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Chronic Liver Disease Foundation

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2024 YEAR IN REVIEW

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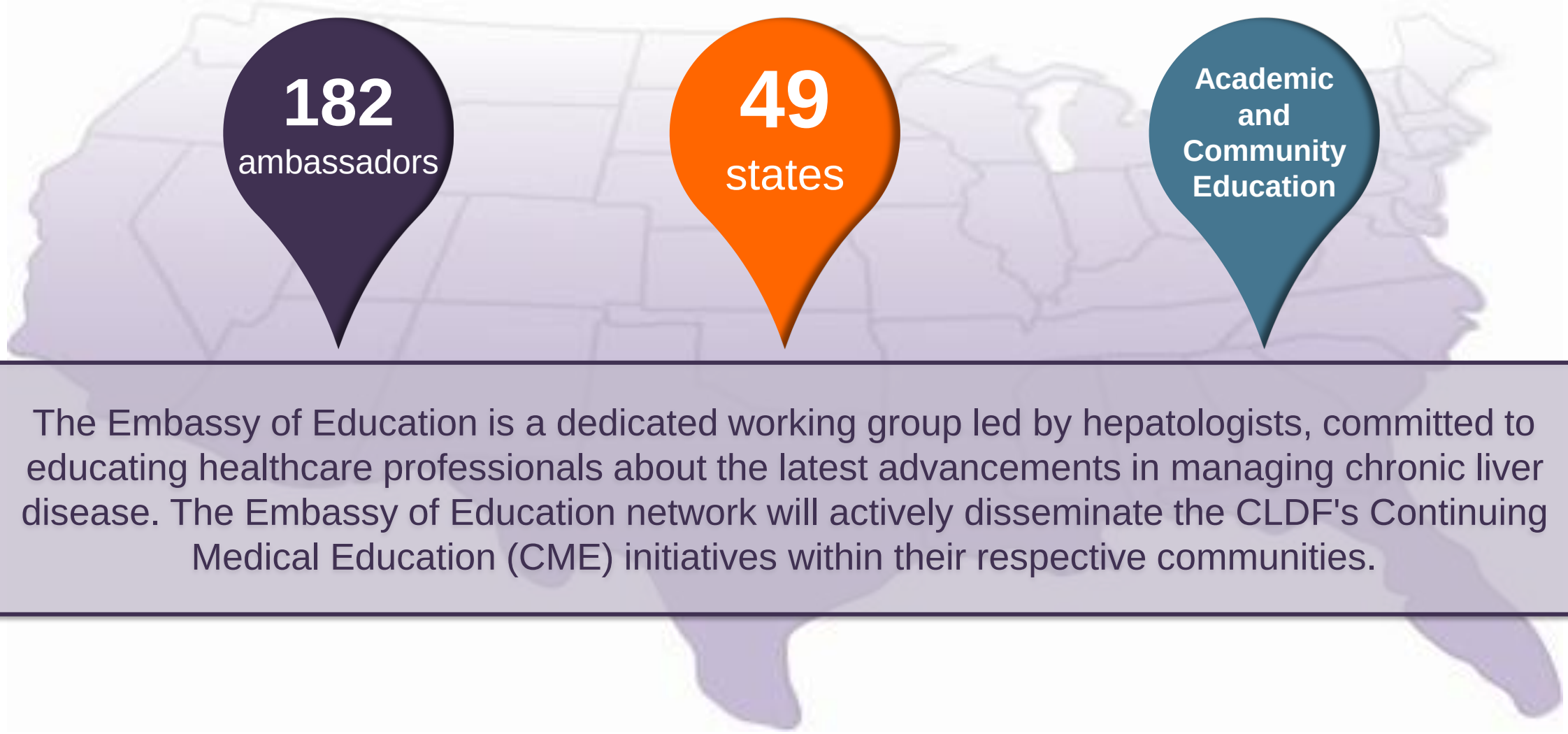

The Embassy of Education is a dedicated working group led by hepatologists, committed to educating healthcare professionals about the latest advancements in managing chronic liver disease. The Embassy of Education network will actively disseminate the CLDF's Continuing Medical Education (CME) initiatives within their respective communities.

