

PAAB FORUM

QUARTERLY REVIEW

A review of the last quarter on the PAAB Forum: April – June 2022

Announcements

- ARO (Accelerated Review Options) has launched as of July 4th
- We have compiled all the relevant documents on to one handy [page](#)
- Questions posed to PAAB about ARO, will be posted publicly at [PAAB Forum – Accelerated Review Options \(ARO\)](#). Please refer to this page prior to reaching out with questions, and feel free to post your questions directly to this space
- Reminder to those looking to register for the [Forum](#), to use a *professional email* for security purposes. You can select to have your email hidden on your profile page after registration. If you do not use a professional email, your registration will not be accepted.

New Documents

- Guidance on Submission Process and Format Requirements
 - [This document](#) covers the new submission requirements for all eFiles submissions. The document applies equally to ARO submissions and standard review submissions. Generating consistency across submissions will help to streamline the review process. The requirements are in effect as of July 4th, 2022.
- Advisory: Increased specificity on series fee criteria
 - [This advisory](#) helps to elaborate on how series fees are applied and can be used to support ARO and standard submissions.
- Complaints Report for 2021
 - [Ruling summaries](#) for all Stage 2 or greater, complaints PAAB ruled on in 2021.

Q&A

31 [Forum questions](#) from industry answered on topics such as:

- Study duration
- 3rd party content
- Patient counselling, preference, DTC
- Patient characteristics from studies
- Pre-NOC RMT
- Fair balance placement/links
- Formulary claims
- Submissions, annotations, referencing
- Retention data

Myths vs. Facts

Keep an eye out for new “Myths vs. Facts” coming later this year and make sure you’re familiar with the common ones posted now so that your company isn’t falling into the “Myths” trap. Check out PAAB [Myths](#) page today.

Let us know if there are any myths you want clarification on, or for PAAB to help dispel for the industry.

eFiles Tag Report

- The first quarter [PAAB Tag Report 2022](#) has been posted. We continue to encourage clients to use the tagging system to help PAAB identify areas of improvement and areas of valued service. We look forward to your continued feedback moving into the second half of 2022. If you want more information on the tagging system, please see [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.