

Opportunities for and barriers to omics-based biomarker discovery in steatotic liver diseases

Maja Thiele, Ida Falk Villesen, Lili Niu, Stine Johansen, Karolina Sulek, Suguru Nishijima, Lore Van Espen, Marisa Keller, Mads Israelsen, Tommi Suvitaival, Andressa de Zawadzki, Helene Bæk Juel, Maximilian Joseph Brol, Sara Elizabeth Stinson, Yun Huang, Maria Camilla Alvarez Silva, Michael Kuhn, Ema Anastasiadou, Diana Julie Leeming, Morten Karsdal, Jelle Matthijnssens, Manimozhayan Arumugam, Louise Torp Dalgaard, Cristina Legido-Quigley, Matthias Mann, Jonel Trebicka, Peer Bork, Lars Juhl Jensen, Torben Hansen and Aleksander Krag on behalf of the MicrobLiver and GALAXY consortia

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nordicPRO-C3™

Regulatory milestone

Year	Description
2019	A letter of intent accepted by the FDA for <i>nordicPRO-C3™</i> as a diagnostic marker

References

Year	Context of use	Aetiology	Reference
2013	Diagnostic	ALD	Leeming et al. Alimentary Pharmacology & Therapeutics DOI: 10.1111/apt.12484
2014	Diagnostic	HCV/HIV co-infection	Jansen et al. PLoS One DOI: 10.1371/journal.pone.0108544
2015	Diagnostic/Prognostic	HCV	Nielsen et al. Liver Int. DOI: 10.1111/liv.12700
2018	Prognostic	PSC	Nielsen et al. Alimentary Pharmacology & Therapeutics DOI: 10.1111/apt.14806
2019	Diagnostic	T2D	F. Bril et al. Diabetes Care DOI: 10.2337/dc18-2578
2019	Secondary endpoint	MASH	S.A. Harrison et al. Lancet DOI: 10.1016/S0140-6736(19)32517-6
2019	Diagnostic	MASLD	S. J. Daniels et al. Hepatology DOI: 10.1002/oby.22344
2019	Diagnostic	MASLD	M. Boyle et al JHEP Reports DOI: 10.1016/j.jhepr.2019.06.004
2021	Diagnostic	ALD	B. S. Madsen et al. AP&T DOI: 10.1111/apt.16513
2021	Diagnostic	MASLD/MASH	P.B. Lassen et al. J of Clinical Endocrinology & Metabolism DOI: 10.1210/clinem/dgab897
2021	Diagnosis (systemic review)	MASLD	Mak et al. Biomedicines DOI: 10.3390/biomedicines9121920
2021	Trial inclusion (diagnostic)	MASH	M.J. Nielsen et al. Journal of Hepatology DOI: 10.1016/j.jhep.2021.08.016
2022	Diagnostic	MASLD	L Tang et al. Hepatology International DOI: 10.1007/s12072-022-10420-w
2022	Diagnostic	MASLD	L Tang et al. Metabolism Clinical and Experimental DOI: 10.1016/j.metabol.2021.154958.
2023	Screening (diagnostic)	NAFLD/NASH	Y. Vali et al. (LITMUS) Lancet Gastro Hep DOI: 10.1016/S2468-1253(23)00017-1

2023	Prognostic	ALD	S. Johansen et al. Liver International DOI: 10.1111/liv.15595
2023	Diagnostic and monitoring	MASLD	A. Armandi et al. J of Clinical Medicine DOI: 10.3390/jcm12020650
2023	Prognostic	HCV and a mixed cohort	M. J. Nielsen et al. JHEP reports DOI: 10.1016/j.jhepr.2023.100743

Enhanced Liver Fibrosis (ELF) test

Regulatory milestones

Year	Description
2004	Publication in Gastro with ELF measured on Immuno 1 platform
2011	CE mark. The first time ELF was commercially available for sale as an in vitro diagnostic device
2021	Approved by the FDA as a prognostic marker