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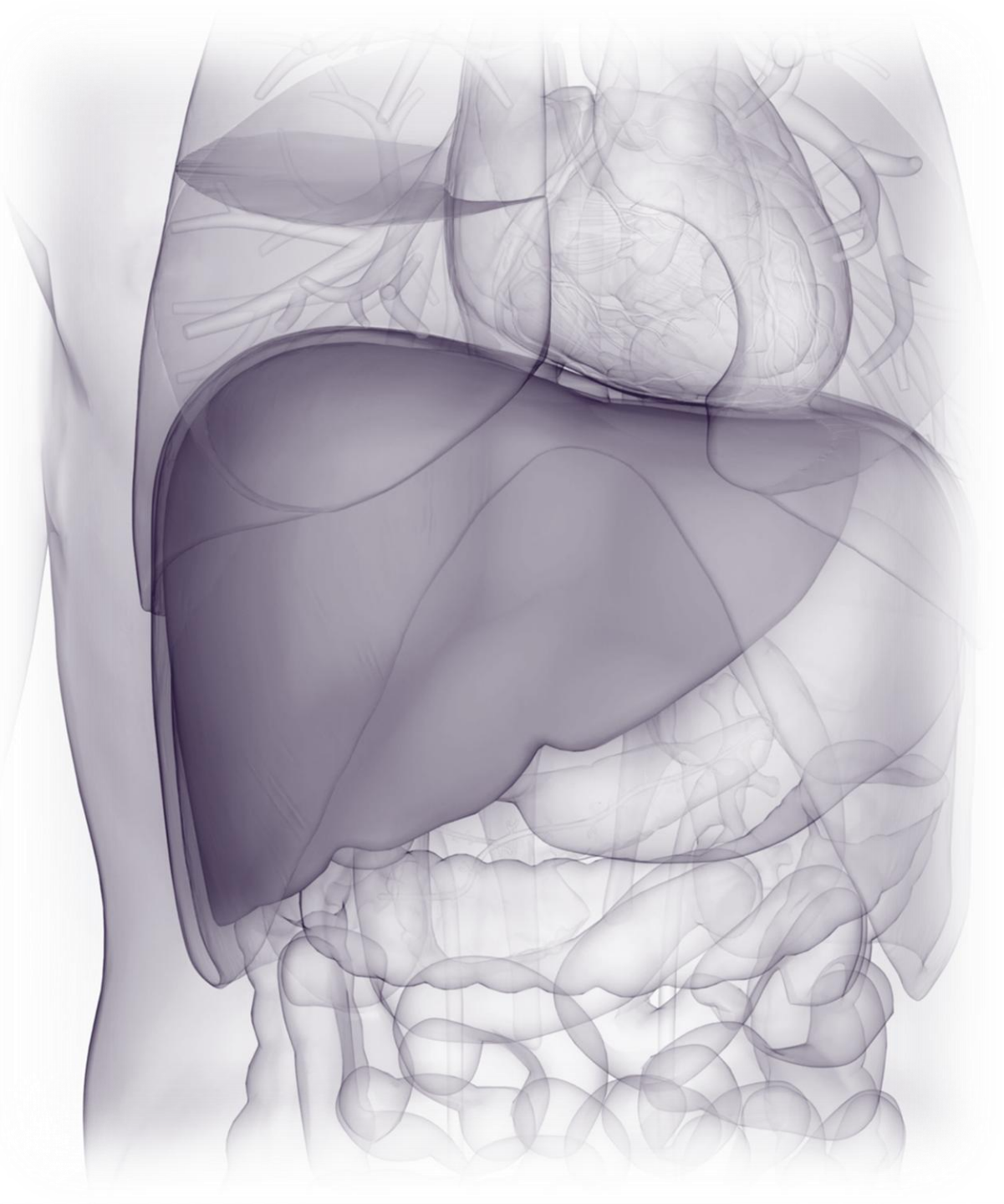

Advances in Non-Invasive Assessment and Management of MASLD

UC Irvine, DOM Research Retreat

Rohit Loomba, MD, MHSc

Professor of Medicine
Director, MASLD Research Center
Chief, Division of Gastroenterology and Hepatology
Department of Medicine
University of California at San Diego
Email: roloomba@ucsd.edu

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MASH-PATH:
A 2024 NASH-TAG Satellite Symposium

A satellite symposium experience that will provide education on the latest emerging data for the management and treatment of patients with MASLD/MASH

Friday, January 5, 2024 at 12:45 PM

The Chateaux Deer Valley
7815 Royal Street East
Park City, Utah, 84060

Speaker:

Rohit Loomba, MD, MHSc
Director, NAFLD Research Center
Director of Hepatology, Professor of Medicine
Vice Chief, Division of Gastroenterology
University of California at San Diego
La Jolla, CA

This activity is jointly provided by Medical Education Resources and the Chronic Liver Disease Foundation.

MEDICAL EDUCATION RESOURCES

Supported by an educational grant from Madrigal Pharmaceuticals.

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Chronic Liver Disease Foundation

4th ANNUAL CONFERENCE

LIVER CONNECT

PARTICIPANTS

500+

Participants in Liver Connect 2024 conference

OBJECTIVES

87%

of attendees who completed an evaluation determined that the learning objectives were met

92%

of attendees who completed an evaluation rated the speakers 'Excellent' or 'Very Good'

SCOPE AND BIAS

100%

of attendees who completed an evaluation form started the education was free of commercial bias and matched their current scope of practice

INTENT TO CHANGE

91%

of attendees who completed an evaluation form agreed that the education presented would cause them to make a change in their practice

LOGISITICS

97%

of attendees who completed an evaluation form agreed that the activity improved their ability to perform as a more efficient healthcare team member

Innovations in the Management of MASH

Breakthroughs in MASH Diagnosis and Management

A Liver Connect City Series

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THE GLOBAL NASH COUNCIL

GHAPP Gastroenterology & Hepatology Advanced Practice Providers

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MAJOR ADVANCEMENT IN MASH MANAGEMENT

Navigating New Horizons: Evolution of MASH Care

Supported by an educational grant from Madrigal Pharmaceuticals.

