

Expanded Access Submission Receipts Report

Oct 01, 2018 – Sep 30, 2019

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	425
Individual (Single) Patient INDs, Emergency allowed to proceed	423
Individual (Single) Patient INDs, Non-Emergency received	1110
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	1080
Intermediate Size Patient Population INDs received	20
Intermediate Size Patient Population INDs allowed to proceed	18
Treatment INDs received	3
Treatment INDs allowed to proceed	2
Expanded Access Protocols	
Individual (Single) Patient protocols, Emergency received	21
Individual (Single) Patient protocols, Emergency allowed to proceed	21
Individual (Single) Patient protocols, Non-Emergency received	28
Individual (Single) Patient protocols, Non-Emergency allowed to proceed	28
Intermediate Size Patient Population protocols received	14
Intermediate Size Patient Population protocols allowed to proceed	13
Treatment Protocols received	18
Treatment Protocols allowed to proceed	18
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1639
Total Number of Expanded Access INDs and Protocols allowed to proceed	1603