
CLINICAL TRIAL PARTICIPATION

Among People Living With Hepatitis B

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Patient Engagement Program



Patient-Focused
Drug
Development
Meeting
PFDD



Global online
survey



One-on-one
Interviews with
PLHB

Patient Engagement Survey



1,700

Survey
Participants

- ▷ Document the physical, emotional, and social impact of living with chronic hepatitis B (CHB)
- ▷ Treatment experiences, challenges and perceived value of current treatments
- ▷ Perspectives on future treatments and clinical trial participation



15%

Were tested
they were having
symptoms



81%

Less than 45 yo
- 18-30 years old: 32%
- 31-45 years old: 49%



67%

Male



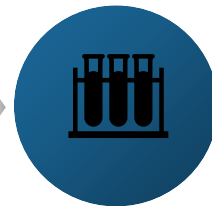
83%

Lived outside
the U.S.



50%

Black
- 29% AAPI
- 13% White



53%

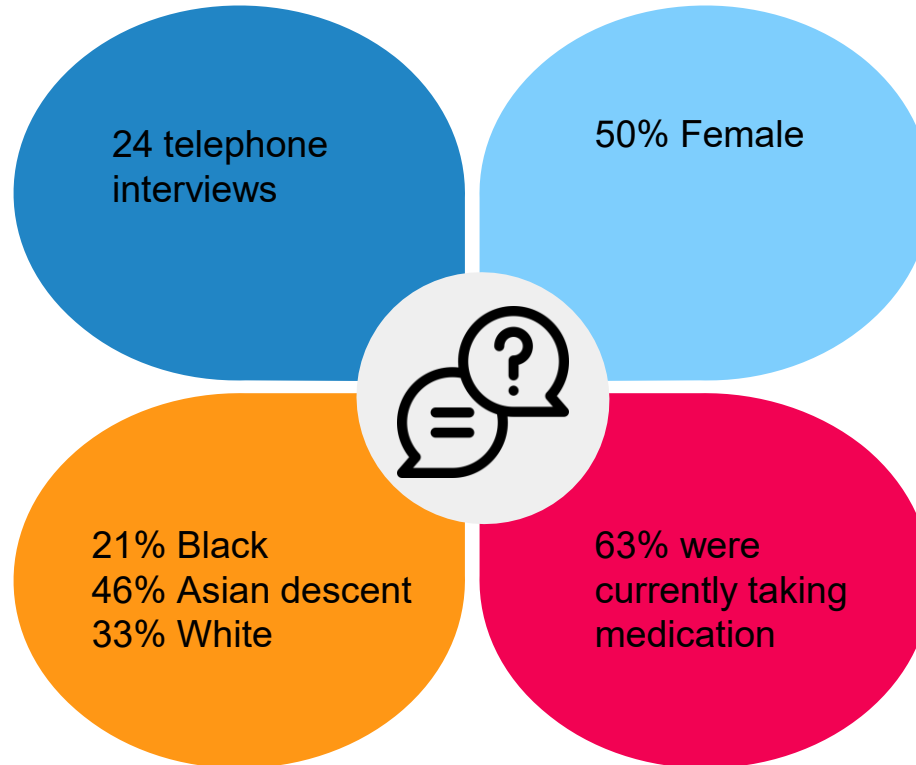
Diagnosed
in the past
5 years



56%

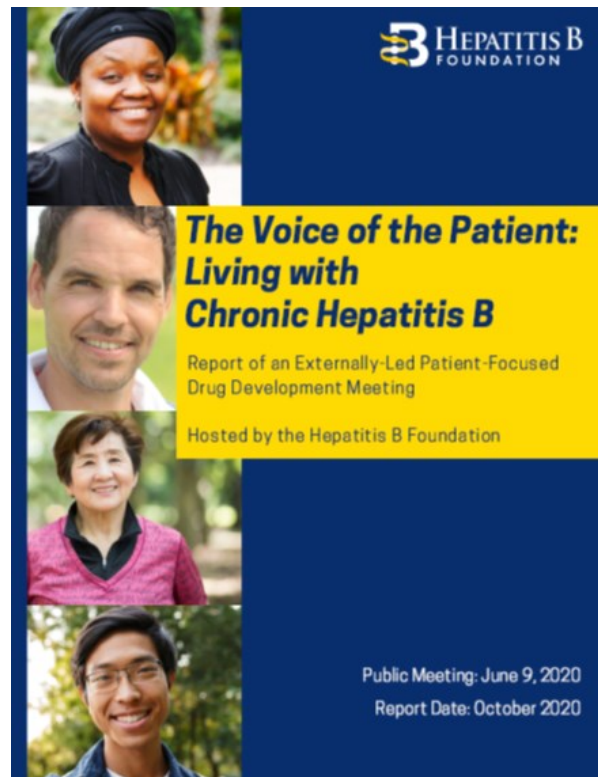
Experience with
CHB medication

Telephone Interviews

