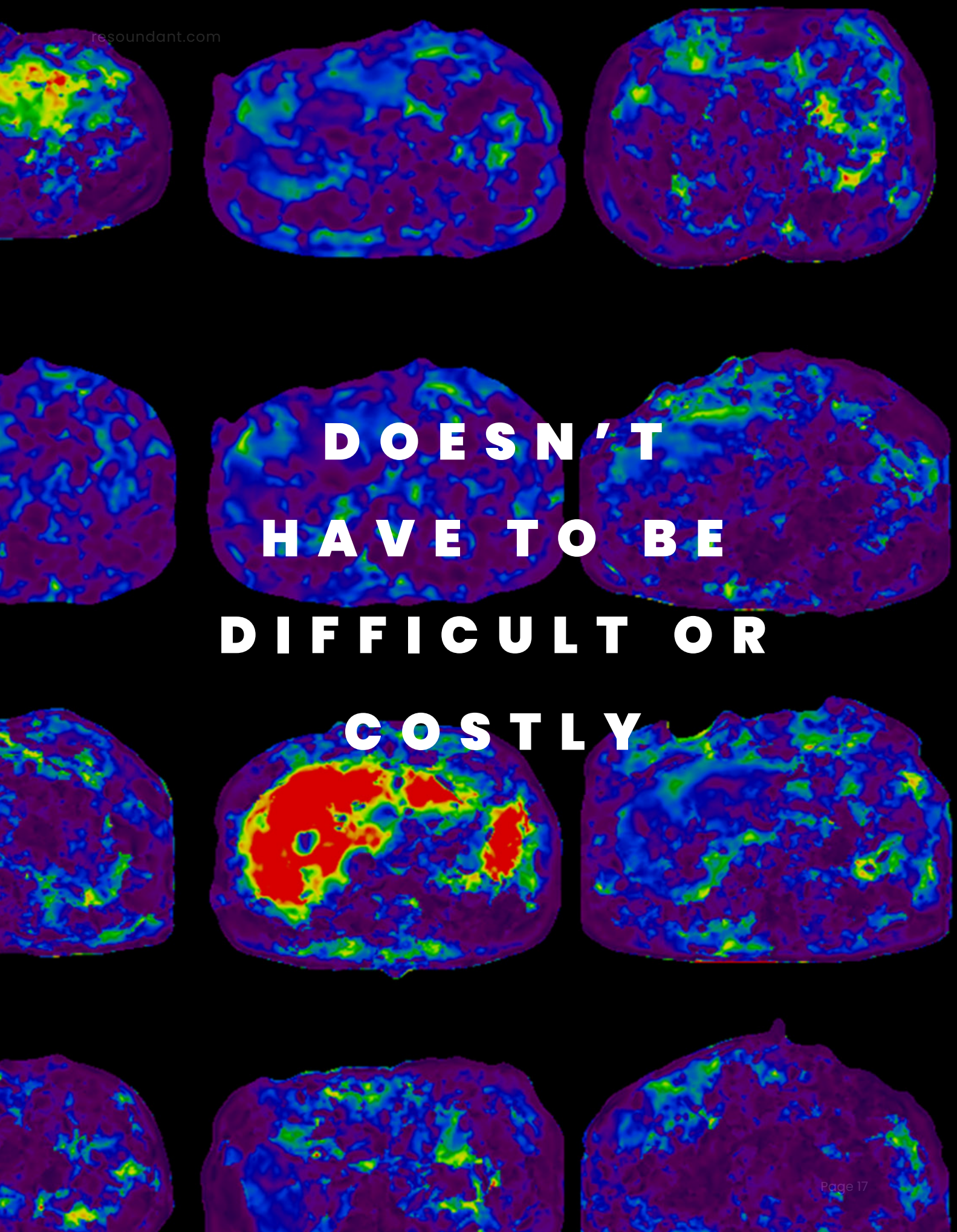
Total cost: $275,000
45% reduction in cost

