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

EATG European AIDS Treatment Group

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From Exclusion to Inclusion

Developing Evidence - Based Guidance to Include People Living with HIV in Non-HIV Clinical Trials Through a Community-Lead and Multi - Stakeholder Process

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WHY WE ARE ADVOCATING FOR CHANGE AND HOW WE DID IT

Why This Guidance is Needed

ART has transformed HIV into a manageable chronic condition. People living with HIV are living longer and increasingly experience non-HIV-related conditions such as cardiovascular disease, chronic kidney disease, cancer, diabetes, osteoporosis, and neurocognitive disorders, often earlier and with worse outcomes than the general population.

Yet they are frequently excluded from the clinical trials addressing these very conditions. In many cases, no scientific justification is provided. Risk-mitigation strategies are rarely explored before exclusion is applied.

The consequences are serious:

- Safety and efficacy data for this population remain limited.
- Access to new therapies is delayed or denied.
- Existing health inequities are deepened.

Research has shown that inclusion is safe and feasible in many cases. The EATG first addressed this in a 2022 position paper. This guidance builds on that foundation.

Read the position paper

How the Guidance Was Developed

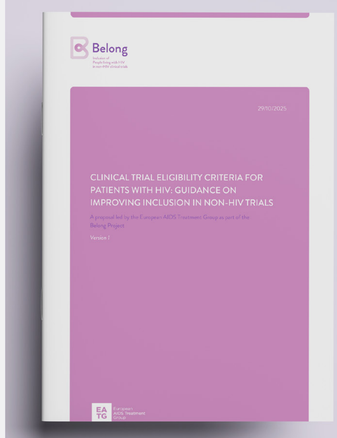
The guidance was developed between July and October 2025 through a structured, community-led, multi-stakeholder process.

At every stage, the active involvement of people living with HIV was prioritised.

The process included:

- A desk review of the scientific literature.
- A stakeholder map covering academia, clinical research, industry, patient advocacy groups, professional organisations, community-based organisations, and NGOs.
- Consultation with ten pharmaceutical companies on their current practices, priorities, and challenges.
- Draft recommendations published for public consultation in August 2025.
- A virtual multi-stakeholder consultation in October 2025, with experts in advocacy, industry, clinical research, and subject-matter specialisation.

A Community Advisory Group provided input throughout, ensuring that lived experience shaped both the process and its outcomes.



Read the Guidance

PRINCIPLES OF THE GUIDANCE

The Core Principle

Guidance 1

Inclusion should be the default. Exclusion must be justified, documented, and proportionate to a clearly identified risk.

Standardised protocol templates must not be used without justification. Where concerns exist, risk-mitigation strategies such as enhanced monitoring, ART adjustment, management of drug-drug interactions, should be prioritised over exclusion.

Participation of people living with HIV must be systematically recorded, with data handling meeting ethical and regulatory standards.

Confidentiality is especially important given persistent HIV-related stigma.

People and Systems

Guidances 9, 10

Inclusion requires more than revised protocols. It requires people and systems to be ready.

Community engagement (G9): people living with HIV should be involved proactively, from the earliest stages of trial design, even where inclusion in Phase 1 is not yet feasible.

Early engagement builds trust and improves the relevance and acceptability of research.

The HIV community has a long record of meaningful engagement and should be given opportunities to contribute to non-HIV research.

Training and capacity building (G10): exclusion is partly driven by a lack of awareness among non-HIV researchers and healthcare professionals. Sponsors must inform investigators that people living with HIV can participate safely.

Mandatory data collection and reporting on inclusion will help track progress.

Evaluating the Participant

Guidances 4, 5, 6

HIV status alone should never determine eligibility. Assessment should be based on the individual's clinical profile.