MAJOR ADVANCEMENT
IN MASH MANAGEMENT

- CCGI
- GALA
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- Miami Gastro Congress
- Mid-Atlantic
- MIGI
- NCSCG
- New Innovations
- RUSH Liver
- SCSG
- United GI and Liver
- Allied Digestive Health
- Giant Leap
- RUSH into GI
- Liver Connect
- IU GI and Hepatology
- One GI
- Pacific Northwest

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Innovations IN THE Management OF MASH

Supported by an educational grant from Madrigal Pharmaceuticals.

Breakthroughs in MASH Diagnosis and Management

A Liver Connect City Series

- Atlanta, GA
- Chicago, IL
- Cleveland, OH
- Coral Gables, FL
- Dallas, TX
- Denver, CO
- Detroit, MI
- Houston, TX
- Kansas City, MO
- Menlo Park, CA
- Morristown, NJ
- New York, NY
- Pasadena, CA
- Scottsdale, AZ

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Navigating New Horizons: Evolution of MASH Care

Virtual and Live Meetings

146
Outreach Meetings

4
Virtual Broadcasts

1,680
Participants

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MASH Alliance: Digital Education Hub

AI Management Tools

Symposium Vignettes

Supported by an educational grant from Madrigal Pharmaceuticals.

EXPERT PERSPECTIVES

POST CONFERENCE HIGHLIGHTS ON MASLD/MASH FROM...

LIVE BROADCASTS

470
Participants

12
Faculty

LIVE OUTREACH

DDW

Rohit Loomba, MD, MHSc

Nadege Gunn, MD, CPI

HoChong Gilles, DNP, FNP-BC

ACG

Nadege Gunn, MD, CPI

Marcelo Kugelmas, MD

Christine Hanson, FNP-C

EASL

Kimberly Brown, MD

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https://www.ghapp.org/expert-perspective-webcasts/post-conference

Supported by an educational grant from Novo Nordisk Inc.

