

HBV Clinical Trials and Why They Are Important

Presenters:

Robert G. Gish, MD, FAASLD

Moon S. Chen, Jr, PhD, MPH



Hepatitis B Foundation
Baruch S. Blumberg Institute



hepbunited.org

What Is a Clinical Trial?

- Studies in which people volunteer to test new drugs or devices
- Learn whether new treatment works and is safe for people
- Therapies in clinical trials NOT the same as available drugs (routine care)
 - Available therapies have been tested & approved

Why Are Clinical Trials Important?

- New treatments must pass many tests before they get to patients
- Can advance science and help others in the future
- Other considerations:
 - Patients may access therapies in development
 - Tests, treatment usually free for study volunteers
 - Patients may be observed more closely during trial

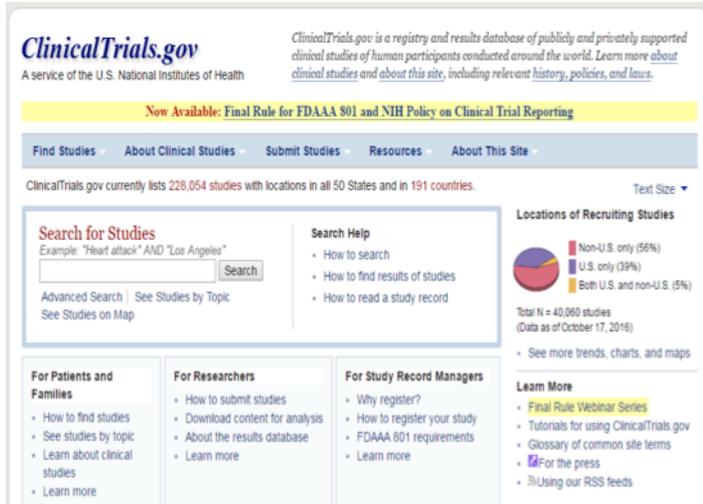


What Does the Healthcare Provider Do in Clinical Trials?

- Physician (principal investigator, PI)
 - Organizes & directs the study
 - Reviews the data
- Clinical research coordinator
 - Handles day-to-day activities
 - Main contact for patients



How to Find HBV Clinical Trials



ClinicalTrials.gov
A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Find Studies - About Clinical Studies - Submit Studies - Resources - About This Site

ClinicalTrials.gov currently lists 228,054 studies with locations in all 50 States and in 191 countries. Text Size ▾

Search for Studies
Example: "Heart attack" AND "Los Angeles"

Advanced Search | See Studies by Topic
See Studies on Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies



Total N = 40,060 studies
(Data as of October 17, 2016)

- See more trends, charts, and maps

Learn More

- Final Rule Webinar Series
- Tutorials for using ClinicalTrials.gov
- Glossary of common site terms
- For the press
- Using our RSS feeds

For Patients and Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more

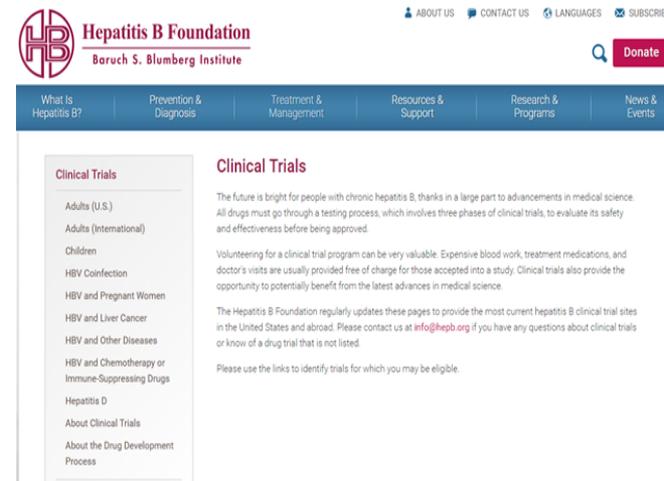
For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more

For Study Record Managers

- Why register?
- How to register your study
- FDAAA 801 requirements
- Learn more

ClinicalTrials.gov- lists all clinical trials



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Clinical Trials

The future is bright for people with chronic hepatitis B, thanks in a large part to advancements in medical science. All drugs must go through a testing process, which involves three phases of clinical trials, to evaluate its safety and effectiveness before being approved.

Volunteering for a clinical trial program can be very valuable. Expensive blood work, treatment medications, and doctor's visits are usually provided free of charge for those accepted into a study. Clinical trials also provide the opportunity to potentially benefit from the latest advances in medical science.

The Hepatitis B Foundation regularly updates these pages to provide the most current hepatitis B clinical trial sites in the United States and abroad. Please contact us at info@hepb.org if you have any questions about clinical trials or know of a drug trial that is not listed.

Please use the links to identify trials for which you may be eligible.

