



## **TiP-Hep C Registry Information Sheet**

**Last updated: July 27, 2022**

### **What is the TiP-HepC Registry?**

The Treatment In Pregnancy for Hepatitis C (“TiP-HepC”) Registry is an observational study to assess the mother-infant outcomes of exposures to direct-acting antivirals (DAAs) during pregnancy. The registry was developed by the Coalition for Global Hepatitis Elimination at the Task Force for Global Health. Funding for the registry is provided by the U.S. Centers for Disease Control and Prevention.

### **Why is the TiP-HepC Registry needed?**

Clinical interventions to reduce the risk of vertical transmission of hepatitis C virus (HCV) infection from mother to infant are highly limited. DAAs have demonstrated excellent safety and efficacy in non-pregnant individuals, but there is a lack of data regarding the safety of these medications in pregnant women and the effectiveness of these medications in reducing mother-to-child transmission. TiP-HepC is the first registry for DAA exposures in pregnancy.

### **What are the inclusion criteria the registry?**

In order to be included in the registry, an individual must have the following: estimated date of conception (by last menstrual period or ultrasound), date of delivery, documented chronic HCV infection prior to or during pregnancy (by positive test for HCV RNA or HCV core antigen), and documented DAA exposure occurring within 30 days of the estimated date of conception and before the pregnancy outcome. DAA exposures that include ribavirin or interferon are not eligible given established harm during pregnancy. It is preferred to submit data after outcomes of the pregnancy are available, but outcomes of the pregnancy or infant are not required to be included in the registry.

### **How do I contribute data for the TiP-HepC Registry?**

Data is voluntarily contributed by health care providers. You may provide information regarding eligible cases by filling out a line-by-line survey for each case on the registry portal or by completing a data template (.xls file) provided on the portal. If you have another preferred format to submit data, you may contact us at [lhiebert@taskforce.org](mailto:lhiebert@taskforce.org).

### **Will I be contacted for additional data?**

After submission of data for the registry, you will be provided a unique Registry Identification Number for each patient registered. You may be contacted with requests for clarification of missing or incomplete data. You will not be contacted for follow-up data on individual cases.

**Does the TiP-HepC Registry have IRB approval? Is patient consent required?**

The TiP-HepC Registry was reviewed and approved by the U.S. CDC Institutional Review Board. The IRB determined that the study poses minimal risk to subjects and approved the inclusion of pregnant women and children. The IRB approved waiver of informed consent determining that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals. The full study protocol can be found at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).

**How and when will data from the Registry be analyzed and disseminated?**

Data will be reviewed twice yearly by the TiP-HepC Scientific Advisory Committee, which is comprised of a panel of experts in the field. Registry data will be analyzed and released twice yearly through the TiP-HepC Community of Practice. To join the Community of Practice, please refer to the CGHE website.

**Can I get more information before contributing data to the registry?**

Yes, please contact us for more information! You can email us at [lhiebert@taskforce.org](mailto:lhiebert@taskforce.org).