

Expanded Access Submission Receipts Report

Oct 1, 2012 - Sep 30, 2013

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	315
Individual (Single) Patient INDs, Emergency allowed to proceed	313
Individual (Single) Patient INDs, Non-Emergency received	550
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	550
Intermediate Size Patient Population INDs received	28
Intermediate Size Patient Population INDs allowed to proceed	27
Treatment INDs received	0
Treatment INDs allowed to proceed	0
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	2
Individual (Single) Patient Protocols, Emergency allowed to proceed	2
Individual (Single) Patient Protocols, Non-Emergency received	62
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	62
Intermediate Size Patient Population Protocols received	8
Intermediate Size Patient Population Protocols allowed to proceed	8
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	977
Total Number of Expanded Access INDs and Protocols allowed to proceed	974