References

Year	Context of use	Aetiology	Reference
2004	Diagnostic	Mixed	Rosenberg et al. Gastroenterology DOI: 10.1053/j.gastro.2004.08.052
2008	Diagnostic	MASLD	Guha et al. Hepatology DOI: 10.1002/hep.21984
2008	Prognostic	PBC	Mayo et al. Hepatology DOI: 10.1002/hep.22517
2009	Diagnostic	MASLD	Nobili et al. Gastroenterology DOI: 10.1053/j.gastro.2008.09.013
2010	Diagnostic	Mixed	Friedrich-Rust et al. BMC Gastroenterol DOI: 10.1186/1471-230X-10-103
2010	Prognostic	Mixed	Parkes et al. Gut DOI: 10.1136/gut.2009.203166
2011	Diagnostic	HCV	Parkes et al. J Viral Hepat DOI: 10.1111/j.1365-2893.2009.01263.x
2012	Diagnostic	HBV	Kim et al. PLoS One DOI: 10.1371/journal.pone.0041964
2013	Diagnostic / Normal Range	HCV	Lichtinghagen et al. J Hepatol DOI: 10.1016/j.jhep.2013.03.016
2013	Normal Range	---	Yoo et al. Liver Int. DOI: 10.1111/liv.12136
2014	Prognostic	HBV	Kim et al. Hepatology

			DOI: 10.1002/hep.27389
2015	Diagnostic	Mixed	Fagan et al. Liver Int. DOI: 10.1111/liv.12760
2015	Prognostic	PSC	Vesterhus et al. Hepatology DOI: 10.1002/hep.27825
2016	Prognostic	Mixed	Irvine et al. Liver Int. DOI: 10.1111/liv.12896
2016	Diagnostic	MASLD	NICE guideline NG49 https://www.nice.org.uk/guidance/ng49
2016	Prognostic	HIV/HCV	Peters et al. AIDS DOI: 10.1097/QAD.0000000000000975
2016	Prognostic	HCV	Puigvehí et al. PLoS One DOI: 10.1371/journal.pone.0164883
2017	Prognostic	PSC	de Vries et al. Liver Int. DOI: 10.1111/liv.13402
2017	Diagnostic	MASLD	Miele et al. Int J Biol Markers DOI: 10.5301/ijbm.5000292
2018	Prognostic	Mixed	Loo et al. Clin Chem DOI: 10.1373/clinchem.2018.289108
2018	Diagnostic	ALD	Thiele et al. Gastroenterology DOI: 10.1053/j.gastro.2018.01.005
2019	Diagnostic	MASLD	Anstee et al. Hepatology DOI: 10.1002/hep.30842
2019	Diagnostic/Prognostic	Mixed	Day et al. J Appl Lab Med DOI: 10.1373/jalm.2018.027359
2019	Prognostic	HBV	Liang et al. Aliment Pharmacol Ther. DOI: 10.1111/apt.15269
2019	Prognostic	PSC	Muir et al. Hepatology DOI: 10.1002/hep.30237
2019	Prognostic	MASLD	Sanyal et al. Hepatology DOI: 10.1002/hep.30664
2019	Diagnostic	MASLD	Srivastava et al. J Hepatol. DOI: 10.1016/j.jhep.2019.03033
2019	Prognostic	MASLD	Younossi et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2019.02.024
2020	Prognostic	Mixed	Trembling et al. BMC Gastroenterol. DOI: 10.1186/s12876-020-01251-w
2021	Prognostic	MASLD	Are et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2020.06.070

2021	Diagnostic/Prognostic	ALD	Connoley et al. BMC Gastroenterol. DOI: 10.1186/s12876-021-01795-5
2021	Prognostic	ALD	Rasmussen et al. J Hepatol. DOI: 10.1016/j.jhep.2021.05.037
2021	Screening	ALD	Rhodes et al. BMC Gastroenterol. DOI: 10.1186/s12876-021-01728-2
2021	Monitoring	PSC	Trivedi et al. Clin Gastroenterol Hepatol. DOI: 10.1016/j.cgh.2020.07.032
2021	Prognostic	MASLD	Younossi et al. Gastroenterology. DOI: 10.1053/j.gastro.2020.12.003
2022	Screening	Mixed	Åberg et al. United European Gastroenterol J. DOI: 10.1002/ueg2.12323
2022	Prognostic	MASLD	Johnson et al. Hepatol Commun. DOI: 10.1002/hep4.1852
2022	Monitoring	MASLD	Rinella et al. J Hepatol. DOI: 10.1016/j.jhep.2021.10.029
2022	Prognostic/Monitoring	MASLD	Sanyal et al. Hepatology. DOI: 10.1002/hep.32204
2022	Diagnostic	MASLD	Younossi et al. Aliment Pharmacol Ther. DOI: 10.1111/apt.17346
2023	Normal Range (Diagnostic)	---	Palladino et al. Clin Chim Acta. DOI: 10.1016/j.cca.2023.117461
2023	Prognostic	Mixed	Saarinen et al. JHEP Rep. DOI: 10.1016/j.jhepr.2023.100765
2023	Diagnostic	MASLD	Sanyal et al. Nat Med. DOI: 10.1038/s41591-023-02539-6
2024	Diagnostic/Prognostic	MASLD	Rinella et al. Hepatology DOI: 10.1097/HEP.0000000000000323