Clinical Trials

- Adults (U.S.)
- Adults (International)
- Children
- HBV Confection
- HBV and Pregnant Women
- HBV and Liver Cancer
- HBV and Other Diseases
- HBV and Chemotherapy or Immune-Suppressing Drugs
- Hepatitis D
- About Clinical Trials
- About the Drug Development Process

Hepatitis B Foundation (www.hepb.org)

- info@hepb.org

- Call **215-489-4900**

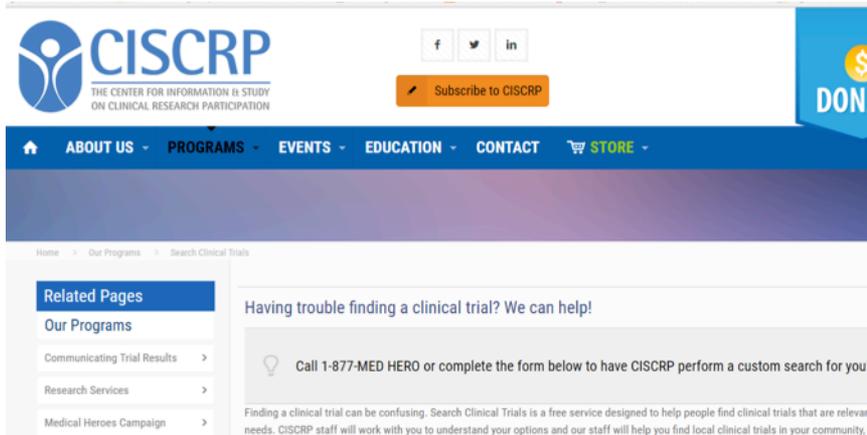
- HBV specific listing

- Provides contact information for trial site (contact research team)

- Local academic and nonacademic institutions
- Pharma companies' website listings



How to Find HBV Clinical Trials



Center for Information & Study on
Clinical Research Participation

- **1-877-MED HERO** (www.ciscrp.org)
- Free service to help find appropriate clinical trials locally or further away
 - Send you contact information for research studies
 - e-mail: ~1 week ; regular mail: 2 weeks
- Free educational brochure (key questions to ask research staff)
- Can also search their CenterWatch clinical trials database yourself



How Can Healthcare Providers Get Involved in a Trial?

- Create database of patients in their practice
 - viral disease, liver disease, demographics
- Publish article on their patient profile
- Approach pharma companies
- Establish a research infrastructure
- Publish

If Healthcare Provider Is Not Involved in a Clinical Trial

If a provider is not involved in a trial but his/her patient wants to participate:

- Referral to research center
- Submit intake form if available
- Transfer records after completing HIPAA forms
- Can still remain involved in patient's care



Barriers to Participating in Clinical Trials

The Healthcare Provider Perspective



Clinical Trials Can Affect Practice

Some trials can run months, years

- Establish protected time for clinical trials
- Allocate staff just for clinical trials
- Budget own time and staff time to balance the business aspect of disease



Other Barriers to Clinical Trials

- Lack of awareness about new drugs, trials
- Lack of urgency for patients to enter trial
 - 7 effective treatments available
- Substantial costs associated with clinical trials

Healthcare Provider Concerns

- Patients may not want to participate
- Patients may not adhere to protocol
 - Language, cultural barriers
 - Take time off work, need to travel to trial site
- May lose patients to clinical trial site

Key Messages for Healthcare Providers About HBV Clinical Trials

To build a database of HBV patients, providers must take the following steps:

1. Test for HBV in all at-risk patients
2. Test for anti-HBc; if positive do not vaccinate; educate about risk of reactivation
3. Prevent HBV with vaccination if all three HBV tests are negative



Key Messages for Patients About Clinical Trials

1. Currently no cure for HBV infection
2. Existing treatments: lifelong, have side effects
3. New drugs with potentially shorter therapy and greater effectiveness could **prevent** hepatitis B-related:
 - a. deaths
 - b. liver transplants
 - c. liver cancer

Talking About Clinical Trials: Strategies to Promote and Motivate

- Talking to individuals with HBV
 - Face-to-face meetings about HBV better than telephone discussions
 - Use enduring materials, pictures, graphics, videos
- Talking to healthcare providers
 - WHO plan to eliminate HBV worldwide by 2030
 - Mention the 30+ new therapies in development for HBV, with the next step being a functional cure



Your Roles in Increasing Asian Americans' Participation in HBV Clinical Trials

Moon S. Chen Jr., PhD, MPH

Co-Founder, National TF on HBV:

Focus on APIs

**Professor & Associate Director for
Cancer Control**

**UC Davis Comprehensive Cancer
Center**

Objectives



From **Review** to *Realization*

From **Realization** to
Responsibilities

From **Responsibilities** to *Roles*

Objectives

From **Review** to *Realization*



Asian American Cancer Mortality Trends Reported By Race/ Ethnicity

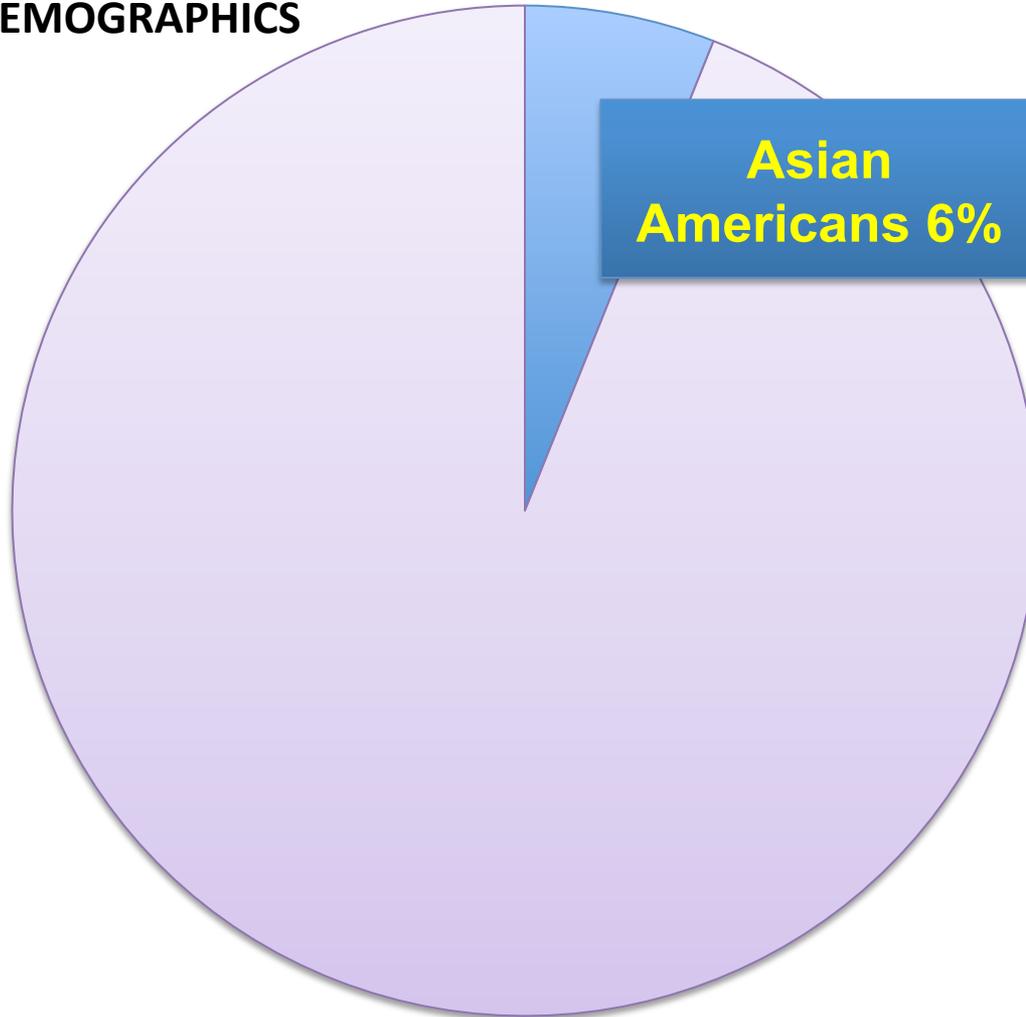
Male		Chinese	Filipino	Japanese	Korean	Vietnamese
(rank)	NHW					
1	Lung 31.0%	Lung 28.13%	Lung 30.7%	Lung 23.9%	Lung 22.8%	Lung 28.1%
2	Prostate 9.2%	Liver 11.7%	Colorectal 10.8%	Colorectal 13.1%	Stomach 14.6%	Liver 22.3%
3	Colorectal 9.1%	Colorectal 10.4%	Prostate 8.9%	Prostate 8.9%	Liver 12.9%	Colorectal 7.9%
4	Pancreas 5.8%	Stomach 6.5%	Liver 7.6%	Stomach 8.8%	Colorectal 11.0%	Stomach 6.5%
5	Leukemia 4.4%	Pancreas 5.9%	Pancreas 5.7%	Pancreas 8.4%	Pancreas 7.4%	Pancreas 4.4%
Female		Chinese	Filipino	Japanese	Korean	Vietnamese
(rank)	NHW					
1	Lung 27.3%	Lung 22.2%	Breast 19.5%	Lung 21.4%	Lung 18.5%	Lung 21.7%
2	Breast 14.6%	Breast 11.8%	Lung 18.1%	Colorectal 12.9%	Stomach 11.6%	Breast 10.3%
3	Colorectal 9.6%	Colorectal 11.9%	Colorectal 9.0%	Breast 10.7%	Colorectal 11.4%	Colorectal 9.6%
4	Pancreas 6.2%	Pancreas 7.2%	Pancreas 6.7%	Pancreas 9.6%	Pancreas 8.2%	Liver 9.3%
5	Ovary 5.6%	Stomach 5.4%	Ovary 6.0%	Stomach 6.5%	Liver 7.2%	Stomach 6.3%

Table 1. Top 5 sites of cancer-related mortality, ranked as a proportion of all cancer deaths, by race/ethnicity (2003–2011)

Thompson, C. A., Gomez, S. L., Hastings, K. G., Kapphahn, K., Yu, P., Shariff-Marco, S., ... Palaniappan, L. P. (2016). The Burden of Cancer in Asian Americans: A Report of National Mortality Trends by Asian Ethnicity. *Cancer Epidemiology, Biomarkers & Prevention: A Publication of the American Association for Cancer Research*, Cosponsored by the American Society of Preventive Oncology, 25(10), 1371–1382. <https://doi.org/10.1158/1055-9955.EPI-16-0167>

