

GENFIT's MASH Diagnostics Technology Long-Term Commercial Opportunity

September 9, 2026

Forward Looking Statements

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This presentation contains certain forward-looking statements with respect to GENFIT, including, but not limited to, statements regarding the potential market opportunity for products based on GENFIT's NIS® technology, the future adoption, commercialization and reimbursement of such products, and the impact of the development of the therapeutic MASH market on the diagnostics market, potential royalty streams and other revenues that could be generated therefrom, the future development of the MASH diagnostics market, guideline inclusion, market access, and expected demand for non-invasive diagnostic testing. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" and similar expressions, is intended to identify forward-looking statements. Certain statements included in this press release are based on market analyses and projections prepared by IQVIA and commissioned by GENFIT. Such analyses are based on numerous assumptions, including assumptions regarding patient identification, disease prevalence, treatment adoption, reimbursement coverage, physician behavior, testing frequency, market penetration and other market factors. The projections described in this press release do not constitute forecasts of GENFIT's future revenues, financial performance or royalty income. Actual market adoption, testing volumes, product sales and economic outcomes may differ materially from those projected. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among others, uncertainties relating to the development, validation, regulatory acceptance and commercialization of diagnostic products, the timing and scope of reimbursement decisions and payer coverage, inclusion in clinical practice guidelines, physician adoption and testing practices, the availability and uptake of therapies for MASH, regulatory developments, the ability to establish and maintain commercial partnerships, evolving competition in the MASH diagnostics field, market acceptance of competing technologies as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Risk Factors and Internal Control" of the Company's 2025 Universal Registration Document filed on April 3, 2026 (no. 26-0221) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in reports filed with the AMF or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this press release. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

Today's Speakers

Pascal Prigent *GENFIT CEO*

Vlad Ratziu, MD, PhD

Professor of Hepatology, Sorbonne University

Pitié-Salpêtrière Hospital

Institute for Cardiometabolism and Nutrition (ICAN)

Paris Editor-in-Chief, Journal of Hepatology

Pascal Caisey *GENFIT COO*

Welcome and Introduction

Pascal Prigent
GENFIT CEO

25+ Years of Focus on Liver Diseases



Partnerships with pharma

Building R&D expertise through Big Pharma collaborations



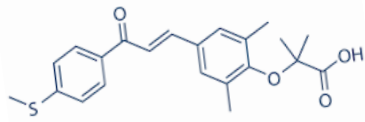
Inception and early years

1999-2004



A shift to in-house programs

Drug discovery of elafibranor and subsequent development in MASH



The MASH years

2005-2020



The turning point

MASH Ph3 results not supportive of MA
Pivot to PBC and later CCA and ACLF
Ipsen deal

The reinvention

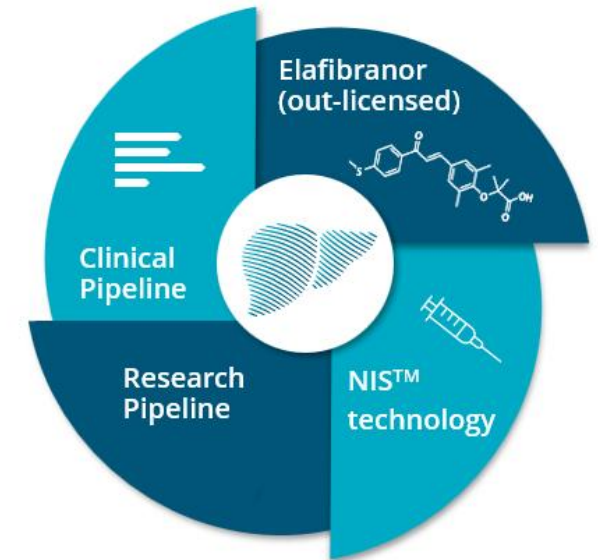
2020-2025

GENFIT was among the first companies focusing on MASH

Pioneering efforts in the Liver Forum (KOL, regulatory, patients)

For over 15 years MASH was our primary focus

GENFIT today



Elafibranor royalty-based stream

NIS™ technology

Pipeline:

- Clinical: GNS561 Ph2, NTZ Ph2
- Research: various ACLF programs

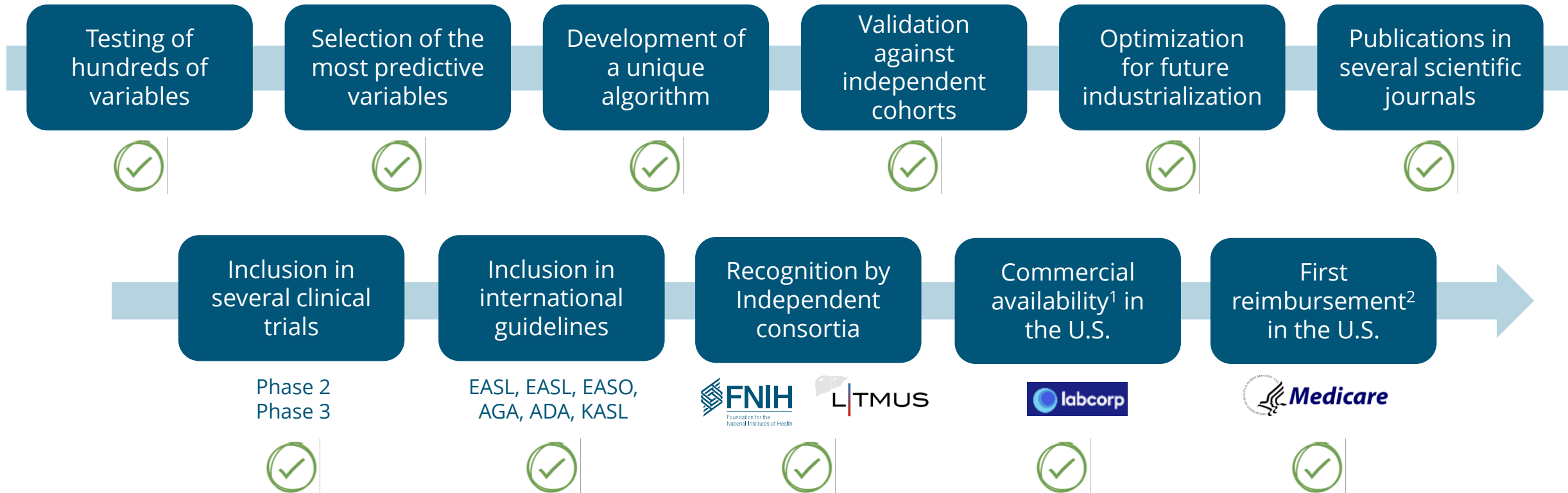
Everybody Needs a Scalable, Reliable Diagnostic Tool

GENFIT recognized early the need for a single, non-invasive blood-based solution serving all stakeholders across the MASH care pathway



The Journey: a Decade of Development

Over the years, GENFIT leveraged its scientific expertise, extensive expert network and unique Phase 2 and Phase 3 tissue and blood sample datasets to develop a differentiated non-invasive technology addressing critical diagnostic and monitoring gaps



1: via partner Labcorp, as a Laboratory Developed Test (LDT)

2: Medicare coverage for eligible U.S. patients

Today the MASH Market Reaches an Inflection Point

**Why Now: bottleneck shifting from treatment availability
to patient identification, disease stratification and long-term management**

Resmetirom Approval & Blockbuster Sales in Year One

The first approved MASH therapy validates the market and creates urgency to identify treatable patients

Imminent Entry of Additional Molecules, incl. GLP-1s

Expanding treatment options raise the value of accurate, scalable diagnosis to find the right patients

Shifting Physician & Market Behavior

**Watch
& Wait**



**Find
& Treat**

Therapy-driven proactive care shifting physicians' behavior toward earlier action

**Passive
Awareness**



**Broad
identification &
monitoring**

Updated guidelines recommend broader identification of at-risk patients, boosting diagnosis, referral, treatment rates and monitoring

Identifying Patients with At-Risk MASH: A Major Unmet Need Across the MASLD/MASH Continuum

Vlad Ratziu, MD, PhD

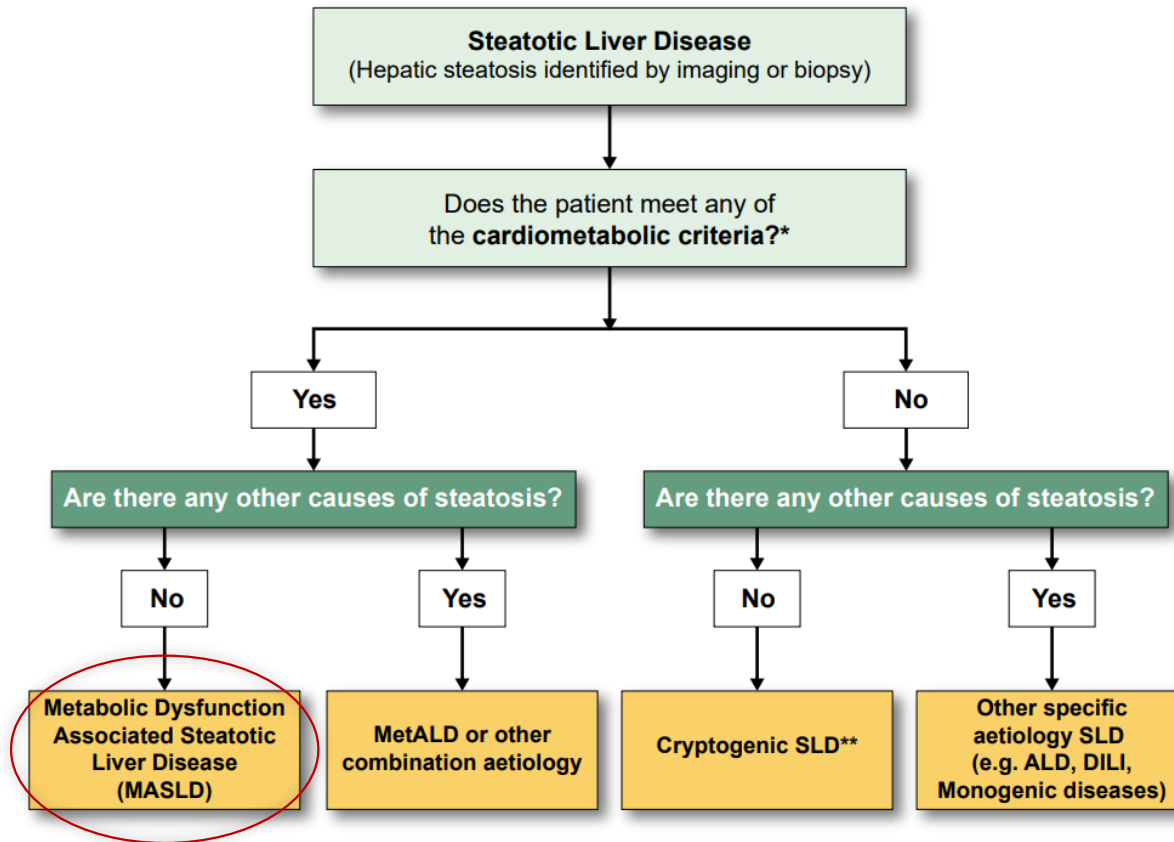
Professor of Hepatology, Sorbonne University

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Paris Editor-in-Chief, Journal of Hepatology

