Structural equation modelling of patient satisfaction with isatuximab administration: perceived time savings and a latent injection experience construct independently predicted satisfaction

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James C Marcus[1], Donald Stull[2], Alexia Tellier[3], Maeva Kyheng[4], Perman Gochyyev[5], Jérôme Msihid[3], Maya Stefanova-Urena[5], Florence Suzan[6], Benoit Arnould[7]

[1]IQVIA, Washington, DC, USA; [2]IQVIA, Port Townsend, WA, USA; [3]Sanofi, Gentilly, France; [4]Aixial Group, Boulogne-Billancourt, France; [5]Sanofi, Morristown, NJ, USA; [6]Sanofi, Vitry-sur-Seine, France; [7]Sanofi, Lyon, France

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Background

- IRAKLIA was a randomised, non-inferiority Phase 3, open-label study (NCT05405166) evaluating subcutaneous (SC) versus intravenous (IV) administration of isatuximab in combination with pomalidomide and dexamethasone (Pd) in adults with relapsed and/or refractory multiple myeloma (RRMM)[1].
- A 9-item Patient Experience and Satisfaction Questionnaire Follow-Up (PESQ-FU) was developed according to FDA guidance to focus in part on patient satisfaction with the method of administration (Item 8).
- PESQ-FU was incorporated in the IRAKLIA study with the key secondary objective of assessing patient satisfaction with isatuximab SC compared to the IV endpoint at Cycle 5 Day 15 (C5D15), in a 28-day cycle. Item 8 asks patients to rate their satisfaction with their injection method using a 5-point Likert scale (very satisfied to very dissatisfied).
- At C5D15, 70.0% of participants in the intent-to-treat (ITT) population receiving isatuximab SC (*n* = 263) versus 53.4% receiving isatuximab IV (*n* = 268) reported being satisfied or very satisfied with the injection method.

Objective

To use structural equation modelling (SEM) to evaluate whether injection-method satisfaction reflected distinct contributions from perceived time saved and a latent Injection Experience construct.

Method

- SEM, a statistical framework that simultaneously evaluates how observed measures reflect underlying constructs and how model variables are related, was used to examine relationships among selected PESQ-FU items in the IRAKLIA ITT population at C5D15.
- The model was guided by conceptual rationale, prior psychometric findings, and predictors identified in the ordinal logistic regression analysis.
- The estimated SEM is presented in **Figure 1**. Injection Experience was modelled as a 3-item latent construct measured by:
  - Discomfort (Item 1)
  - Pain (Item 2)
  - Injection side effects (Item 4)
- Perceived time saved (Item 5) was modelled as a separate observed variable and allowed to correlate with Injection Experience. Injection satisfaction (Item 8) was modelled as the observed endogenous outcome predicted by the latent variable Injection Experience and perceived time saved.
- Factor loadings (λ) were estimated to evaluate the relationships between the indicators and the latent construct, and standardised path coefficients (β) were used to compare the magnitude of associations within the model.
- Model fit was assessed using standard fit indices: comparative fit index (CFI), Tucker-Lewis Index (TLI), root mean square error of approximation (RMSEA), and standardised root mean square residual (SRMR).

Results

Patient characteristics

- A total of 531 participants were enrolled in the ITT population from the IRAKLIA study (isatuximab-IV+Pd arm [*n* = 268] and isatuximab-SC+Pd arm [*n* = 263]).
- Among the 436 participants continuing on treatment at Cycle 5,392 completed the questionnaire at C5D15.
- Median responses were 4 for each 1−5 experience item and 3 for injection satisfaction on the recoded 1−4 scale.

Table 1. Descriptive statistics for PESQ-FU model variables at C5D15

Variable	Mean (SD)	Median
PESQ-FU Item 1. Injection method – Discomfort	3.69 (1.09)	4.00
PESQ-FU Item 2. Injection method – Pain	3.92 (0.93)	4.00
PESQ-FU Item 4. Injection method – Side effects	3.76 (0.96)	4.00
PESQ-FU Item 5. Injection method – Perceived time saved	3.63 (1.07)	4.00
PESQ-FU Item 8. Injection method – Satisfaction	3.15 (0.73)	3.00

Note(s). The SEM included 392 participants with complete PESQ-FU data for the five model variables at C5D15. Higher scores indicate more favourable responses. Discomfort, pain, injection-related side effects, and perceived time saved were analysed on 1–5 scales; injection satisfaction was analysed on a 1–4 scale after the two least favorable response categories were combined. Items 3, 6 and 7 of the PESQ-FU (related to treatment side effects, worth taking, and overall treatment satisfaction) were not included, as they were not relevant to the objective of the analysis, which focused on satisfaction with the administration method.
C5D15, Cycle 5 Day 15; PESQ-FU, Patient Experience and Satisfaction Follow-up Questionnaire; SD, Standard deviation.

Goodness-of-Fit Statistics

- Fit indices of SEM indicated very good model fit: CFI and TLI ≥0.95 and SRMR and RMSEA ≤0.08. (**Table 2**)

