

# Development of Two Versions of a Patient Reported Outcome Measure to Evaluate Participant Experience and Satisfaction During the Intervention and Analytical Treatment Interruption Periods of Cure-Related and Other HIV Trials

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## Conclusions

- Content validation through cognitive debriefing indicated that both versions of the Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV were valid patient-reported outcome measures to assess the experiences and satisfaction of people with HIV regarding HIV cure–related research interventions and analytical treatment interruptions
- Overall, people with HIV interpreted the questionnaires as intended, but several revisions to questionnaire items were identified to improve interpretability and clarity**
- Two versions of the questionnaire, specific to either the intervention or analytical treatment interruption period, will be psychometrically validated during cure-related and other HIV trials

## Plain Language Summary

- Studies focused on an HIV cure or antiretroviral treatment–free control might include a planned break from HIV medicine, known as an “analytical treatment interruption”
- While analytical treatment interruptions are important to assess HIV cure–related research interventions, they may also lead to increased levels of HIV in participants, which can increase the chance of transmission, as well as have psychosocial impacts
- The Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV is being developed to better understand the experiences and satisfaction of people with HIV during HIV clinical studies and during periods when HIV medicines are stopped, as well as the potential psychosocial impacts of HIV cure–related research interventions
- This study looked at whether people with HIV found the questions and instructions easy to understand and whether they interpreted them as intended
- Most people thought the questions and instructions were clear and made sense, and feedback was provided to help improve the questionnaire before testing it further

## Introduction

- Clinical trials that incorporate analytical treatment interruptions (ATIs) are important for assessing potential HIV cure regimens in people with HIV (PWH) but can pose risks, such as viral rebound and psychosocial impacts, that may deter PWH from participating in the clinical trials<sup>1,2</sup>
- Upon review of the literature and existing patient-reported outcome measures (PROMs), a need was identified for a PROM that captures the experiences and satisfaction of PWH during both the intervention and ATI phases of HIV clinical trials
- To address this gap, 2 versions of the Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (QUEST-HIV) were developed; the QUEST-HIV-I evaluates the HIV cure–related research intervention period, and the QUEST-HIV-ATI evaluates the ATI period (**Table 1**)
- The development and content validation of the 2 versions of the QUEST-HIV are reported here, with further assessment and validation planned

Table 1. QUEST-HIV at a Glance<sup>a</sup>

QUEST-HIV-I	QUEST-HIV-ATI
<b>Objective:</b> intended to be completed by PWH during an <b>active intervention period</b>	<b>Objective:</b> intended to be completed by PWH during an <b>ATI period</b>
<b>Recall:</b> 7 days	<b>Recall:</b> 7 days
<b>Number of items:</b> <b>22</b>	<b>Number of items:</b> <b>24</b>
<b>Response options:</b> 5-point verbal descriptor scales (not at all–extremely, very satisfied–very dissatisfied)	<b>Response options:</b> 5-point verbal descriptor scales (not at all–extremely, <b>completely–not at all</b> , very satisfied–very dissatisfied)
<b>Item topics (n)</b>	<b>Item topics (n)</b>
Experience with <b>study intervention period (8)</b>	Experience with <b>ATI observational period (14)</b>
Satisfaction with <b>study intervention period (8)</b>	Satisfaction with <b>ATI observational period (4)</b>
Experience with site, study logistics, and staff (3)	Experience with site, study logistics, and staff (3)
Overall satisfaction (3)	Overall satisfaction (3)

<sup>a</sup>Bolding denotes differences between the QUEST-HIV-I and the QUEST-HIV-ATI. ATI, analytical treatment interruption; PWH, people with HIV; QUEST-HIV-ATI, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Analytical Treatment Interruption); QUEST-HIV-I, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Intervention).

## Objective

- To develop and content validate the 2 versions of the QUEST-HIV to assess the experiences and satisfaction of PWH during the intervention (QUEST-HIV-I) and ATI (QUEST-HIV-ATI) phases of clinical trials