14th Annual International Clinical Exchange

170

Participants

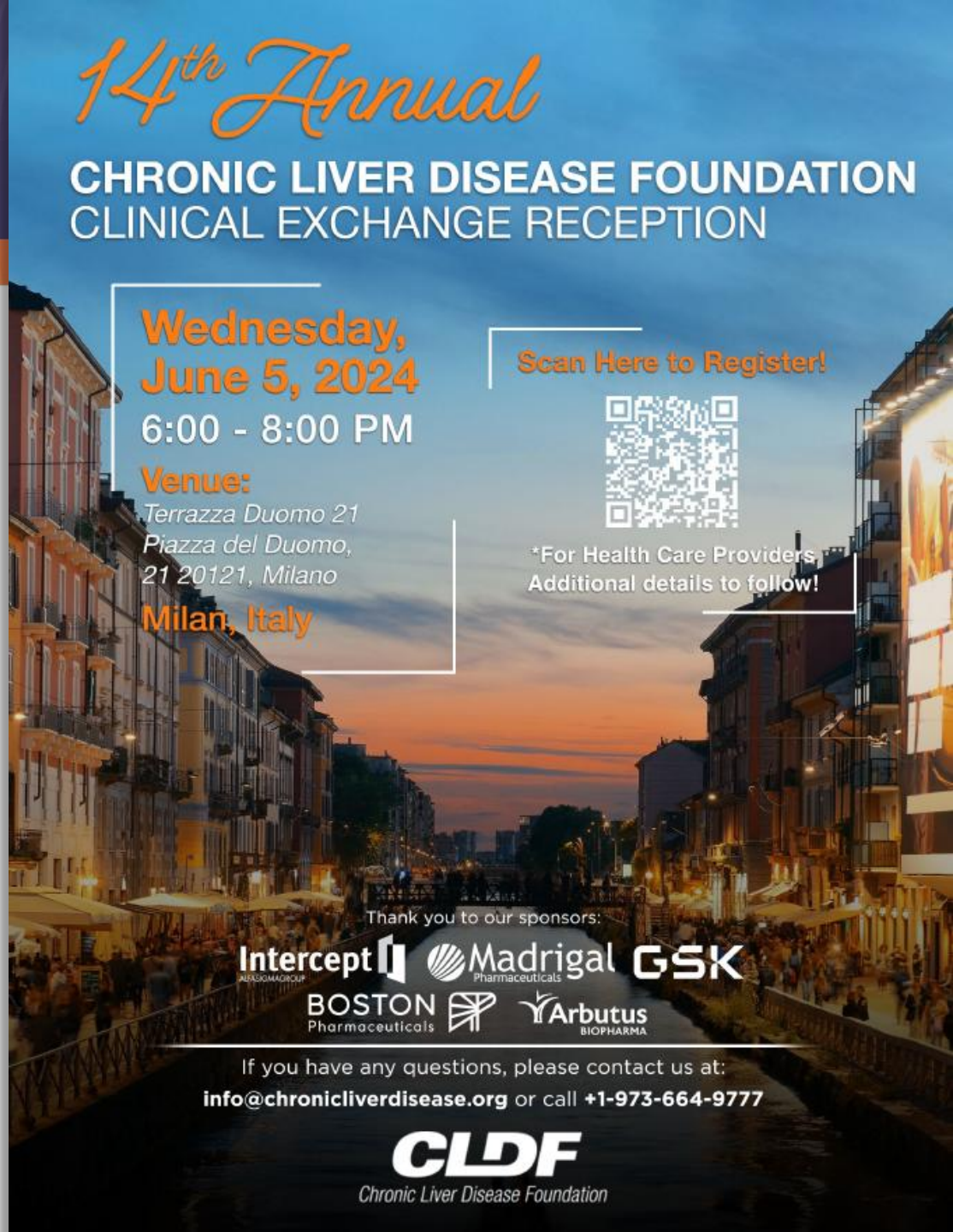
DATE

Wednesday, June 5, 2024

VENUE

Terrazza Duomo 21

P.za del Duomo, 21, 20122 Milano MI, Italy




Join us for the 14th
Annual CLDF
Clinical Exchange Reception
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Thursday, November 14, 2024
6:00 PM – 8:30 PM
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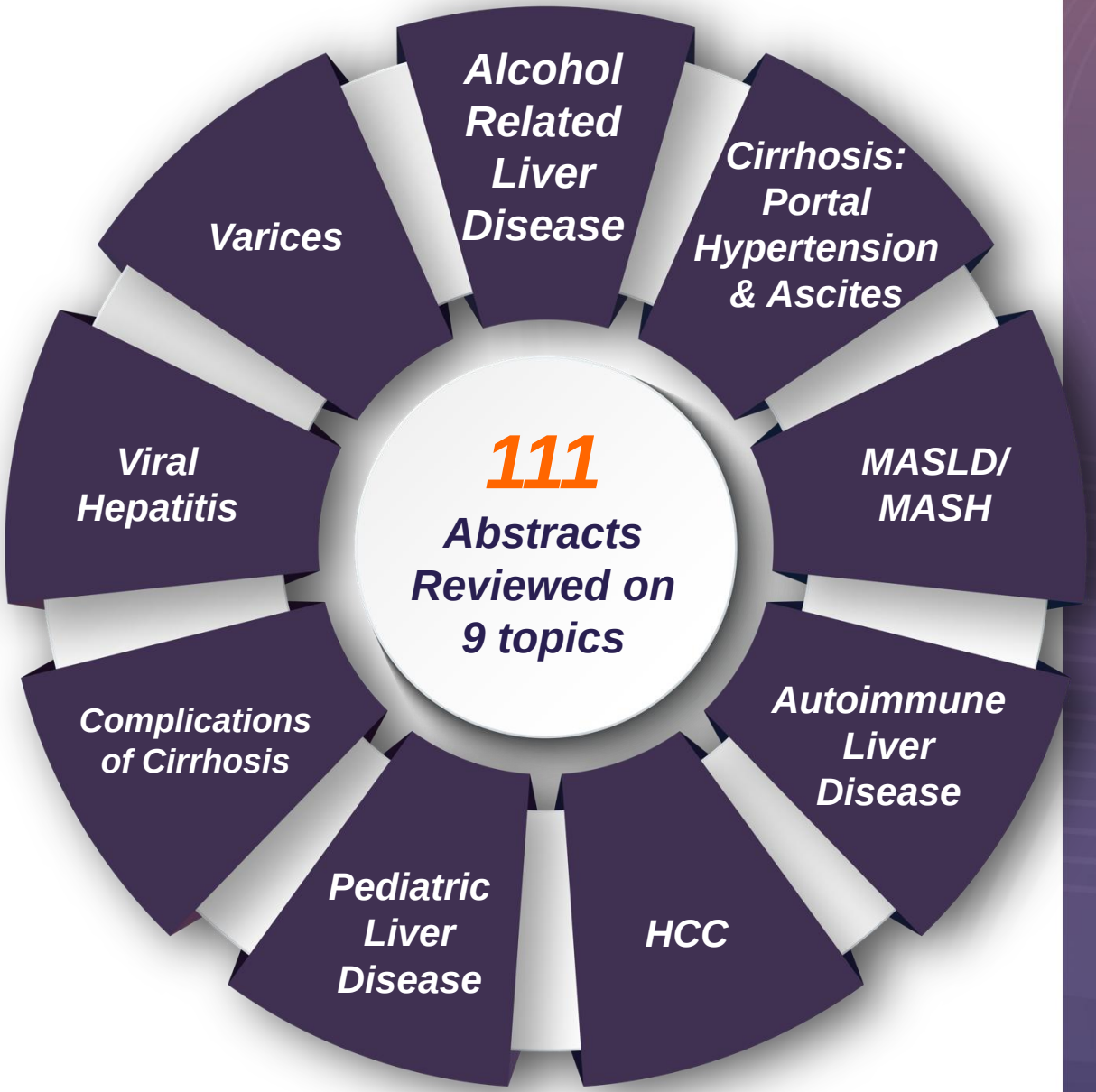
AASLD Abstracts 2024 – Advisors Review



MASLD / MASH

Type	Abstract No.	Title	Grade (A, B, C)
Oral	0112	EFFECT OF RESMETIROM OR PLACEBO IN NASH FIBROSIS PATIENTS WITH < 5% OR > = 5%WEIGHT LOSS AND/OR ON BASELINE GLP-1 THERAPY IN THE MAESTRO-NASH 52 WEEK SERIAL LIVER BIOPSY STUDY	
Oral	0004	2070 | RESMETIROM EFFECTS ON NASH WITH LIVER FIBROSIS IN PATIENTS WITH NASH GENETIC RISK ALLELES	
Oral	0147	520 | METABOLIC DYSFUNCTION ASSOCIATED STEATOTIC LIVER DISEASE (MASLD) IS SIGNIFICANTLY ASSOCIATED WITH BIOLOGICAL AGE AND ITS ACCELERATION AS ASSESSED BY METHYLATION CLOCK	
Oral	0203	USE OF GLUCAGON-LIKE PEPTIDE 1 RECEPTOR AGONISTS (GLP-1 RA) IN PATIENTS WITH MASLD IN A REAL-WORLD SETTING IS ASSOCIATED WITH SLOWER DISEASE PROGRESSION AND LOWER ALL CAUSE MORTALITY	

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59

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Publications

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Supported by educational grants from AstraZeneca and Exelixis, Inc.

