PAAB FORUM
QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: January - March 2024

Announcements

- **CODE UPDATE:** Effective February 1st, 2024. The Code update and new documents, Guidance on Real-World Evidence/Data and Guidance on When the Attention Icon is Required and Its Presentation, have been live since February 1st. We are gradually seeing an increase in submissions including RWE. We continue to recommend use of the opinion service to help evaluate studies prior to development of APS.
- **Burden of Disease Guidance:** Effective February 19th, 2024. Example cases prepared with support from bMod, CORE Health Communications, FCB Health Canada, and GSW are available.
- **Training:** PAAB has launched registration for online training on **RWE, study duration, and disease burden**. The training will consist of three self-paced modules concluding in a one hour live virtual session with Q&A. Follow this link to learn more.
- **Renewals Dashboard:** On February 14, 2024, we launched the Renewals Management Dashboard, intended to assist in easier tracking and submission of Renewals. Take advantage of the early renewal discount by submitting renewals ≥6 weeks prior to the previous eFile's expiry.
- **Creative Imagery Committee:** The committee continues to work through creative examples to create alignment. PAAB is currently in the process of preparing draft ideas to take back to the committee for discussions. Learn more.

New Documents

- Code Change Effective February 1st
  - This document provides the summary of changes to the PAAB Code in order to create alignment with the implementation of new guidance on RWE.
- Guidance on the Presentation of Burden of Disease in Advertising
  - This document describes PAAB's expanded approach to disease burden presentations in advertising materials.
- If you missed last quarter's review, don't forget to review here to make sure you're up to date on all things new at PAAB including pre-NOC administrative guidelines, guidance on study duration, 2023 CEI report, and more.

Q&A

37 Forum questions from industry answered on topics such as:

- Gating
- #1 dispensed
- Ongoing studies
- Demo Kits
- RWE studies
- Search functionality
- Claims of "new" or "now"
- Pre-NOC fees
- Differential diagnosis

In the Works for 2024

AI Assisted Submission Process - PAAB has started the process to build out AI powered systems that will assist clients during the preparation of submissions to know when elements are missing that could result in a delay in the acceptance for review, with aspirations of eventually assisting with referencing and annotating things like previously approved copy in past files. We will be looking for clients who are well versed in AI to be part of a committee which shapes this development, so stay tuned.

Messenger system – Messenger functionality within files has been undergoing testing since late in Q4 of 2023. We hope to have this additional service offering for ARO submissions up and running in Q2 of 2024. Make sure you're registered for the Forum to be the first to know when this service goes live.

External Training – PAAB continues to build out our on-demand training offering with the PAAB 1.0 and a revamp of the PAAB 2.0 online training services. Moving into 2024, let us know what training you would like available and areas of interest with this quick survey.

Monitoring – Reminder that the Guidance on GATING of websites, which was produced in collaboration with Health Canada, has been live for almost one year. As was outlined at the time, manufacturers controlling websites that do not appear to meet the minimum gating standards will be contacted through our monitoring activities.

PAAB has informed Health Canada of 11 infractions through the monitoring system in Q1 of 2024. 7 incidents resulted in monitoring letters sent from PAAB. Health Canada chose to address 4 events through their own communications. These events all had DTC implications.

eFiles Tag and CEI Reports

- We continue to thank all who contributed to the CEIs over 2023 and into 2024. They have allowed us to identify inconsistencies and improve training and internal processes as a result of their use. Similarly, the CEI surveys have provided immensely positive and constructive feedback. We'd like to thank all those who participated, especially our TOP 10 responders! We hope to continue this momentum into 2024 as we strive to provide the best customer service possible.
- As a reminder, the tickets are **completely confidential.** If you want more information on the tagging system, please see Client Tagging System Advisory.
- As a reminder, the CEI captures the **overall experience** with a file and the review process. It helps to impact macro processes and performance. The "tags" help us pinpoint cases where there was an event that could be assessed for learning purposes, checked for consistency or which could be used to implement change. This specific feedback helps us improve performance on a more granular level.

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