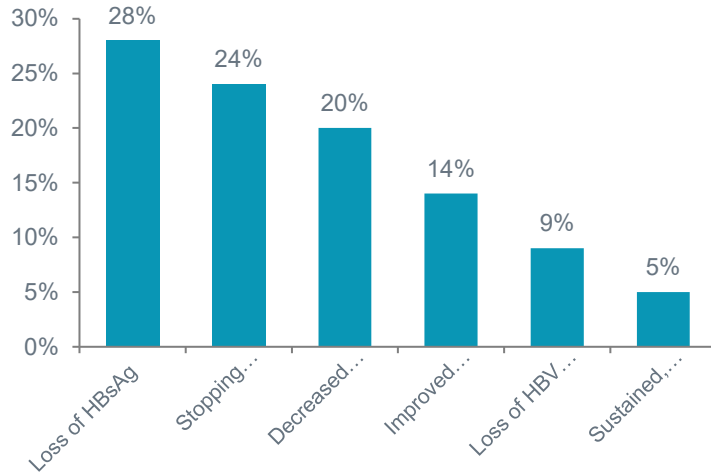


Patient-Focused Drug Development Meeting (PFDD)

- Externally-Led Patient Focused Drug Development Meeting June 2020
 - 650 participants, 12 panelists, 300 email comments



Important Outcomes of Future Treatments



U.S.

1. Decreased risk of HCC
2. Loss of HBsAg
3. Being able to stop meds after 6-12 months
4. Improving quality of life
5. Loss of cccDNA
6. Long-term DNA suppression

International

1. Loss of HBsAg
2. Being able to stop meds after 6-12 months
3. Decreased risk of HCC
4. Improving quality of life
5. Loss of cccDNA
6. Long-term DNA suppression

Preferred Outcomes for Future Hepatitis B Treatments

Willingness to Participate in Hepatitis B Clinical Trials

Journal of Translational Science



Research Article

ISSN: 2059-268X

Attitudes towards clinical trial participation among people living with chronic hepatitis B

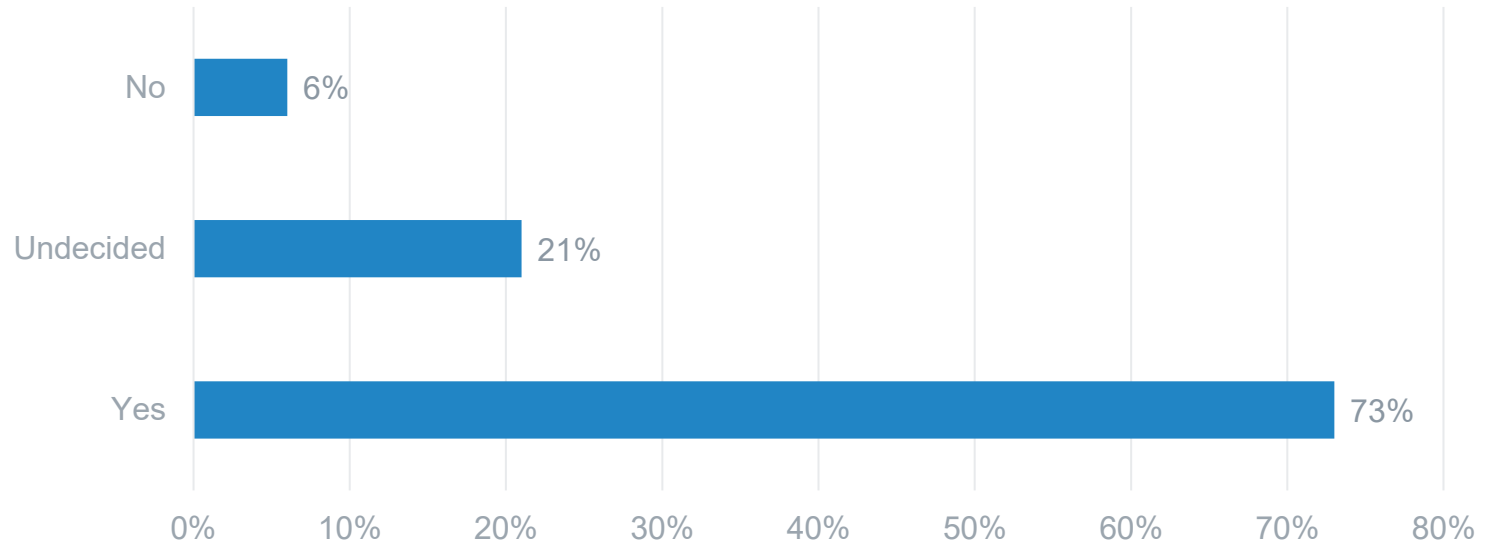
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¹Hepatitis B Foundation (HBF)