Sex and Gender Disparities in Liver Disease

March 2024

Sex and Gender Disparities in Liver Disease

Kimberly Brown, MD[1]; Nancy Reau, MD[2]; Tram Tran, MD[3]; Jessica Mellinger, MD, MSc[4]; Nadege T. Gunn, MD, CPI[5]; Lily Dara, MD[6]; Ani Kardashian, MD[7]; Tatyana Kushner, MD, MSCE[8]; Nicole E. Rich, MD, MSCS[9]; Michelle Lai, MD, MPH[10]; Kali Zhou, MD, MAS[11]

[1]Professor of Medicine, Wayne State University; Gastroenterology and Hepatology, Henry Ford Hospital, Detroit, MI; [2]Rush University Medical Center; [3]UCLA Vatche & Tamar Manoukian Division of Digestive Diseases, Geffen UCLA School of Medicine; [4]Hepatology, Michigan Medicine; [5]Adjunct Assistant Professor, Texas A&M School of Medicine; Medical Director, Principal Investigator, Velocity Clinical Research; [6]Division of GI and Liver Diseases, Department of Medicine, Keck School of Medicine, University of Southern California; [7]Division of Gastrointestinal and Liver Diseases, University of Southern California; [8]Division of Liver Diseases, Department of Obstetrics, Gynecology and Reproductive Sciences, Icahn School of Medicine at Mount Sinai; [9]Department of Digestive and Liver Disease, UT Southwestern Medical Center; Harold C. Simmons Comprehensive Cancer Center, UT Southwestern Medical Center; [10]Beth Israel Deaconess Medical Center; Harvard Medical School; [11]University of Southern California

Introduction

Gender and sex are two terms that are widely used interchangeably but, when pertaining to clinical research and as detailed in Table 1,[1] should be separate and distinct. As shown in the table, sex-based research demonstrates its effect on disease onset, risk factors, prevalence, severity, signs and symptoms, and drug pharmacokinetics and pharmacodynamics. Research on gender has brought to light such important issues as gender inequality, gender stereotypes, and discrimination, which affect patients' lives and well-being.[1]

Table 1. Differences Between Sex and Gender.[1]

Sex	Gender
• Refers to the biological differences between males and females. • Is a biological binary variable that encompasses chromosomal, physiological, and biological differences. • With its associated features, may encompass or affect disease onset, risk factors, prevalence, severity, signs/ symptoms, pharmacokinetics, and pharmacodynamics. These factors may be studied in clinical trials for their effect on efficacy or other clinical outcomes.	• Refers to the social and cultural roles, behaviors, and expectations associated with being male or female. • Relates to important issues that research on gender has brought to light, such as gender inequality, gender stereotypes, and discrimination, which affect patients' lives and well-being.

1

Disparities in Liver Disease

...interest includes the sex and ...ssociated disparities, and ultimate ...eld of liver disease (see Figure 1). ...esent whitepaper is to discuss sex ...in clinical research on liver disease ..., identification, and treatment of ...h sex and gender. This paper was ...fforts of the Women's Committee of ...se Foundation (WHISE) and based ...ng on gender and sex disparities in ...d at the Liver Connect conference

...earch Regarding Sex and Gender ...isease.[2-27]

...isease; AUD, alcohol use disorder; HCC, ...MASLD, metabolic dysfunction-associated

...and Gender in Clinical ...Issues

...pective, a guideline issued by the ...tration (FDA) in 1977, titled "General ...e Clinical Evaluation of Drugs," ...hen of childbearing potential, broadly ...ausal females capable of becoming pregnant," be excluded from participating in phase 1/early phase 2 studies until reproductive toxicology studies were done.[1] This guideline was controversial because it assumed that women of childbearing potential could not have control over avoiding pregnancy in order to be included in studies. It also decided that the protection of the potential fetus outweighed other interests, including the interests of the woman. As the development of experimental therapies accelerated, it was recognized that women needed to be included in earlier studies, especially those related to life-threatening diseases. Thus, in 1993, the FDA reversed the 1977 guideline and, in its place, issued the "Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs."[28] This seminal paper recognized the need for individualized pharmaceutical therapies; called for data to analyze and assess the gender/sex effect, along with age, body size, and hepatic and renal function; and emphasized that rigid sex quotas were not expected in clinical trials, but inclusion in the same trials (not separate trials) was preferred. Furthermore, researchers must also consider the potential for harm to vulnerable populations, such as children, pregnant women, or individuals with mental health disorders, and take appropriate measures to mitigate those risks.[28]