MASLD, the New Nomenclature for NAFLD



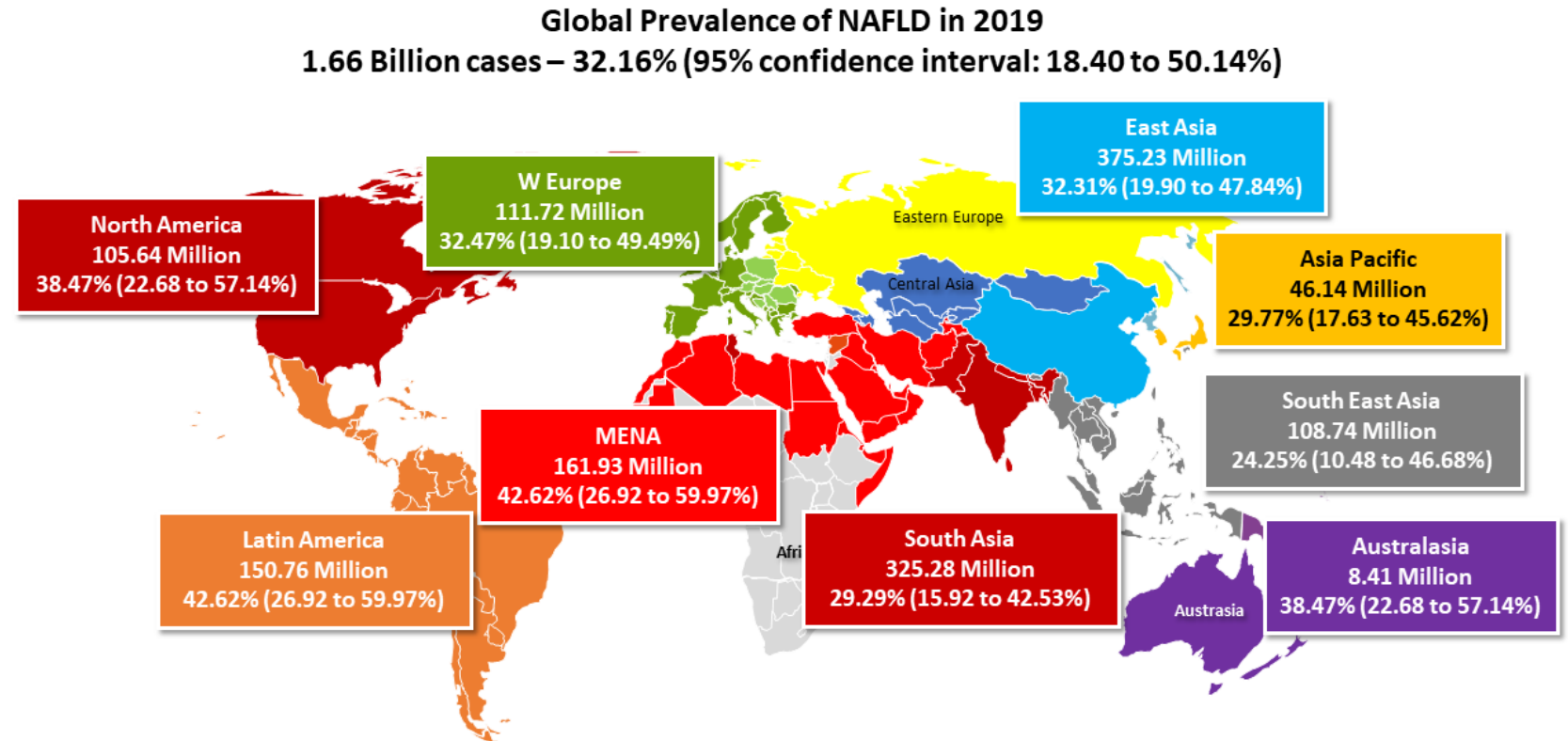
Adult Criteria

At least 1 out of 5:

- ☐ BMI ≥ 25 kg/m² [23 Asia] **OR** WC > 94 cm (M) 80 cm (F) **OR** ethnicity adjusted equivalent
- ☐ Fasting serum glucose ≥ 5.6 mmol/L [100 mg/dL] **OR** 2-hour post-load glucose levels ≥ 7.8 mmol/L [≥ 140 mg/dL] **OR** HbA1c $\geq 5.7\%$ [39 mmol/L] **OR** type 2 diabetes **OR** treatment for type 2 diabetes
- ☐ Blood pressure $\geq 130/85$ mmHg **OR** specific antihypertensive drug treatment
- ☐ Plasma triglycerides ≥ 1.70 mmol/L [150 mg/dL] **OR** lipid lowering treatment
- ☐ Plasma HDL-cholesterol ≤ 1.0 mmol/L [40 mg/dL] (M) and ≤ 1.3 mmol/L [50 mg/dL] (F) **OR** lipid lowering treatment

MASLD, A Worldwide Public Health Concern

- **MASLD is the most common cause of chronic liver disease (CLD) worldwide**, and the most rapidly increasing global contributor to the disease burden related to the complications of CLD, including cirrhosis and liver cancer
- MASLD/MASH has become the **second leading cause of end-stage liver disease and indication for liver transplants**, and the fastest growing etiology of hepatocellular carcinoma (HCC)
- Driven by the pandemic of obesity and type-2 diabetes (T2D), among other factors



Geographical regions are based on epidemiological similarities and geographical proximity from the GBD study

MASLD, A Rapidly Rising Disease, Associated with T2DM and Obesity Pandemic

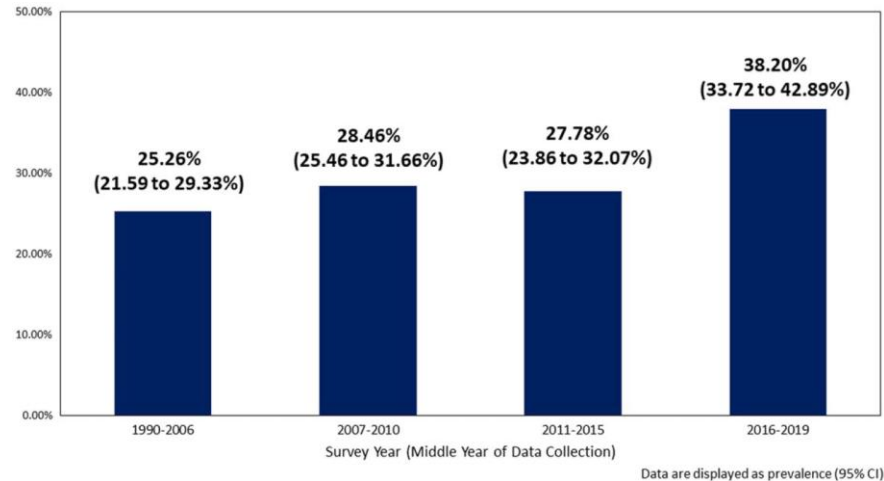
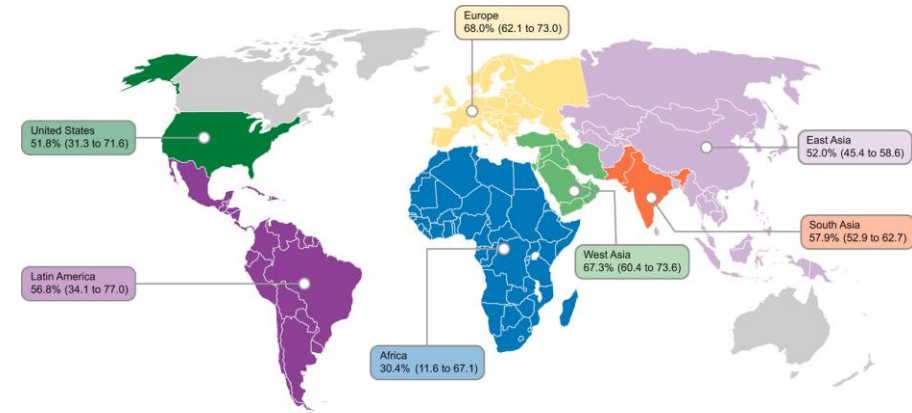


Fig: Global rates of NAFLD increasing over time



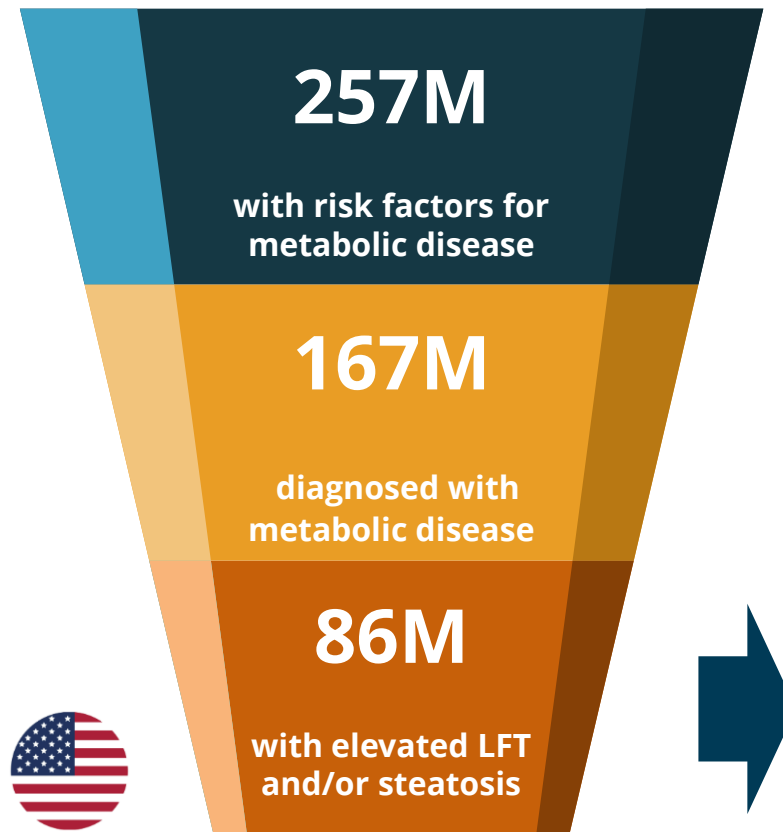
+50.4% prevalence increase, from 25% in 1990-2006 to 38% in 2016-2019, $p < 0.001$



Global prevalence of NAFLD among T2DM patients 55.5%
(95% confidence interval: 47.3-63.7)

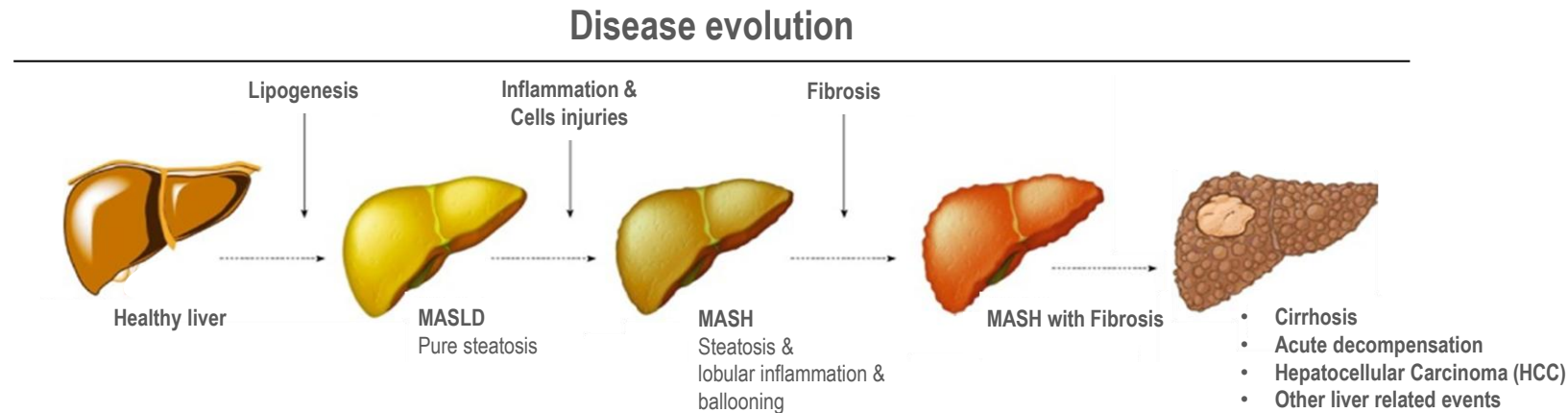
- **≥400 millions people were living with diabetes (2015)**, and caused an estimated 1.5 million deaths (2012)
- In US, ~29 millions thought to have T2DM, 8.1 millions undiagnosed and 1.4 millions new diagnosis every year.
- WHO anticipates that worldwide **deaths from T2DM will double by 2030**
- WHO determined that worldwide, **overweight and obesity rates tripled since 1975**, ≥1.9 billion (39%) adults are overweight, **650 millions (13%) are obese**
- MASLD prevalence proportional with increase in BMI, >90% for very obese individuals undergoing weight reduction procedures and surgeries.

By 2033, Nearly 90 Million U.S. Patients in Care due to MASLD-related Risk Factors



Patients expected to be receiving regular medical attention due to MASLD-related risk factors = subpopulation who would benefit from simple, reliable and scalable testing to identify **“At-Risk MASH”**

MASLD: a Complex Continuum of Histopathological Liver Conditions¹⁻¹⁰



The natural history of MASLD can be nonlinear, with potentially rapid progression (or regression) of disease.

MASLD Activity Score [MAS] (0-8)

Steatosis
(0-3)

Lobular inflammation
(0-3)

Ballooning
(0-2)

- Scoring established by histopathological examination of a liver biopsy (LB)
- MAS score corresponds to the sum of 3 histological scores

At-risk MASH: A Specific Stage of Interest in MASLD

“At-risk MASH” does not mean ‘at risk of developing MASH’

With metabolic risk factors, MASLD, etc.

