EATG European AIDS Treatment Group

Belong

Inclusion of
People living with HIV
in non-HIV clinical trials

THE SITGES MEETINGS

"What We Wanted was What We Needed"

A MODEL OF INCLUSIVE COMMUNITY ADVOCACY

ABOUT THIS CASE STUDY

This case study documents experiences, results, and lessons learned from the Sitges meetings, a series of multi-stakeholder meetings, community owned, held in 2007-2017 to promote the inclusion of HIV/hepatitis C coinfected people in clinical trials for emerging hepatitis treatments, and rapid access to new, safe and effective treatments. Convened by EATG, the meetings adopted a methodology where all relevant stakeholders were gathered together to discuss key issues and find concrete and pragmatic solutions. Stakeholders included community representatives and activists from the HIV and hepatitis fields, medicines regulators, physicians, researchers, and the pharmaceutical industry.

There were several important and impactful outcomes from the meetings, and this case study is intended to be used to provide examples and guidance for applying this methodology in other contexts and disease areas.

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We will strive to use it as best we can to improve the inclusion of people living with HIV in non-HIV clinical trials in the WHO European Region.

This work is the result of the involvement of a diverse set of individuals from the European AIDS Treatment Group (EATG), acknowledged below:

Ian Hodgson
CASE STUDY AUTHOR

Rocco Pignata
PUBLICATION COORDINATION

Apostolos Kalogiannis & Rocco Pignata
EDITORS-IN-CHIEF

Giorgio Barbareschi
CASE STUDY REVIEW

Alain Volny-Anne, Alessandra Cerioli, Brian West, Grzegorz Jezierski, Luís Mendão, Memory Sachikonye, Sean Hosein
BELONG COMMUNITY ADVISORY GROUP

Fiona Greenhalgh
PROOFREADING

Dimitris Kanellopoulos @ Synthesee
LAYOUT DESIGN

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ACRONYMS

Belong	A project promoting inclusion of people living with HIV in non-HIV clinical trials
CAB	Community Advisory Board
DAA	Direct-Acting Antiviral Agents
EATG	European AIDS Treatment Group
ECAB	European Community Advisory Board
EMA	European Medicines Agency
GIPA	Greater Involvement of People Living with HIV/AIDS
HCAB	Hepatitis C Community Advisory Board
HCV	Hepatitis C virus
HBV	Hepatitis B virus
TAG	Treatment Action Group
PARADIGM	Patients Active in Research and Dialogues for an Improved Generation of Medicines
UNGASS	United Nations General Assembly Special Session

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EXECUTIVE SUMMARY

Between 2007 and 2017, European AIDS Treatment Group (EATG) facilitated a series of multi-stakeholder meetings. These had two key aims: ensuring the inclusion of people living with HIV and coinfected with hepatitis C (HCV) in clinical trials for emerging treatments for HCV; and promoting rapid access to new and effective treatments. The meetings were organised and led by community activists, HIV and hepatitis organisations, and people living with hepatitis and HIV. Other key stakeholders attending the meetings included medicines regulators, physicians, academics and researchers, public health agencies, and industry representatives. Attendees were based mainly in the WHO European region, though there was strong representation from the U.S.

The meetings from the beginning used a collaborative approach to find solutions based on the contribution of all stakeholders. There was a strong egalitarian ambiance, with each stakeholder holding equal power and influence. This resulted in, according to one attendee, a "platform of credibility". The discussions were enriched by important narratives of lived experience shared by people affected by HIV and hepatitis C, underlining the urgency to find effective treatments underpinned by data from clinical trials.

There were several important outcomes of the Sitges series of meetings. They increased awareness of HIV/HCV comorbidity and coinfection, combining the human experience with robust advocacy in the context of medical research and medication development. Significantly, following the early meetings, exclusion criteria were amended to include coinfected people in clinical trials, and EMA guidelines reworked to reflect this. Another outcome was the meaningful bridge building that took place between stakeholders, especially the HIV and hepatitis communities, and between the community, pharma, and physicians. The meetings also comprised a successful evolution of the existing model of the European Community Advisory Board (ECAB), providing an opportunity to use the Sitges approach as a resource to increase the overall effectiveness of CAB meetings.

When considering the application of the Sitges Model in other disease areas, a number of factors need to be considered. Finding the right people from communities to lead is key, as well as having all available scientific information to hand. The facilitation of meetings must seek a cocreation of solutions, with all people contributing to reach an agreement, or at least a compromise. The meetings must also be organised efficiently with clear agendas and post-event reporting with recommendations and, if appropriate, a joint statement signed by all stakeholders.

The Sitges meetings demonstrated the power of combining two groups of patients/advocates working alongside other key stakeholders towards a shared vision and to achieve stated goals.

1. Introduction

Between 2007 and 2017, the European AIDS Treatment Group (EATG) facilitated a series of multi-stakeholder meetings. These had two key aims: ensuring the inclusion of people living with HIV and coinfected with hepatitis C (HCV) in clinical trials for emerging treatments for HCV; and promoting rapid access to new and effective treatments.

> 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**, opening the 10th and final Sitges meeting in 2017

Advocacy context

The Sitges meetings were introduced into a febrile and turbulent era of community activism. The decade 2001-2010 represents a crucial period in the history of treatment activism and advocacy, especially in the context of HIV. HIV-specific funding streams were coming online, and after the push during the 1990s to create effective, safe, and convenient treatment for people living with HIV, during the 2000s the main focus was to maximise treatment access, with community-led advocacy that was becoming increasingly effective. The three major statements of the decade – UNGASS Declaration (2001), the Dublin Declaration (2004)[1] and the Swiss Statement (2008),[2] encapsulate the rapid changes during the decade.