Despite the evolution of the FDA-issued guidelines, sex and gender issues in clinical research continue to be complex, multifaceted, and pose challenges. One main issue is the lack of representation of diverse populations. Historically, research has been conducted mainly on male participants, with the assumption that findings could be generalized to both sexes. This practice has led to the exclusion of women, transgender individuals, and other groups from research studies, limiting our understanding of their experiences and needs and leading to a lack of knowledge on the effectiveness and safety of medications for these populations. For example, through animal studies to early first-in-human and phase 1/2 studies in cell-based therapies, 67%-76% of data are acquired in male cells/species or humans.[29] Recent data have demonstrated that appropriate sex participation in clinical trials is still imbalanced. Chen and colleagues examined the demographics of clinical trial participants and the presence of efficacy and safety analyses by sex for new drugs approved by the FDA between 2013 and 2015.[30] Of the 102 newly approved drugs, sex was reported for >99.9% of trial participants, and women accounted for 40.4% of the patients studied. When taking into account the proportion of women in the clinical trials relative to their estimated proportion in the specific disease population, appropriate sex participation

2

Sex and Gender Disparities in Liver Disease

...% of new drug indications.[30] As a result, ...earch studies may not be applicable to all ...ger global populations or to the general ...g to health disparities and inequalities.

...search can also have ethical implications. ... confidentiality, and privacy are essential ...that must be upheld in research studies, ...er research can pose challenges in these ..., asking sensitive questions about sexual ...ty can be uncomfortable or distressing for ...archers must ensure that participants are ...he risks and benefits of participation and ...and confidentiality are protected.

...e issues requires a commitment to ...and inclusion in research, as well as an ...the ethical considerations involved. Better ...ice and a better understanding of these ...ded positive and significant progress. ...hers must continue to strive to include ...ns in their studies, avoid perpetuating ...oes and biases, and uphold ethical ...tages of the research process. By doing ...archers can enhance the understanding ...teractions between gender and sex and ...being of all individuals, regardless of their ...biological sex.

...nction-Associated Steatotic Liver ...abolic Dysfunction-Associated

...e American Association for the Study of ...nnounced a new nomenclature for fatty ...terms *metabolic dysfunction-associated ...ease* (MASLD) and *metabolic dysfunction-...ohepatitis* (MASH) replace the terms *...liver disease* (NAFLD) and *nonalcoholic ...ASH).*[31] With a rising global prevalence, ...millions of people worldwide and has ...ing cause of liver transplant (LT) across ...In the US, MASLD still lacks an FDA-...ent, and many patients will ultimately ...osis, hepatic decompensation, and/or ...rcinoma (HCC). One area of growing ...differences associated with MASLD and ...ate to prevalence, disease progression,

and treatment approaches. However, there is a paucity of research and publications on gender and sex differences in MASLD.[33] A comprehensive understanding of how these factors affect MASLD would positively influe... ...developments and improve outcomes.

Previous studies that primarily included ...<65 years showed a higher prevalence of ...men than among women.[33-36] As women ...the prevalence of MASLD increases.[37] A ...study suggested that the prevalence of MA... ...influenced by estrogen, with a greater preval... ...in postmenopausal (57.9%) than in p... ...(32.2%) women.[38] Furthermore, the seve... ...fibrosis also increases as women age beyo... ...In an analysis of 244 Italian women (74 p... ...and 170 postmenopausal) and 244 age-m... ...nonsignificant trend was observed betwee... ...status and F2-F4 fibrosis, but no associa... ...between male sex and fibrosis.[39] In another... ...who experienced menopause before the a... ...(N = 143) had a 90% increased risk of more... ...(ACOR = 1.9; [95% CI: 1.3-2.7]; p = 0.0... ...with women with an age of menopause ≥... ...345).[40] These data suggest that estrogen p... ...hepatic steatosis and fibrosis, as has bee... ...other metabolic disorders[2-5]; this illustrates ... ...of including not only women but also wor... ...hormonal stages (i.e., reproductive, menopa... ...and postmenopause[41]) in such studies.

Younossi and colleagues identified a ...between MASLD and increased anxiety an... ...The correlation of impaired mental health ...syndrome has also been well described ...connected to the hypothalamic pituitary ... ...Despite the known associations between t... ...known how sex and, more specifically, horm... ...between the sexes play a role. Xiao a... ...identified female sex as an important risk fa... ...underlying depression in MASLD.[43] In ac... ...severity of depression increases, so does ...steatosis and fibrosis. This correlation is m... ...females than males.[6,7] A more sophisticated ...of the potential bidirectional effect of men... ...MASLD in females will allow for a more tailo... ...approach with current and future therapies.

Emerging data regarding MASLD in pregna... ...prevalence of 14% among pregnant indivi...

3

Sex and Gender Disparities in Liver Disease

during early pregnancy; this rate has nearly tripled in the last decade.[44,45] MASLD during pregnancy appears to increase risks for both mother and baby, including the risks of hypertensive complications, bleeding after delivery, and preterm birth.[45] Further research on the identification and management of women with MASLD during pregnancy is warranted.

