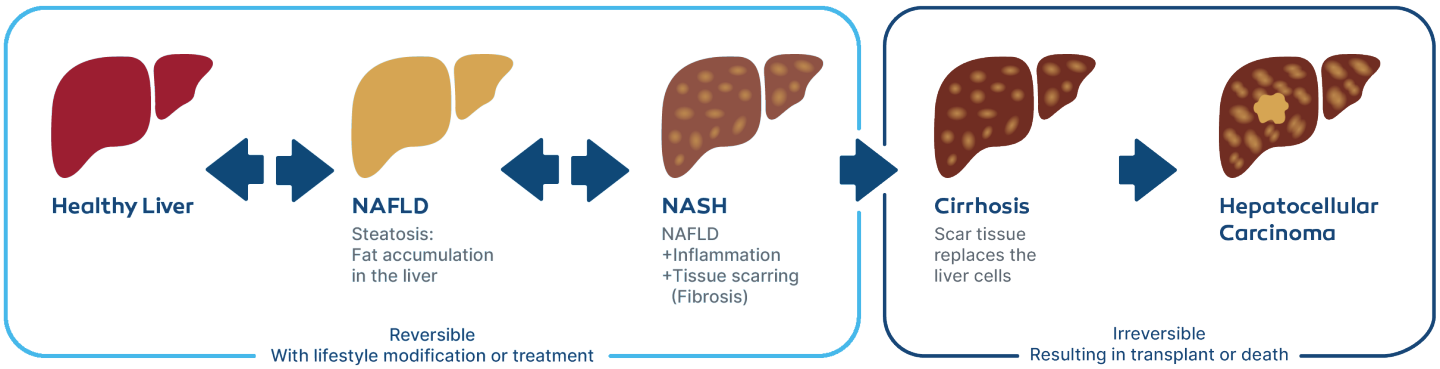
FACT SHEET

SonicIncytes
Health Insights You Can Count On

The Prevalence and Diagnosis of Chronic Liver Disease

- Fatty liver disease is the fastest growing and largest segment of chronic liver disease, resulting in chronic illness for millions of people around the world and a projected ten-fold increase in US healthcare costs from $103 billion[1] in 2014 to $1 trillion[2] in 2024.
- The liver is a critical organ that rids the body of harmful substances. Non-alcoholic Fatty Liver Disease (NAFLD) is an early stage form of fatty liver disease that occurs when there is an accumulation of fat in the liver, most commonly caused by obesity, diabetes and insulin resistance.
- NAFLD can progress to a more severe form of fatty liver disease called Non-alcoholic Steatohepatitis (NASH) characterized by inflammation and the formation of scar tissue. Left untreated, the disease can lead to chronic illness, organ failure, cancer and ultimately death. Early diagnosis is key to preventing – and reversing – disease progression and rising healthcare costs.



- Approximately 1 in 4 persons worldwide has fatty liver disease, a number that rises to 1in 3 Americans (100 million) because of the greater prevalence of diabetes and obesity in the US.[3] Of this 100 million:
  - 50 million Americans are underdiagnosed, and unaware of their fatty liver disease.[4]
  - 9.5 million Americans have NASH, the advanced form of the disease.[5] By 2030, it is estimated that 27 million Americans will have NASH.[6]
- At least 20%–30% of patients with NAFLD develop NASH, which can lead to cirrhosis and associated complications, including hepatocellular cancer (HCC).[7]
- NASH is also associated with an increased risk of cardiovascular disease[8] and increased cardiovascular and liver-relaated mortality.[9-11]
- NASH is already the number 1 indication for liver transplantation in women, patients older than 54 years, and Medicare recipients.[12]
- NAFLD prevalence is highest among Hispanics, non-Hispanic whites and African Americans.[13]
- The upward trend in NAFLD/NASH incidence and prevalence underscores the importance and urgency of developing and implementing effective screening, diagnosis, and treatment strategies in the United States, particularly among emerging at-risk cohorts, such as patients with diabetes and obesity.

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- This growing epidemic puts a strain on both the healthcare system and clinical practices. The continued growth in patient cases and emergence of potential new treatments creates an urgent need for a cost-effective, quick and accurate solution to assess and manage this disease.

- Currently, physicians can diagnose liver disease with a combination of blood tests, ultrasound, and MRI or biopsy.
  - While blood tests and general ultrasound are easy and inexpensive to administer, they are unable to provide a reliable diagnosis on their own.
  - Ultrasound elastography improves the ability to quantify liver disease, but provides inconsistent results due to technical limitations.
  - On the other hand, while MRI and biopsy are considered the gold standard, they are expensive, invasive and inconvenient.

- Sonic Incytes has developed the first handheld 3D liver tissue assessment tool with diagnostic accuracy comparable to MRI. It is accurate, accessible and affordable.

- **Accuracy:** Velacur™ offers greater reliability and accuracy than the current standard of care:
  - 30x greater tissue sampling
  - 2x deeper tissue measurement
  - 3D volumetric acquisition with AI image guidance
  - Data shows high concordance to MRE for all body types

- **Accessibility:** Velacur™ is convenient and accessible for a variety of practice settings. It's a scalable solution for use by physicians at point of care, allowing for broad assessment of patients and those at-risk.

- **Affordability:** Velacur™ is the most cost-effective in comparison to MRI, biopsy and other diagnostic tools, and provides a new revenue stream for clinicians.

- Velacur™ has been evaluated in various clinical studies by top medical specialists in North America and results show it to be equivalent to the gold standard (MRI).

- Given this emerging global health crisis, rising healthcare costs, and imminent NASH drug approvals, Velacur™ offers a promising solution for this unmet need.

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