²FDA Office of Minority Health and Health Equity (OMHHE)

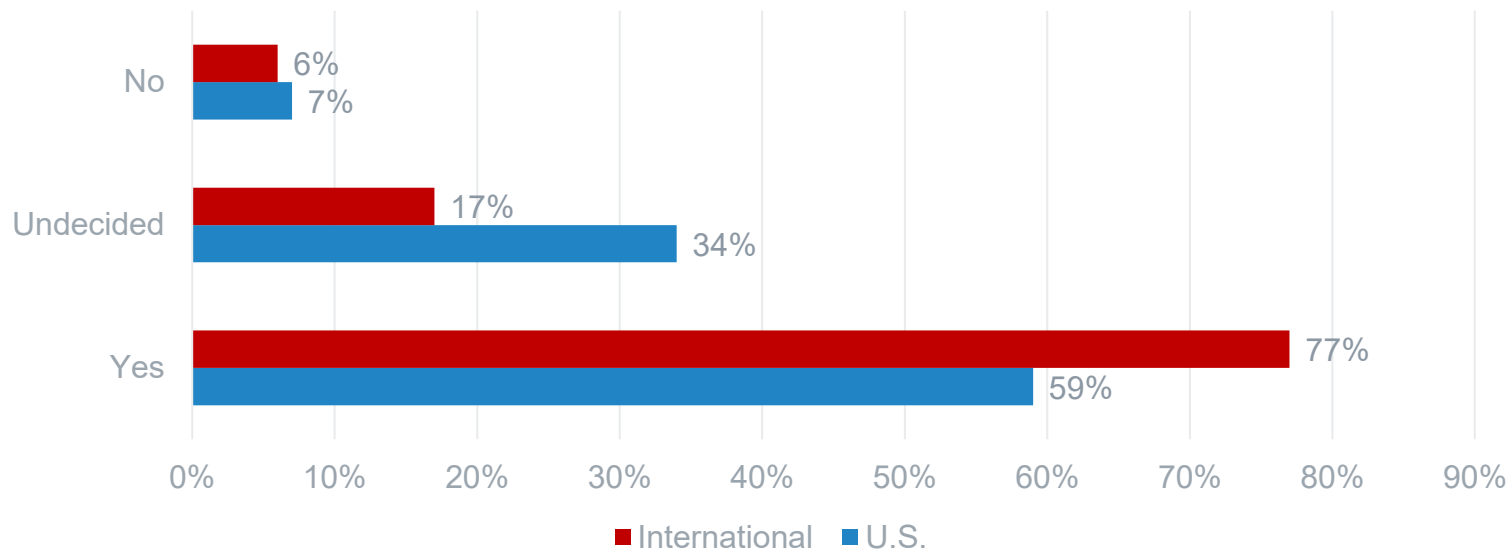
³Oregon Health and Science University

Would you be interested in participating in a future clinical trial for a new hepatitis B treatment?