With MASH

With “At-Risk MASH”

Disease progression engine

MASLD Activity Score

Progression stage
Fibrosis Score

	0	1	2	3	4	5	6	7	8
0									
1									
2					At-risk MASH				
3									
4									

- At-risk MASH is defined as patients having biopsy-confirmed **MASH with a MAS $\geq$ 4 and F $\geq$ 2**
- Most MASH clinical trials evaluating new drugs are recruiting at-risk MASH patients, as **the targeted population to be treated** and on which primary endpoints are evaluated as requested by authorities.
- At-risk MASH was shown to be about 4.4% in the general U.S. population and up to 18.3% in patients with T2D

Individuals with **at-risk MASH** generally have a **higher risk of disease progression, all-cause mortality, cardiovascular disease and liver-related morbidity** (i.e., liver cancer, decompensated cirrhosis)

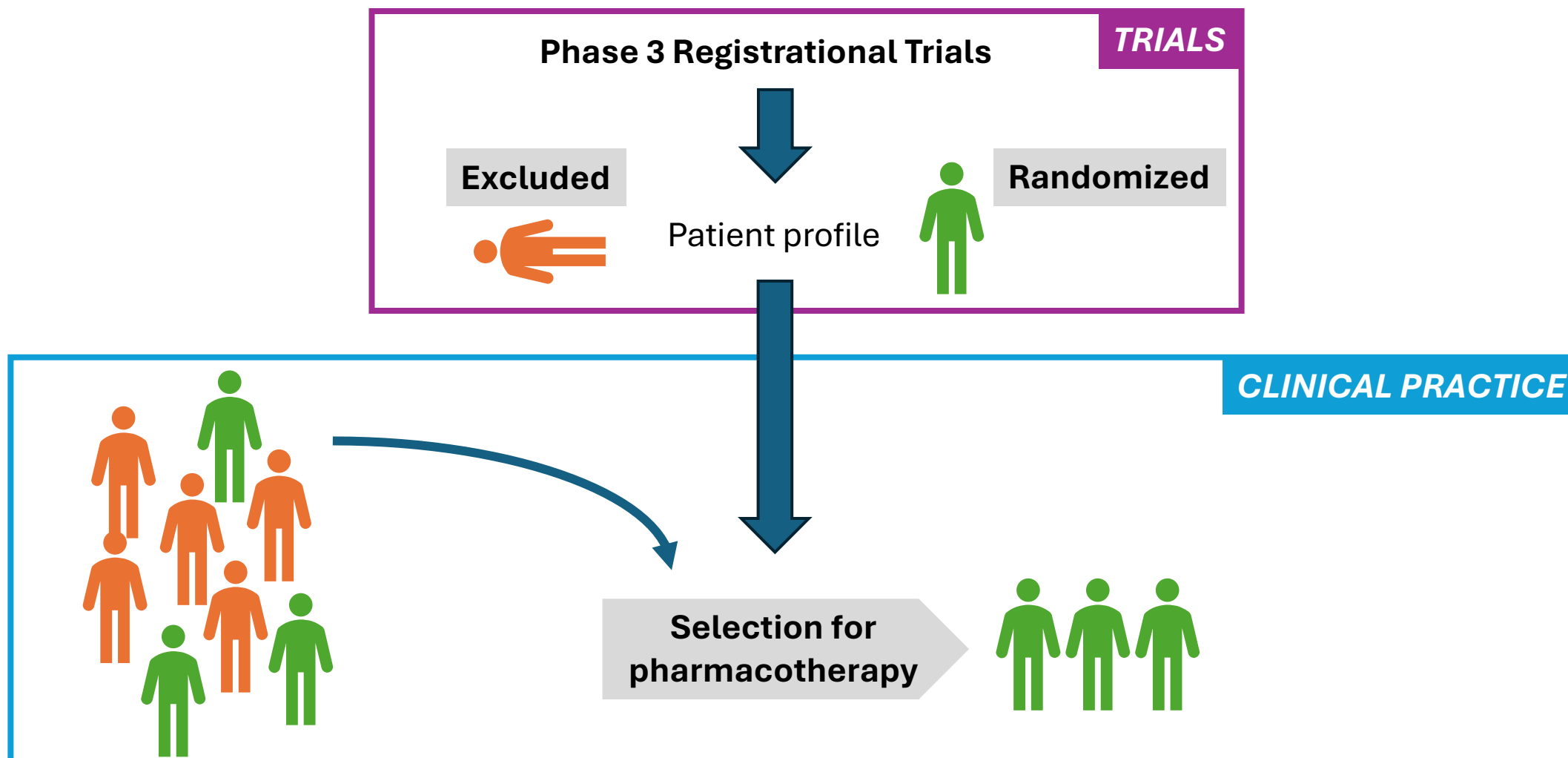
Harrison SA, Ratziu V, et al. *Lancet Gastroenterol Hepatol*. 2020. ; Harrison, Stephen A., et al. "Prospective evaluation of the prevalence of non-alcoholic fatty liver disease and steatohepatitis in a large middle-aged US cohort." *Journal of hepatology* 75.2 (2021): 284-291.

Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment. US Food & Drug Administration, 2020

Taylor, et al. *Gastroenterology*. 2020;158:1611-1625. ; Baratta, et al. *Clin. Gastroenterol. Hepatol.*, 2020; 18(1):2324-2331.

Noureddin, Mazen, et al. "Predicting NAFLD prevalence in the United States using National Health and Nutrition Examination Survey 2017–2018 transient elastography data and application of machine learning." *Hepatology Communications* 6.7 (2022): 1537-1548.

At-risk MASH: Registrational Trials vs. Clinical Practice



At-risk MASH: Registrational Trials vs. Clinical Practice

Phase 3 registrational trials

Phase 3 Trial of Semaglutide in Metabolic Dysfunction–Associated Steatohepatitis

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Mette Skalskjær, M.D., Ph.D.,⁴ Anna M.G. Cali, M.D.,⁴
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A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis

S.A. Harrison, P. Bedossa, C.D. Guy, J.M. Schattenberg, R. Loomba, R. Taub, D. Labriola, S.E. Moussa, G.W. Neff, M.E. Rinella, Q.M. Anstee, M.F. Abdelmalek, Z. Younossi, S.J. Baum, S. Francque, M.R. Charlton, P.N. Newsome, N. Lanthier, I. Schiefke, A. Mangia, J.M. Pericàs, R. Patil, A.J. Sanyal, M. Nouredin, M.B. Bansal, N. Alkhouri, L. Castera, M. Rudraraju, and V. Ratziu, for the MAESTRO-NASH Investigators*

Patient profile

NAS_≥4

Fibrosis stage 2 or 3

VCTE, 50% had LSM outside 10-15 kPa*
19% LSM <8 kPa; 32% LSM >15kPa#

or

ELF ... 25% had ELF<9,2*
21% had ELF<9,2#

NIS2+

NAS_≥4

Fibrosis stage 2 or 3

*MAESTRO NASH trial Hepatology AASLD guidance 2025
ESSENCE trial Hepatology AASLD guidance 2026

Selection for pharmacotherapy

Limitations of Current Diagnostic Approaches

Liver Biopsy

The historical reference standard

Invasive procedure with risk of bleeding, pain, and complications

Samples a tiny fraction of the liver — subject to significant sampling variability

Not scalable or repeatable — impractical for population screening or routine monitoring

Patient reluctance limits uptake and follow-up testing

Imaging

MRI-PDFF, elastography (e.g. FibroScan)

Measures fat content or liver stiffness, but not inflammation or ballooning directly

Cannot reliably grade disease activity — only part of the MASH definition

Requires specialized equipment; limited access outside major centers

Results can be indeterminate in patients with obesity or ascites

Existing Blood-Based Tests

Liver enzymes (ALT/AST), legacy panels

Standard liver enzymes are often normal even in confirmed MASH

Not specific — cannot reliably distinguish MASH from simple steatosis

Many legacy panels yield indeterminate results, requiring biopsy to confirm

Not validated to identify the at-risk (MAS $\geq$ 4, F2/F3) population specifically

► **No existing approach reliably identifies at-risk MASH at scale**

NIS4®/NIS2+® Technologies: From Scientific Evidence to Broad Recognition

Vlad Ratziu, MD, PhD

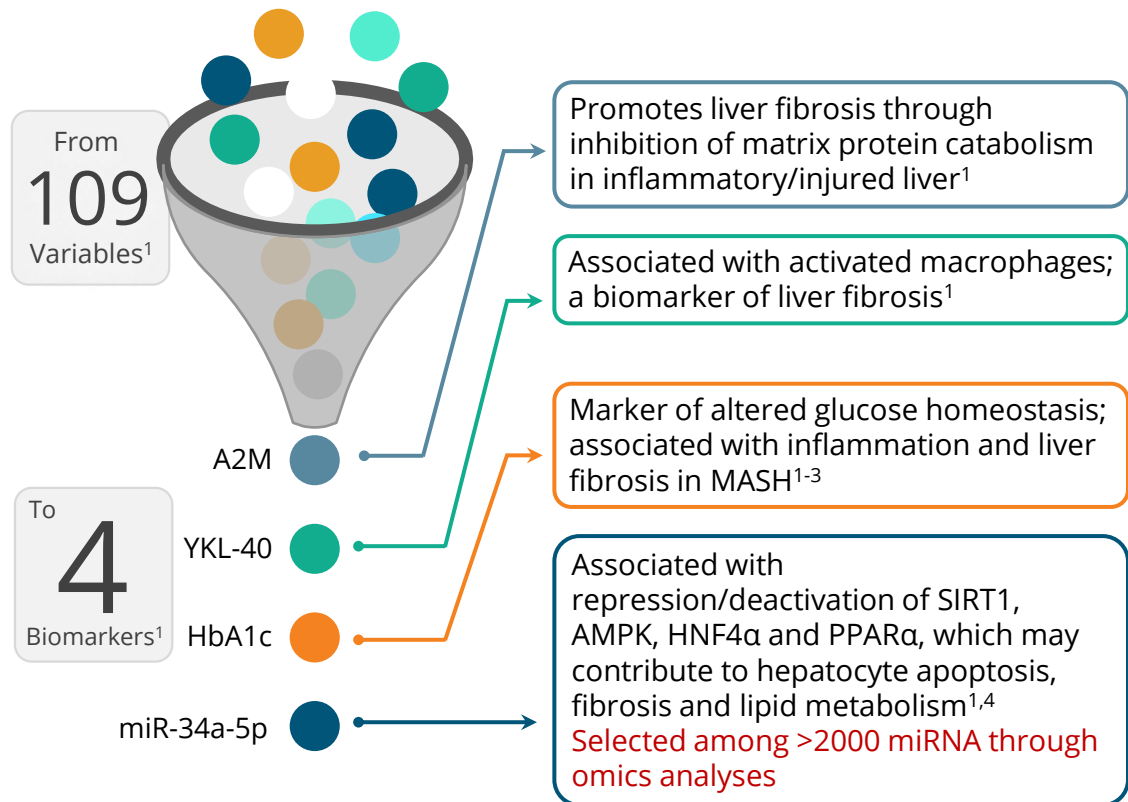
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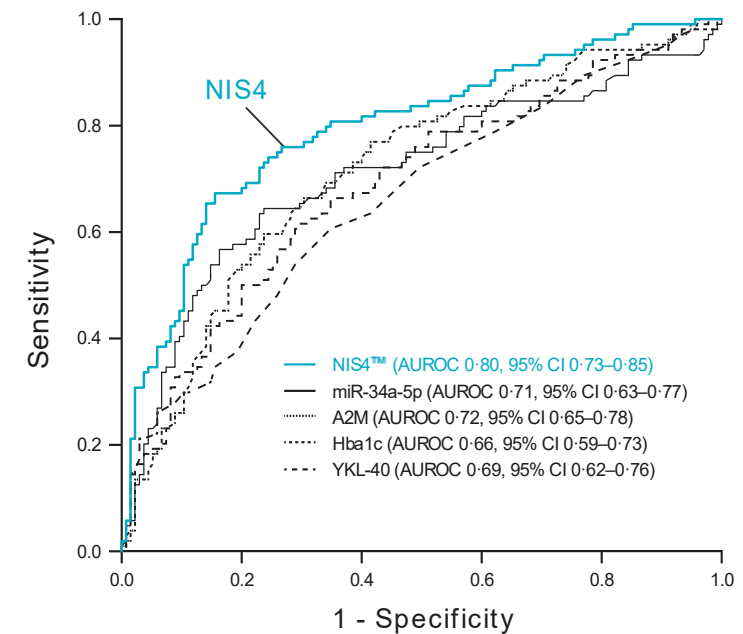
Institute for Cardiometabolism and Nutrition (ICAN)

Paris Editor-in-Chief, Journal of Hepatology

NIS4® Biomarkers Show Strong Biological Plausibility for Association with MASH Activity and Fibrosis



Comparison of NIS4 vs individual biomarker components to identify patients with at-risk MASH within the discovery cohort (n=239)



1. Harrison SA, Ratziu V, et al. *The lancet Gastroenterology & hepatology*, 5(11), 970-985, 2020.

2. Chao HW, et al. *Int J Mol Sci*. 2019;20(2):298. 3. Kumagai E, et al. *Sci Rep*. 2016;6:35282. 4. Cermelli S et al. *PLoS One*. 2011;6(8):e23937.