The nature of the problem

The launch of the Sitges meetings in 2007, with a focus on access to treatments for HCV, illustrates the broadening power of communities in improving research and development (R&D) in access to treatments and policies that would improve their quality of life and reduce mortality, and was emblematic of the time. It also reflected the centrality of the GIPA Declaration[3] as a key principle for both the Sitges meetings, and (subsequently) the *Belong* project. The essential problem the Sitges meetings aimed to address was rooted in urgency: although HCV was treatable regardless of HIV status, the treatment available for coinfected people was not established as safe, with several adverse side-effects. Coinfected people were also less likely to respond to treatment, making HCV-associated end-stage liver disease a leading cause of death for people living with HIV in Europe. Despite these critical factors and the pressing need for new treatments, HIV/HCV coinfected individuals were routinely excluded from participating in clinical trials at that time. Addressing this shortfall in care, and the lack of information about the impact of hepatitis treatments on coinfected people, was the primary goal of the Sitges meetings.

1 That HIV must be an important political priority for the countries of Europe and Central Asia. Available here: https://www.osce.org/secretariat/29873

2 That an HIV positive person on effective HIV treatment (ART) cannot transmit HIV through sexual contact. Summarised here: https://i-base.info/guides/pregnancy/swiss-statement

3 Greater Involvement of People Living with or Affected by HIV/AIDS (GIPA): https://data.unaids.org/publications/irc-pub01/jc252-gipa-i_en.pdf

EATG's role and planning for the meetings

EATG's extensive experience in engaging with pharmaceutical companies and regulators in the HIV field was a crucial asset to the Sitges meetings. Many of the companies developing hepatitis treatments were also involved in the HIV field. The Sitges meetings' general approach, characterised by community leadership and involving multiple stakeholders, was derived from a model that EATG had been employing since 1997, known as the European Community Advisory Group (ECAB). Comprising treatment expert community members and treatment activists, ECAB aimed to advance research on HIV and coinfections while also expanding access to treatment. Indeed, Sitges was launched at a time when EATG already had a very strong ECAB, with regular meetings with pharma seeking information about ARV pipelines (including in the context of hepatitis C coinfection).

According to one EATG member and Sitges participant, "We would put an emphasis on the fact there had to be research into HCV [but] we realised we could not monopolise ECAB with hepatitis C. We needed a dedicated space where we could do specific advocacy." This last point is important, for a powerful driver of discussions that would result in the Sitges meetings was that, though activists were working in Europe, and the specific issue of HIV/HCV coinfection was being addressed at EATG's ECAB, the overall impact was limited in focus and effectiveness. The need for an initiative to address the issue – with urgency – was paramount to coalesce activities into a single point.

Planning for the initial Sitges meetings could be challenging. One issue was convincing pharma to attend and discuss with community representatives the management of clinical trials. However, for one of the organisers, making an *economic* argument helped smooth the way: "my ultimate argument was that we were missing an important market like in Spain." There's no doubt that the presence of scientific researchers and industry representatives at the Sitges meetings facilitated direct community access to research mechanisms and drug development processes. This foundation provided a focused avenue for advocacy in an area that, as of 2007, lacked coordinated activism on behalf of people living with HIV and coinfected with HCV.

Case study methodology and structure

This case study is based on two sources of information: documentary analysis of reports from the Sitges meetings and related material, and 19 semi-structured interviews with participants of one or more meetings. Respondent details are included in Appendix 1.

The case study is structured in the following way:

- Voices: verbatim reflections on the meetings by 5 participants.
- The Sitges Model: its nature and characteristics.
- Consolidation of the Sitges Model: outcomes, lessons learned, and further reflections.
- Transferability: applying the Sitges Model in the context of *Belong* and similar initiatives.
- Concluding comments.

2. Voices

This section includes a selection of quotes taken from a series of interviews undertaken in August and September 2023.

COMMUNITY POWER

The core of the 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 coinfected 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

COALITION

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 to get 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.

VOICES

Koen Block
EATG former Executive Director
EATG Member
Belgium

ACTIVISM

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.

VOICES

Joan Tallada
Independent Consultant
EATG Member
Spain

CONNECTION

I remember walking to the restaurant along the promenade, talking with an industry representative. We were able to speak as individuals – not as community representatives and scientists – and we could see that we had the same feeling and the same target. We were like, "let's do it!" Those conversations are great. This is when you take off your hat and you realise that we are all human beings going in the same direction.

VOICES

Diego García
Director of Sevilla Checkpoint
EATG Member
Spain

TRANSFERABILITY

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.

VOICES

Tracy Swan
Independent Consultant
Spain

3. The Sitges Model: its nature and characteristics

This section

This section considers the features of the meetings characterising the 'Sitges Model'.

3.1 It was a place for learning

The meetings were a **learning experience**, for the community and other stakeholders such as regulators and industry. For example, it was seen as important for an individual's work if they are involved in facilitation at other events. For one community respondent, "sometimes as a community we think we know a lot, but then you realise you don't," and "Pharma [also realised] the picture is not complete" by exposure to information from affected people. Learning was therefore horizontal, and the sharing of information from industry, community, academics, and regulators was vital for creating a *complete* picture of the situation. This was especially crucial in the late 2000s when the context of hepatitis C treatment and HIV coinfection was in a state of flux.

There was also a **thirst for evidence,** and data to confirm including people living with HIV in clinical trials for hepatitis treatments would be safe. There was a "risk/benefit equation" that required as much information as possible to justify proposals that may, at least in theory, have negative effects on people initiating new treatments.

3.2 It was community-led

An essential aspect of all the Sitges meetings was the **significant leadership from, and impact of the community**, which, in this context refers to patients, activists affiliated with community-led organisations, and representatives of associations dedicated to supporting people affected by hepatitis. The agendas and presentations from all the meetings confirm the content heavily favoured the community. For instance, all meetings were inaugurated and concluded by community representatives, who were also responsible for planning the agenda and facilitating all the sessions.

Robust discussion followed most presentations, with opportunities for discourse and knowledge sharing. A powerful example of this was during Sitges IV which featured a session on treating specific difficult-to-treat populations. Perspectives were shared by people living with hepatitis C, and included testing, knowledge of adverse events, organ transplantation, and willingness to try new drugs. For one participant, "At this time I can consider myself a dead man walking." Community views were sought on multiple occasions which ensured the dominant narrative was *always* the perspective of coinfected people, or those with extensive experience working with and supporting this group.

