**Viral Hepatitis C Infection Long-term Cohort Study (V-HICS)**

**Brief Description:** A5320/V-HICS is an observational, prospective, long-term follow-up study in HCV mono-infected and HCV/HIV-1 co-infected participants who received direct acting anti-viral (DAA) therapy for HCV infection in a clinical trial. Eligible participants are enrolled any time after HCV/DAA treatment outcome determination (sustained virologic response (SVR) determination) provided it is within 1 year after end of treatment in the HCV/DAA treatment study and prior to initiation of any subsequent HCV treatment. SVR is defined by the HCV/DAA treatment study.

**Objectives:**

- **Primary**
  - Describe HCV resistant variants and their frequency in HCV mono-infected and HCV/HIV-1 co-infected participants who do not attain a sustained virologic response (non-SVR).
  - Characterize the long term clinical and virologic outcomes in HCV mono-infected and HCV/HIV-1 co-infected participants who have a SVR to DAA therapy for HCV.
  - Compare the long term clinical and virologic outcomes in HCV mono-infected and HCV/HIV-1 co-infected participants who have a SVR to participants who did not attain an SVR.

- **Secondary**
  - Assess the impact of selected HCV resistant variants on virologic responses to subsequent HCV treatment regimens (ie, salvage regimens).
  - Assess the occurrence of HCV re-infection or relapse following SVR in participants treated with DAA containing regimens.
  - Assess the impact of successful HCV therapy on participant well-being.
  - Assess the impact of host genetic factors and expression of host genes and proteins on participant outcomes.
  - Assess the association between metabolic factors and participant outcomes.
  - Assess HIV-1 control and evidence of HIV-1 drug resistance evolution.

**Inclusion Criteria:**
- Documentation of HIV-1 antibody infection status.
- Documentation of HCV genotype and subtype (if available) prior to entry.
Receipt of at least one HCV/DAA within the past 12 months as part of a clinical trial.

**NOTE A:** DAA is defined as a therapy that acts directly on the hepatitis C virus (or a specific host cellular co-factor) at various points in the viral life cycle. If uncertain whether an agent is a DAA, please contact the A5320 protocol team.

**NOTE B:** Only candidates who were treated with a DAA as a component of their HCV regimen are permitted into V-HICS.

Documentation of treatment response (SVR or non-SVR) as defined by the HCV/DAA treatment study.

Men and women age ≥ 18 years.

Ability and willingness of participant to provide informed consent.

**NOTE A:** Individuals who prematurely discontinue HCV/DAA treatment for safety or other reasons are eligible for V-HICS entry.

**Exclusion:**
Currently on HCV treatment.

**Note:** Following V-HICS entry, participant may begin new HCV treatment.

Serious illness or active drug or alcohol use or dependence that, in the opinion of the site investigator, would interfere with adherence to study requirements.

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<th>Duration of Study:</th>
<th>Each participant will be followed for 5 years.</th>
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