

Expanded Access Submission Receipts Report

Oct 1, 2013 - Sep 30, 2014

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	1069
Individual (Single) Patient INDs, Emergency allowed to proceed	1066
Individual (Single) Patient INDs, Non-Emergency received	696
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	692
Intermediate Size Patient Population INDs received	52
Intermediate Size Patient Population INDs allowed to proceed	50
Treatment INDs received	0
Treatment INDs allowed to proceed	0
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	9
Individual (Single) Patient Protocols, Emergency allowed to proceed	9
Individual (Single) Patient Protocols, Non-Emergency received	35
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	35
Intermediate Size Patient Population Protocols received	9
Intermediate Size Patient Population Protocols allowed to proceed	9
Treatment Protocols received	12
Treatment Protocols allowed to proceed	12
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1882
Total Number of Expanded Access INDs and Protocols allowed to proceed	1873