Asian Americans with Chronic HBV

US DEMOGRAPHICS



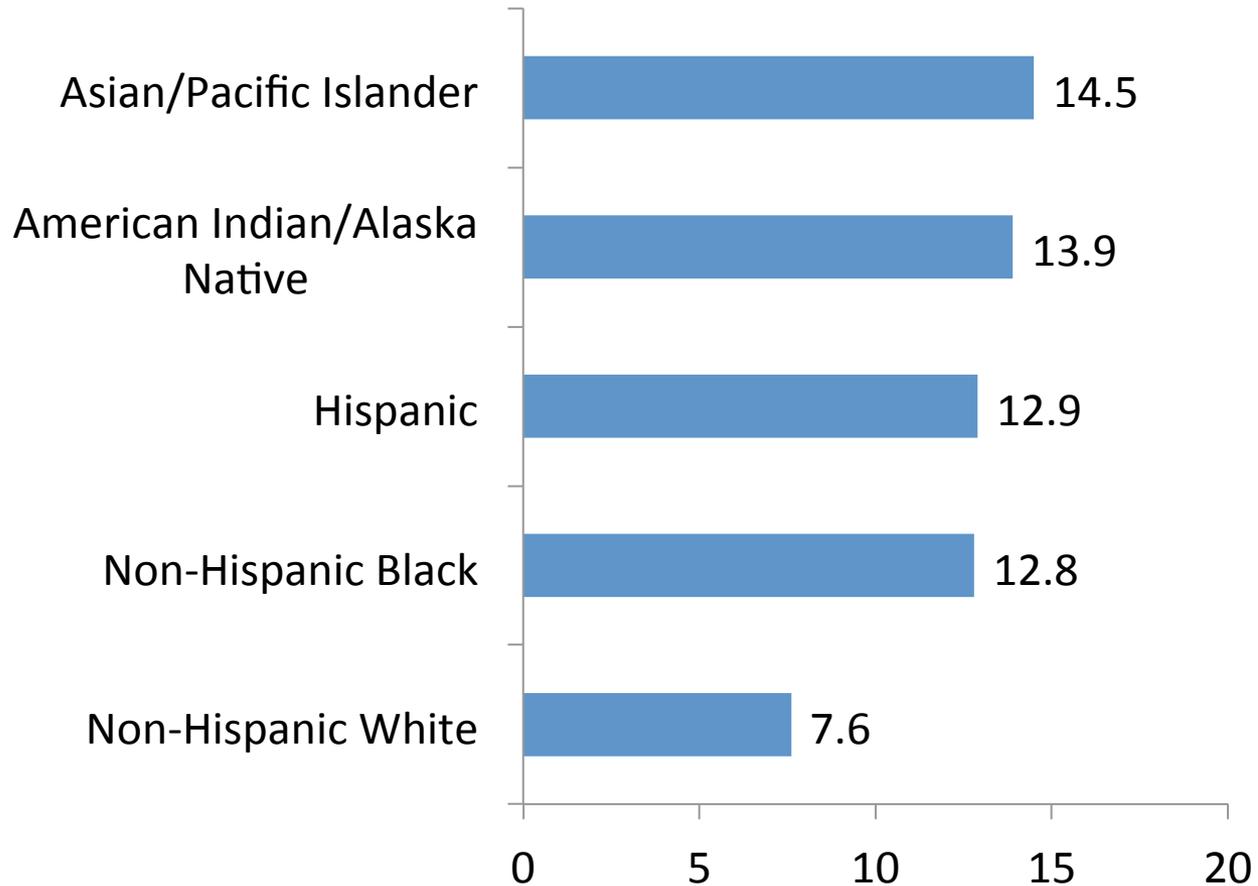


Our cancer burden is **unique**, because, among all racial groups in the United States, Asian Americans were the *first* to experience cancer as the leading cause of death. In all other racial groups, heart disease is the leading cause of death.

