

PAAB Tags and CEI 2024

QUARTERLY REVIEW

A Quarterly Review of the eFiles Customer Experience Index (CEI)

The CEI Survey launched on February 13, 2023. This review of the CEI data accounts for the data captured between **October 1 – December 31, 2024.**

148

Completed Surveys

October 1 to December 31, 2024.

Averages of the CEI question survey results by question:

1. Staff connected with this eFile (e.g., file coordinators, reviewers, senior reviewers, etc.) were helpful and responsive

4.5/5

Indicating an average response between “Agree” and “Strongly Agree”

2. Comments and suggestions in response letters, calls and messenger were clear and actionable.

4.4/5

Indicating an average response between “Agree” and “Strongly Agree”

3. I felt the review was:

1. Highly inconsistent
2. Somewhat inconsistent
3. Somewhat consistent
4. Highly consistent
5. I don't know

3.8/4*

Indicating an average response between “Somewhat consistent” and “Highly Consistent”

*This average rating is calculated from Responses 1-4 as including ratings of 5 (or “I don't know”) would have skewed the average upward. There were 4 ratings of “I don't know” in this data set.

4. Please provide any other feedback specific to this file:
[optional open text field]

See feedback themes below.

5. Please rate your overall experience with this particular review

8.8/10

- 1 – highly negative experience
10 – highly positive experience

Indicating a positive average overall experience.

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Key Themes and Actions Taken from Open-text Feedback:

1. **Clear and Actionable Feedback (n=7).** Some clients reported that it would be helpful if comments from reviewers were more specific and actionable (n=2). In the other instances, the comment from the reviewer was felt to be vague resulting in additional rounds of comments to clarify the initial request (n=3). Other clients reported receiving clear and actionable feedback (n=2).

Action Taken: Reviewers have been reminded to provide as much specificity as possible when commenting and to provide examples and suggestions when possible and where appropriate.

2. **Appreciation for quick reviews and helpful interactions with reviewers (n=3).** Comment highlighted positive experiences with the speed of the review process as well as helpful interactions with reviewers and file coordinators. This is extremely helpful for providing positive feedback to the team about what clients are finding particularly helpful.

Action Taken: Reviewers were provided a summary of key features that resulted in a positive experience for clients with the goal of reinforcing these behaviours.

Key Takeaways:

- Survey Completion Rate is 22.2%, with this data capturing 148 responses out of 519 surveys sent. Data should be interpreted with this in mind, as this is a relatively low sample size.
- Ratings for all questions, on average, have been positive. This data set is reflective of the complete quarter. Results have remained generally positive and consistent with the data from all quarters of 2023.

Did you know? Now you can forward your CEIs to non-eFiles users for completion. In response to feedback that not all team members have eFiles accounts, we have updated our systems to allow the most appropriate team member to complete the CEI regardless of whether or not they have an eFiles account. Simply forward the CEI invitation to the appropriate team member and they can complete it. Please note that the survey can only be completed once.

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We continue to encourage you to be as specific as possible when providing feedback in order to help us best understand your experience with PAAB and create a meaningful action-plan to improve or disseminate best practices. Thank you for your continued participation in the CEI surveys!

Confidence in confidentiality

As a reminder, client tags trigger internal audits for validation by PAAB's Director of Pre-clearance Services, Yin Man. Any tags pertaining to Yin are validated by the Commissioner and removed from the report provided to Yin. No Reviewer or Senior Reviewer is EVER aware of tags generated by clients. The CEI Surveys follow the same processing flow. You can be confident in the confidentiality of the tagging system and CEI Surveys. For additional reassurance, the tagging system, tag assessments, and documented actions taken will periodically be reviewed by an external auditor.

If you'd like to learn more about the client tagging system, check out the [Client Tagging System Advisory](#). You'll also find links to useful videos on [tagging a review](#) and [tagging phone calls](#).

If you'd like to learn more about CEIs, see [Customer Experience Index](#).

A Quarterly Review of the eFiles Tag Report

Total number of submissions*

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2304	2467	2147	1940

*Refers to unique eFiles. This number does not account for iterations within each file.

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
13	14	19	15

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Tag submitting company and manufacturer distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
3 & 1	7 & 0	6 & 1	3 & 0

Therapeutic area distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4 Immunology	5 Biologic/ Immunomodulator	6 Pulmonary	8 Biologic/ Immunomodulator
2 Neurology	4 Gastrointestinal	4 Infection & Infestation	5 Other
2 Vaccine	2 Vaccine	3 Immunology	1 Vaccines
2 Dermatology	2 Oncology	2 Obstetrics & Gynaecology	1 Oncology
1 Gastrointestinal	1 Women's Health	1 Psychiatric	
1 Endocrine and Metabolic	1 Other	1 Endocrine & Metabolic	
1 Cardiovascular		1 Oncology	
		1 Dermatology	

Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4	5	7	6

Validated tag breakdown

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2 New issue raised late in the review	3 Particularly helpful comment	2 New issue raised late in the review	1 Issue with level of expertise

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1	<i>Inconsistencies with historic approvals for the same brand</i>	1	<i>Consider changing the code guidance</i>	2	<i>Particularly helpful comment</i>	1	<i>Inconsistent with code guidance</i>
1	<i>Particularly helpful comment</i>	1	<i>Inconsistent with code guidance</i>	1	<i>Inconsistencies with historic approvals for the same brand</i>	1	<i>Inconsistencies with historic approvals for another brand</i>
				1	<i>Requested revision was unclear</i>	1	<i>Consider changing PAAB process/procedure</i>
						1	<i>Particularly helpful comment</i>

Q4 PAAB Action Taken:

We adjusted an incorrect tag to a more appropriate one: *Consider changing PAAB process/procedure*. The issue stemmed from the client’s preference for a suggested revision to help address the concern earlier in the review process. While PAAB staff aren’t expected to be copywriters, we encourage them to provide suggestions when possible and collaborate with their therapeutic teams to brainstorm copy corrections.

Internally, we continue to present weekly cases for discussion on new guidances such as burden of disease, RWE, and creative cases. Our hope is that this creates greater alignment across reviews, therapeutic categories, and brands.

Not all valid tags trigger office-wide action. When beneficial for the team and customer experience, the Director of Preclearance provides feedback at a team level, while some tags lead to individual training. However, reviewers are not informed of file specifics for training reasons. Every valid tag prompts appropriate action, reinforcing their value—thank you for using them!

Reasons for not validating a tag:

Three tags were deemed invalid because the files were returned for clarification due to inaccuracies in submission details, shading, and annotations. While these tags were marked invalid, we have reminded reviewers to clearly communicate that a full review has not yet been conducted and will only take place after the client provides the necessary corrections. This

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helps ensure clients understand that their copy still requires review beyond just fixing referencing and annotations.

Is there more information you would like to know and see in the next quarterly update? Let us know on the [Forum](#).