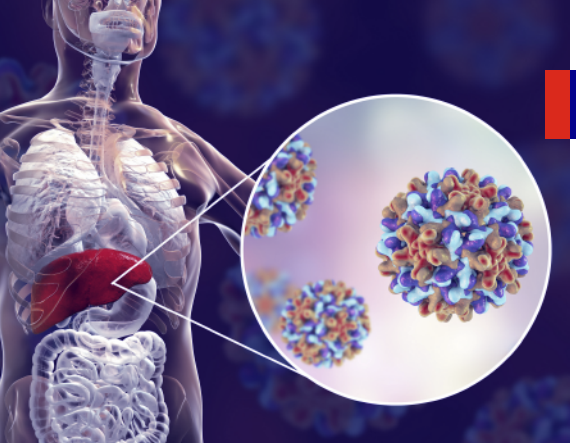

CASE STUDY

# Longitudinal Research Leads the Way

## Chronic Hepatitis B

### MISSION

**To collect blood samples from patients living with HBV for biomarker discovery and drug development.**

### CHALLENGES

**Find qualified participants infected with HBV but free of viral coinfection and collect blood samples weekly for 1 year.**

### SOLUTION

**We enrolled more than 100 patients and deployed mobile phlebotomists to collect whole blood specimens.**

## Why Does Hepatitis B Turn Chronic? Who Is at Risk?

An estimated 300 million people live globally with chronic infection due to hepatitis B virus (HBV); about 862,000 of these individuals live in the U.S.[1,2] Although most adults who contract HBV clear the infection and go on to live without symptoms, some develop long-lasting infections which places them at greater risk of developing liver diseases or dying. Young children are particularly vulnerable, even though HBV is preventable with vaccination. When mothers pass the virus to their newborns, or when children younger than 6 years old acquire HBV, 90% of these cases become chronic.[1]

There are medicines to suppress the virus in people living with HBV. Nevertheless, there continues to be an unmet need for these patients and the nearly 1 million people who die from HBV each year[1] — for better therapies or a cure.

## Recruiting Patients Living With HBV—And no Viral Coinfection

Our challenge was to find patients 18 to 65 years old living with HBV but who were free of viral coinfections and advanced liver diseases. This inclusion and exclusion criteria allowed researchers to narrow potential biomarker discoveries to only those associated with HBV infection—which also shrank our pool of potential participants. By partnering with the Hepatitis B Foundation and through independent outreach initiatives targeting our patient member community, we identified more than 1,000 HBV patients and enrolled 106 who met these criteria.

**The initial timeline for this study was 1 year, but our recruitment success has led to ongoing renewal.**

**>100 originally enrolled patients,**

**95% are still participating today;**

**Two blood specimen collections per week over a period of 3 years to date.**

## HBV Surface Antigen Testing and Delivery

After sample collection, our core laboratory partner services were leveraged to screen for levels of two antigens in participants' blood serum: HBsAg surface antigen and HBeAg secreted antigen. These provide researchers with information about current infection and whether the virus is actively replicating. Test results were conveyed to researchers, and shipment of biospecimens to their site coordinated seamlessly.

## Peer-Reviewed and Published

Our innovative approach empowers scientific studies and drives the sort of discoveries set to make a tangible difference in the lives of people living with HBV. In this case, we've worked together with Arbutus to longitudinally collect criteria acceptable blood specimens and data, which enabled work recently published in *Nature Communications*, Checkpoint inhibition through small molecule-induced internalization of programmed death-ligand 1.[4]

See how studying hepatitis B-specific immune responses ex vivo contributed to their ability to identify a novel small molecule-induced inhibition mechanism of the PD-1/PD-L1 axis with potential therapeutic implications in chronic viral infections and oncology.

## Spotlight on The Sanguine Difference



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