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 **April 1 – June 30, 2024.**

322

Completed Surveys
April 1 to June 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.
	3.7/4*
	
	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
	8.8/10
	
	Indicating a positive average overall experience.

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Key Themes and Actions Taken from Open-text Feedback:

1. **Reviews could have been completed in less rounds** (n=6) In one instance, the submitters felt the review responses could have been more complete to help streamline revisions in a more efficient manner to reduce the number of rounds. In another instance it took multiple rounds to come to a mutual understanding of the purpose of the copy and nature of the reference.

Action Taken: Reviewers have been reminded to take time to clearly explain the relevant issues and how they may impact other parts of the APS. While the expectation is not to provide an exhaustive list of all possible outcomes, they have been encouraged to look for solutions and be clear about the rationale to assist clients in their revisions.

2. **Late-stage comments delayed timeline** (n= 1) In one instance a late-stage comment arose that required additional rounds of review and resulted in delays on a file which was submitted through the accelerated review options (ARO) to address a tight timeline by the client.

Action Taken: Reviewers have been reminded that while we can all appreciate that late-stage comments may arise on occasion, the reviewer should work proactively with the client to ensure that it does not result in delays to approval. This may include proactively reaching out through phone, email or eFiles, and expediting the revision turnaround when the file is returned.

3. **Positive comments and directions around the reviewer interactions and process** (n= 13)**:** There was a significant increase in the number of positive responses and comments provided around the review process and reviewer interactions. This is extremely helpful for providing positive feedback to reviewers 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 21.8%, with this data capturing 322 responses out of 1477 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.

Have your voice heard! Help us 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 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.

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A Quarterly Review of the eFiles Tag Report

Total number of submissions

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
2304	2467		

Total number of client tags (prior to validation)

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
13	14		

Tag submitting company and manufacturer distribution

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

Therapeutic area distribution

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4 *Immunology*	5 *Biologic/ Immunomodulator*		
2 *Neurology*	4 *Gastrointestinal*		
2 *Vaccine*	2 *Vaccine*		
2 *Dermatology*	2 *Oncology*		
1 *Gastrointestinal*	1 *Women's Health*		
1 *Endocrine and Metabolic*	1 *Other*		
1 *Cardiovascular*			

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Total number of tags deemed valid following internal review

QUARTER 1	QUARTER 2	QUARTER 3	QUARTER 4
4	5		

Validated tag breakdown

QUARTER 1		QUARTER 2		QUARTER 3	QUARTER 4
2	*New issue raised late in the review*	3	*Particularly helpful comment*		
1	*Inconsistencies with historic approvals for the same brand*	1	*Consider changing the code guidance*		
1	*Particularly helpful comment*	1	*Inconsistent with code guidance*		

Q2 PAAB Action Taken:

In two instances, the tag was deemed invalid as they were not the appropriate tags. We revised the tags as the clients' issues were still valid when labelled with an alternative tag. The report reflects the revised tags.

The valid reassigned tags prompted additional training on disease burden for the office to build continuous improvement on consistency and application across reviewers. The second reassigned tag resulted in a change in review practice for inclusion of disclaimers for consumer resources in certain scenarios. This change was applied during the review of that file and will be applied moving forward.

Reasons for not validating a tag:

It's important to remember to wait until the issue has been resolved to completion. Twice a tag of "Inconsistency perceived because objection was maintained after demonstrating that the same presentation was approved for a different brand". This was tagged early in the review and upon a clarification letter in one instance and a phone call in the other, it was determined that the wrong backfiles had initially been provided. In another instance the claim of being charged for an extra round of review was inaccurate.

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When using tags such as "Ruling perceived to be inconsistent with code/guidance" or "Consider changing the code/guidance", it can be beneficial for the client to provide details about what they think could be changed and solid rationale for consideration. While it is helpful to point to the comment that prompted the tag, additional context will help PAAB to assess if changes are warranted and better understand the root issue behind the request for consideration.

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