NIS2+® – An Optimization of NIS4® Technology

NIS4® (2020)

- miR-34a-5p
- YKL-40
- Alpha-2 macroglobulin
- HbA1c



NIS2+® (2022)

- miR-34a-5p
- YKL-40
- Sex information ♀/♂



THE LANCET Gastroenterology & Hepatology

ARTICLES | VOLUME 5, ISSUE 11, P970-985, NOVEMBER 2020

A blood-based biomarker panel (NIS4) for non-invasive diagnosis of non-alcoholic steatohepatitis and liver fibrosis: a prospective derivation and global validation study

Prof Stephen A Harrison, MD * • Prof Vlad Ratziu, MD * • Prof Jérôme Boursier, MD • Prof Sven Francque, MD • Prof Pierre Bedossa, MD • Zouher Majd, PhD • et al. [Show all authors](#) • [Show footnotes](#)

Published: August 04, 2020 • DOI: [https://doi.org/10.1016/S2468-1253\(20\)30252-1](https://doi.org/10.1016/S2468-1253(20)30252-1) • [Check for updates](#)

JOURNAL OF HEPATOLOGY

The Home of Liver Research



RESEARCH ARTICLE | VOLUME 79, ISSUE 3, P758-767, SEPTEMBER 2023

NIS2+™, an optimisation of the blood-based biomarker NIS4® technology for the detection of at-risk NASH: A prospective derivation and validation study

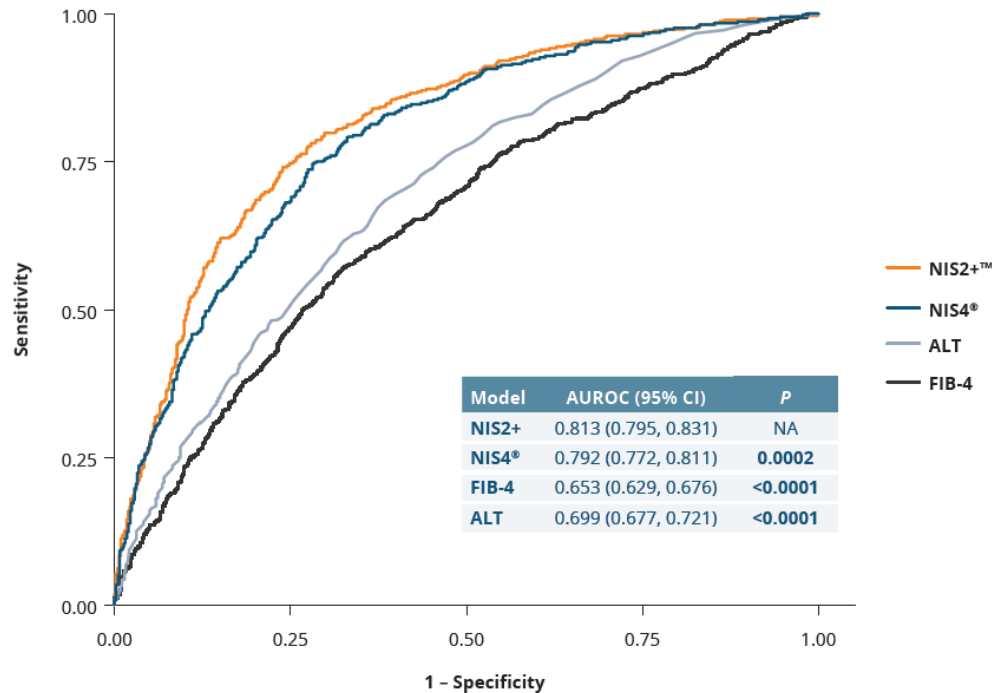
Stephen A. Harrison † • Vlad Ratziu † • Jeremy Magnanensi ✉ • ... Bart Staels • Quentin M. Anstee • Arun J. Sanyal ‡ • [Show all authors](#) • [Show footnotes](#)

[Open Access](#) • Published: May 22, 2023 • DOI: <https://doi.org/10.1016/j.jhep.2023.04.031>

NIS2+® Showed Improved Diagnostic Performances

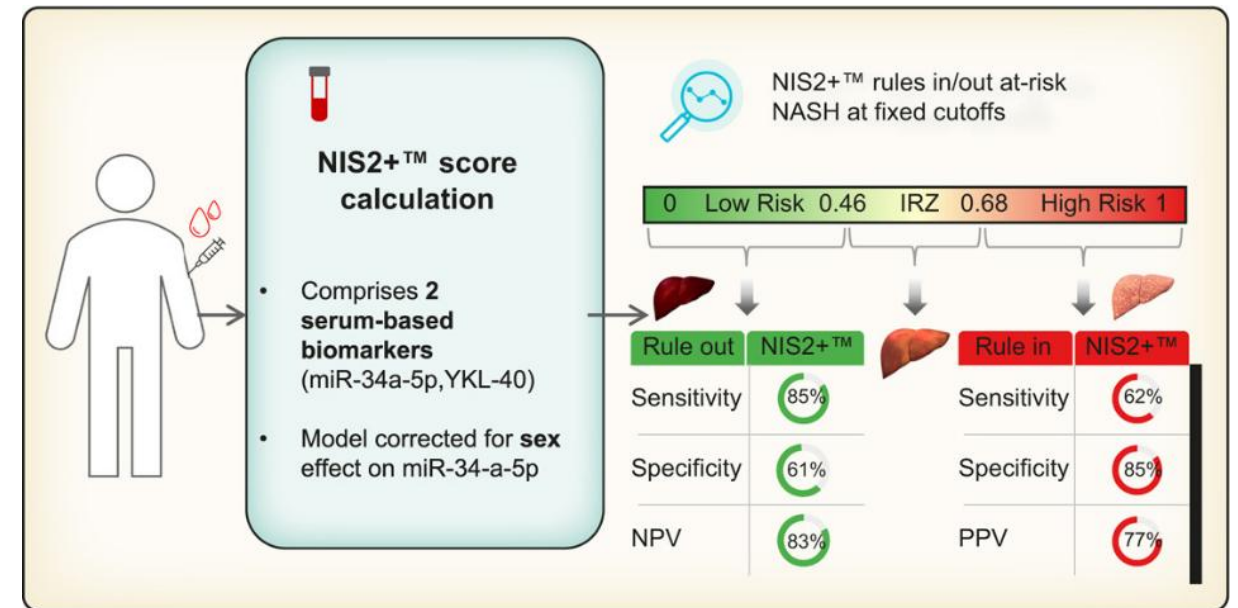
Resolve-It Phase 3 MASH clinical trial database – N=2035

Figure 1. ROC curves and AUROC values for NIS2+™, NIS4®, FIB-4, and ALT for detection of at-risk NASH



Test cohort, N=2035 (929 [45.65%] patients with at-risk NASH). AUROCs were compared using paired Delong tests.
ALT, alanine aminotransferase; AUROC, area under the receiver operating characteristic curve; F, fibrosis stage; FIB-4, fibrosis-4; NA, not applicable; NAS, nonalcoholic fatty liver disease activity score; NASH, nonalcoholic steatohepatitis; ROC, receiver operating characteristic

Figure 2. NIS2+® score interpretation and diagnostic performances



NIS2+® is not impacted by age, T2DM status, sex, BMI, hypertension or dyslipidemia, allowing physicians to interpret results irrespective of patients' characteristics

Age as an Important Confounding Factor for NITs: Stable Score Distributions with NIS2+®

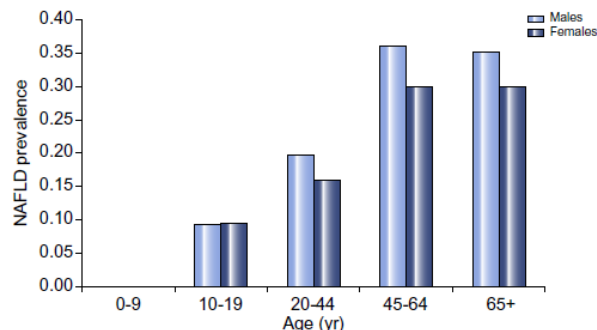


Fig. 2. Trends in the prevalence of NAFLD by age.^{7,13} NAFLD, non-alcoholic fatty liver disease.

Patients of all ages are affected by MASLD, even if age is a risk factor for MASLD so that prevalence of MASLD is rising with age

- It's known and published that biomarkers and **some NITs are impacted by age**, limiting the interpretation of test score vs cutoffs when being applied to patients ranging different ages
- It's of major importance for market penetration and large-scale use to **provide physician with a robust tool which could be easily interpreted irrespective of age of patients**
- Genfit developed **NIS2+** as a robust test against age, among other characteristics

Fig. NITs scores distributions by age and at-risk MASH status

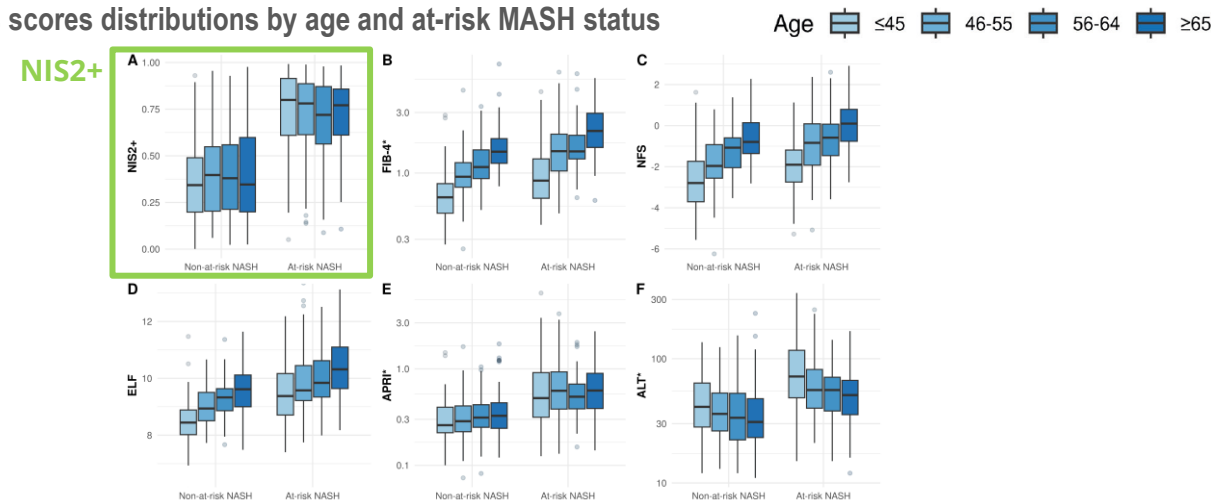
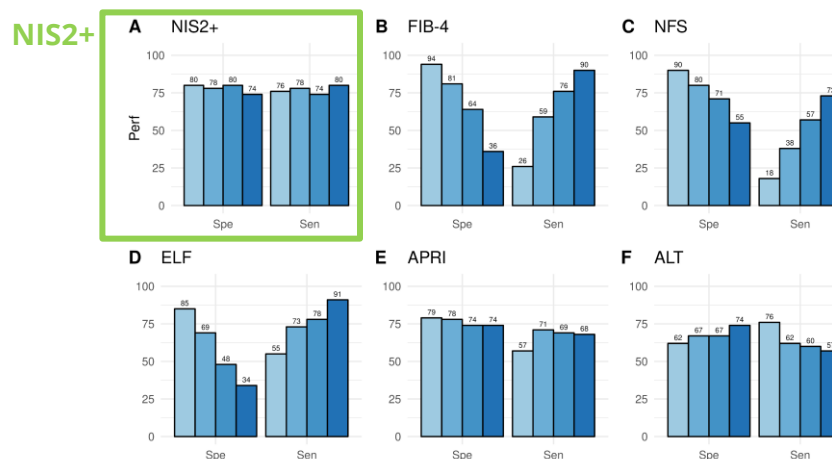


Fig. Impact of age on clinical performances of NITs for the detection of at-risk MASH, utilizing Youden cutoffs



NIS2+® Diagnostic Performance Recognized by International Expert Consortia (1/2)

Non-Invasive Biomarkers of MetaBolic Liver Disease (NIMBLE) Stage 1 validation – N=1073

nature medicine



Article

<https://doi.org/10.1038/s41591-023-02539-6>

Diagnostic performance of circulating biomarkers for non-alcoholic steatohepatitis

Topline results from NIMBLE consortium, stage 1 (N=1073)

	MASH		At-risk MASH		F stage ≥2	
	AUROC (95% CI)	p (vs ALT)	AUROC (95% CI)	p (vs ALT)	AUROC (95% CI)	p (vs FIB4)
ALT	0.678 (0.639, 0.717)		0.726 (0.694, 0.759)			
FIB4			0.704 (0.671, 0.737)		0.798 (0.768, 0.828)	
NIS4®	0.832 (0.801, 0.864)	< 0.001	0.815 (0.786, 0.844)	< 0.001	0.874 (0.848, 0.899)	< 0.001
ELF	-	-	-	-	0.828 (0.800, 0.857)	0.013
PROC3	-	-	-	-	0.809 (0.779, 0.839)	0.279
FibroM VCTE	-	-	-	-	0.841 (0.796, 0.886)	< 0.001

NIS4® utility has been recognized in a Stage 1 study undertaken by the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) initiative, with unique performances



**768 | VALIDATION OF THE
DIAGNOSTIC ENRICHMENT UTILITY
OF NIS2+® FOR VARYING
PHENOTYPES OF METABOLIC
DYSFUNCTION ASSOCIATED
STEATOTIC LIVER DISEASE**

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Katherine Yates⁴ Roberto Calle⁵ Alexander Pasek⁶
Tania Kamphaus⁶ Claude Sirlin² Anthony Samir⁷
Theodore Pierce⁷ Michael Middleton² Kathryn Fowler²
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Hatfield¹ Kris Kowdley¹⁰ James Tonascia⁴ Sudha
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University, ²University of California, San Diego, ³Cytel,
⁴Johns Hopkins University, ⁵Regeneron, ⁶FNIH,
⁷Massachusetts General Hospital, ⁸Pfizer, ⁹Saint
Louis University, ¹⁰Liver Institute Northwest, ¹¹Astra
Zeneca



