

SITGES STATEMENT

Research Agenda and Access to HCV
→ experimental drugs for HIV/HCV
Coinfected People

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International workshop

Community activists, doctors, researchers, company representatives and members of regulatory agencies, concerned about the life expectancy and the quality of life of people living with HIV and HCV, hereby declare that:

Collaboration between the community, regulatory agencies, academia and industry is a crucial part of the HCV drug development process. The community is an important stakeholder, and must be given the opportunity to provide input into HCV drug development. We want to participate in:

The development of regulatory guidance for HCV drug development

- We believe that regulators with experience in HIV drug development and treatment need to be involved in the development of regulatory guidance for new HCV drugs.

The development of industry-sponsored clinical trials

- We ask to meet regularly with sponsors of novel HCV therapies and combined modalities, and to participate in designing clinical trials, and oversight of these trials via Data Monitoring and Safety Boards (DSMBs) of these trials.

The development of research networks

- We support building additional research networks, public-private partnerships, investigator-initiated studies and registries of data from multi-center collaborations to bring HCV therapies forward quickly and explore new therapeutic paradigms before and after their approval.
- We encourage creating networks of investigators with expertise in treating HCV coinfection to study novel HCV therapeutic modalities in coinfecting people.

We believe that the health care needs of different populations and the patient perspective must be considered part of the HCV drug development process. Studies should include people with the most urgent need for new HCV therapies.

Trials of novel HCV therapies in HIV/HCV coinfecting people should begin before approval is granted for their use in HCV monoinfection, once results from Phase 2B studies are known, and there are indications from earlier toxicology, pharmacokinetic and drug-drug interaction studies that the specific agent, or agents, under investigation will not have the potential for significant drug-drug interactions, or other toxicities relevant to HIV.

It is clear that combination therapy will be necessary to prevent or delay HCV drug resistance. We need to consider the most expeditious methods for co-

developing drugs; this may depend on the outcome of early monotherapy studies of each agent. Since safety is paramount, we believe that *in vitro* and *in vivo* drug interaction studies must be conducted early, to facilitate pre-approval multi-agent trials and studies in persons likely to be using other medication, such as coinfecting persons, and transplant recipients.

We support trials that look at methods to delay, or reverse fibrosis progression as well as trials to eradicate HCV. It is important that trials in different populations consider different outcomes for different patient populations (Sustained Virological Response (SVR) vs. histological improvement or averting/delaying transplantation). We also support investigation into alternative and complementary therapies for HCV.

We ask that all possibilities be explored for conducting pre-approval studies of HCV therapies in the highest prevalence population, including people who use drugs. We encourage studies in people using methadone, buprenorphine, naltrexone and heroin substitution prior to approval.

In addition, we ask that sponsors design studies that:

- Enroll sufficient numbers of women to yield information on potential gender-specific side effects of new HCV treatments,
- Include TDM (therapeutic drug monitoring) in studies of persons with advanced liver disease
- Accelerate pediatric research

When possible, trials should include:

- Characterization of resistance
- Non-invasive assessments of liver damage, to see if they can be validated as an alternative to biopsy
- Assay standardization

Research to optimize the current standard of care must continue. Studies on management of side effects and models of care, especially those that will continue to explore the use of multidisciplinary care, are a priority. Interferon will still be part of HCV treatment for the next few years, but it may be possible to find a less toxic alternative to ribavirin.

We have seen high rates of liver-related mortality in the last few years. Since it will take time for new drugs to become available, we must raise awareness of the need for donor organs, promote policies to increase organ donation, and remove obstacles to transplantation for HIV-positive and coinfecting people. Organ transplantation, and access to the highest-quality care and treatment, must be provided to HIV-positive and coinfecting people throughout Europe and the rest of the world.

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