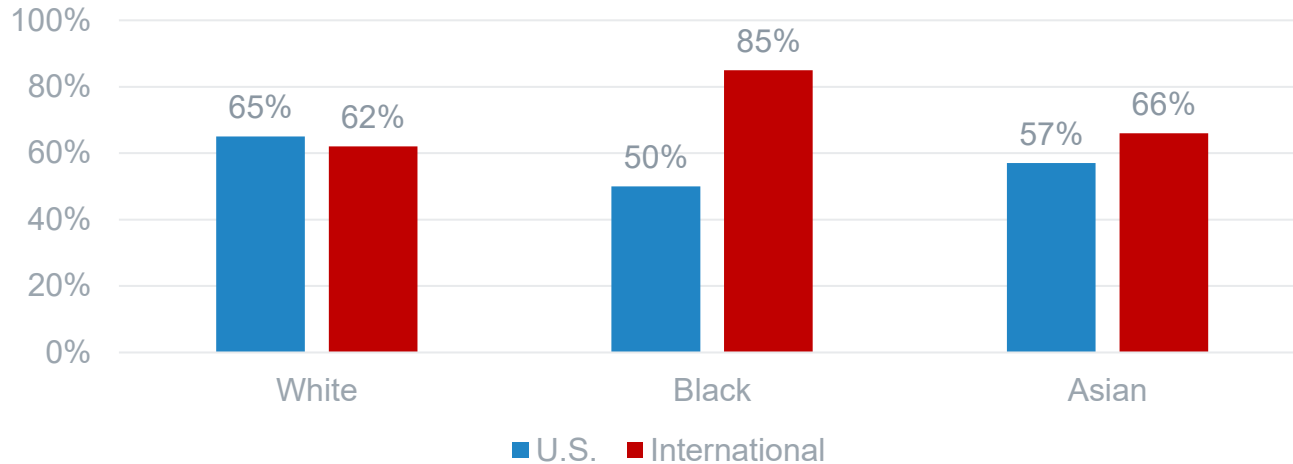
Willingness to participate in clinical trials for new hepatitis B medication (all respondents). Three possible responses (n): yes (563), undecided (162), no (46)

Participants living outside U.S. were more willing to participate in a new hepatitis B clinical trial.



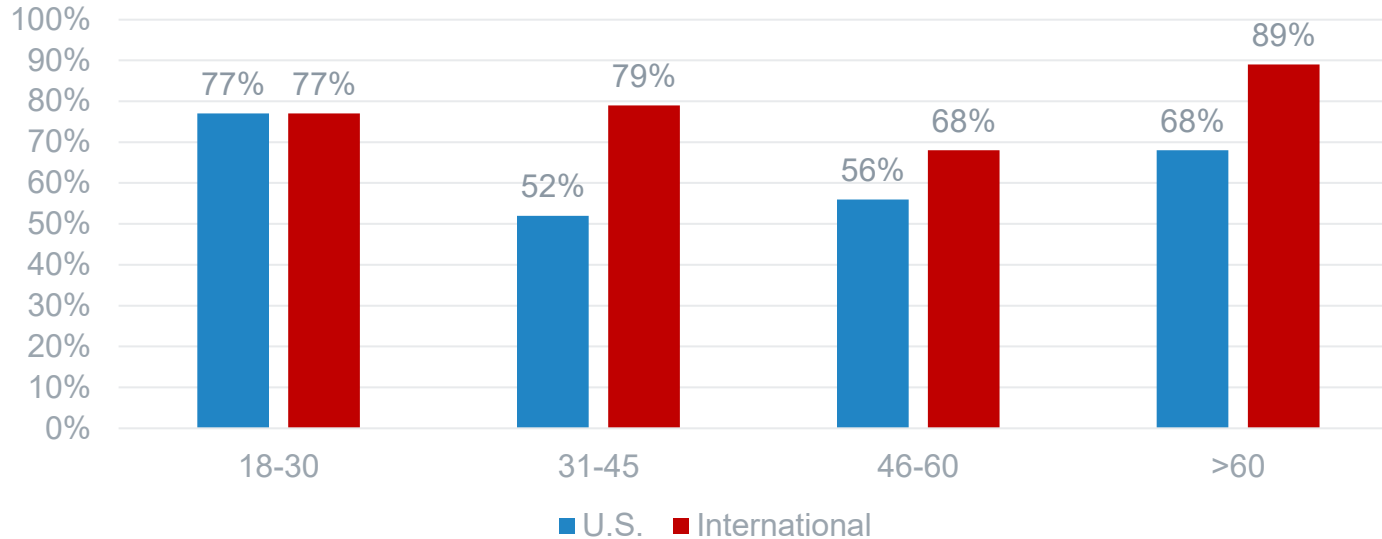
Willingness to participate in clinical trials for new hepatitis B treatment by location (U.S. vs. international)

Black participants living outside U.S. showed the highest rate of willingness to participate in a new hepatitis B clinical trial.