*Model inputs:
MRE: $2000
Biopsy: $5000


Clinical screen factors:
BMI ≥ 30
FIB-4 ≥ 2.5
Expected prevalence: 18%
n= 100
Needle biopsy
.83 Sens/.83 Spec.
MR Elastography
.93 PPV/.74 NPV
Sub-group prevalence:
13/15 (92.6%)
n= 15
n= 85
excluded
4 FNs
n= 28
enrolled
n= 72
excluded
n= 14
enrolled
n= 1
excluded



ENROLLING PATIENTS WITH THE RIGHT CRITERIA



DOESN'T HAVE TO BE DIFFICULT OR COSTLY

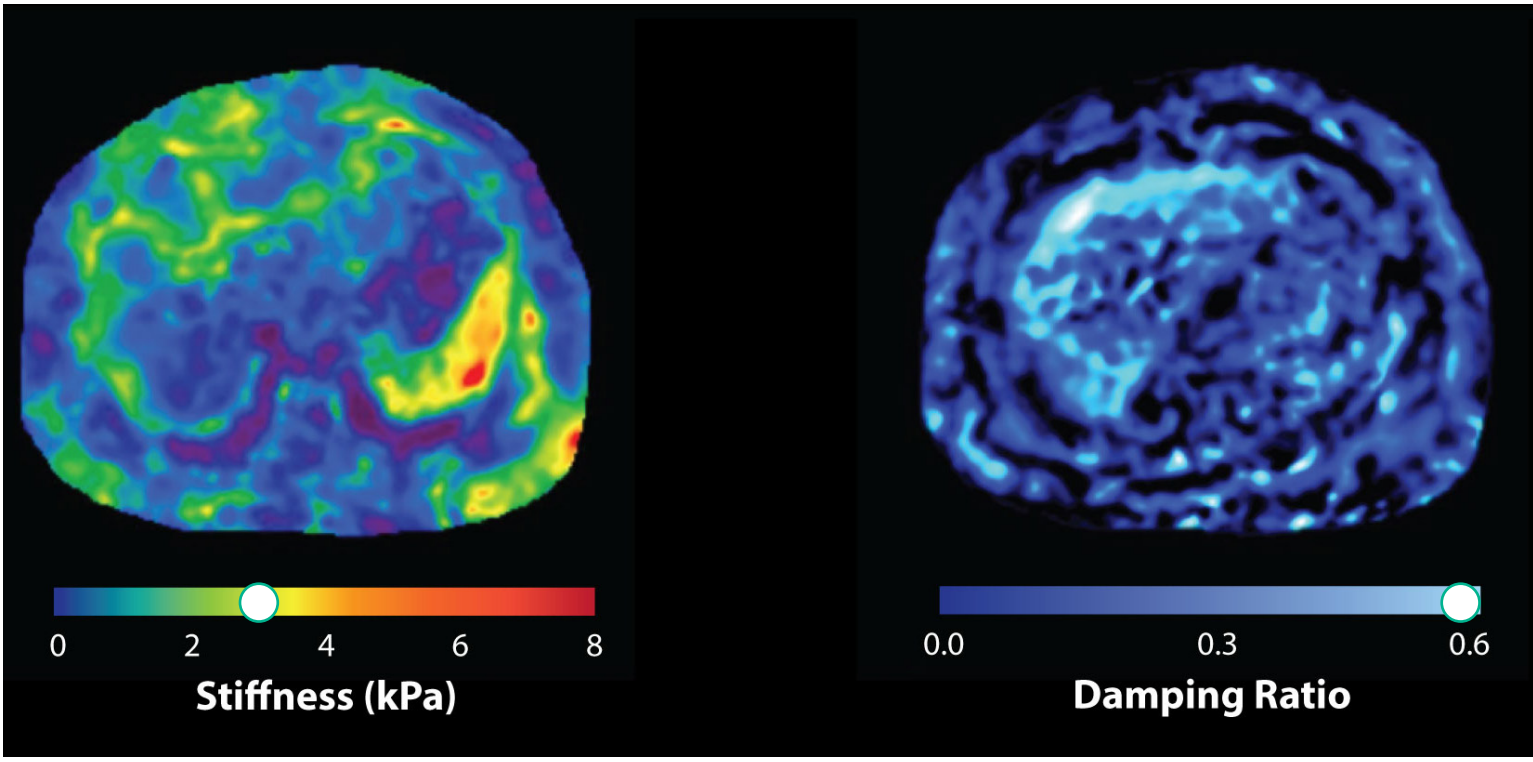
THE FUTURE

While standard 2D MRE and PDFF are powerful tools for diagnosing NASH (AUROC: 0.87), emerging advanced MRE technology will add new capabilities for the assessment of liver health. In addition to liver stiffness, scientifically known as the magnitude of the complex shear modulus, additional parameters can be used to describe tissue mechanical properties.

