

PAAB Tags and CEI 2023

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, 2023**.

215

Completed Surveys

October 1 to December 30, 2023.

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

4.4/5

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

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

4.3/5

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

3.7/4*

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

8.6/10

- 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. **Reviewer overly consistent and perceived to have defaulted to previous rulings** (n= 2)

There have been three comments pertaining to reviewers being overly consistent with previous rulings and they were perceived to not consider new claims or arguments.

Action Taken: Reviewers have been reminded that agencies and manufacturers may revisit and adapt creative and messaging, and that new rationale and presentations should be considered with fresh eyes. We will continue to map this issue to see if trends develop.

2. **Reviews could have been completed in less rounds** (n=5) In five instances, the submitters felt the review could have been completed in fewer rounds.

Action Taken: Reviewers have been reminded that while we do not review layout for copy correctness, they should be acknowledged, and any easily identifiable issues should be raised as early as possible. Reviewers were encouraged to make mention of issues even if they expect the copy to change, if they do not perceive that change to impact the flow of the piece. Similarly, reviewers were asked to advise clients if they did not perform the French review and to perform the French review if the remaining change would not impact the French (i.e. revision of a number or update repositioning of a footnote).

3. **No comments** (n= 5): Five comments read “no comment” or “straight renewal”.

Action Taken: We would like to ask that if clients are filling out the CEI and there were no issues with the review, could clients please provide suggestions that would have improved the interaction or what limited the experience to a “3” so that we can try to take action.

Key Takeaways:

- Survey Completion Rate is 16.8%, with this data capturing 215 responses out of 1067 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 Q1 through Q3, with all scores being similar across the quarters.

Have your voice heard! Help us in continually improve by completing your CEI surveys. You can find them in the “My CEI Surveys” Tab in the top navigation bar in eFiles. This helps us identify trends and implement quality improvement initiatives both internally and externally.

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We continue to encourage you to be as specific as possible when providing feedback in order to 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 |
|-----------|-----------|-----------|-----------|
| 2969 | 2621 | 2452 | 2104 |

Total number of client tags (prior to validation)

| QUARTER 1 | QUARTER 2 | QUARTER 3 | QUARTER 4 |
|-----------|-----------|-----------|-----------|
| 0 | 17 | 21 | 12 |

Tag submitting company and manufacturer distribution

| QUARTER 1 | QUARTER 2 | QUARTER 3 | QUARTER 4 |
|-----------|-----------|-----------|-----------|
| 0 | 5 & 9 | 7 & 8 | 3 & 4 |

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Therapeutic area distribution

| QUARTER 1 | QUARTER 2 | QUARTER 3 | QUARTER 4 |
|-----------|------------------------------------|----------------------------------|------------------------------------|
| 0 | 7 <i>Oncology</i> | 4 <i>Endocrine and Metabolic</i> | 7 <i>Biologic/ Immunomodulator</i> |
| | 2 <i>Gastrointestinal</i> | 1 <i>Dermatology</i> | 4 <i>Oncology</i> |
| | 1 <i>Biologic/ Immunomodulator</i> | 1 <i>Immunology</i> | 1 <i>Vaccine</i> |

Total number of tags deemed valid following internal review

| QUARTER 1 | QUARTER 2 | QUARTER 3 | QUARTER 4 |
|-----------|-----------|-----------|-----------|
| 0 | 10 | 6 | 2 |

Validated tag breakdown

| QUARTER 1 | QUARTER 2 | QUARTER 3 | QUARTER 4 |
|-----------|---|--|--|
| 0 | 4 <i>Inconsistent with code guidance</i> | 2 <i>Inconsistent with code guidance</i> | 1 <i>New issue raised late in the review</i> |
| | 3 <i>Inconsistencies with historic approvals for the same brand</i> | 1 <i>Call not returned at agreed upon time</i> | 1 <i>Inconsistent with code guidance</i> |
| | 2 <i>Request unclear after clarifying call</i> | 1 <i>New issue raised late in the review</i> | |
| | 1 <i>Issue with level of expertise</i> | 1 <i>Particularly helpful comment</i> | |
| | | 1 <i>Issue with level of expertise</i> | |

NEW: Q4 PAAB action taken:

For the tag on “New issue raised late in the review”, the issue was identified in the first round but was missed in the second and was caught on the third. The perception that the issue was adequately addressed is valid and reviewers have been reminded to double check that all issues

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have been addressed prior to sending the response. We'll continue to track to ensure this does not become a trend.

