

Expanded Access Submission Receipts Report

Oct 1, 2014 - Sep 30, 2015

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	431
Individual (Single) Patient INDs, Emergency allowed to proceed	428
Individual (Single) Patient INDs, Non-Emergency received	747
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	745
Intermediate Size Patient Population INDs received	46
Intermediate Size Patient Population INDs allowed to proceed	45
Treatment INDs received	0
Treatment INDs allowed to proceed	0
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	7
Individual (Single) Patient Protocols, Emergency allowed to proceed	7
Individual (Single) Patient Protocols, Non-Emergency received	14
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	14
Intermediate Size Patient Population Protocols received	9
Intermediate Size Patient Population Protocols allowed to proceed	9
Treatment Protocols received	8
Treatment Protocols allowed to proceed	8
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1262
Total Number of Expanded Access INDs and Protocols allowed to proceed	1256