

CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: October 1, 2023 - September 30, 2024

Data as of September 30, 2024

| Fiscal Year | Total Requests Received | Granted | Denied | Withdrawn |
|-------------|-------------------------|---------|--------|-----------|
| 2024 | 134* | 52 | 51 | 11 |

* Requests that are still pending a decision are included in the total requests received column.