

## CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: July 9, 2012\* - September 30, 2023

Data as of December 31, 2023

| Fiscal Year  | Total Requests Received | Granted    | Denied     | Withdrawn  |
|--------------|-------------------------|------------|------------|------------|
| 2023         | 88                      | 37         | 44         | 7          |
| 2022         | 78                      | 26         | 46         | 6          |
| 2021         | 103                     | 42         | 46         | 15         |
| 2020         | 125                     | 58         | 53         | 14         |
| 2019         | 156                     | 67         | 68         | 21         |
| 2018         | 136                     | 59         | 60         | 17         |
| 2017         | 111                     | 50         | 49         | 12         |
| 2016         | 106                     | 46         | 48         | 12         |
| 2015         | 93                      | 32         | 43         | 18         |
| 2014         | 96                      | 31         | 51         | 14         |
| 2013         | 92                      | 31         | 52         | 9          |
| 2012         | 2                       | 1          | 1          | 0          |
| <b>Total</b> | <b>1186</b>             | <b>480</b> | <b>561</b> | <b>145</b> |

\* Breakthrough therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.