There was also a **strategic collection of community inputs.** In seven out of the 10 meetings, closed community meetings (exclusive to EATG members) were conducted to facilitate discussions on progress and address specific issues relevant to this group. In certain instances (e.g., Sitges V), these closed meetings were followed by presentations of the findings to the entire assembly.

For the community of coinfected people, there was an appreciation "that pharma came and talked and were open to dialogue." Pharma could appreciate that the patient community could utilise genuine knowledge and skills to further their cause. This is something that, according to one respondent, has "grown and evolved, [and] there are powerful patient advocates in other diseases that are even stronger than HIV patient advocates."

The meetings created an **ambience of egalitarianism**, where people listened to each other and moved their thinking away from fixed positions. The meetings were also founded on trust, with a shift in power among multiple stakeholders in the room, each holding equal influence and sharing information and demands. This allowed a strong collaborative platform to develop a joint position. A key feature was also the frequency of the meetings over time. Developments from the previous meeting could be critiqued, and with the strengthening of relationships there was a "platform of credibility."

For one participant:

> When I think about Sitges, I think about something positive - **it had a very constructive approach.** As an activist group, you might often be angry and negative (good sometimes) but at Sitges it was turned into a constructive mechanism. This is the reality we want to address so let's work together. Also, there was no rivalry. There was an equal level of collaboration and appreciation of people's intentions. I haven't always seen this in [other CABS]. Companies come in and present same kind of data that isn't always revealing and leads to a negative atmosphere, but I don't remember this with Sitges.

3.3 A broad palette of participants attended

Over the course of 10 meetings, more than 200 people attended one or more event. Where the information is available, their affiliations were:

- Community: 109
- Company/pharma: 62
- Academic/researchers: 16
- Public health agencies: 16
- European Medicines Agency.

Countries represented by the community were primarily led by Spain, the UK, and France, but by the end of the meeting series, people from 33 countries attended one or more of the meetings, 27 within the European WHO region. Two additional demographic features of the attendees were significant:

- Countries with the highest prevalence of co-infection were represented in Sitges, such as Italy, Portugal, Scotland, and Spain.
- The focus was not exclusively on the European context – U.S. activists were also present (one of the lead organisers of the Sitges meetings was at the time working with the Treatment Action Group [TAG]), and representation from Egypt. According to one participant, "it was an international advocacy project, not just a European one."

During the Sitges meetings, presenters and facilitators were primarily composed of community members and representatives from liver disease organisations. For specialised expertise, experts from regulatory bodies and academia were also included. While the pharmaceutical industry offered very few actual presentations, they actively participated in a roundtable (or similar format) during each meeting. These roundtable sessions facilitated extensive discussions on drug development, access to new medications, and sharing of community demands.

3.4 It was a forum to exchange ideas and reach consensus

One important function of each Sitges meeting was to **provide an update** of the *current* state of hepatitis treatment access and the development of new drugs. There was a regular frank exchange of views, especially in how to address novel opportunities and/or barriers (for example, Sitges III and direct acting antiviral medication [DAA]). The ecology of Sitges allowed the sharing and critique of knowledge and information, and according to a previous evaluation of the Sitges meeting series for the PARADIGM project,[4] **EATG and community stakeholders** gained new insights into:

- Medicines research and development (R&D).
- The design of clinical trials, and participation.
- The landscape of organisations working in the field of medicines R&D for coinfected patients.

Industry and regulatory stakeholders were exposed to knowledge and information about:

- Patients' needs and barriers to participation in clinical trials.
- Challenges to medicines access in different countries.
- What was, for patients, ethically acceptable in the context of clinical trial design.

It was also a **think tank** where stakeholders engaged in a safe space. The meetings weren't always peaceful, and arguments with industry over pricing could be especially adversarial, and this is one area where the Sitges meetings did not make significant progress.

There was a **collective approach to knowledge generation** resulting from the exchange of ideas. This is illustrated by the agreed declarations at the close of nine of the 10 meetings. Especially important was the Sitges Statement following Sitges I,[5] and others included a declaration and commitment (Sitges II), community consensus (Sitges IV and V) (see Appendix 3), and advocacy recommendations for different stakeholders (Sitges IX).

Finally, the meetings **created an important linkage** between the HIV and hepatitis communities. It created a structure where all voices could be heard and there was bi-directional learning.

4 A framework and metrics as a tool to enhance engagement: draft case study report, EATG Sitges Series 2007-2017 (2019).

5 Indeed, the Sitges Statement (2007) begins: "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…"

3.5 There was willingness to change and evolve

Thematic adaptability and flexibility reflected changing contexts. It was inevitable that, over the course of 10 years, there would be changes in the treatment and care of HIV and HCV coinfection (in part due to the success of the Sitges series). Building progressively upon one another, the meetings evolved from discussing existing perspectives and key issues (Sitges I, reflecting the situation facing coinfected people in 2007) to focusing on trial designs and more specific areas such as children and HCV, the use of theories of distributive justice to promote better access to treatment, and access to DAAs (reflecting the context of the early 2010s). Indeed, the title of each meeting reflected the evolving topics over the course of the 10 meetings.

These are best illustrated here in summary form:

Meeting	Year	Title summary	Output
Sitges I	2007	Research, and access to HCV drugs [benchmark meeting]	Sitges Statement
Sitges II & III	2008/9	Trial design: experimental HCV drugs	Sitges Commitment
Sitges IV	2011	Difficult to treat groups	Community Consensus
Sitges V	2012	Interferon-free HCV treatment	Community Consensus
Sitges VI	2013	Treatment for those left behind	Agenda for stakeholder discussions
Sitges VII	2014	The treatment pipeline [format as ECAB]	Sitges 7 Declaration
Sitges VIII	2015	Access to treatment [global perspective]	Community testing focus
Sitges IX	2016	Access to DAAs [policy meeting – format as ECAB]	Recommendations for all stakeholders
Sitges X	2017	Multi-stakeholder meeting [final Sitges meeting]	-