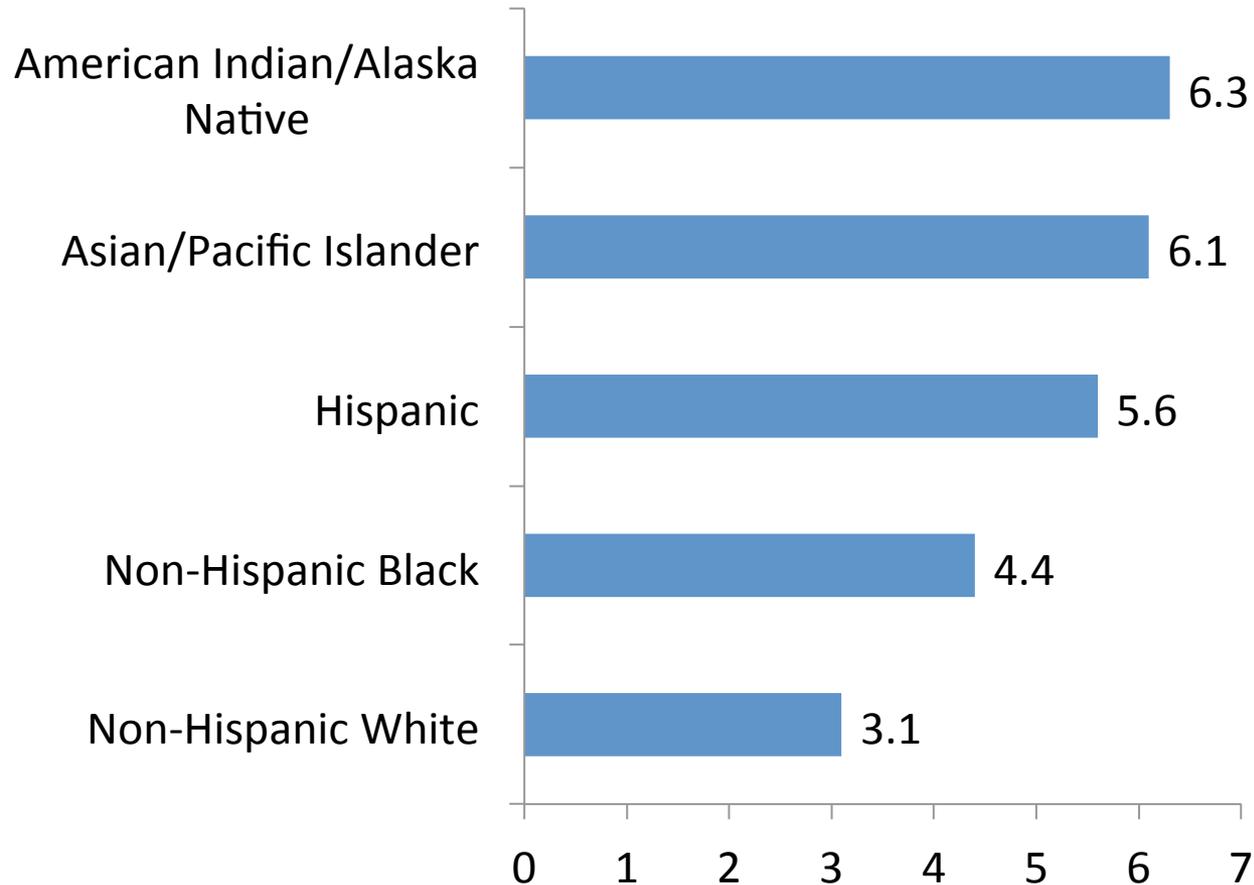


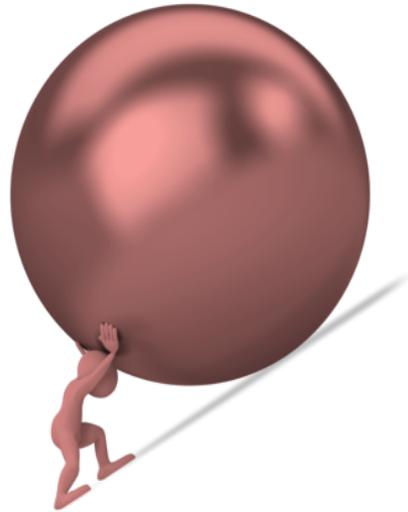
The cancer burden that affects Asian Americans is **unusual**, because more than any other racial/ethnic group, Asian Americans experience proportionally more cancers of *infectious* origin, such as liver cancer, cervical cancer, and stomach cancer.

Liver & Intrahepatic Bile Duct Cancer Mortality Rates for *Males* USA, 2008-2012 per 100,000



Liver & Intrahepatic Bile Duct Cancer Mortality Rates for *Females* USA, 2008-2012 Per 100,000





The cancer burden that affects Asian Americans may be **unnecessary**, at least in part, because prevention is better than a cure and earlier detection and other behavioral changes can reduce the risk of dying from cancer or acquiring cancer.