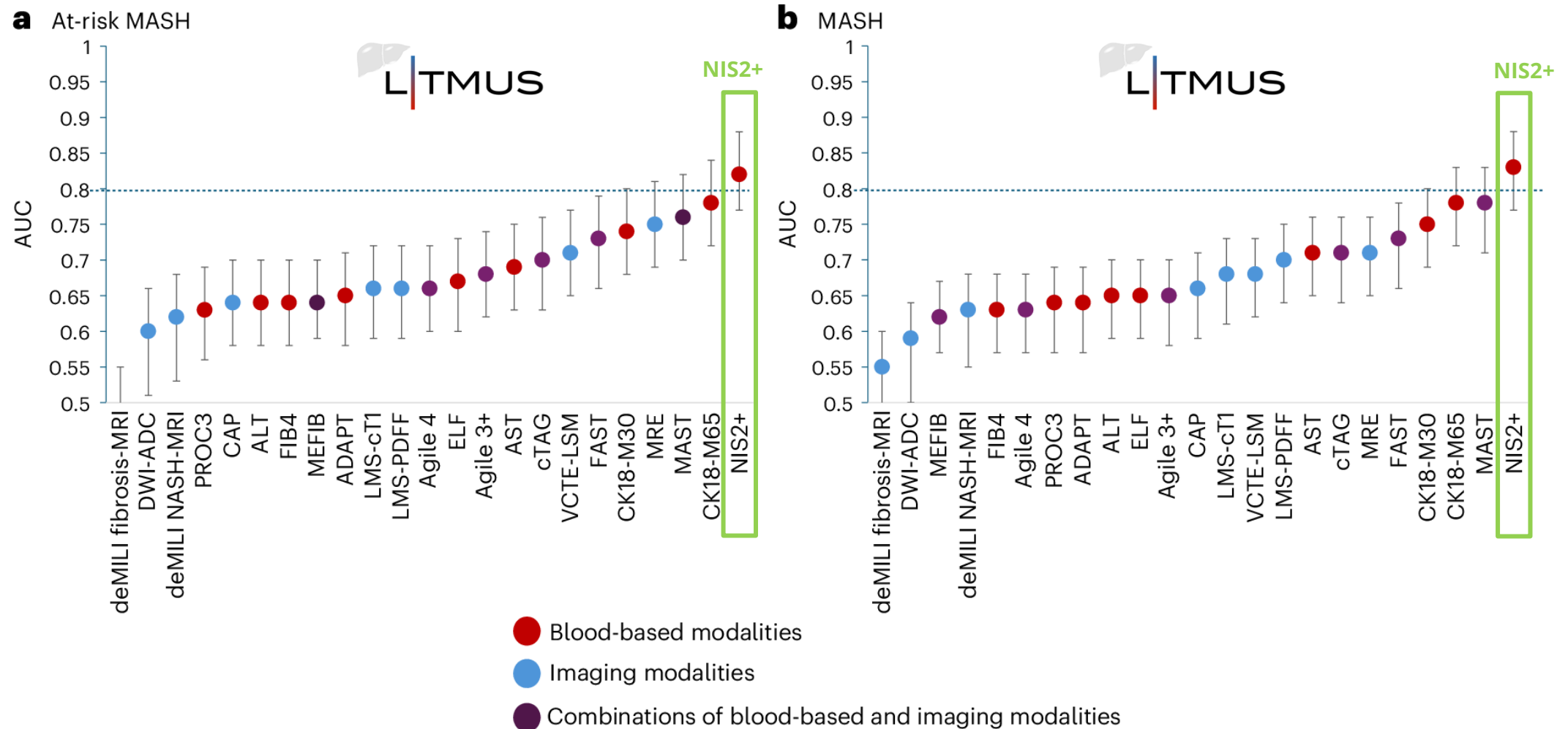
NIS2+® AUROC for at-risk MASH = **0.825** (N=810)

“NIS2+® significantly enriches the likelihood of identifying those with at-risk MASH in a population with MASLD. Its performance is weighted towards identification of those with stage 2 fibrosis and is as good as its predecessor NIS4® for its intended use.”

Manuscript in preparation

NIS2+® Diagnostic Performance Recognized by International Expert Consortia (2/2)

Liver Investigation: Testing Marker Utility in Steatohepatitis (LITMUS) Imaging Study – N=357



NIS2+® Showed Consistent Performance for Screening in Primary Care Settings

TABLE 1 | Clinical characteristics of participants divided into 3 groups based on their NIS2+ scores. Continuous variables are expressed as mean ± SD and categorical variables as percentages.

Variable	Low-risk MASH (NIS2+ < 0.46) n = 528	Intermediate-risk MASH (NIS2+ ≥ 0.46 – < 0.68) n = 145	At-risk MASH (NIS2+ ≥ 0.68) n = 125	p
Age (years)	55 ± 12	58 ± 11 ^a	58 ± 9 ^a	0.044
Sex, female (%)	56	61	57	0.559
Prevalence of obesity (%)	47	63	78	<0.001
Prevalence of hypertension (%)	51	56	56	0.424
Prevalence of T2D (%)	38	72	76	<0.001
Haemoglobin A1c (%)	6.0 ± 1.3	6.6 ± 1.3 ^a	6.8 ± 1.4 ^a	<0.001
% with elevated HOMA-IR (≥ 3.0)	35	66	82	<0.001
% with elevated Adipo-IR (≥ 2.0)	70	88	94	<0.001
Plasma AST (U/L)	21 ± 6	25 ± 8 ^a	37 ± 15 ^{a,b}	<0.001
Plasma ALT (U/L)	20 ± 10	27 ± 13 ^a	44 ± 25 ^{a,b}	<0.001
CK-18 (U/L)	120 ± 76	163 ± 93 ^a	323 ± 200 ^{a,b}	<0.001
Adiponectin (µg/mL)	6.6 ± 4.4	5.1 ± 3.1 ^a	4.4 ± 3.1 ^a	<0.001
% with elevated FIB-4 ^c	22	25	44	<0.001
% with elevated MRE (≥ 3.14 kPa)	21	28	46	0.003
% with VCTE CAP (≥ 288 dB/m)	40	72	81	<0.001
% with VCTE-LSM (≥ 8 kPa)	5	17	42	<0.001
FibroScan-AST (FAST) score ^d				<0.001
Intermediate-risk MASH (%)	2	16	36	
At-risk MASH (%)	0	1	22	

Figure 1. Prevalence of at-risk MASH determined by NIS2+ (NIS2+ ≥ 0.68) stratified by body mass index (BMI) category and presence of T2D.

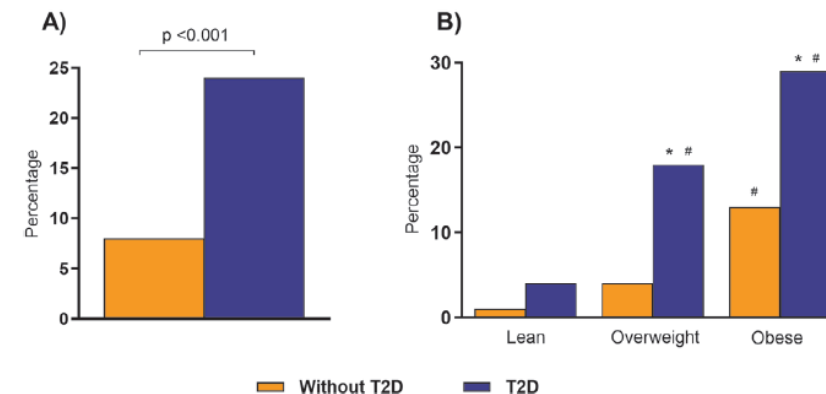
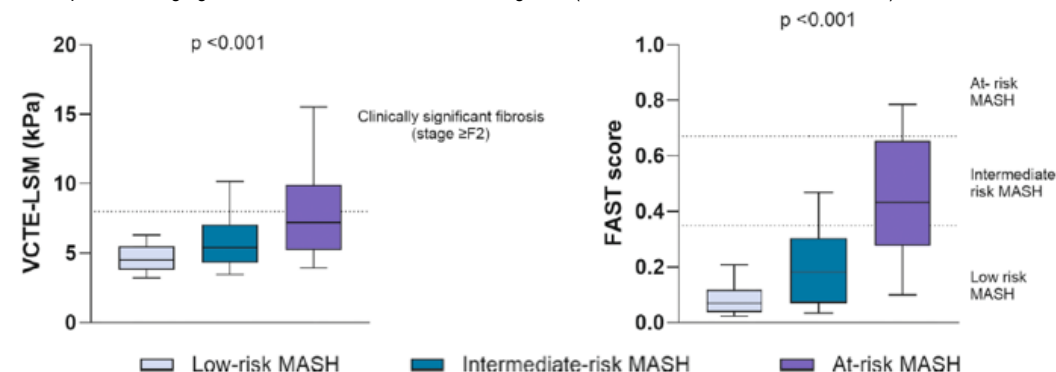


Figure 2. Box plots of imaging biomarkers across NIS2+ risk categories (low, intermediate and at-risk MASH)

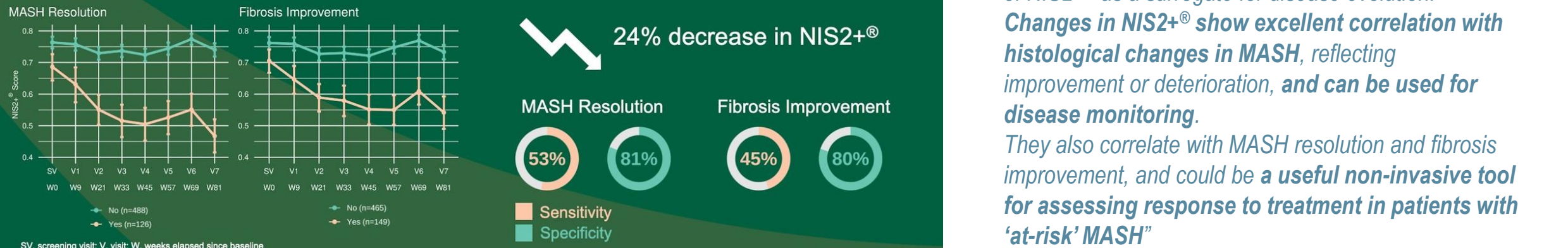


“NIS2+ compared to VCTE-LSM (or FAST) detected more people with stage F2 in intermediate risk groups (i.e., with obesity only or nonobese with T2D), a preliminary observation that warrants additional studies. [...]

Our results provide the groundwork for NIS2+ to be considered in primary care as a valid diagnostic complement to the current 2-tier approach (FIB-4 +/- VCTE-LSM) or an alternative blood-based test when transient elastography or other imaging is unavailable.”

Serial Measurements of NIS2+® Allow for Effective Monitoring of Disease Evolution

Serial measurements of NIS2+® enable monitoring disease evolution in patients with MASH: A retrospective cohort analysis



- 614 patients included in the RESOLVE-IT Phase 3 trial (NCT02704403) with MAS $\geq$ 4 and F2-F3 at baseline
- Mean follow-up of 19 months

A 24% decrease in NIS2+® led to a sensitivity of 0.53 and specificity of 0.81 for the detection of MASH Resolution, and a sensitivity of 0.45 and a specificity of 0.80 for Fibrosis Improvement

“Emerging data support the role of serial measurement of NIS2+® as a surrogate for disease evolution.

Changes in NIS2+® show excellent correlation with histological changes in MASH, reflecting improvement or deterioration, and can be used for disease monitoring.