THE SITGES MEETINGS:
WHAT WE WANTED WAS WHAT WE NEEDED - A TIMELINE

1989	1992	1998	2001	2011	2013	2014	2016
Hepatitis C Virus (HCV) is identified	**Ribavirin is tested as therapy for HCV**	**Interferon + Ribavirin becomes standard of care**	**Pegylated Interferon is introduced**	**First generation DAAs** (protease inhibitors) **are approved**	**Sofosbuvir** (first NS5B inhibitor)	**First all-DAA regimen is approved** (Sofosbuvir + Ledipasvir)	**First pangenotypic regimen is approved** (Sofosbuvir + Velpatasvir)

Sitges I 2007	**Sitges II** 2008	**Sitges III** 2009	**Sitges IV** 2011	**Sitges V** 2012	**Sitges VI** 2013	**Sitges VII** 2014	**Sitges VIII** 2015	**Sitges IX** 2016	**Sitges X** 2017
Research, and access to HCV drugs [benchmark meeting]	**Trial design: experimental HCV drugs**	**Trial design: experimental HCV drugs**	**Difficult to treat groups**	**Interferon-free HCV treatment**	**Treatment for those left behind**	**The treatment pipeline** [format as ECAB]	**Access to treatment** [global perspective]	**Access to DAAs** [policy meeting – format as ECAB]	**Multi-stakeholder meeting** [final Sitges meeting]
Sitges Statement	Sitges Commitment	Sitges Commitment	Community Consensus	Community Consensus	Agenda for stakeholder discussions	Sitges 7 Declaration	Community testing focus	Recommendations for all stakeholders	-

Throughout this journey, there were significant milestones and key turning points:

Sitges I (2007)
launched the Sitges Statement on HCV drug development.

Sitges II (2008)
highlighted the need to include more women in HCV treatment trials to yield information on potential gender- specific side effects of new HCV treatment.

Sitges III (2009)
promoted the creation of a hepatitis C taskforce (HCAB) with European and American expert community.

Sitges IV (2010)
demonstrated increasing focus on key populations.

Sitges VII (2014)
provided greater emphasis on curative treatment for those with the greatest clinical need.

Sitges VIII (2015)
set new targets, HCV diagnostics and treatments for hard-to-reach populations.

Sitges X (2017)
emphasised the need to address gaps in the treatment of HCV and TB coinfected patients, as well as access to HBV vaccination for children and adults.

3.6 It adopted a new approach

> EATG's community advisory board was already stepping in that direction, but they weren't multi-stakeholder. In my opinion, [Sitges] was a novel approach and new way.
>
> **Participant**

The ECAB model used by EATG had been replicated in other countries, and represented an approach that was not common outside of the HIV context and involved communities and industry only. There were also some similarities to meetings involving people living with HIV and coinfected with TB, but at Sitges, this was the first-time large scale (and repeated) multi-stakeholder events were held for people coinfected with HIV and hepatitis. Crucially, the Sitges meetings were also predicated on the *urgency* to address the fact coinfected people were responding well to HIV treatment but succumbing to the damage caused by hepatitis – especially when there had been recent advances in the treatment of hepatitis.

The meetings forced the HIV and hepatitis cohorts together, revealing different approaches to advocacy, activism, and community engagement. "HIV advocacy and activism has *always* focused on human rights, protection of minorities, inclusion, and diversity. The hepatitis associations were primarily focused on fighting the disease," according to one participant. Indeed, this new coalition of people affected by HIV and hepatitis helped build bridges between two groups and possibly mitigate negative attitudes towards the HIV community, sometimes perceived by people with different diseases to capture disproportionate attention and funding.

The experience brought by the HIV community, with its long history of activism, was certainly reflected at Sitges:

> A unified group response [does have an impact]. The way was paved through HIV activism, having fought for inclusion in all kinds of trials. For hepatologists, this was a new concept. HIV activism served as a blueprint for community driven engagement in hepatology.
>
> **Participant**

For EATG, as this was perhaps their first in-depth engagement with another disease area, this institutional memory was something that could be applied to a different context.

Finally, perhaps the key difference from existing community advisory boards, according to one participant, is that the Sitges meetings sought *alliances* ("rather than just a mouthpiece for activists") between stakeholders (researchers, clinicians, international hepatitis advisers, and opinion leaders), all of whom could help with convincing industry that it was not ethically acceptable to delay treatment access to coinfected people.

4. Consolidation of the Sitges Model

This section

The Sitges meetings achieved several significant outcomes, and this section unpacks more about what the meetings delivered.

4.1 The impact of Sitges

What did the 10 meetings achieve? Documentary analysis and respondents suggest there are a melange of outcomes – some concrete, and some 'soft'.

General outcomes

Sitges remains a significant meeting of its kind. For example, before Sitges I, new HCV drugs were not tested on coinfected people. In addition, representatives from the HIV and HCV communities worked together towards goals common for both groups. The meetings offered an opportunity to share the latest data and forge community consensus among multiple stakeholders. A positive outcome of Sitges III, for example, was the formation of Hepatitis C Community Advisory Board (HCAB), a network of international activists from the HCV and HIV/HCV community that provided a mechanism through which activists could work with companies on their HCV drug development programmes, review protocols, and participate in investigator meetings. In some countries, HCAB provides early access to experimental HCV drugs. EATG's role in raising issues as a community priority in core forums is vital.

Inclusion in clinical trials

The impact of the Sitges meetings on *inclusion of coinfected people in clinical trials for hepatitis medication* was positive, growing from the "synergy coming from the different stakeholders", according to one attendee. As a result of discussions, exclusion criteria were amended, and EMA guidelines reworked to reflect this. For one participant, the discussions "normalised the idea that coinfected people, candidate [liver] donors and transplant recipients should be included in trials from Phase 2b onwards. We needed interaction data, and once there was data we could start fighting for access."