Table 2. Global fit statistics for the SEM at C5D15

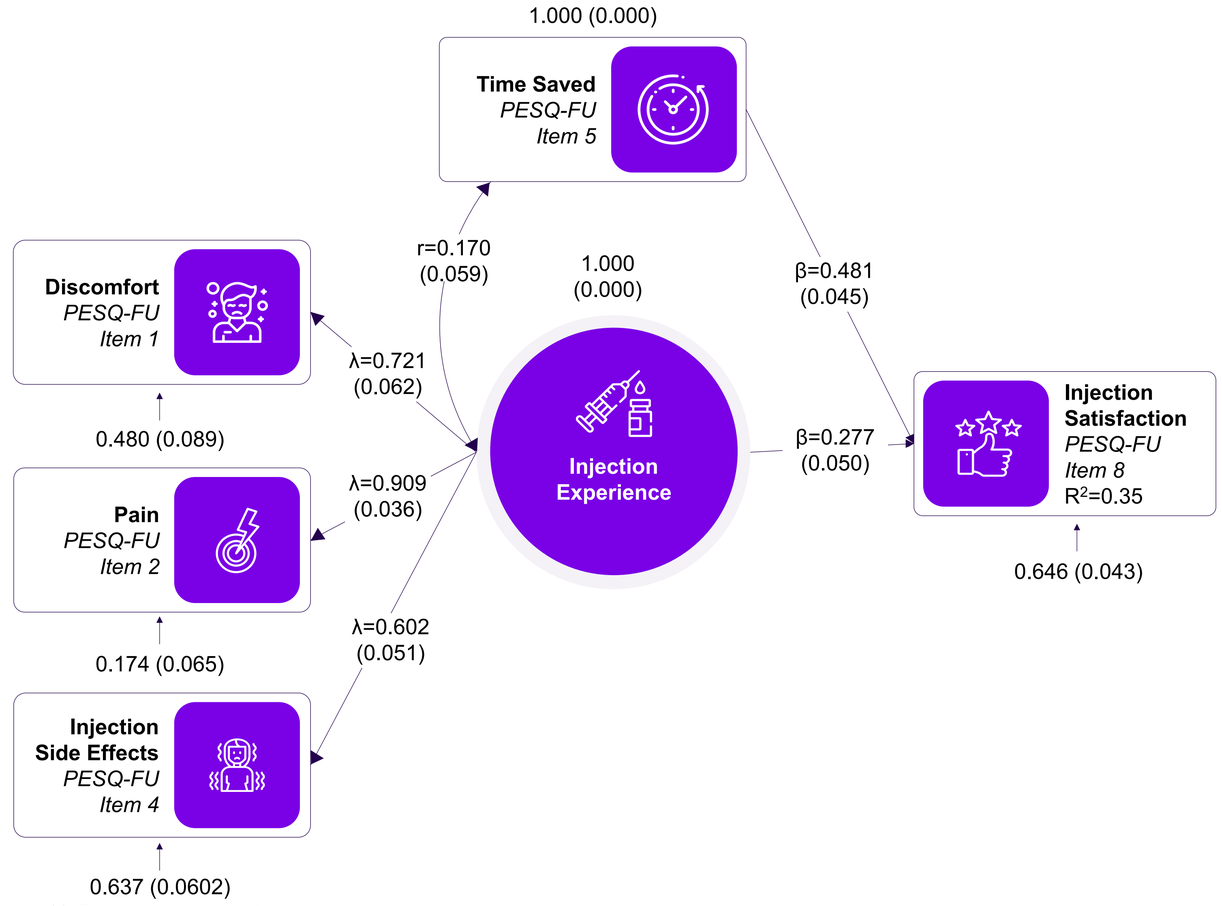
Fit domain	Statistic	Value
RMSEA	Estimate	0.020
	90% CI	0.000 – 0.081
	Prob. RMSEA ≤ 0.05	0.72
CFI/TLI	CFI	0.998
	TLI	0.994
SRMR	Estimate	0.014

Note: Fit indices were interpreted collectively; values of CFI and TLI≥ 0.95 and SRMR and RMSEA ≤0.08 indicate good or acceptable fit.
CFI, Comparative fit index; CI, Confidence interval; RMSEA, Root mean square error of approximation; SEM, structural equation modelling; SRMR, Standardised root mean square residual; TLI, Tucker–Lewis Index.

Standardised path coefficients

- Standardised factor loadings (λ) supported the Injection Experience construct: pain, 0.909; discomfort, 0.721; and injection-related side effects, 0.602. (**Figure 1**)
- Perceived time saved and Injection Experience were weakly correlated (r=0.170, p=0.004), supporting their interpretation as related but distinct aspects of the administration experience. Each independently predicted injection satisfaction (β=0.481 and 0.277, respectively; both p<0.001), with perceived time saved showing the stronger association. Together, they explained 35% of the variance in satisfaction (**Figure 1**).

Figure 1. Path diagram of the SEM with standardized estimates at C5D15



Note(s): The analysis included 392 participants with complete data for the five model variables. Standard errors are presented in parentheses.
C5D15, Cycle 5 Day 15; PESQ-FU, Patient Experience and Satisfaction Follow-up Questionnaire; SEM, Structural equation modelling.

Limitations

- Satisfaction was assessed using a single ordinal item (PESQ-FU Item 8), limiting the evaluation of its measurement properties relative to a multi-item scale.
- The favourable satisfaction response distribution restricted variability and may have affected the estimated associations.
- The cross-sectional analysis supports associations but does not establish causal relationships.

Conclusions

- SEM indicated that patient satisfaction with isatuximab administration reflected independent contributions from perceived time saved and the latent Injection Experience construct.
- Perceived time saved showed a stronger independent association with satisfaction, while pain, discomfort, and injection-related side effects cohered as a distinct experience construct.
- These findings support the importance of considering convenience alongside local injection tolerability when interpreting patient-reported satisfaction with treatment administration.
- These findings highlight the value of assessing administration-related convenience alongside efficacy, safety, and tolerability in oncology trials.

References
1. Ailawadhi S., *et al*., *J Clin Oncol*. 2025;43:2527–2537.

Conflicts of Interest
AT, PG, JM, MSU, FS and **BA** are employees of Sanofi and may hold stock or stock options.
JCM and **DS** are employees of IQVIA, and **MK** is an employee of Aixial Group, both of which received funding from Sanofi for this research.

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