The combination of liver stiffness with the storage modulus, loss modulus, damping ratio and volumetric strain has been used to distinguish between hepatic inflammation, fibrosis, venous congestion, and portal hypertension. A rapid, noninvasive exam that includes MRE and proton density fat fraction (PDFF) may be used to predict the NASH Activity Score [32].

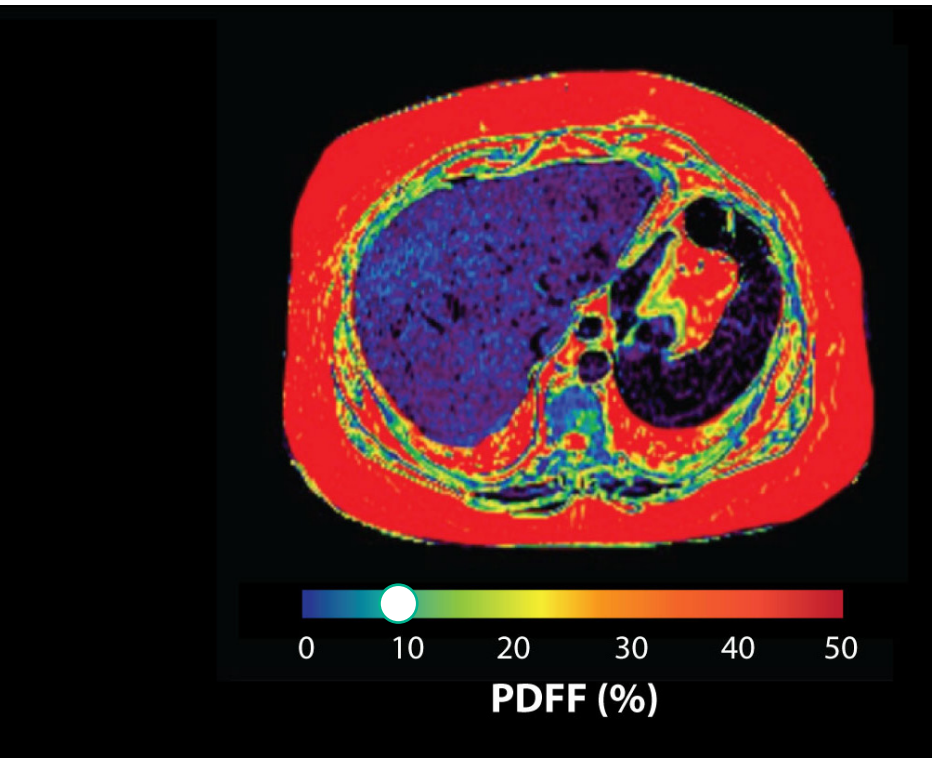
FIBROSIS

INFLAMMATION



Distinct biomarkers for NASH, combined into a model for predicting NASH probability

STEATOSIS



Composite Analysis:

Predicted NAS: 6 - 7

Probability of NASH: 0.98

OUR SERVICES

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.
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.