Access to medication

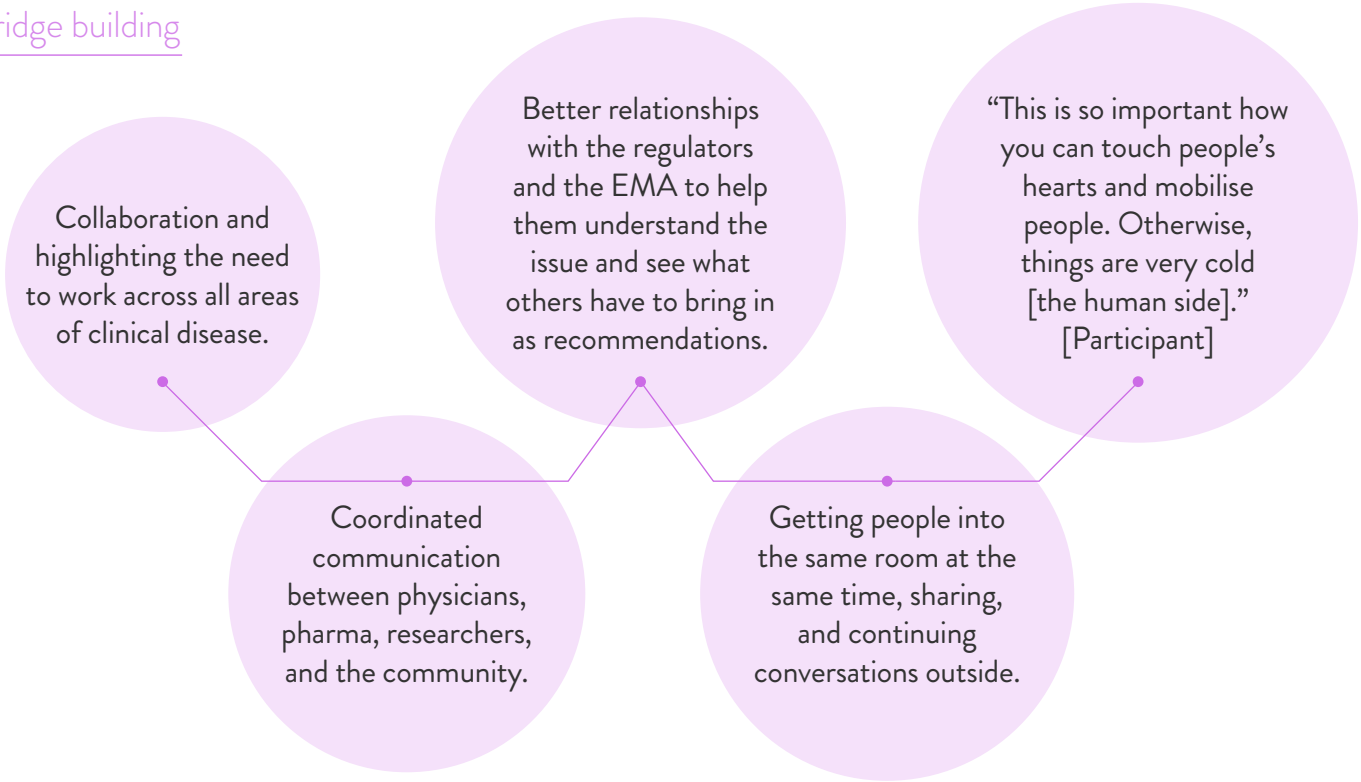
The impact of the Sitges meetings on *access to medication* was less clear, though there were significant discussions during the event. One key barrier was around **pricing**, which participants believe was minimally impacted. Additionally, though the Sitges discussions demonstrated the benefits of providing coinfected people with hepatitis treatments (with support from regulators), health services in many countries were unwilling or unable to pay. Prices varied across the European region, but one key outcome of the Sitges meetings was at least to raise awareness in other fora. For example, a 2012 high level meeting in Paris was attended by people who had already been involved in the Sitges meetings. They made sure to advocate for the production of cheaper hepatitis medications, determined to prevent the repetition of what one participant called the "12 years delay in access to HIV medicines" a few years earlier. Some participants also built on gains made at the Sitges meetings to obtain treatment in their own country (e.g., Portugal), but this was not the case elsewhere. However, advocacy at Sitges may have had some impact on expanding access to the 'compassionate use' programme.

One key challenge was convincing stakeholders that people who use drugs were *reliable* and should not be excluded. There remained a great deal of stigma against this group – often labelled as non-adherent – as well as other groups, such as prisoners.[6] For one participant, it was vital to discuss this at Sitges:

> We could sit there and say, 'you need to include coinfected people and substance users in clinical trials'. We could bring evidence to the table that they need treatment as quickly as possible and could also go through a clinical trial. Substance users are not unreliable! They know best how to get the best effect on their bodies and know precisely when they need their next dose. Instead of assuming they won't adhere, [we should assume] the opposite.
>
> **Participant**

4.2 Outcomes summary

Bridge building



6 Negative attitudes continue, even now, to affect access to optimal treatment and care for these groups: Rockstroh JK, Swan T, Chang J, Elamouri F, Lloyd AR. The path to hepatitis C elimination: who are we leaving behind and why? J Int AIDS Soc. 2023;26(7):e26136.

Addressing current needs

Highlighting the importance of bringing advances of hepatitis C drug development to PLHIV with increased risk of disease progression. There was an urgent need.

Emphasising urgency, expressed, and informed by the voice of affected communities.

Increased awareness of comorbidity and coinfection, and the feeling that something needed to be done in addition to HIV treatment and improving coinfected peoples' quality of life.

Advocacy

Combining the human experience with robust advocacy in the context of medical research and medication development.

Giving a voice to coinfected people in a powerful format.

Information for participants to use during personal and professional activities away from Sitges (such as current clinical trials and medication side effects).

Concrete outcomes

Indication of liver transplant for coinfected added to guidelines.

A European guide on how coinfected people should be evaluated and with what kinds of procedures (e.g. Fibroscan).

People living with HIV are recruited onto more HCV trials (especially stage 3 onwards). HIV was on the HCV agenda. Companies changed their rules around keeping data 'clean' and created new trial designs to accommodate coinfected people.

Helped access to treatment, including raising issues around 'compassionate use' rule, with DAA available for those with greatest need.