Autoimmune Hepatitis and Primary Biliary Cholangitis in Women of Color

Autoimmune liver diseases, such as autoimmune hepatitis (AIH) and primary biliary cholangitis (PBC), disproportionately affect women. Although both AIH and PBC are considered rare diseases, they are both rising in prevalence,[46,47] partly because of factors associated with increases in all autoimmune conditions that are not fully understood and partly because of increased diagnosis and life-prolonging treatments. Both AIH and PBC were initially described and studied in Caucasian women, and despite the growth of a multiracial and multiethnic US population, most studies and therapeutic trials continue to underrepresent racial and ethnic minorities.[8] Minorities with AIH and PBC often present with cirrhosis and advanced fibrosis, and they are less responsive to treatment; moreover, they have higher rates of hospitalization and worse outcomes compared with Caucasian women.[10,48-50]

The incidence of PBC in women of color is increasingly being recognized. Latinx patients have higher odds of hospitalization for PBC, a decreased response to ursodeoxycholic acid (UDCA), and a higher incidence of PBC-AIH variant syndrome.[8,10] Older studies have suggested that PBC is rare in Asian women; however, recent studies suggest the prevalence of PBC in the Asia-Pacific region is 11.9/100,000 persons, with the highest prevalence among Japanese and Chinese women.[8] Furthermore, PBC is underdiagnosed in Black women. In the largest cohort study of PBC in the US, which used data from the Fibrotic Liver Disease (FOLD) consortium, the prevalence of PBC in Black patients was greater than previously reported, at 19.7/100,000 persons.[12] Black patients with PBC presented at a younger age and had a lower likelihood of receiving UDCA.[12] A follow-up study on the same cohort showed that although the untreated Black PBC patients had increased all-cause mortality (HR 1.34; 95% CI 1.08-1.67), this risk was reversible with UDCA.[11] Similar findings were reported for Asian Americans and Pacific Islanders; when untreated, they had higher rates of LT and death.[51] UDCA improves LT-free survival; therefore, it is evident that a correct and early diagnosis leading to prompt treatment is essential to improve outcomes.

The data on racial and ethnic minorities with AIH also point toward disparities in this disease. The odds of hospitalization for AIH are much higher for patients of color compared with White patients. Black patients with AIH present at a younger age, with more severe disease. They are more difficult to treat; furthermore, they have increased rates of cirrhosis on liver biopsy and higher mortality.[13,14] Latinx patients with AIH have more severe disease and more cirrhosis at presentation.[8] Notably, given the high female predominance of disease, it is not surprising that 75%-80% of patients of color in these retrospective AIH cohorts are women.

Overall, AIH and PBC are underrecognized and undertreated in women of color, and this affects outcomes. Although HLA associations have been noted for these diseases, which may be influenced by race and ethnicity, the more prominent issue seems to be the role of the environment and social determinants of health in women of color.[8] Such factors as access to healthcare, health literacy, a physical environment free of pollutants, toxins, exposure to xenobiotics, and economic factors can all affect these autoimmune disorders and should be systematically studied.

The "Pinking" of Drinking: The Rise in Women's Alcohol Consumption and Alcohol-Related Liver Disease

From 2002 to 2012, rates of AUD rose more rapidly for women compared with men (80% increase vs. 30% increase).[10] In a meta-analysis of 6 large population-based national surveys, rates of any past-year drinking and past-year binge drinking (consumption of 5 or more drinks for men or 4 or more drinks for women in 2 hours) increased more rapidly among women compared with men.[16] The increases in overall population-level drinking observed in many of these datasets appeared to be driven almost entirely by drinking increases among women. This finding has been mirrored in studies of age cohorts, which demonstrated that from age 26 onward, drinking increased much more rapidly among women than among men.[51]

The effects of the COVID-19 pandemic worsened many of the trends described above, with the US experiencing a 25% increase in overall alcohol consumption in the earliest days of the pandemic; since this time, there has been some decline, but no return to pre-pandemic baseline drinking.[52-54] One study used online surveys to assess pandemic effects on alcohol consumption and found that men drank more

