

Expanded Access Submission Receipts Report

Oct 1, 2016 - Sep 30, 2017

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	461
Individual (Single) Patient INDs, Emergency allowed to proceed	461
Individual (Single) Patient INDs, Non-Emergency received	1111
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	1107
Intermediate Size Patient Population INDs received	36
Intermediate Size Patient Population INDs allowed to proceed	35
Treatment INDs received	0
Treatment INDs allowed to proceed	0
Expanded Access Protocols	
Individual (Single) Patient protocols, Emergency received	4
Individual (Single) Patient protocols, Emergency allowed to proceed	4
Individual (Single) Patient protocols, Non-Emergency received	14
Individual (Single) Patient protocols, Non-Emergency allowed to proceed	14
Intermediate Size Patient Population protocols received	4
Intermediate Size Patient Population protocols allowed to proceed	4
Treatment Protocols received	7
Treatment Protocols allowed to proceed	7
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1637
Total Number of Expanded Access INDs and Protocols allowed to proceed	1632