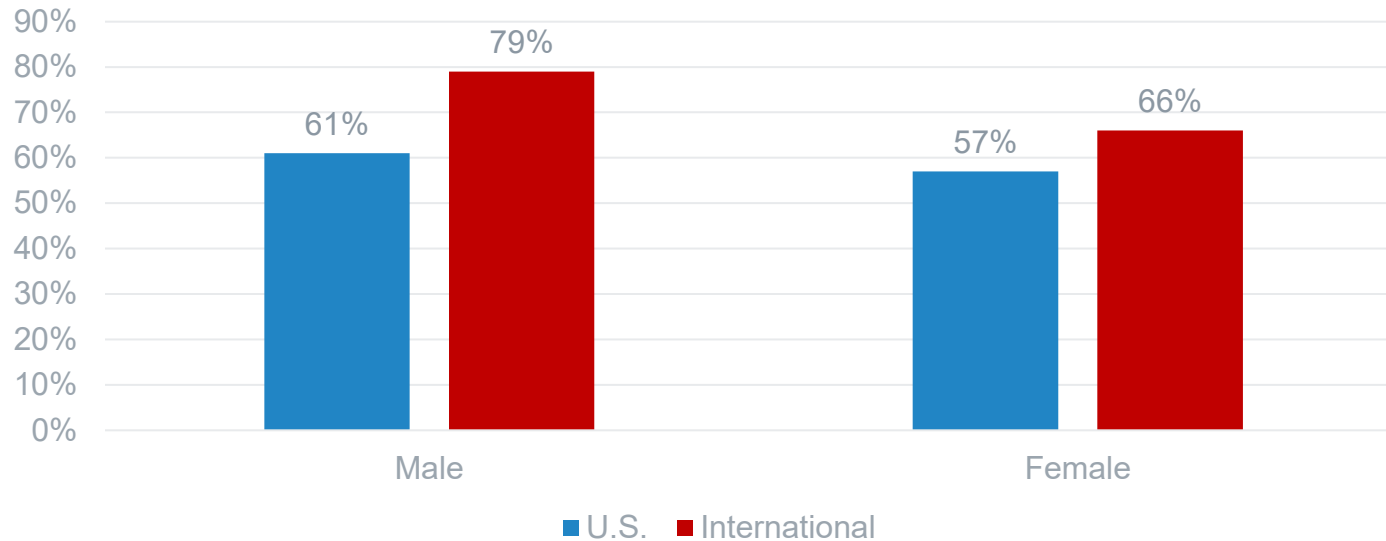
Those willing to participate in clinical trials by race and location (U.S. vs. international)

Age is an important factor in willingness to participate in hepatitis B clinical trials.



Those willing to participate in clinical trials by age group and location (U.S. vs. international)

Male participants were more willing to participate in a new hepatitis B clinical trial.



Those willing to participate in clinical trials by gender and location (U.S. vs. international)

What Did We Learn?

- ▶ Willingness to participate in CHB clinical trials vary by race, gender, age, and geographical location
- ▶ In U.S., there is need for culturally competent efforts to recruit minority populations to participate in clinical trials.
- ▶ Globally, there is need to work closely with local authorities
 - The legal environment
 - Research infrastructure

What We Still Need to Learn is..

- ▶ How do the different barriers to clinical trial participation interplay in the hepatitis B space:
 - Incorporating the new treatment in current hep B management
 - Disease-related stigma
 - Immigration and Socio-cultural status of people living with hepatitis B
- ▶ It is important to understand
 - how to reach those who are willing but not participating?
 - why there are 34% of respondents from U.S. were undecided?

Thank You!