*They also correlate with MASH resolution and fibrosis improvement, and could be **a useful non-invasive tool for assessing response to treatment in patients with ‘at-risk’ MASH***”

Theocharidou, Eleni, et al. Drugs (2026): 1-25

NIS technology in clinical guidelines

Clinical Practice Guidelines

JOURNAL OF HEPATOLOGY

EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD)[☆]

European Association for the Study of the Liver (EASL)^{*}, European Association for the Study of Diabetes (EASD), European Association for the Study of Obesity (EASO)

CLINICAL PRACTICE UPDATE

Gastroenterology

AGA Clinical Practice Update on the Role of Noninvasive Biomarkers in the Evaluation and Management of Nonalcoholic Fatty Liver Disease: Expert Review

CONSENSUS REPORT

Diabetes Care

Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD) in People With Diabetes: The Need for Screening and Early Intervention. A Consensus Report of the American Diabetes Association

NIS4® for monitoring treatment response in independent publications from clinical trials

akero THE LANCET Gastroenterology & Hepatology

Safety and efficacy of once-weekly efruxifermin versus placebo in non-alcoholic steatohepatitis (HARMONY): a multicentre, randomised, double-blind, placebo-controlled, phase 2b trial

Table S4. Absolute changes in serum markers of fibrosis, collagen turnover, and liver stiffness at week 24 (full analysis set)

	Placebo	Efruxifermin 28 mg	Efruxifermin 50 mg
NIS-4 score			
n	39	35	31
LS mean change from baseline (SE)	0.0 (0.03)	-0.3 (0.04)	-0.3 (0.04)
95% CI	(-0.1, 0.0)	(-0.4, -0.2)	(-0.4, -0.3)
P vs baseline	0.413	<0.001	<0.001
Placebo-corrected LS mean change from baseline (SE)	NA	-0.3 (0.05)	-0.3 (0.05)
95% CI	NA	(-0.4, -0.2)	(-0.4, -0.2)
P vs placebo	NA	<0.001	<0.001



THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Tirzepatide for Metabolic Dysfunction–Associated Steatohepatitis with Liver Fibrosis

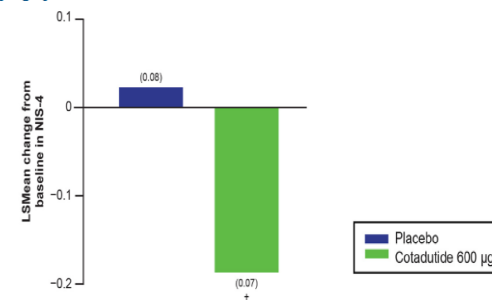
Table 2. Changes from Baseline to Week 52 in Selected Liver End Points.^a

End Point	Tirzepatide, 5 mg (N=47)	Tirzepatide, 10 mg (N=47)	Tirzepatide, 15 mg (N=48)	Placebo (N=48)
NIS4 test score				
Absolute change	-0.29±0.04	-0.36±0.04	-0.39±0.04	-0.02±0.04
LS mean difference between tirzepatide and placebo (95% CI)	-0.27 (-0.39 to -0.15)	-0.34 (-0.45 to -0.22)	-0.36 (-0.48 to -0.24)	—



Clinical Gastroenterology and Hepatology

Safety and Efficacy of Novel Incretin Co-agonist Cotadutide in Biopsy-proven Noncirrhotic MASH With Fibrosis



1662 | IMPROVEMENTS IN NON-INVASIVE MARKERS OF MASH AND FIBROSIS WERE ASSOCIATED WITH HISTOLOGICAL MASH RESOLUTION WITH TIRZEPATIDE TREATMENT OF NON-CIRRHOTIC MASH ♦

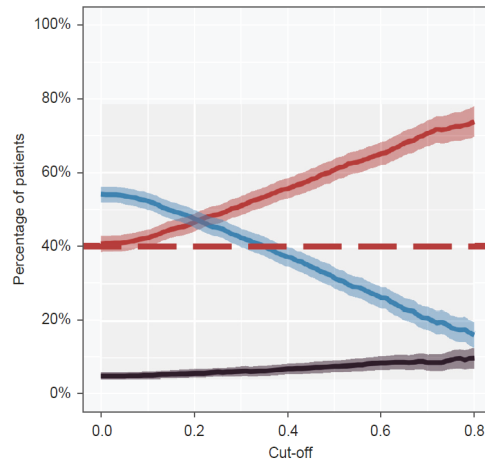
Rohit Loomba¹, Jerome Boursier², Elisabetta Bugianesi³, Raj Vuppalanchi⁴, Masato Yoneda⁵, Eric Lawitz⁶, Yuanyuan Tang⁷, Bram Brouwers⁸, Mark Hartman⁹, Anun Sanyal¹⁰, ¹University of California, San Diego, ²Angers University Hospital, Angers, France, ³University of Torino, Torino, Italy, ⁴Indiana University School of Medicine, Indianapolis, United States, ⁵Yokohama City University, Yokohama, Japan, ⁶Texas Liver Institute, University of Texas Health, San Antonio, United States, ⁷Eli Lilly and Company, Indianapolis, United States, ⁸Virginia Commonwealth University

“Reductions in ALT, AST, GGT, NIS4®, MRI-PDFF, and cT1 were significantly greater among participants achieving MASH resolution without worsening of fibrosis (responders) compared with those not achieving this endpoint (non-responders).”

NIS2+ Could Significantly Reduce Liver Biopsy Rates (LBFR) and Overall Costs of MASH Clinical Trials

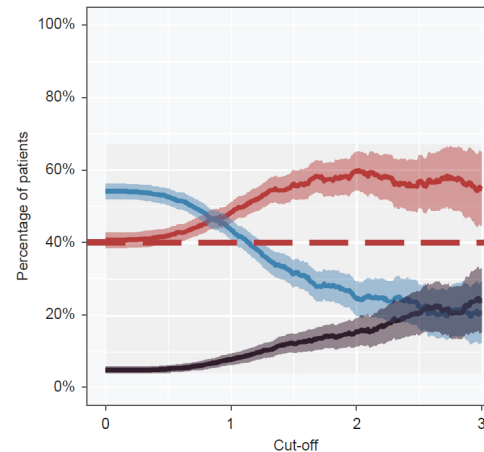
NIS2+™

NIS2+™ screening pathway

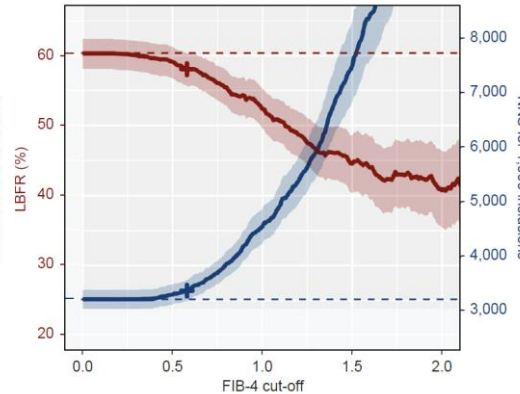
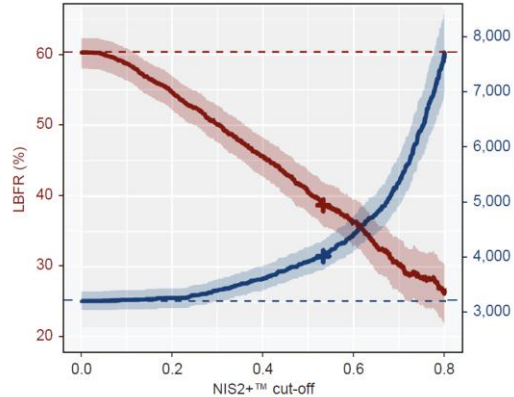


FIB4

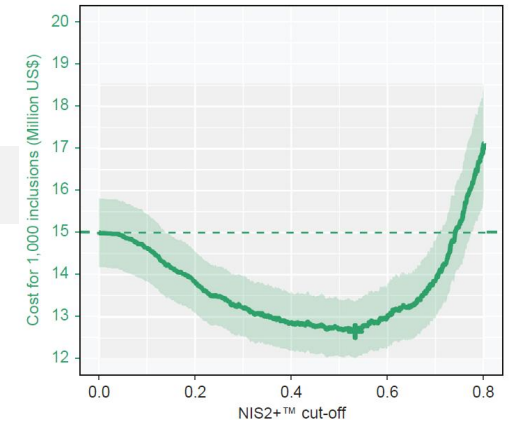
FIB-4 screening pathway



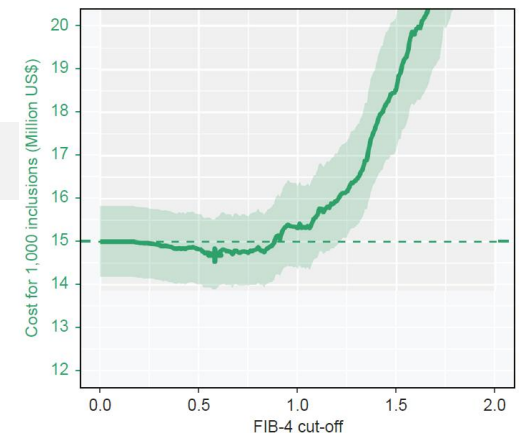
At-risk MASH
Not at-risk MASH
Cirrhosis



NIS2+™



FIB4



Using NIS2+, the LBFR could have been reduced to <30% and a 16% (-\$2.6M) reduction in overall cost could have been reached

NIS2+ Directly Measures the Biological Components Targeted by Current and Emerging MASH Therapies: Disease Activity and Fibrosis (Published Data)

Criteria	NIS2+	FIB-4	ELF	FibroScan (VCTE/FAST)
Captures MASH disease activity	✓ Yes	✗ No	✗ No	⚠ Limited (FAST only)
Captures fibrosis	✓ Yes	✓ Indirectly	✓ Yes	✓ Yes
Designed for at-risk MASH diagnosis (MASH + F≥2)	✓ Yes	✗ No	✗ No	⚠ Partially
At-risk MASH AUROC (LITMUS data)	0.83	0,64 Significantly lower than NIS2+	0.67 (intermediate FIB-4 population)	~0.73 (FAST)
What are the diagnostic tools specifically needed to manage treatment-eligible F2-F3 patients?				
Detection of F2 patients	Strong / weighted toward F2 disease	Weak	Moderate	Moderate
Monitoring disease activity / Correlation with MASH resolution	✓ Yes	✗ No	⚠ Limited	⚠ Limited
Advanced fibrosis (F≥3) AUROC	0.64	NA	0.74	~0.81

Current & Emerging MASH Therapies: GLP-1s / THR-β agonists / FGF21 analogues / Combination therapies



Treatment target in all FDA authorized registration trials* = MASH activity + F2-F3 fibrosis

Qualifying the Market Opportunity: Insights from IQVIA Research

Pascal Caisey
GENFIT COO

***NIS2+: Enabling Scalable
Adoption of MASH Therapies***

GENFIT Sought to Evaluate How NIS2+ Will Redefine the Market for MASH Diagnostics

Overall Project Goal

Evaluate need, fit, and opportunity for NIS2+ to improve MASH diagnostic & monitoring in the US

Research Methodology

Triangulated primary research findings with IQVIA experts ensuring robust, credible insights from breadth and depth of input to minimize bias and maximize strategic confidence

Quantitative Survey (n=50)

Surveyed gastroenterologists, hepatologists, endocrinologists, and primary care to capture **broad provider perspectives on diagnostic practices, treatment landscape, and NIS2+ positioning**



Qualitative Interviews (n=5)

Interviewed **key opinion leaders** to gather **deep expert insights on treatment paradigm shifts**, validating quantitative trends, and exploring nuanced clinical design-making factors



In the MASH therapy era, **the bottleneck is no longer treatment availability, it's finding/staging the right patients** early and monitoring them well

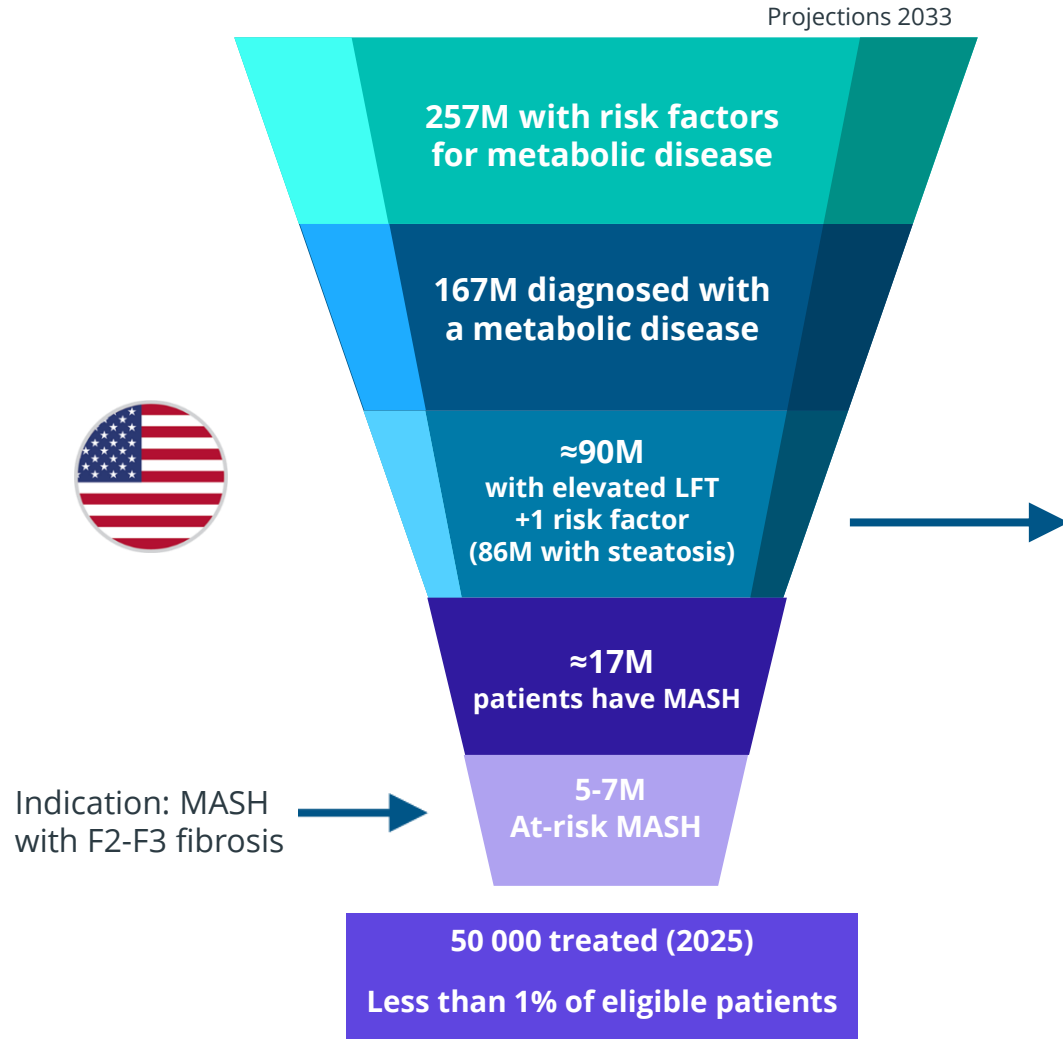
The MASH therapy era changes the growth equation

