

## Cumulative CBER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: July 9, 2012\* - September 30, 2024

Data as of December 31, 2024

Fiscal Year	Total Requests Received	Granted	Denied	Withdrawn
2024	21	6	14	1
2023	24	7	16	1
2022	19	8	8	3
2021	10	4	6	0
2020	15	3	12	0
2019	20	8	12	0
2018	21	7	13	1
2017	25	9	15	1
2016	23	8	14	1
2015	20	8	9	3
2014	26	7	19	0
2013	12	1	10	1

2012	0	0	0	0
------	---	---	---	---

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