Long term

Normalising research in coinfection and drug-drug interaction portfolio.

Also, a reminder that HIV activists, with their extensive drug knowledge, were unusual at the time – "treatment nerds" who worked well with companies. This is unusual in other patient groups.

Gave EATG a "taste" of dealing with wider medical conditions and their idiosyncrasies.

Putting coinfection as a public health issue on the table.

4.3 Reflections on Sitges

> The idea of bringing everyone together is essential. You have to build a momentum. With pharma, it's all about money, so building a strong voice can have an impact for patients.
>
> **Participant**

For attendees, the experience of attending the Sitges meetings was positive, for example around information sharing, the professional approach, and friendly atmosphere.[7] The meetings were also perceived as well prepared, with clear aims and objectives and an impetus that was clearly community driven. A participant notes that "I had the feeling that even where there was critical reflection and opposition relating to pricing, it was done in a community focused way. It also opened doors [and] the companies (not pleasantly always!) were committed to having that communication."

For others, it was a "profound" experience not least because of the "importance of personal relationships between different stakeholders", in particular between the community and regulators. The "energy of the place" was also evident, and, for one physician attending Sitges, "it was useful to see the community and what they would like. Already people were beginning to involve the community in trial boards, but this strengthened this, and I came away with things I would like on a study."

7 Many respondents noted the atmosphere of camaraderie.

The sheer breadth of topics discussed was also a feature appreciated by participants, for example issues around the exclusion of substance users from treatment and transplants, as well as the use of methadone.[8]
For one attendee:

> We advocated for [people receiving methadone] and we had to work hard to make it clear to our stakeholders [regulatory agencies, pharma] that methadone was essential for some people. We have made significant progress in reducing the stigma associated with the prejudice that people who use drugs and have co-infections could not be adherent to therapy.
>
> **Participant**

For another participant:

> It was very open, and it helped create and enhance the momentum that was rising - about people living with HIV being excluded from clinical trials. In the course of DAA trials, all the companies decided to include people living with HIV coinfected into their trials in a separate study. Now, in 2023, my clinic [HIV] has no hepatitis C. They are all cured. So, thinking about what came out of Sitges, it was tremendous.
>
> **Participant**

8 Lack of strong representation of this group at the Sitges meetings was noted by at least one respondent as a limitation.

5. Applying the Sitges strategies to the *Belong* project and other milieu

This section

The purpose of this case study is to provide an analysis, based on documentation and reflections of participants, into the nature, gains, and lessons learned from the Sitges series of meetings. This section focuses on how the Sitges Model could be transferred to other contexts. Respondents did suggest some specific examples, such as **pandemic preparedness**. There may be the emergence of a severe variant that causes COVID-19 or new viruses leading to different pandemics in the future.

Therefore, it is important to bring together organisations that represent all the diverse populations and to create networks ready to promote an inclusive approach to clinical trial development, gathering the maximum amount of data. Another application of learnings from Sitges is for application in the field of **ageing with HIV**, where increasing risk of cardio-vascular disease requires a much broader dataset, through clinical trials that include people living with HIV, on the impact of different medicines on HIV-affected people. Along similar lines, a third suggestion was **fatty liver disease**, where there are limited data relating specifically to people living with HIV. Much broader inclusion in clinical trials is required.

Five core features of Sitges are identified below that could be used in other areas to maximise the community voice and strengthen advocacy.

5.1 Getting the right people in the room

The positive outcomes of Sitges were achieved in part because of the **broad base of participants** bringing their knowledge, experience, and influence around trial designs, drug development, and people's lived experience. This was a genuinely multi-stakeholder series of meetings, with each person being a leader in their field and knowledgeable about the situation and challenges. Sitges was also characterised by its melange of HIV *and* hepatitis advocates, working together to seek solutions.

Perhaps most importantly, they met *regularly*. For one participant, "the way some of the people put themselves into that process – the personal drive was very important as well. Not even people living it, but also in Sitges you could see people who were so committed to do something. We can only be grateful to them for continuing and doing that, even when, at the beginning, success was hard to see."

As highlighted above in section 3.2, the Sitges meeting were an international advocacy initiative that was not limited to the European region. There was strong activist representation from the U.S., for example. This feature is important to replicate in the *Belong* project and similar initiatives, as it ensures viewpoints from countries with multiple health, social, and non-governmental systems.

5.2 Having the right information

Current information about pathology, epidemiology, and standards of care, is vital. In the context of Sitges, this helped aiding prioritisation and making an informed selection of which trials and which drugs to focus on. Scientific savvy coupled with moral urgency will increase the impact of advocacy initiatives. What was especially beneficial at Sitges was the knowledge generated by *affected* people – their lived experiences and personal insights into the impact of treatments. Attendance at Sitges was driven by genuine interest and motivation, much like the beginning of the HIV epidemic brought together a range of powerful community groupings seeking to initiate change. Then, people were dying and whilst treatment was available this was inaccessible to most. Sitges brought the same spirit.

5.3 Getting the right people to lead

As noted throughout this case study, this was essentially a **community-led** initiative with focused demands. It's vital that affected people, patient groups, and patient-focused organisations are central in the planning, facilitation, and reporting of events. Coinfected people are the consumers affected by the disease and benefit most from effective treatment.

5.4 Using an appropriate format in planning and facilitation

Organising and facilitating the meetings required significant commitment and coordination. There were clear agendas, with details of expectations and goals (that would evolve over time), together with effective reporting highlighting of actions and next steps. For one attendee, meetings such as Sitges "need an agenda (not just an agenda on paper) and what you are working towards. Unwrapping big problems and identifying where to start. Then, you advance based on the outcomes."

Facilitation must also focus on the *cocreation* of solutions, outside of silos, and talking with all people to broker a compromise. When decisions are made, these must be based on the notion of equal rights, participation and decision making of all stakeholders. Solutions may not emerge for a while, so *patience* is required – in the context of the Sitges meetings, there was a 'turning point' around meeting III, when there was clear evidence of a shift (especially from industry representatives), "companies said, 'OK, we'll listen to you, and we'll discuss how those trials can be designed'." Indeed, on occasion, bilateral talks with regulators and physicians were held *before* an event, to reduce bottlenecks during meetings and bring them onside when asking industry for concessions.

