

Expanded Access Submission Receipts Report

Oct 1, 2015 - Sep 30, 2016

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	472
Individual (Single) Patient INDs, Emergency allowed to proceed	472
Individual (Single) Patient INDs, Non-Emergency received	999
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	994
Intermediate Size Patient Population INDs received	37
Intermediate Size Patient Population INDs allowed to proceed	33
Treatment INDs received	1
Treatment INDs allowed to proceed	1
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	6
Individual (Single) Patient Protocols, Emergency allowed to proceed	6
Individual (Single) Patient Protocols, Non-Emergency received	16
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	16
Intermediate Size Patient Population Protocols received	13
Intermediate Size Patient Population Protocols allowed to proceed	13
Treatment Protocols received	10
Treatment Protocols allowed to proceed	10
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1554
Total Number of Expanded Access INDs and Protocols allowed to proceed	1545