## Methods

- To guide the development of the QUEST-HIV, we reviewed the literature and existing PROMs assessing patient experiences and satisfaction
- The QUEST-HIV-I included questions related to experiences and satisfaction with the HIV cure–related research intervention, whereas the QUEST-HIV-ATI included questions related to experiences and satisfaction with not receiving any HIV medications during an ATI (**Table 1**)
  - Both versions of the QUEST-HIV had a 7-day recall period, with each item assessed on a 5-point verbal descriptor scale
- A PWH advocate and 3 external disease experts reviewed the original drafts of both versions of the questionnaire
  - Based on their feedback, we refined the drafts by adding items to assess the impact of the intervention or ATI on partners of PWH and to capture the satisfaction of PWH with how they are monitored during an ATI
- We then evaluated the refined questionnaire to confirm content validity, clarity, and appropriateness through structured, 90-minute cognitive debriefing interviews conducted virtually with 14 PWH in the United States between March and June of 2025
  - PWH were recruited to ensure diversity in age, sex, gender, race/ethnicity, education, and treatment experience; PWH were ≥18 years of age and currently on antiretroviral therapy
- Interviewers used a conversational, think-aloud method, in which they encouraged PWH to verbalise their thoughts while completing the QUEST-HIV to assess comprehensibility and clarity, as well as whether the recall period and response options were appropriate
- We analysed transcripts of completed interviews using MAXQDA (v22.6.0 or higher) to identify potential issues with the content, language, structure, and format of the QUEST-HIV

## Results

### Study Population

- Characteristics of PWH who participated in the cognitive debriefing interviews are summarised in **Table 2**

### Overview of Cognitive Debriefing Results

- Among the 19 PWH who participated in the interviews, 14 cognitively debriefed the QUEST-HIV-I and 10 cognitively debriefed the QUEST-HIV-ATI
- All instructions and most items from both versions of the QUEST-HIV were interpreted as intended and clear (**Table 3** and **Figure 1**)
  - Item 10 from the QUEST-HIV-I was reported as unclear by 4 of 13 PWH (31%) with evaluable data due to the use of “modes,” with suggestions to revise to “types” or “doses” or to specify the modes of medication (**Figure 2**)
  - Item 9 from the QUEST-HIV-ATI was misinterpreted by 2 of 10 PWH (20%) with evaluable data due to issues with understanding what the central concept of “feeling closer to how one did pre–HIV diagnosis” meant (**Figure 3**)
  - Items 11 and 12 from the QUEST-HIV-ATI were reported as unclear by 2 of 10 PWH (20%) with evaluable data due to the broadness of the concept of “feeling happy” and the use of “partner,” with suggestions to use the term “HIV-negative person” instead (**Figure 3**)
- Proposed revisions based on feedback from PWH are summarised in **Figures 2** and **3**
  - Revisions included reordering items to help with interpretation and rephrasing items to clarify the meaning of central concepts

Table 2. Characteristics of PWH

Characteristic, n (%)	Recruitment Goal (%)	PWH (N = 19) <sup>a</sup>
<b>Sex assigned at birth</b>		
Male	≥50	14 (73.7) ✓
Female	≥25	5 (26.3) ✓
<b>Gender</b>		
Nonbinary/transgender	≥10	1 (5.3) ⚠
<b>Age, y</b>		
18–24	≥10	1 (5.3) ⚠
25–34	≥30	5 (26.3) ⚠
35–44	≥20	3 (15.8) ⚠
≥45	≥20	10 (52.6) ✓
<b>Race</b>		
African American	≥40	8 (42.1) ✓
White	≥30	10 (52.6) ✓
<b>Ethnicity</b>		
Hispanic/Latino(a)	≥15	6 (31.6) ✓
<b>Highest education level</b>		
High school diploma or less	≥20	6 (31.6) ✓
<b>Treatment burden<sup>b</sup></b>		
VS on a single-tablet regimen	≥33	12 (63.2) ✓
VSTE on a complex regimen	≥10	2 (10.5) ✓
HTE	≥6.7	2 (10.5) ✓

Key: ✓, goal met; ⚠, goal partially met.  
<sup>a</sup>Due to time constraints, 14 PWH completed the cognitive debriefing interview for the QUEST-HIV-I and 10 PWH completed the cognitive debriefing interview for the QUEST-HIV-ATI.  
<sup>b</sup>Treatment burden categories VSTE and HTE were defined by criteria provided by Gilead Sciences, Inc.; participants could be counted in multiple treatment burden categories.  
HTE, heavily treatment experienced; PWH, people with HIV; QUEST-HIV-ATI, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Analytical Treatment Interruption); QUEST-HIV-I, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Intervention); VS, virally suppressed; VSTE, virally suppressed treatment experienced.

