

Are High Failure Numbers a Good Sign?

Below is a piechart of the therapeutic areas for products mentioned in the Complete Response Letters (CRLs). In some cases, due to redaction, it was not possible to determine the indication from the CRL, which is why “N/A” is also a sizable category. Note that FDA Division was redacted in the letters and, therefore, could not provide a clue to the indication.

I know that piecharts are terrible for comparing percentages. I’m not interested in the exact numbers because these numbers are meaningless. After all, we have no idea how many applications for a given therapeutic area are currently under review, so we have no idea what percent of that pie they represent.

Oncology was the largest contributor. Perhaps the relatively large number of failures reflects a high level of activity in this drug development space.

Disclaimer:

Everything stated here is my opinion only and based only on publicly-available information which I have analyzed independently.

Link to the CRLs:

<https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89>

FDA Complete Response Letters