Final Readout

May 2026



Large Addressable Patient Population With Over 99% of Eligible Patients Still Untreated



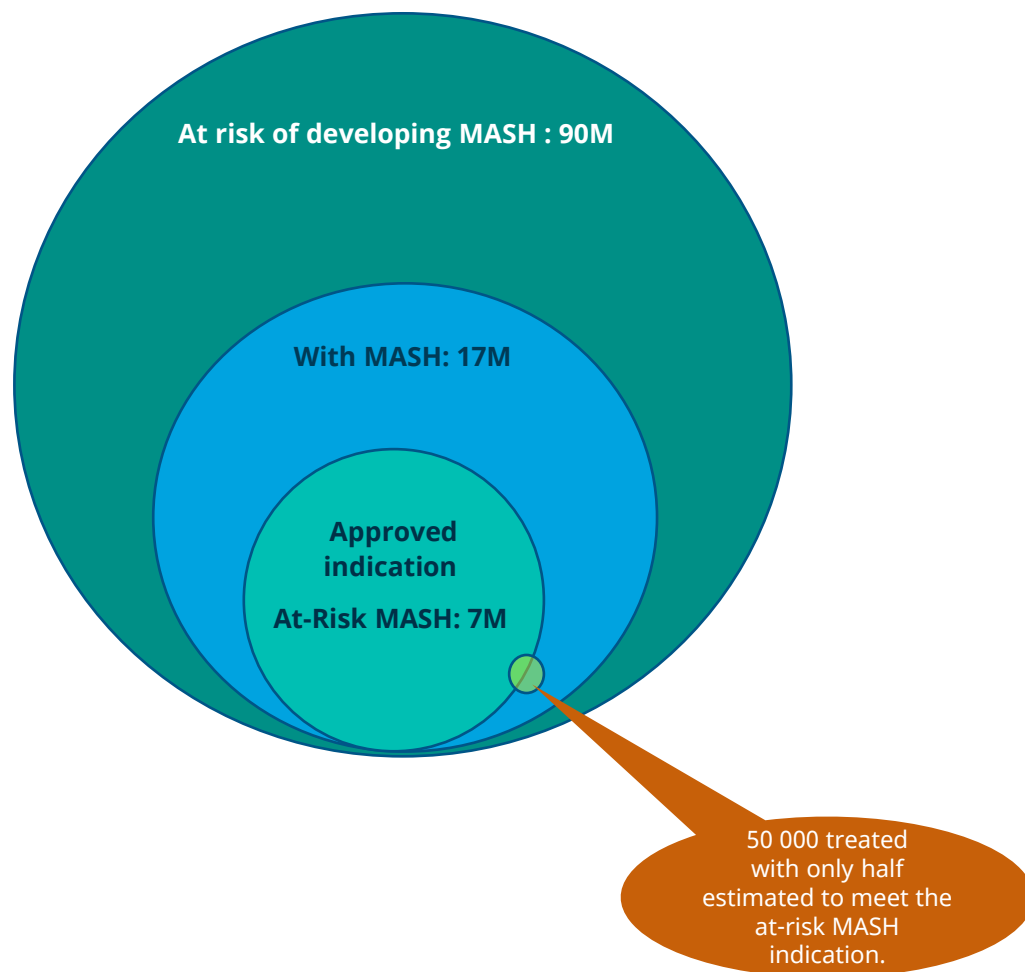
MASH is emerging as one of the largest new chronic care markets

- ~90M patients with elevated LFTs and ≥ 1 metabolic risk might have MASH and could be at-risk. They **should be systematically screened for MASH** to enable timely diagnosis, referral, and treatment.
- As a result, MASH Dx has the potential to:
 - Significantly expand the diagnosed patient population
 - Accelerate referral and treatment initiation directly by PCPs or Specialists



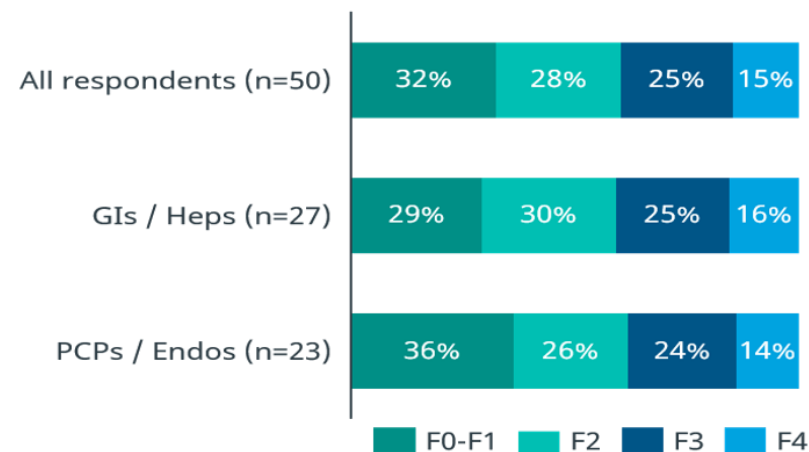
Only a Small Fraction (1%) of Eligible Patients Currently Receive Treatment Yet Almost Half (47%) of Treated Patients are Outside the Approved Indication

Current MASH market



Insights from IQVIA Research*

- **Lack of awareness** about MASH and more specifically tests to detect it: less than 1% of eligible patients currently receive treatment.
- **Lack of trust in current tests:** even when at-risk MASH is identified only about half of patients are treated
- Poor specificity: **47% of treated patients are F0-F1 or F4 patients = Off label patients**





Why Are So Few Patients Treated Despite a Large Eligible Population? (1/2)

Insights from IQVIA Research*

No efficient way to identify at-risk MASH patients at scale	▪ Current screening pathways are inadequate for identifying at-risk MASH patients at scale ▪ Existing diagnostic tools fail to fully address clinical and operational needs ▪ As a result, many at-risk MASH patients remain undiagnosed until advanced fibrosis develops
Liver biopsy is invasive, costly, and unsuitable for broad screening	▪ Liver biopsy remains the diagnostic gold standard but is unsuitable for population-scale screening due to its invasive nature, cost (~US\$2,000-4,000 per procedure), and associated patient risks. ▪ Beyond procedural limitations, biopsy suffers from sampling variability and inter-/intra-reader variability, creating challenges for consistent disease assessment ▪ There is a growing need for non-invasive, scalable and accessible diagnostic solutions capable of identifying patients efficiently outside specialist centers
Limited physician confidence in first-line blood tests such as FIB-4	▪ Designed to exclude advanced fibrosis, not to identify at-risk MASH ▪ Poor specificity for at-risk MASH + Does not measure disease activity → Limited ability to detect disease activity (MASH) and F2-F3 patients ▪ Large indeterminate “grey zone” ▪ FIB-4 is an effective rule-out tool, but not a stand-alone test



Why Are So Few Patients Treated Despite a Large Eligible Population? (2/2)

Insights from IQVIA Research*

FibroScan requires specialized equipment and is primarily available in specialist settings for fibrosis measurement	Today Imaging is utilized more frequently than blood-based biomarkers despite : • Limited accessibility: appointment availability may delay patient evaluation and diagnosis. • Limited performance for at risk MASH : • Measures liver stiffness, not MASH disease activity • Cannot directly identify at-risk MASH (MASH + F2/F3 fibrosis) • Limited ability to distinguish fibrosis due to active MASH versus other causes
Low awareness and adoption of alternative diagnostic modalities	▪ Limited awareness of MASH leads to missed or delayed recognition of early symptoms and confusion with other metabolic conditions ▪ Even when MASH is suspected, blood testing practices inconsistent with lack of sensitivity and specificity for inflammation or fibrosis ▪ GI and HI have mixed confidence in existing blood tests, often performing 2 NITs to validate results. ▪ Only small % of patients suspected of MASH are referred by PCPs & without biomarker testing ▶ Fragmented diagnostic pathway delays patient identification and treatment initiation
Until recently, the absence of approved therapies provided little incentive to diagnose	▪ No therapeutic actionability: Physicians had limited incentives to actively identify MASH patients in the absence of approved treatment options ▪ Low PCP prioritization: MASH screening was often deprioritized relative to other cardiometabolic conditions. ▪ Complex diagnostic pathway: Multi-step assessment and specialist referral created significant barriers to diagnosis. ▪ Low patient awareness and engagement: Most at-risk patients were unaware of their disease status and progression risk. ▶ The clinical & economic value of broad screening was difficult to demonstrate without available therapies

The next breakthrough in MASH is not another drug. It's the ability to identify patients at scale



The Virtuous Circle: Effective Therapies Create the Reason to Diagnose, the Urgency to Refer and the Need to Monitor

PHARMA IS THE PRIMARY DRIVER OF MASH MARKET DEVELOPMENT THROUGH THE LAUNCH OF NEW THERAPIES



GREATER PHYSICIAN AWARENESS & EDUCATION



MORE TREATMENT ELIGIBLE PATIENTS IDENTIFIED



HIGHER PRESCRIBING & TREATMENT PERSISTENCE

GREATER NEED FOR TREATMENT MONITORING



Why Pharma Needs Scalable Diagnostic tool to Unlock the Full MASH Opportunity

- Therapeutic innovation creates clinical actionability
- Efficient patient identification is the primary bottleneck to treatment uptake
- Scalable diagnostic solutions are essential to unlock the treatable population
- PCP engagement requires simple, accessible diagnostic pathways
- Disease activity and fibrosis assessment increase treatment confidence
- Longitudinal monitoring supports treatment optimization
- Market access and reimbursement depend on robust diagnostic evidence

Broad adoption of MASH therapies and diagnostics are mutually reinforcing
More therapies drive testing demand, while better diagnostics accelerate therapy adoption.

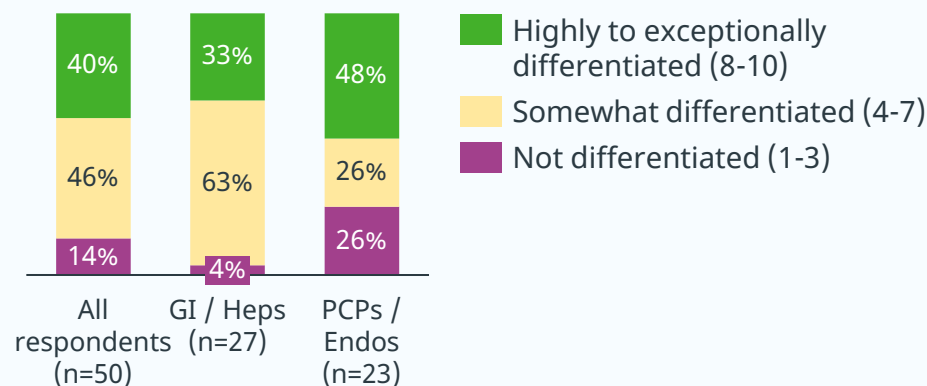


NIS2+ Differentiates From Existing Biomarker Tests Through Simplicity, Sensitivity, and Workflow Fit

Insights from IQVIA Research*

NIS2+ Strengths per physicians

NIS2+ differentiation vs. other blood-based panels



- Point-of-care accessibility available at any phlebotomy site
- **Dual sensitivity for inflammation and fibrosis staging provides comprehensive disease characterization**
- Workflow simplicity for PCPs and Endocrinologists compared to complex imaging logistics

Competitive Landscape Context

- **FIB-4:** Cheap and embedded in workflows but has limited sensitivity in gray zones
- **FibroScan:** Only looks at fibrosis, and specialists prefer immediate results, but accessibility limited in PCPs
- **ELF/FibroTest:** Good diagnostic accuracy for fibrosis only, but limited ability to detect earlier stage patients

NIS2+ has incremental meaningful advantages over other blood tests, and its success hinges on longitudinal data, payer adoption, and outcome linkage

New value proposition for PCP/Endo : Triage + referral efficiency with both disease activity & fibrosis staging

NIS2+ Directly Measures the Biological Components Targeted by Current and Emerging MASH Therapies: Disease Activity and Fibrosis (Published Data)

Criteria	NIS2+	FIB-4	ELF	FibroScan (VCTE/FAST)
Captures MASH disease activity	✔ Yes	✗ No	✗ No	⚠ Limited (FAST only)
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Current & Emerging MASH Therapies: GLP-1s / THR-β agonists / FGF21 analogues / Combination therapies

