

2009



# SITGES II COMMITMENT

European AIDS Treatment Group (EATG)

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## Sitges I

In 2007, a group of activists, many living with HIV and hepatitis C, met with researchers, clinicians, regulators, and representatives from Abbott, Roche, Schering-Plough, and Tibotec in Sitges, Spain. They met to address a critical issue: clinical development of HCV therapies in HIV/HCV coinfecting people.

Meeting participants created *The Sitges Statement* (see annex), a ground-breaking, collaborative statement on HCV drug development in HIV/HCV coinfecting people.

Sitges I meeting was sponsored by the European AIDS Treatment Group (EATG) and GTT (Grupo de Trabajo sobre Tratamientos) and co-planned by Joan Tallada (EATG/GTT) and Tracy Swan from Treatment Action Group.

## Sitges II

In 2008, a second meeting was held to discuss HCV trial design. Activists, researchers, clinicians and representatives from Abbott, Gilead, Pfizer, Roche, Schering-Plough, and Tibotec gathered to discuss immunologic, virologic, pharmacokinetic, regulatory and population-specific aspects of HCV drug development.

Sitges II meeting was sponsored by the European AIDS Treatment Group (EATG) and VyH en Contexto and co-planned by Joan Tallada (EATG/VyH en Contexto) and Tracy Swan from Treatment Action Group.

Participants at this meeting recognized the value of collaboration in HCV drug development. Trial design involves numerous complex scientific and ethical issues. The participants' mutual goal is a productive and dynamic relationship between community, academia, industry, and regulatory agencies.

### **To this end, drug companies listed below as signatories commit to:**

Share information about the class of agent, timeline for entering clinical trials, and study populations (healthy volunteers versus people with HCV or HIV/HCV) of HCV drugs in development.

Under confidentiality agreement, solicit HIV/HCV community perspectives on treatment paradigms and input into study designs for use in upcoming protocols when modifications are feasible.

Commit to consulting experts in addiction medicine and multi-disciplinary care in the design of trials that include patients who are receiving stable substitution therapy.

Support efficacy studies in high-prevalence populations.

Thoroughly screen HCV antiviral agents for activity against HIV.

Assess pharmacokinetics and pharmacodynamics of novel HCV therapies in HIV-positive people.

Explore cross-company collaboration for multi-experimental agent trials.

Engage in dialogue with HIV/HCV community about expanded access programs for novel HCV compounds.

Work with organizations, including EASL, AASLD, health authorities, and HIV/HCV community members to define consistent and precise terminology for study populations and treatment outcomes.

**In turn, HIV/HCV community members under the EATG representation will:**

Commit to working across companies and with regulators to advocate for, and facilitate development of multi-experimental agent trials.

Provide companies with a list of community priorities for a portfolio of, and timeline for drug-drug interaction studies specific to each agent.

Facilitate inclusion of our priority populations, including HIV/HCV coinfecting people, women, people with cirrhosis, transplant candidates and recipients, and people on substitution treatment, in early PK, safety, and efficacy studies.

Serve on Data and Safety Monitoring Boards.

Review protocols and informed consents.

Review proposals for investigator initiated research.

Jointly signed by:

The European AIDS Treatment Group  
and Tibotec, Roche & Schering-Plough

EATG is registered as a non-profit organisation at the Amtsgericht Duesseldorf, Germany (no: 8542) and at the tax office Duesseldorf-Mitte (Charity No. 133/5906/0955).

EATG is also registered in Belgium as an Association Internationale Sans But Lucrative (AISBL) in accordance with Article 58 of the Law of 27 June 1921 and the Royal Decree of 2 April 2003.

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*The European AIDS Treatment Group (EATG) is a NGO at the forefront of the development of the civil society response to the HIV/AIDS epidemic in Europe. The EATG is a European patient-led advocacy organisation that represents and defends the treatment-related interests of people living with HIV and AIDS. Its mission is to achieve the fastest possible access to state of the art medical products, devices and diagnostic tests that prevent or treat HIV infection or improve the quality of life of people living with HIV, or who are at risk of HIV infection. For more information, please visit [www.eatg.org](http://www.eatg.org)*