Objectives

From **Realization** to
Responsibilities

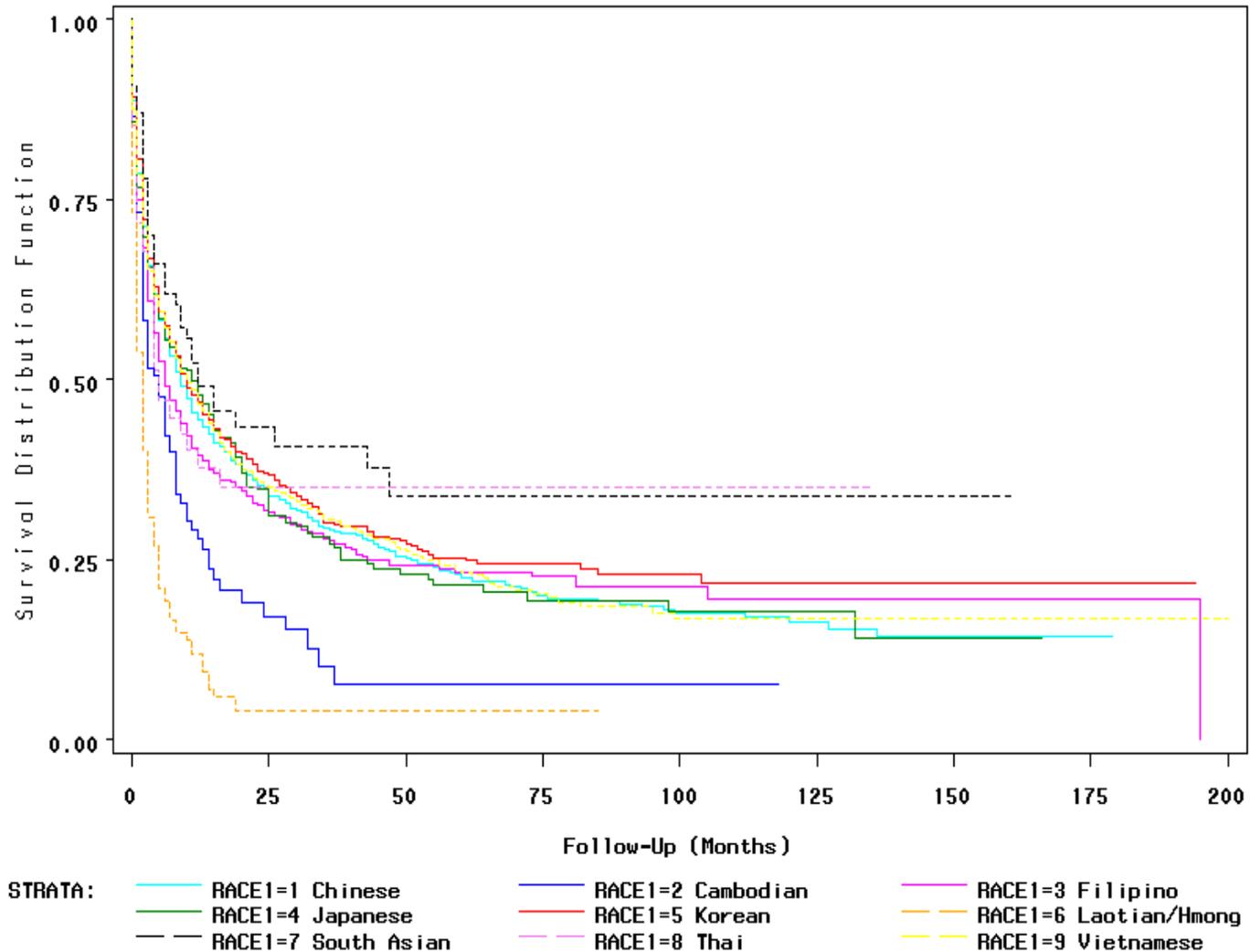


Reducing Cancer Health Disparities Among Asian Americans: Progress & Prognosis



Kaplan-Meier Curves of Cause Specific Survival from HCC

Cause-specific hepatocellular carcinoma survival by Asian American Ethnic Groups, California, 1988–2005



Thousand Asian American Study (TAAS)



FREE HEPATITIS B TESTING

In honor of
Asian Pacific Islander Heritage Month and
National Hepatitis Testing Day

The UC Davis Comprehensive Cancer Center will be offering
free Hepatitis B testing

WHEN: Sunday, May 13, 2013
10 a.m. - 2 p.m.

WHERE: UC Davis Comprehensive Cancer Center
4801 X Street
Sacramento, CA 95817

RSVP: Tina Fung, MPH, CHES
Tina.fung@ucdavis.ucsf.edu
916-734-5171

DID YOU KNOW

- Hepatitis B is dangerous because there are often no symptoms. By the time symptoms occur, it is often too late for treatment to be effective.
- One out of 10 adults have hepatitis, and a majority do not know they have been infected.
- Among Asian Americans, nearly 50% of liver cancer cases can be linked to Hepatitis B virus infection.

Additional risk factor screenings (Diabetes, C, diabetes and blood pressure), health education and light refreshments will also be provided.

Be qualified for a Free Hepatitis B test, you must be:

- A foreign born Asian American or an adult child of foreign born Asian American
- A resident of Sacramento County
- 18 years of age or older

Participants will get a \$10 gift card to Walgreens for their participation in the study.

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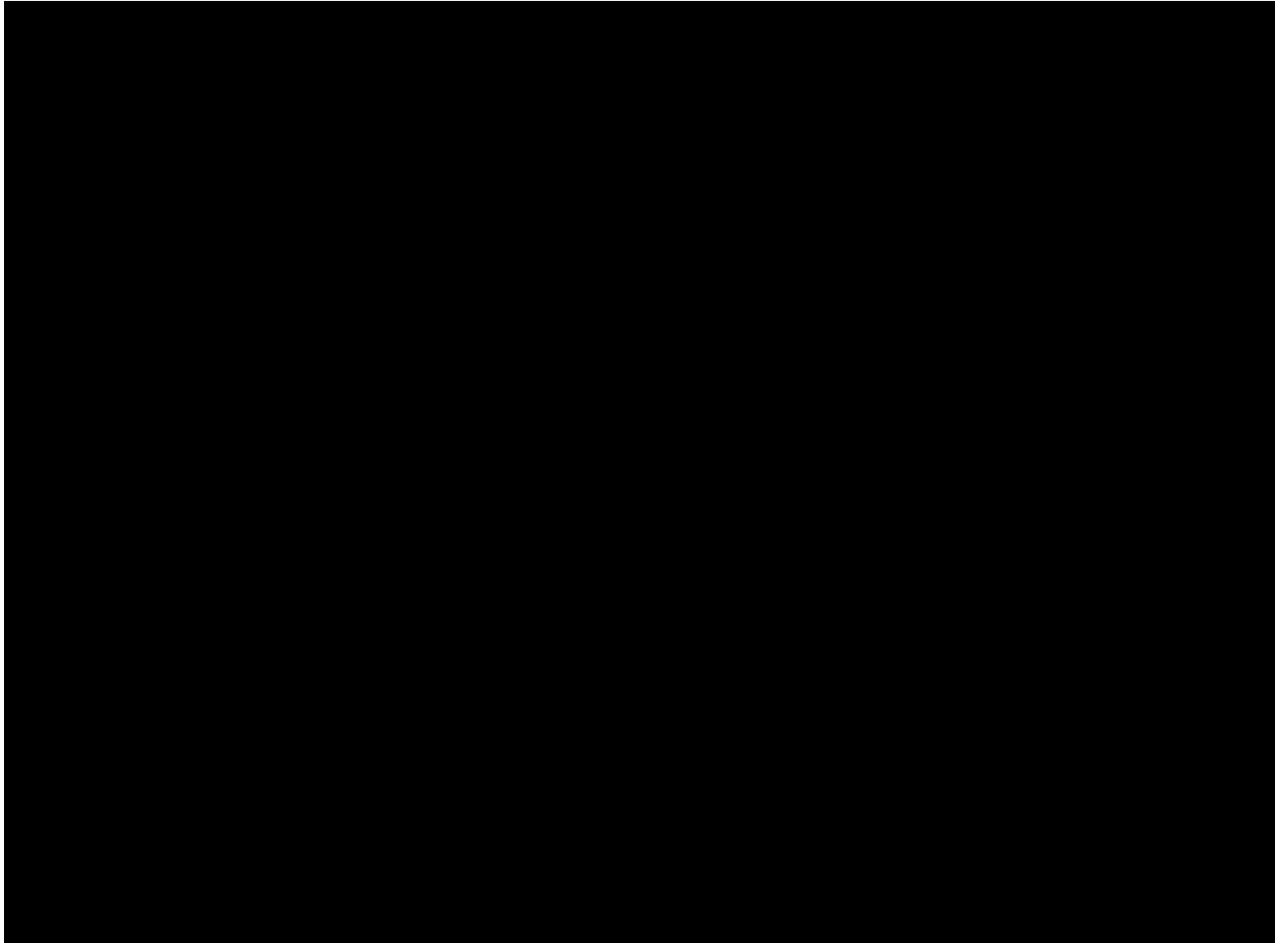
Member of the American Cancer Society

