



What We Wanted was What We Needed

COLLABORATIVE COMMUNITY ADVOCACY FOR INCLUSIVE CLINICAL TRIALS IN EMERGING HEPATITIS C RESEARCH: LESSONS FROM THE EATG SITGES MODEL.

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BACKGROUND

How can community activism be galvanised to generate real change?

The European AIDS Treatment Group (EATG) is currently involved in a project focusing on the inclusion of people living with HIV in non-HIV clinical trials (Belong), and its approach is being shaped by lessons learned from a previously successful project with many similarities. Between 2007 and 2017, EATG organised a series of community-owned multi-stakeholder meetings in Sitges, Spain, to promote the inclusion of people with HIV and hepatitis C virus (HCV) coinfection in clinical trials for emerging HCV treatments. Stakeholders included community representatives from the HIV and hepatitis fields, medicines regulators, physicians, and pharmaceutical industry. A case study developed in November 2023 documented the experiences, results, methodologies, and lessons learned from the Sitges meetings to guide the Belong project.⁴



The Sitges meetings were an attempt to get something done where you put together different stakeholders, with their individual approaches, and combine that experience together for a strong platform. You can [then] justify your asks, build on each other, and come to a joint statement, decision, or position. It's a collaborative forum.

Koen Block
EATG former Executive Director, Belgium



RESULTS

Equity, inclusion, and structure are central to community-led changes

The Sitges meetings had a strong egalitarian, multistakeholder ambiance. They built a platform of credibility, raised awareness of HIV/HCV coinfection among stakeholders, and combined human experience with medical research advocacy. All participants, regardless of status or role, contributed equally to discussions and decisions.



One of the most important achievements of this model was its ability to bring together specialists in the field of HCV, European institutions such as the European Centre for Disease Prevention and Control (ECDC) and the European AIDS Clinical Society (EACS), policy makers and regulators, dialogue with the European Medicines Agency (EMA) and to bring pharmaceutical companies around the table.

Luís Mendão, EATG Member, Portugal, opening the 10th and final Sitges meeting in 2017



Key outcomes included: the amendment of exclusion criteria so / people with coinfection could be included in clinical trials, a reworking of EMA guidelines, and building meaningful bridges between stakeholders.



The core of the Sitges model is that it was community driven. The needs were formulated by the community. Not just HIV+ but also the hepatitis community. There was a need to change policy for coinfecting people, and we put together those people we needed to convince, such as regulators, pharma. But the main targets were regulators and pushing pharma over the edge. The meetings were multi-stakeholder and driven by the community. Everyone was around the table, and we did make policy changes.

Wim Vandervelde, GNP+ and on secondment to UNITAIDS Community Delegation, EATG Member, South Africa and Belgium



When applying the Sitges Model in other disease areas, there must be close involvement of community leaders, and current scientific information available for scrutiny. Meetings must also aim for the co-creation of solutions and collaborative agreements. Other key components include efficient organisation, clear agendas, detailed post-event reporting with recommendations, and unanimous joint statements.

METHOD

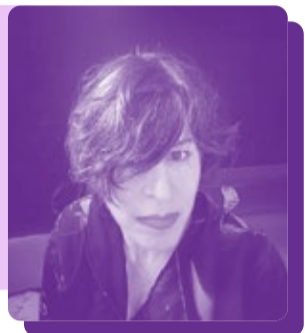
Data collection

The case study of the Sitges meetings is based on documentary analysis of available materials and 19 semi-structured interviews with participants. It includes verbatim reflections from 5 community participants, presents the nature, characteristics, and outcomes of the Sitges Model, and the transferability of this model to advocate for the inclusion of people living with HIV in non-HIV clinical trials as part of Belong.



To use this model successfully in other areas, it needs to be adapted and more about data and strategy. Moral outrage is always what propels me, but some of the people with power don't care! So, we need to be strategic to get something we want.

Tracy Swan, Independent Consultant, Spain



CONCLUSIONS

Community power IS effective

The Sitges case study offers a powerful tool for use in other disease areas. Highlighting the concept of 'patient expert', it also provides one example of a successful advocacy model emphasising the value of community advisory settings. It demonstrated how community advocates can collaborate effectively with other stakeholders to work towards a shared vision and common goals.



It was very open, and it helped create and enhance the momentum that was rising - about PLHIV being excluded from clinical trials. During direct-acting antiviral (DAA) trials, all the companies decided to include coinfecting PLHIV into their trials in a separate study. Now, in 2023, my [HIV] clinic has no hepatitis C. They are all cured. So, thinking about what came out of Sitges, it was tremendous.

Participant, Sitges meetings



RECOMMENDATIONS

There are five core features of the Sitges Model that can be used in other areas to maximise the community voice and strengthen advocacy.

- 1. Getting the right people in the room: The positive outcomes were achieved by a diverse group of experts in trial design, drug development, and lived experience.
- 2. Accurate information: Current knowledge of pathology, epidemiology, and standards of care is essential.
- 3. Appropriate leadership: The initiative was community-led with clear demands, ensuring patient groups and organisations were central to the process
- 4. Effective planning and facilitation: Well-structured agendas and clear goals evolved over time, with strong reporting of actions and next steps.
- 5. Setting: Sitges, a seaside and friendly venue, provided a pleasant ambience for challenging discussions.



You need a politicised community - it's moral and ethical to do, has urgency behind it, and someone who needs the inner drive to get something done. People need to feel your passion, and you can't convince someone of something if you don't transmit that passion.

Joan Tallada
EATG Member, Independent Consultant, Spain



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Read the Case Study