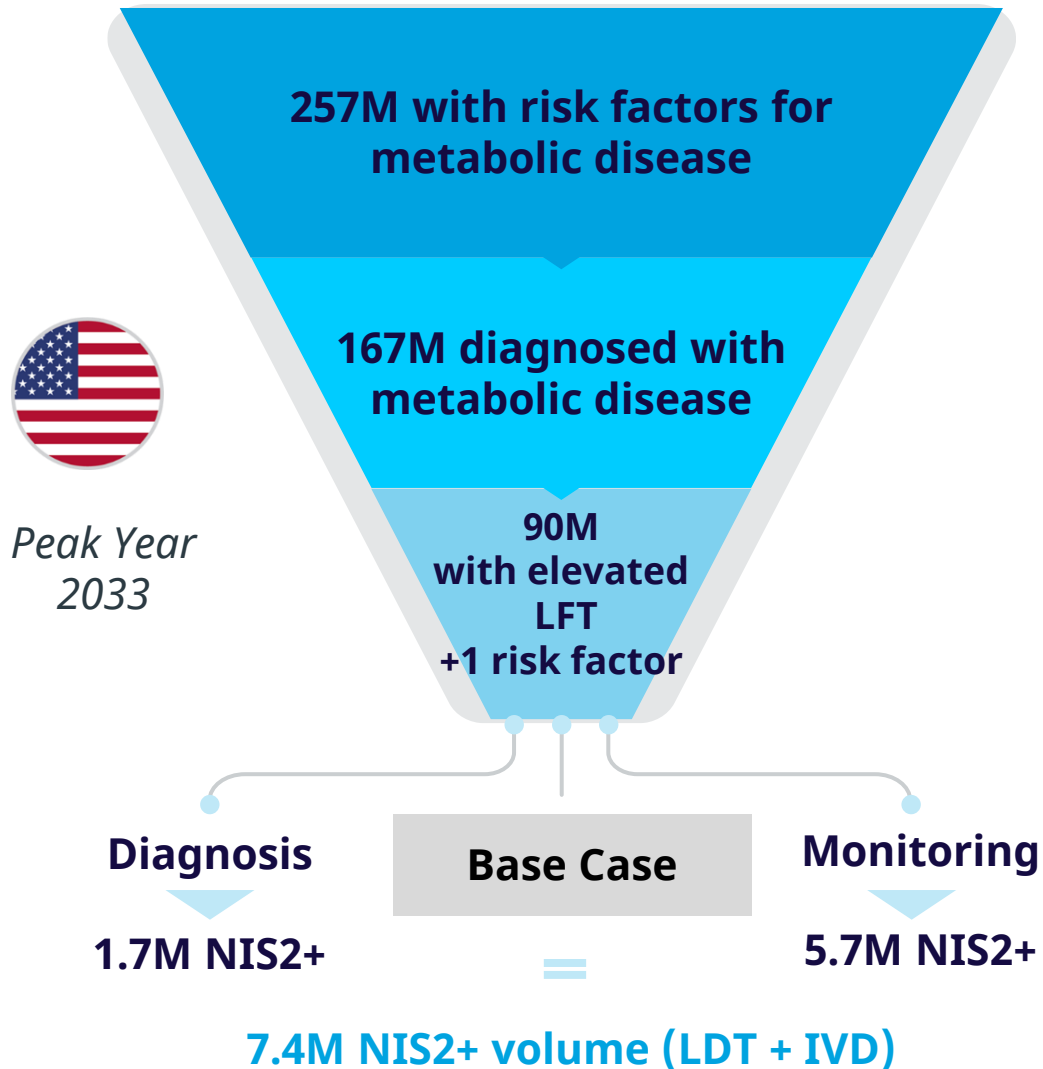


Treatment target in all FDA authorized registration trials* = MASH activity + F2-F3 fibrosis

**: Anania F et al, Nonalcoholic Steatohepatitis: Current Thinking From the Division of Hepatology and Nutrition at the Food and Drug Administration, Hepatology 2021*



Monitoring Increases Duration, Persistence and Value Per Patient (cf. LDL, Hb1c monitoring cases ...)



- **Monitoring is a highly differentiate case vs other diagnostic tests**
- While the eligible population is large (90M), NIS2+ volume is driven primarily by **monitoring treatment response** and **disease progression / regression**
- **Key Value of Monitoring**

For Pharma :

- Demonstrates treatment effectiveness in real-world settings
- Improves patient persistence and adherence
- Optimizes treatment decisions
- Strengthens payer value proposition with real-world outcome data supporting reimbursement and market access.

For GENFIT :

- Recurring testing revenue
- Expanded testing volume per patient
- Stronger partnerships with Pharma
- Higher barriers to entry for competitors

Why GENFIT Should Pursue IVD Beyond LDT: LDT Validates the market. IVD Scales the Market.

LDT = Time to market and lower risk

Limited investment
Early market development
Generates clinical utility data
Restricted scalability and value capture



IVD = scale and value creation

Broader adoption by laboratories
Greater accessibility for PCPs and endocrinologists
Larger diagnostic and monitoring volumes
Higher long-term economics
Stronger strategic control and asset value



IVD is critical to unlock the full value of pharma partnerships

For pharma, broad patient identification requires an IVD solution
LDT can establish the market, but IVD is needed to scale it.

Start: 1H26

Completion target: 2028

Translating the Opportunity into Revenue: Corporate Guidance

A Decade of Vision and Execution Now Entering the Next Phase: Progressive Adoption and Commercial Scale-Up

Two historically
complementary programs

Therapeutic program
(elafibranor in MASH¹)

2015

2020

Strategic groundwork
and pre-positioning

Key steps toward
large-scale adoption

DIAGNOSTIC

+

MONITORING

2026

2027

2028

Diagnostic program

(NIS non-invasive technology for the identification of patients with at-risk MASH)

6 major scientific publications (*Nature Medicine*,
The Lancet Gastro & Hep, *Journal of Hepatology*, etc.),
and >20 congress posters & oral presentations



Recognition by leading EU and US consortia
(LITMUS, NIMBLE)



Deployment in large-scale clinical trials



Inclusion in international clinical guidelines
(EASL / EASD / EASO – ADA – AGA – KASL)



1 Commercial rollout via Labcorp's offering



2 Reimbursement of NASHnext® (Labcorp)
by Medicare for patients meeting eligibility
criteria



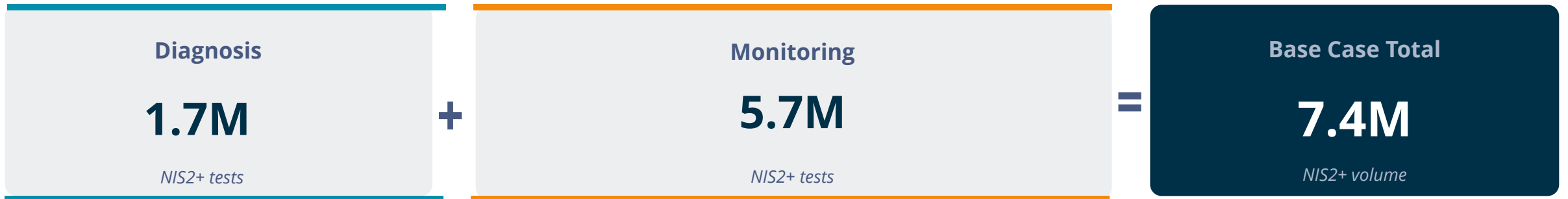
3 Strategic partnerships with major
pharmaceutical and diagnostic players

4 Development of an IVD kit for
NIS2+® and proceed with
large-scale commercialization

1. At the time of the elafibranor development the indication was still named NASH and was only more recently changed into MASH

Expected Adoption Dynamics: Diagnostics vs. Monitoring

Base Case volume assumptions across the patient testing journey, from initial diagnosis to long-term monitoring



Volume peak year 2033 (U.S.)

Volume Split: Diagnostic Testing vs. Monitoring

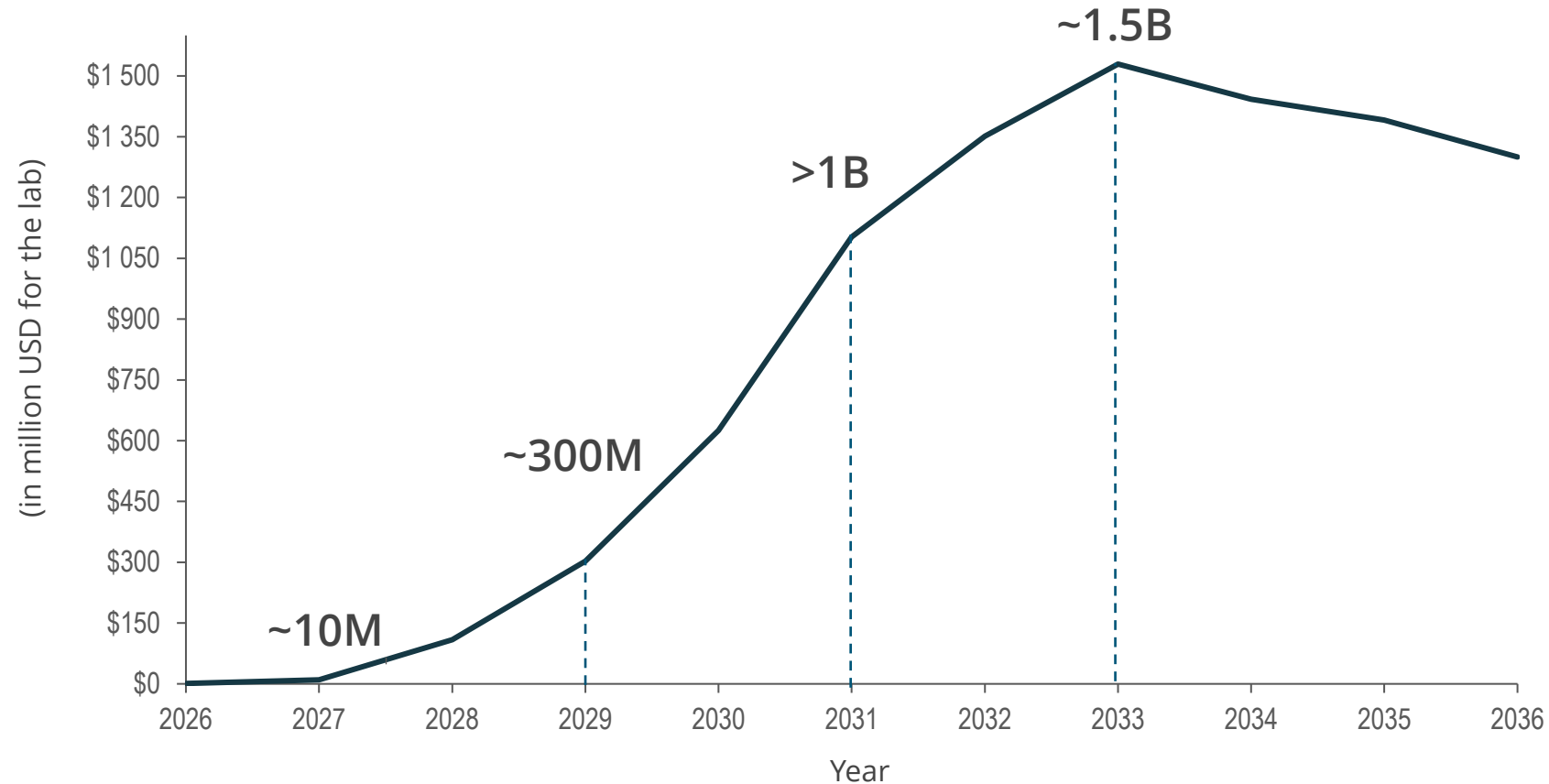


Monitoring Drives the Majority of Base Case NIS2+ Volume

10.3M total NIS2+ volume in the Base Case — ongoing monitoring outweighs initial diagnosis and re-testing combined

IVD Unlocks a ~\$1.5B Peak Annual Laboratory Market Opportunity¹

NIS2+ Estimated Revenue to Partner Lab (LDT+IVD)



The diagnostics opportunity is no longer constrained by therapy availability, but by the ability to identify and manage eligible patients at scale

Assumptions overview

- Number of patients at the various stages of the funnel is based on averages of published epidemiological data and generally aligned with other industry communications.
- Conservative adoption assumption: in the model NIS2+ is expected to capture only ~35% of frontline blood-based testing, even though 60% of prescribers currently see NIS2+ as clearly differentiated and better than other tests.
- Access: payer coverage has been capped at 60%, reached gradually over a four-year ramp-up period which seems conservative considering current Medicare coverage of NIS4. This has been combined with a 40-60% (industry benchmark) IVD manufacturer to laboratory discount assumption.
- Longitudinal monitoring as an approved use of the IVD kit
- 2028 as the target year for broad commercialization: the IVD launch is expected in 2028. This means that the broader access and adoption typically seen when a diagnostic moves from specialized LDT use will start at that point.

Q&A

Merci Beaucoup
