

Expanded Access Submission Receipts Report

Oct 01, 2019 – Sep 30, 2020

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	1779
Individual (Single) Patient INDs, Emergency allowed to proceed	1776
Individual (Single) Patient INDs, Non-Emergency received	1034
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	1014
Intermediate Size Patient Population INDs received	6
Intermediate Size Patient Population INDs allowed to proceed	4
Treatment INDs received	5
Treatment INDs allowed to proceed	2
Expanded Access Protocols	
Individual (Single) Patient protocols, Emergency received	10
Individual (Single) Patient protocols, Emergency allowed to proceed	10
Individual (Single) Patient protocols, Non-Emergency received	10
Individual (Single) Patient protocols, Non-Emergency allowed to proceed	10
Intermediate Size Patient Population protocols received	26
Intermediate Size Patient Population protocols allowed to proceed	26
Treatment Protocols received	19
Treatment Protocols allowed to proceed	18
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	2889
Total Number of Expanded Access INDs and Protocols allowed to proceed	2860