# The PROP UP Study The Patient-Reported Outcomes Project of HCV-Target

September 12, 2016 By Alan Franciscus

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The PROP UP study is a prospective, observational study that is evaluating patient-reported outcomes associated with the treatment of chronic hepatitis C infection and benefits of viral cure. PROP UP was funded by the Patient Centered Outcomes Research Institute (PCORI) last August and the study is actively recruiting patients. The outcomes the study is evaluating hepatitis C treatment-related side effects, adherence to the treatment medications, the cost that patients have to pay out-of-pocket, long-term benefits of cure, and the potential harms of treatment. The study will also evaluate whether hepatitis C symptoms and patient functioning improve after treatment. The study will continue to track side effects and toxicities that may occur up to 1 year after treatment ends. The patient reported outcomes will be compared between the various hepatitis C medications.

Patient Centered

The study will answer certain questions in a “real world” setting. This is different than past studies conducted by pharmaceutical companies. The study was designed by investigators at the University of North Carolina: lead investigator, Donna M. Evon Ph. D, and co-investigators, Michael W. Fried, MD and Carol E. Golin, MD., along with a patient engagement group. The patient engagement group includes people who have had hepatitis C with a wide variety of experiences. They have been involved in every step of designing PROP UP, since 2013 when the original proposal was submitted.

Patients with HCV helped to decide which outcomes were important to evaluate, and how we would measure them. I am part of the patient engagement group and The Hepatitis C Support Project / HCV Advocate is the patient advocacy group who will help to disseminate the study’s findings to the larger HCV Community. We are all still involved in the ongoing collaboration.

The study will enroll 1,600 people nationwide. People can earn up to $155.00 for participating in the study. The surveys take about 20-minutes over email or on the phone. There are a total of 5 surveys over a period of 15 to 20 months that covers how patients feel before, during and up to 1 year after treatment ends.

You may be eligible if you are prescribed treatment for hepatitis C by your doctor and have not

started treatment yet. The study is enrolling patients with all genotypes and five major oral treatments.

I hope that people with hepatitis C who are thinking about starting HCV treatment will be eager to enroll in this study. It is a way to give back to the hepatitis C community. It will help countless others in the future who may not have to deal with the some of the same issues that many of us have had to face. The best outcome of this study is that patients and providers will be able to make educated health care choices—that is the ultimate outcome of clinical studies. We will also find out answers to other important issues that are vital to each and everyone one of us.

Patients are being enrolled at 9 medical centers. (Click here to see the list of participating centers.) If you are being treated at these liver centers and you are interested in the study, please contact the research coordinator listed below. Please note: the study is only recruiting patients who have not yet started their treatment.

For more information about this study: Call Shani Alston, PROP UP Project Director at 919-966-4847 http://propup.web.unc.edu/

PROP UP is also listed on www.clinicaltrials.gov

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