5.5 Setting

Finally, a feature noted by respondents was the **location of the Sitges meetings**. A pleasant seaside Spanish town, Sitges provided a pleasant ambience for what were at times difficult and confrontational discussions. Branding the series – 'Sitges' – was also beneficial, improving its visibility.

6. Conclusion

This case study has explored the Sitges series of meetings, described their key outcomes, and highlighted key characteristics that could be used in other settings. As an example of advocacy, it reflected the best features of EATG's ECAB model, but adopted a wider remit to ensure that all stakeholders involved in treatment for hepatitis C were included to achieve the goals of the meetings. This successful evolution of the ECAB model may also have offered an opportunity for EATG and other forums already employing the CAB approach to expand and develop their own formats – such as reviewing protocol designs – to enhance the effectiveness of their work.

At its core, the Sitges series was driven by anger and impatience – why was a clear need for people affected by HIV not being addressed?[9] The conduct of the meetings – bridge-building and collaboration – allowed this anger to be channelled into meaningful and productive conversations, that allowed significant progress to be made towards the goals of the Sitges series.

The notion of 'expert patients', long recognised as vital in the HIV sector, continues to gain increasing traction in several areas of medicine.[10] [11] Sitges demonstrated the power of combining two groups of patients/advocates working alongside other key stakeholders towards a shared vision. Using this approach in other contexts is clearly a worthwhile endeavour.

9 As were the HIV CABs, usefully critiqued in: Bereczky T. A discussion of patient involvement in novel forms of knowledge production - a case study of the European Advisory Group on HIV/AIDS. 2011. Available here: https://www.eatg.org/wp-content/uploads/2021/04/the-impatient-patient-a-discussion-of-patient-involvement-ecab-case-study.pdf

10 Porter LD, Goodman KA, Mailman J, Garrett WS. Patient Advocates and Researchers as Partners in Cancer Research: A Winning Combination. Am Soc Clin Oncol Educ Book. 2023;43:e100035.

11 Cordier JF. The expert patient: towards a novel definition. Eur Respir J. 2014;44(4):853-7.

APPENDIX 1: INTERVIEW RESPONDENTS

NAME	AFFILIATION
Giorgio Barbareschi	EATG (Belgium)
Tamás Bereczky	Deutsche AIDS Hilfe (Germany) and EATG
Sanjay Bhagani	Royal Free Hospital, London (UK)
Koen Block	IPPF (Belgium) and EATG
Alessandra Cerioli	LILA (Lega Italiana per la Lotta Contro l'AIDS) (Italy) and EATG
Daniel De Schryver	Janssen
Nikos Dedes	Greek Association of People living with HIV (Greece) and EATG
Theresa Finlay	University of Oxford (UK)
Diego García	Sevilla Checkpoint (Spain) and EATG
Robert James	University of Sussex (UK)
Filip Josephson	Swedish Medical Products Agency
Maxime Journiac	Independent consultant (France)
Luís Mendão	GAT (Portugal) and EATG
Jürgen Rockstroh	University of Bonn (Germany)
Tracy Swan	Independent Consultant (Spain)
Joan Tallada	Independent Consultant (Spain) and EATG
Wim Vandevelde	GNP+ (Belgium/South Africa) and EATG
Brian West	EATG (UK)
Peter Wiessner	Action against AIDS (Germany) and EATG

APPENDIX 2: SITGES STATEMENT [SITGES 1] [2007]

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 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 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-centre 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 therapies in coinfected 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 coinfected 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 avoid 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 coinfected 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 (SVR vs. histological improvement or averting/delaying transplantation). We also support investigation into alternative and complementary therapies for HCV.

We ask that all possibilities are explored for conducting pre-approval studies of HCV therapies in the highest -prevalence population, 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:

- Enrol sufficient numbers of women to yield information on potential gender-specific side effects of new HCV treatments.
- Include TDM in studies of persons with advanced liver disease.
- Accelerate paediatric research.

When possible, trials should include:

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

Research to optimise 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 coinfected people. Organ transplantation, and access to the highest-quality care and treatment, must be provided to HIV-positive and coinfected people throughout Europe.

APPENDIX 3: COMMUNITY DECLARATION [SITGES 7] [2014]

A plan for action: The development of, and community representation in, a European Union (EU)-wide Strategic Action Plan on HIV, Viral Hepatitis, Tuberculosis and STIs that will mobilise, support and augment national agencies and systems.

Support from industry: Pharmaceutical companies must support compassionate use and other for free access programmes; these must be immediately scaled-up to provide unrestricted access to optimal DAA regimens to people in clinical need. These compassionate use to molecules and combinations without market authorisation, need to be in place until the companies apply for national approval and also until the agreements with national health authorities are in place.

Better standard of care: Interferon and first generation protease inhibitors must be eliminated from the standard of care for hepatitis C. Development and use of ribavirin-free regimens should be prioritised and expedited.

Guidelines for clinical care, not reimbursement or rationing: Guidelines for HCV screening, diagnosis and management must focus on clinical and public health benefits of treatment, rather than providing a framework for treatment rationing.

Updated guidelines: HCV treatment guidelines must be updated to include optimal regimens upon their approval.

Continued treatment development and optimisation: Community engagement in the development and optimisation of HCV treatments and formulations must continue. Companies should accelerate development of optimal regimens for paediatric use. Inclusion of people from all marginalised populations in DAA clinical studies including feasibility of new models of treatment delivery must be a high priority.

Real world research: Late phase DAA clinical studies should be conducted in real-life populations, including people who inject drugs. Studies of older HCV treatment report similar adherence and treatment outcomes among people who inject drugs and non-users. Without an evidence base to support treatment in the highest-prevalence population, treatment will continue to be unjustifiably withheld from drug- users.

Prisons: Governments and heath and justice authorities need to provide access to the right to voluntary testing, best prevention and treatment for hepatitis C in prisons.