Photo provided by U.S. Centers for Disease Control and Prevention





Clinical Trials

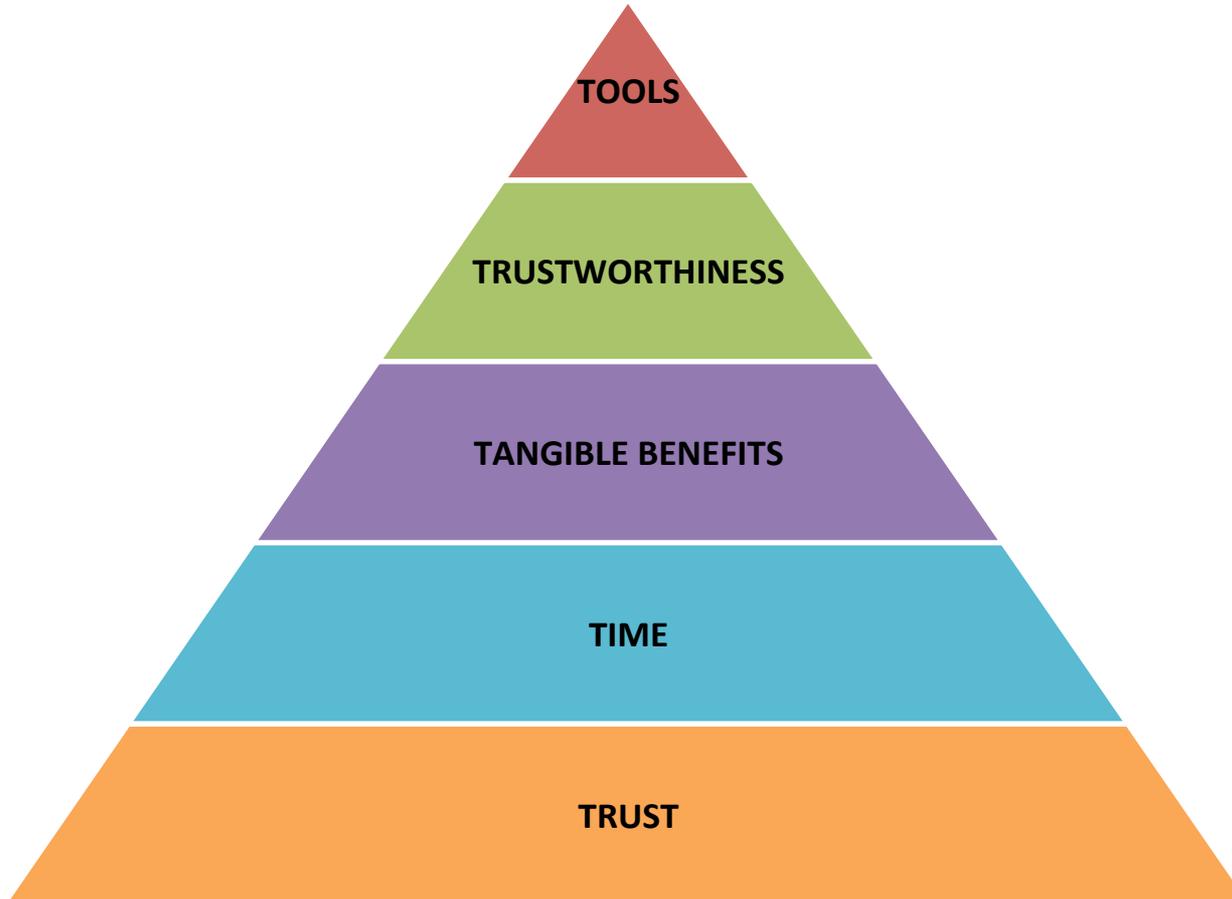
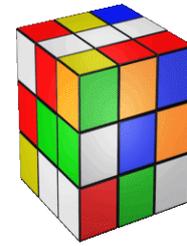