Table 3. Interpretation and Clarity of the QUEST-HIV-I and QUEST-HIV-ATI

Instructions/Item	QUEST-HIV-I		QUEST-HIV-ATI	
	Interpretation	Clarity	Interpretation	Clarity
<b>Instructions (overall experience)</b>				
Item 1 (concern about viral load)	✓	✓	✓	✓
Item 2 (concern about side effects)	✓	✓	–	–
Item 2 (concern about lingering side effects)	–	–	✓	✓
Item 3 (preoccupied with HIV status)	✓	✓	✓	✓
Item 4 (concern about keeping up with the study intervention)	✓	✓	–	–
Item 4 (concern about keeping up with the clinical study)	–	–	✓	✓
Item 5 (emotional instability)	✓	✓	✓	✓
Item 6 (worry about viral rebound)	✓	✓	✓	✓
Item 7 (worried about HIV status disclosure due to medication)	✓	✓	–	–
Item 7 (worried about HIV status disclosure due to clinical study)	–	–	✓	✓
Item 8 (worried about transmission)	✓	✓	✓	✓
<b>Instructions (satisfaction with study intervention period)</b>				
Item 9 (convenience)	✓	✓	–	–
Item 9 (feel closer to before diagnosis)	–	–	⚠	✓
Item 10 (frequency of multiple modes of medication)	✓	✗	–	–
Item 10 (improve self-esteem)	–	–	✓	✓
Item 11 (multiple modes of medicines)	✓	✓	–	–
Item 11 (feel happy)	–	–	✓	⚠
Item 12 (study intervention injections)	✓	✓	–	–
Item 12 (improve communication with partner)	–	–	✓	⚠
Item 13 (study IV infusions)	✓	✓	–	–
Item 13 (positively impact relationship status)	–	–	✓	✓
Item 14 (study pills)	✓	✓	–	–
Item 14 (positively impact sex life)	–	–	✓	✓
Item 15 (amount of pain or discomfort)	✓	✓	–	–
Item 15 (daily HIV medicines)	–	–	✓	✓
Item 16 (number of medicines)	✓	✓	–	–
Item 16 (remain undetectable)	–	–	✓	✓
<b>Instructions (experience with site, study logistics, and staff)</b>				
Item 17 (communication with site staff)	✓	✓	–	–
Item 17 (frequency of monitoring)	–	–	✓	✓
Item 18 (amount of time required)	✓	✓	–	–
Item 18 (satisfaction with monitoring process)	–	–	✓	✓
Item 19 (logistics)	–	✓	✓	✓
Item 20 (overall satisfaction with study intervention)	✓	✓	–	–
Item 21 (impact of study intervention on relationship)	✓	✓	✓	✓
Item 22 (overall satisfaction with ATI period)	–	–	✓	✓
Item 23 (satisfaction on relationships)	–	–	✓	✓
Item 22/24 (overall satisfaction with clinical study)	✓	✓	✓	✓

Key: ✓, misinterpreted or reported as unclear by <20% of PWH who provided evaluable data; ⚠, misinterpreted or reported as unclear by 20% to 30% of PWH who provided evaluable data; ✗, misinterpreted or reported as unclear by >30% of PWH who provided evaluable data. ATI, analytical treatment interruption; IV, intravenous; PWH, people with HIV; QUEST-HIV-ATI, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Analytical Treatment Interruption); QUEST-HIV-I, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Intervention).

Figure 1. Representative Feedback Confirming the Content Validity of the QUEST-HIV (Both Versions)