FibroScan

Regulatory milestones

Year	Description
2003	CE mark as a class IIa medical device
2013	First 510(k) FDA clearance for FibroScan medical device

References

Year	Context of use	Aetiology	Reference
2003	Diagnostic	HCV	Sandrin et al. Ultrasound in Medicine & Biology

			DOI: 10.1016/j.ultrasmedbio.2003.07.001
2006	Diagnostic	Mixed	Foucher et al. Gut DOI: 10.1136/gut.2005.069153
2007	Diagnostic	Mixed	Talwalkar et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2007.07.020
2008	Diagnostic	Mixed	Friedrich-Rust et al. Gastroenterology DOI: 10.1053/j.gastro.2008.01.034
2009	Monitoring	HCV	Vergniol et al. J Viral Hepat DOI: 10.1111/j.1365-2893.2008.01055.x
2010	Diagnostic	MASLD	Wong et al. Hepatology DOI: 10.1002/hep.23312
2011	Prognostic	HCV	Vergniol et al. Gastroenterology DOI: 10.1053/j.gastro.2011.02.058
2013	Prognostic	HBV	Ledinghen et al. Aliment Pharmacol Ther DOI: 10.1111/apt.12307
2014	Monitoring	HCV	Vergniol et al. Hepatology DOI: 10.1002/hep.27069
2014	Monitoring	HBV	Jang et al. Clin Res Hepatol Gastroenterol DOI: 10.1016/j.clinre.2013.10.003
2016	Prognostic	MASLD	Boursier et al. Journal of Hepatology DOI: 10.1016/j.jhep.2016.04.023
2018	Monitoring	HBV	Wu et al. Liver International DOI: 10.1111/liv.13623
2018	Monitoring	HBV	Liang et al. J Viral Hepat DOI: 10.1111/jvh.12814
2018	Monitoring	HBV	Li et al. Clinical and Experimental Medicine DOI: 10.1007/s10238-018-0486-5
2018	Diagnostic	ALD	Nguyen-Khac et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(18)30124-9
2019	Diagnostic	MASLD	Siddiqui et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2018.04.043
2019	Diagnostic	MASLD	Eddowes et al. Gastroenterology DOI: 10.1053/j.gastro.2019.01.042
2020	Diagnostic	Mixed	Papatheodoridi et al. Journal of Hepatology DOI: 10.1016/j.jhep.2020.11.050
2020	Prognostic	MASLD	Petta et al. Clin Gastroenterol Hepatol DOI: 10.1016/j.cgh.2020.06.045
2020	Monitoring	MASH	Harrison et al. Journal of Hepatology

			DOI: 10.1016/j.jhep.2020.02.027
2020	Monitoring	MASH	Newsome et al. New England Journal of Medicine DOI: 10.1056/NEJMoa2028395
2021	Monitoring	MASH	Rinella et al. Journal of Hepatology DOI: 10.1016/j.jhep.2021.10.029
2021	Prognostic	MASH	Sanyal et al. Hepatology DOI: 10.1002/hep.32204
2021	Diagnostic	MASLD	Mözes et al. Gut DOI: 10.1136/gutjnl-2021-324243
2022	Diagnostic	MASLD	Sanyal et al. Journal of Hepatology DOI: 10.1016/j.jhep.2022.10.034
2022	Prognostic	MASH	Loomba et al. Gut DOI: 10.1136/gutjnl-2022-327777
2022	Monitoring	MASH	Alkhouri et al. Journal of Hepatology DOI: 10.1016/j.jhep.2022.04.003
2023	Monitoring	MASH	Sanyal et al. Journal of Hepatology DOI: 10.1016/j.jhep.2023.07.014
2023	Prognostic	MASLD	Mözes et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(23)00141-3
2023	Diagnostic	MASLD	Vali et al. Lancet Gastroenterol & Hepatol DOI: 10.1016/S2468-1253(23)00017-1