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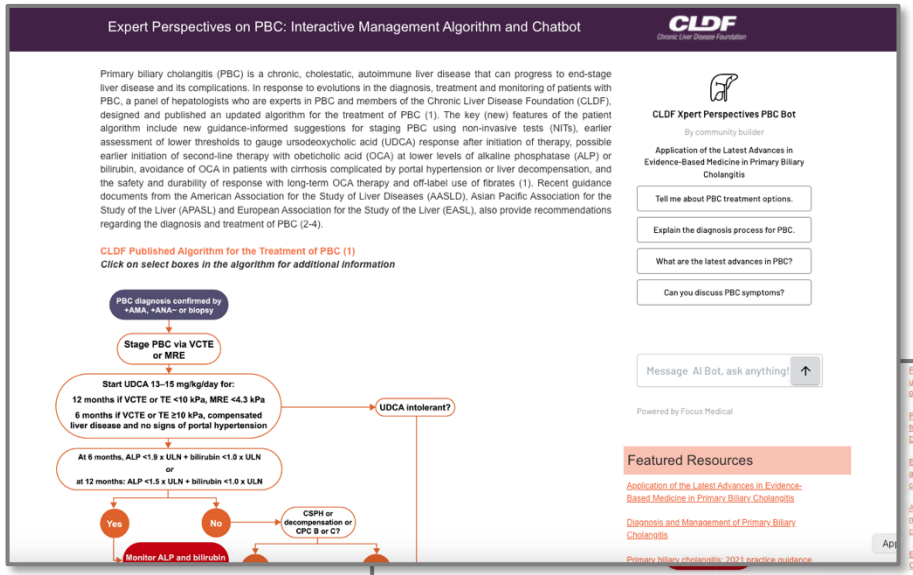
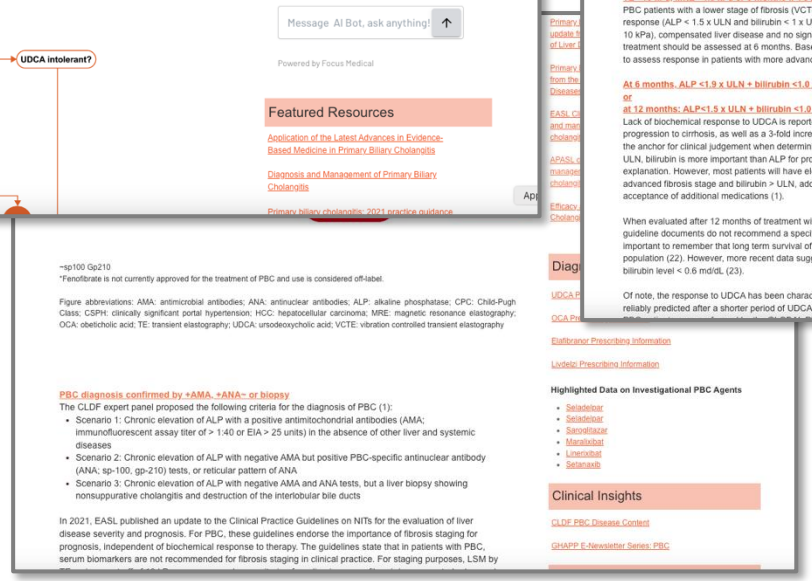
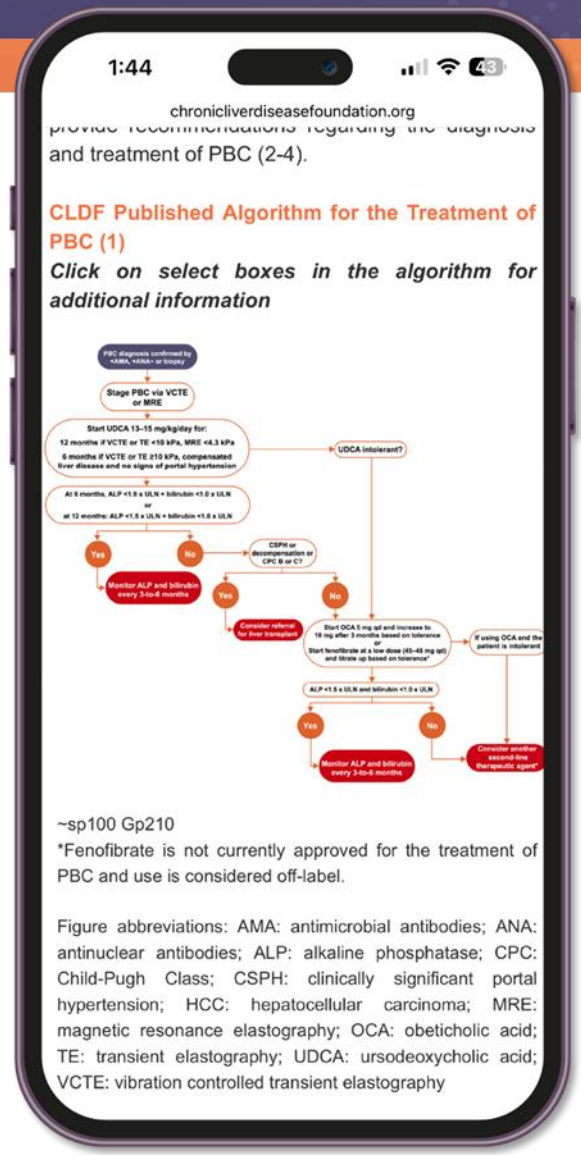
This whitepaper was supported by an unrestricted educational grant to the Chronic Liver Disease Foundation from Exelixis, Inc., Mallinckrodt Pharmaceuticals, and Salix Pharmaceuticals. The selection of the authors and the creation of this whitepaper were done independently, and Exelixis, Inc., Mallinckrodt Pharmaceuticals, Salix Pharmaceuticals did not play a role.

PBC Expert Perspectives Algorithm and ChatBot

March 2024







Supported with an unrestricted educational grant from Ipsen.

Hepatocellular Carcinoma (HCC) Surveillance Beyond the Guidelines:

Surveillance in Non-Cirrhotic Viral Hepatitis and Metabolic Dysfunction-Associated Steatohepatitis, and the Role of HCC Biomarkers

July 2024

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CLDF Education Portal
Online Tools – Featured Resources

Social Media Engagement

110
Posts Published

60
New Followers

Total Reach
3948

Total Impressions
6406

922
Followers

167
Tweets Published

99
Posts Published

16.5% Healthcare Services
14.7% Research

830
New Followers

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Engagement Rate
8.2%

Total Impressions
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947

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