To learn more, contact **Kay Pepin**, PhD, Director of Research Translation at kpepin@resoundant.com

Resoundant Clinical Trial Services analysts are leading experts in the field of MRE and are trained at the MRE lab at Mayo Clinic.

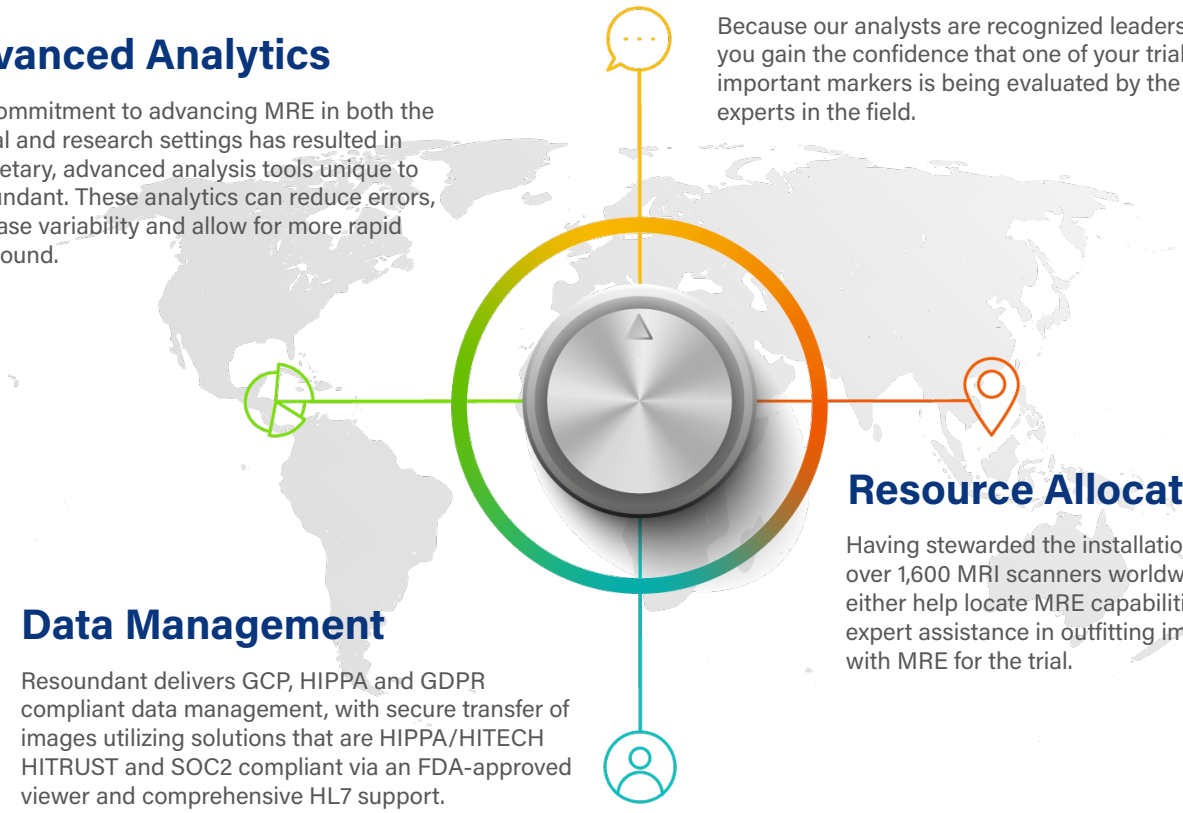
Clinical Trial Services

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 leading 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 1,600 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 delivers GCP, HIPPA and GDPR compliant data management, with secure transfer of images utilizing solutions that are HIPPA/HITECH HITRUST and SOC2 compliant via 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 on our work towards 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 support and other timely 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.

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