Reasons for not validating a tag:

The tag "The requested revision was unclear to me even following a clarification phone call" was used when no call was requested or occurred. This tag should only be used when a call has occurred, otherwise it will be deemed invalid.

The tag "Inconsistency perceived because objection to content previously approved for the brand was maintained after directing PAAB to the prior approval file" is often invalidated when the client does not provide backfiles. For this tag to be valid, the client needs to provide relevant past files or concurrent files and a response needs to be provided in order for a reviewer to reconsider an issue. As a reminder, backfiles should be provided upfront as part of the initial submission.

Q3 PAAB action taken:

The issue raised about inconsistency with the code guidance was accurate and identified a training opportunity for the individual reviewer. The Director of Preclearance also presented the case at a reviewer meeting to ensure a consistent understanding of the code sections application was held across the office.

In the case where a call was not returned, the issue had been addressed in an email which was not received. The administrative staff will ask for confirmation of receipt to help address this issue moving forward.

Reasons for not validating a tag:

In a number of instances, the revision to the claim in question was not as the reviewer requested and the revised copy prompted a comment. The client viewed this comment as a new issue. It's important to remember that copy is reviewed and approved as the totality of the presentation. When copy changes that affects other aspect or copy is added, it may prompt a comment that appears new, but would not qualify as "new comment late stage" because it's been prompted by a change the client made. Nonetheless, this did prompt a reminder to reviewers that clearly explaining this at first mention of the comment may help to reduce this perception.

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“Perceived issue with expertise” with no additional context. A complete review of the file did not appear to have any aspects that would warrant or support this tag. In another case, a potential inconsistency was tagged as an expertise issue which was not an accurate use of the tag. PAAB added an inconsistency tag that was deemed valid in that case. As a reminder, adding additional context to a tag can help in the validation process. It helps the Director of Preclearance focus on the specific aspect that the client felt was an issue.

In another instance of this tag, the issue raised appeared to be based on not providing enough guidance around what had been done with the brand in the past. From a PAAB training perspective, we did remind the review team to provide accurate backfiles when they are readily available. As a reminder to clients, it is the clients’ responsibility to be familiar with their brand and previously discussed claims, copy, images etc. Sponsors should have access to all backfiles and communications. Sharing/requesting these when agency changes occur or turnover happens, may help to alleviate this issue.

For tags regarding “Inconsistency perceived because objection to content previously approved for the brand was maintained after directing PAAB to the prior approval file”, these cannot be validated when previous approved presentation was not within the same context. The same words when presented in a different context may not have the same message.

Q2 PAAB action taken:

One key issue raised was not being clear on an issue even after a clarifying call. In both instances, the issues had been previously discussed in a past file, so the reviewer did not re-explain. Reviewers have been directed to reiterate the rationale for revisions to facilitate understanding. A trend across the “inconsistent with historical approvals” was that new information had been brought forward since the previous approval. Reviewers have been reminded to clearly convey this to clients when applicable and provide the rationale for why it requires changes to previously approved copy.

A case was identified where a reviewer was inconsistent with the guidance. Discussions with the review team were had on the application of guidance in relation to non-clinical claims.

Q1 PAAB action taken:

Not tags reported in Q1 of 2023. As a reminder, both CEI and Tags are important and serve different but complementary purposes. Additional details can be found in the [PAAB resource Client Tagging System Advisory](#)

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