Clinical status (G6): Four parameters should be evaluated case by case:

- History of AIDS-defining illness: resolved past illness should not preclude participation. A 12-month period since resolution is a reasonable threshold.
- Immune function: CD4+ count ≥350 cells/μL on suppressive ART generally supports eligibility. Thresholds must not be used as automatic exclusion criteria.
- ART: virological suppression should be the standard. Viral blips and nadir CD4+ count should not trigger automatic exclusion.
- Comorbidities: HIV should be managed like any other comorbidity, not used as grounds for exclusion.

HIV testing (G5): should not be a routine eligibility requirement. Where offered, it should be part of a broader blood-borne infection strategy and must minimise stigma.

Diversity (G4): eligibility criteria must account for the full diversity of people living with HIV across gender, age, geography, and social determinants of health.

Contextualising the Trial

Guidances 2, 3, 7, 8

The trial itself, its product, health condition, stage, and design, determines what is appropriate.

Investigational product (G2): the mechanism of action, existing safety data, and potential drug-drug interactions with ART must be assessed. A temporary ART switch should be considered before exclusion is applied.

Health condition under investigation (G3): where a health condition disproportionately affects people living with HIV, their inclusion should be the default, not the exception.

Development stage (G7): exclusion may be justified in Phase 1, where the focus is on safety. From Phase 2 onwards, inclusion should be the norm.

Trial design (G8): where phased inclusion is needed, protocols should build in flexibility from the outset. Staggered inclusion, HIV stratification, subgroup estimands, and adaptive eligibility criteria are all practical options.

Risk mitigation runs across all four themes: the question is not whether to include, but how to include safely.

HOW WE CAN DO IT

Community

- Advocate for the right of people living with HIV to participate in clinical research that may benefit their treatment and care.
- Engage with commercial and non-commercial trial sponsors to highlight the value of inclusive research.
- Contribute to the design and implementation of non-HIV clinical trials from an early stage.
- Participate in educational programmes that build awareness of diversity and inclusion in research.

Sponsors

- Revise eligibility criteria to replace arbitrary exclusions with documented, risk-based assessments.
- Assess drug-drug interactions with ART using available tools before applying exclusion criteria.
- Explore temporary ART switches or managed treatment interruptions as alternatives to exclusion.
- Proactively inform investigators and research staff that people living with HIV can participate safely in non-HIV trials.
- Collaborate to develop evidence-based guidelines for conditions that disproportionately affect people living with HIV.

Regulators

- Require explicit scientific justification for the exclusion of people living with HIV in trial protocols.
- Uphold ethical principles on the fair distribution of research benefits during protocol review.
- Ensure implementation of ICH guidelines recommending inclusion of populations representative of those who will use the product in practice.
- Encourage scrutiny of exclusion criteria at both national and supranational levels.
- Mandate collection and reporting of data on the inclusion of people living with HIV in non-HIV trials.

All Stakeholders

- Foster collaboration between people living with HIV, regulatory agencies, and trial sponsors throughout the drug development process.
- Track the participation of people living with HIV in non-HIV clinical research to understand progress and identify gaps.
- Build trial teams' capacity to manage HIV as a comorbidity, including ART management and drug interaction assessment.
- Ensure that people living with HIV are engaged in research preparedness activities from the earliest stages, regardless of trial phase.

CONCLUSION

The arbitrary exclusion of people living with HIV from non-HIV clinical trials is largely avoidable.

This guidance offers a practical, evidence-based framework to improve the participation of people living with HIV in non-HIV trials. Its core message is simple: inclusion should be the default. Exclusion must be justified, documented, and proportionate to a clearly identified risk.

The changes required are achievable now. Sponsors and investigators can revise eligibility criteria. Ethics committees and regulators can require explicit scientific justification for exclusion. Trial teams can build in risk-mitigation strategies before resorting to exclusion. Communities of people living with HIV can be engaged from the earliest stages of trial design.

No single stakeholder can drive this change alone. Progress requires coordinated action across industry, academia, regulators, and civil society. This guidance provides the tools to start.

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