

# PAAB eFILES TAG REPORT

2020 REVIEW

PAAB had a record breaking year with **9080** unique eFiles submissions

Below, we have provided a breakdown of the client tags used in 2020. You'll see total number of tags, types of tags used and distribution across therapeutic areas.



The distribution of the 77 tags was spread across 21 different agencies. These 21 agencies make up 45.4% (n=4121) of all submissions in 2020.

The 77 tags were spread across 21 different manufacturers



### Top Tags:

Upon internal audit, here are the top three validated tags.

- 19** New issues were raised late in the review process
- 16** Particularly helpful comments, discussions, or actions were acknowledged
- 5** Inconsistencies with historic approvals for the same brand were noted



- 17** Diabetes
- 8** Biologics/Immunomodulators
- 6** Eye/Ear/Nose/Skin
- 4** Oncology
- 18** Other/Not recorded

## PAAB Actions Taken:

### *New issues were raised late in the review process:*

- Reminder to all Reviewers to be aware of late comments and the impact to clients
- Reminder to communicate extenuating circumstances or rationale for late reviews, clearly and concisely to the agency/client
- Strategy sharing and development meeting across all Reviewers to outline ways in which late comments can be minimized

### *Inconsistencies with historic approvals for the same brand were noted:*

- Issues were raised at a reviewer meeting with team being asked to bring examples of how they applied the code across their respective brands for the issues
- Inconsistency was confirmed and resolution for review practice moving forward was achieved and documented in our internal knowledge management system
- External documents providing further clarification of application of the Code were created and distributed

Is there more you'd like to know about the tags or tagging system? Let us know on the [PAAB Forum](#).