[YouTube](#)
[Link](#)

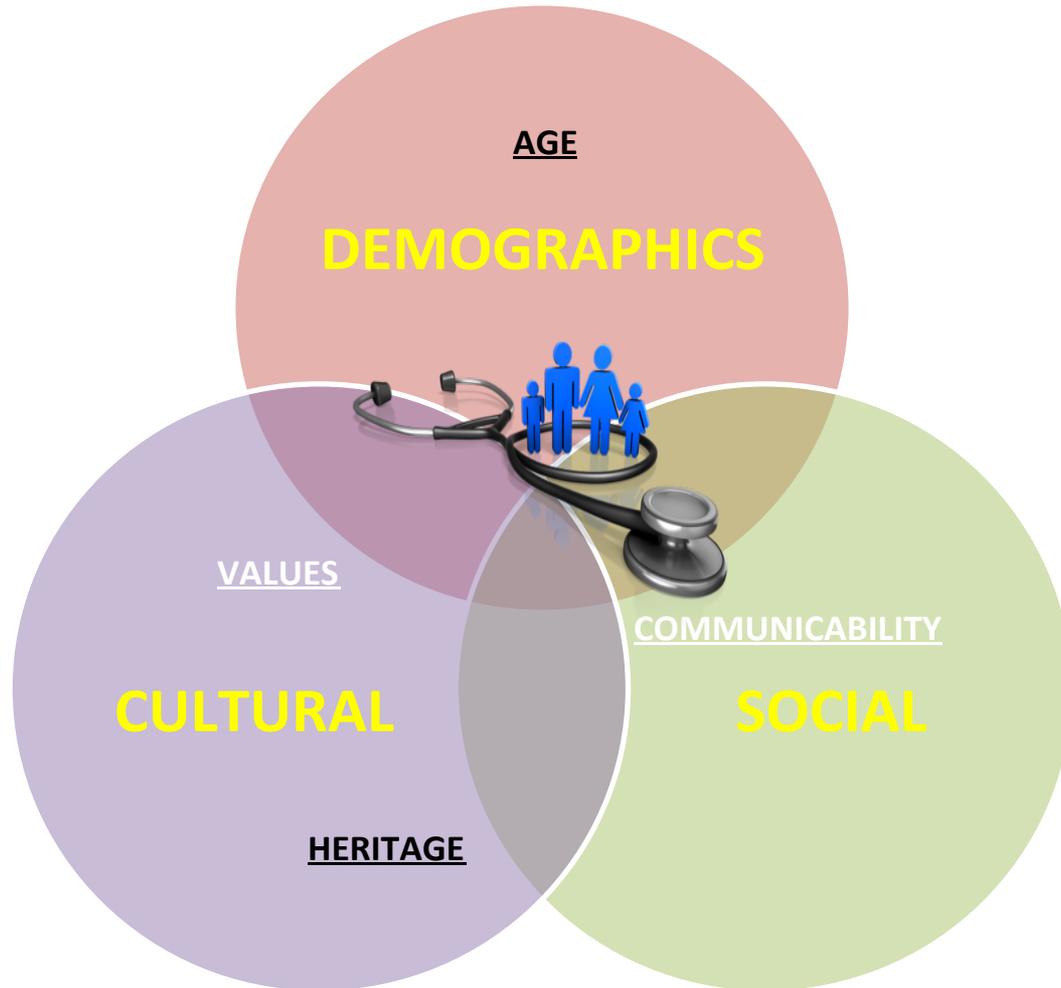
Perspectives



Paradigm



Patient's Perspective



HOW: FACILITATORS

- Doctor-recommended
- Trust earned
- Cultural sensitivity
- Linguistic competence

Does This Work?



Brown M, Moyer A.
Predictors of awareness of clinical trials and feelings about the use of medical information for research in a nationally representative US sample. *Ethnic Health*. 2010;15:223-226.



Tong EK, Fung LC, Stewart SL, Paterniti DA, Dang JHT, Chen MS Jr. Impact of a biospecimen collection seminar on willingness to donate biospecimens among Chinese Americans: Results from a randomized, controlled community-based trial. *Cancer Epidemiol Biomarkers, & Prevention* 2014



Dang JHT, Rodriguez EM, Luque JS, Erwin DO, Meade CD, Chen MS Jr. Engaging diverse populations about biospecimen donation for cancer research. *Journal of Community Genetics* 2014



Yes, minorities are willing to participate in health research



**Yes,
TRUST is
the key**

Objectives



From **Review** to *Realization*

From **Realization** to
Responsibilities

From **Responsibilities** to *Roles*

Asian American Community Responses to Blood Biospecimen Drives: Findings and Implications



The 3 R's: Roles and Responsibilities

If you are:



Healthcare provider....

Your responsibilities are:

Recommend clinical trials to your patients



Person with HBV

Request that your provider inform you about clinical trials



Public health or community group....

Be a **Resource** for linking providers and patients to clinical trials

How to Find HBV Clinical Trials

- Clinicaltrials.gov
- **Hepatitis B Foundation**
 - info@hepb.org
 - 215-489-4900
- **CISCRP (*Search Clinical Trials*)**
 - 1-877-MED HERO (www.ciscrp.org)
- Local academic / nonacademic institutions
- Pharmaceutical company websites