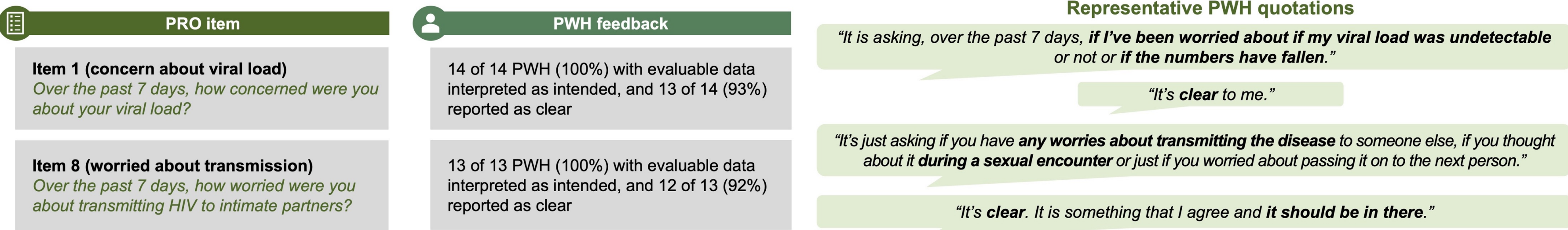
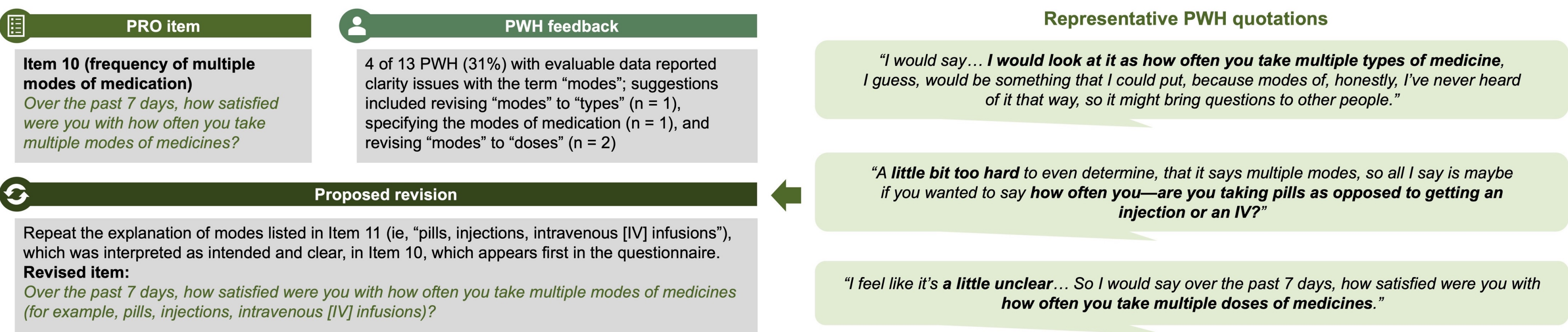
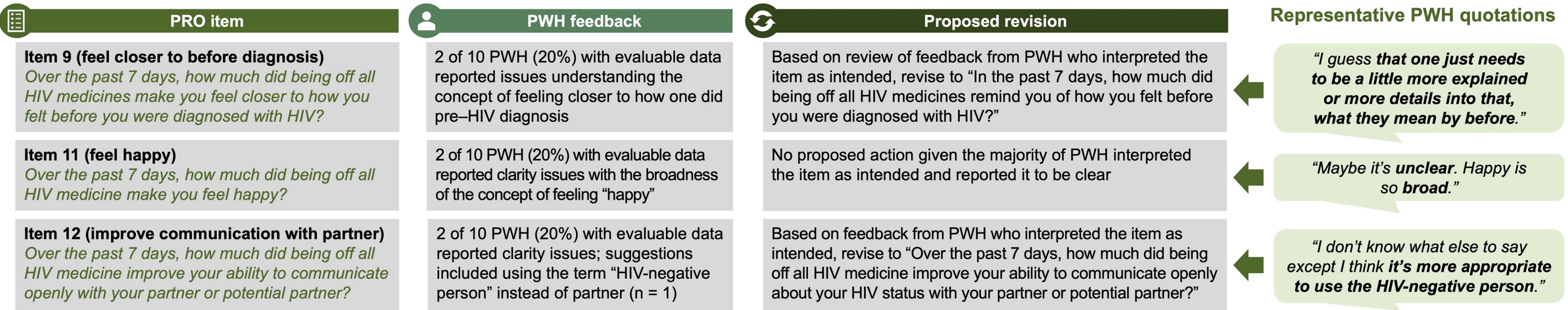


Figure 2. Summary of Feedback on and Revisions to the QUEST-HIV-I



IV, intravenous; PRO, patient-reported outcome; PWH, people with HIV; QUEST-HIV-I, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Intervention).

Figure 3. Summary of Feedback on and Revisions to the QUEST-HIV-ATI



PRO, patient-reported outcome; PWH, people with HIV; QUEST-HIV-ATI, Questionnaire to Understand the Experiences and Satisfaction in a Trial in HIV (Analytical Treatment Interruption).

**References:** 1. Jung B, et al. *Lancet HIV*. 2019;6:e259-68. 2. Dubé K, et al. Presented at: International Society for Pharmacoeconomics and Outcomes Research (ISPOR); 13-16 May 2025; Montreal, QC, Canada. Poster PCR126.

**Acknowledgements:** This study was funded by Gilead Sciences, Inc. We extend our thanks to the participants, their families, and all participating investigators. Medical writing and editorial support were provided by Katherine Townsend, PhD, of Lumanity Communications Inc., and were funded by Gilead Sciences, Inc.

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**Disclosures:** KD provides advisory services to Gilead Sciences, Inc., and Merck & Co., Inc., Rahway, NJ, USA; and previously provided advisory services to AbbVie Inc. and Viiv Healthcare. SS-M, KP, CB, and JJ are stockholders and employees of Gilead Sciences, Inc. MD received travel grants or honoraria from Gilead Sciences, Inc., MSD, and Viiv Healthcare. MG, KV, HS, and IW are employees of Lumanity Patient-Centered Outcomes.