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 **July 1– Sept 30, 2023.**

256

Completed Surveys
July 1 to September 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	**4.5/5** 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
 	
*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.
	3.8/4*
	
	Indicating an average response between "Somewhat consistent" and "Highly Consistent"

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
 	
    1 – highly negative experience
    10 – highly positive experience
	8.9/10
	
	Indicating a positive average overall experience.

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Quick Complete CEI Data:

Upon the launch of the CEI Survey dashboard and their associated emails, a "quick complete" function was added in the emails only. This was added inadvertently and made live prior to its intended launch. It has since been deactivated. However, based on the data collected in this time frame, 36 CEIs were submitted via "quick complete" which indicate that these submitters were "happy with the overall experience with this eFile".

Key Themes and Actions Taken from Open-text Feedback:

1. **Clarity of comments** (n= 3): Open text responses suggested that in a few instances, reviewer comments could have been clearer. In all instances, the issues were clarified and resolved with the help of a phone call.

Action Taken: Reviewers have been reminded to ensure comments are written in clear, concise language and to provide examples and suggestions when possible.

2. **Reviewer overly consistent and perceived to have defaulted to previous rulings** (n= 3) 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.

3. **Inconsistencies identified within the same brand** (n=5) In five instances, there were comments made by the reviewer that were inconsistent with previous rulings for the same brand. In three cases, when the reviewer was notified, the reviewer ultimately accepted the copy in question. In the other cases, the context of the current APS was different and the reviewer continued to question the copy.

Action Taken: When it is brought to a reviewer's attention that their current comment may be inconsistent with previous rulings for the brand, unless there is a significant context difference that impacts the ruling, the comment will be brought to the Director of Preclearance Services to ensure the comment is necessary. Reviewers have also been reminded to try to elaborate when context is different to help facilitate understanding of why a ruling may be perceived to be different.

Key Takeaways:

- Survey Completion Rate is 17.6%, with this data capturing 256 responses out of 1452 surveys sent. Data should be interpreted with this in mind, as this is a relatively low sample size.

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- 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 and Q2, with all scores being the same or slightly higher than the average scores reported in Q2. We will continue tracking for trends through Q4.

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.

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.

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QUARTERLY REVIEW

A Quarterly Review of the eFiles Tag Report

Total number of submissions

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2969	2621	2452	

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
0	17	21	

Therapeutic area distribution

QUARTER 1	QUARTER 2		QUARTER 3		QUARTER 4
0	7	*Oncology*	4	*Endocrine and Metabolic*	
	2	*Gastrointestinal*	1	*Dermatology*	
	1	*Biologic/ Immunomodulator*	1	*Immunology*	

Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
0	10	6	

Validated tag breakdown

QUARTER 1	QUARTER 2		QUARTER 3		QUARTER 4
0	4	*Inconsistent with code guidance*	2	*Inconsistent with code guidance*	
	3	*Inconsistencies with historic approvals for the same brand*	1	*Call not returned at agreed upon time*	

	2	*Request unclear after clarifying call*	1	*New issue raised late in the review*	
	1	*Issue with level of expertise*	1	*Particularly helpful comment*	
			1	*Issue with level of expertise*	

NEW: 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 effects 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.

"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

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