National community representation: The community must be represented and participate on the boards of national competent authorities in Europe, whose remit it is to determine pricing and indications.

Governments must play a role: Governments across WHO Europe – along with pharmaceutical industry – must prioritise access to the best, most effective HCV treatments at an affordable price through their public health systems in view of elimination in 15 years.

The EU must play a role: The EU must ensure affordable access to the best most effective HCV DAAs in all member state countries and not impede access to WHO Europe nations outside the EU enforcing trade agreement that harm access to health.

Treatment is available where it is needed most: A new strategy must be implemented to provide widespread access to optimal DAA regimens in middle-income countries where the majority of people with HCV live.

Transparent registration timelines: Total transparency and regular updates with timelines for DAA registration and licensing is essential. This includes transparency in regulatory and pricing negotiation between stakeholders.

Simple, affordable diagnostic tests: The development of affordable, rapid, reliable and accurate point of care HCV diagnostics – that can be used in all settings – must be prioritised and expedited.

Ukraine: Ukraine is facing terrible problems including a huge health crisis, namely on HIV, hepatitis and TB where prevalence and incidence are among the highest in Europe. Ukraine needs voluntary licensing agreements with no royalties. Like Eastern Europe, Central Asia, and South Caucasus countries such as Belarus, Moldova and Georgia, Ukraine also needs substantial health aid by the EU and U.S. to save the national health system.

The outcomes of the conference and further progress are continually monitored by the Hepatitis Consultant and the Hepatitis Portfolio members of the EATG. Progress and results will be discussed further at the Sitges VIII Meeting on 2-4 October 2015.

European
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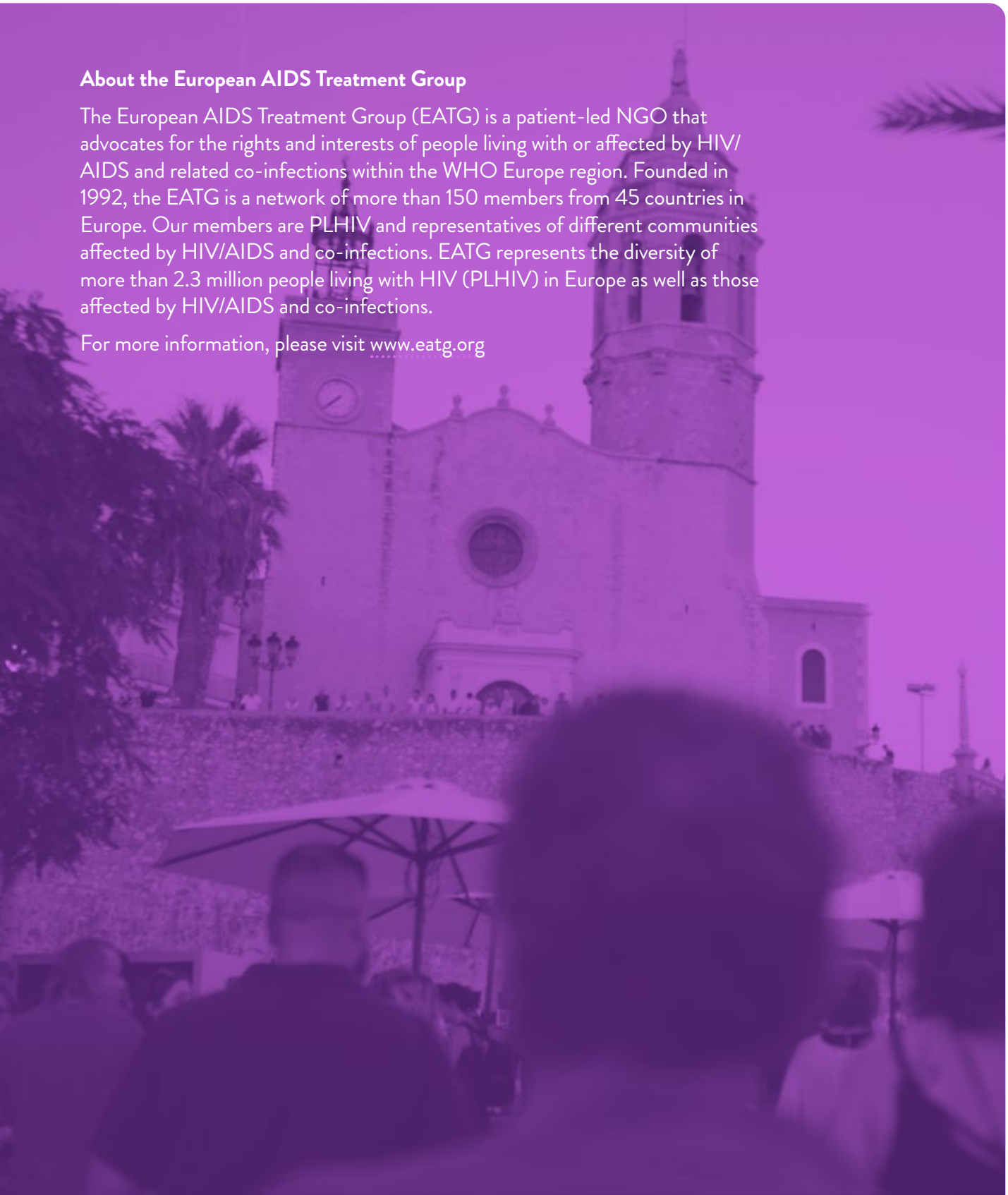

About the European AIDS Treatment Group

The European AIDS Treatment Group (EATG) is a patient-led NGO that advocates for the rights and interests of people living with or affected by HIV/AIDS and related co-infections within the WHO Europe region. Founded in 1992, the EATG is a network of more than 150 members from 45 countries in Europe. Our members are PLHIV and representatives of different communities affected by HIV/AIDS and co-infections. EATG represents the diversity of more than 2.3 million people living with HIV (PLHIV) in Europe as well as those affected by HIV/AIDS and co-infections.

For more information, please visit www.eatg.org