PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

CER Questions
Head to Head Trials

1. ***Which of two all-oral inteferon-free strategies for the treatment of chronic genotype 1 hepatitis C infection, including sofosbuvir/ledipasvir and paritaprevir/ritonavir/ombitasvir/dasabuvir +/- ribavirin, will maximize sustained virologic response (SVR) and minimize adverse effects and harm?***
    a. In patients without cirrhosis
    b. In patients with compensated cirrhosis
    c. In patients with decompensated cirrhosis
    d. In patients who are post-liver transplant
    e. In patients with HCV-HIV coinfection
    f. In sub-groups defined by viral genotype
    g. In patients with end-stage renal disease (ESRD)I
    h. In patients who inject drugs (PWID)

2. ***Which of the available therapies - existing and recently introduced - for treatment of Hep C demonstrate the best outcomes with the fewest side effects?***
    a. Does interferon still have a role in the treatment of hepatitis C?
    b. Can interferon shorten the duration of DAA-based regimen – let's say from 12 weeks to 4-8 weeks?
    c. Is the magnitude of reduction in risk from complications of hepatitis C, particularly hepatocellular carcinoma, the same with sustained viral response achieved by interferon-free regimens as it is for SVR achieved by interferon-based regimens?
    d. What is the extended SVR of these regimens, what is the long-range and population-based toxicity of these regimens, how are these regimens directly compared with one another in terms of response rate, what situation would one regimen be used over the others, and do patients who are traditionally difficult to treat have different outcomes?
    e. How do the various available treatments compare on patient adherence?
    f. What treatment dosages and durations of therapies have the best long term results and fewest side effects?
    g. Does antiviral therapy ameliorate the common nonspecific symptoms of chronic hepatitis C?

3. ***Would those failing one DAA-based combination regimen respond to another regimen?***

4. ***What are the real-world rates of reinfection, particularly among IV drug users?***
    a. Do any of the antiviral regimens provide long-term protection against reinfection?