

Expanded Access Submission Receipts Report

Oct 1, 2011 - Sep 30, 2012

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	289
Individual (Single) Patient INDs, Emergency allowed to proceed	287
Individual (Single) Patient INDs, Non-Emergency received	498
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	496
Intermediate Size Patient Population INDs received	14
Intermediate Size Patient Population INDs allowed to proceed	14
Treatment INDs received	0
Treatment INDs allowed to proceed	0
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	0
Individual (Single) Patient Protocols, Emergency allowed to proceed	0
Individual (Single) Patient Protocols, Non-Emergency received	121
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	121
Intermediate Size Patient Population Protocols received	8
Intermediate Size Patient Population Protocols allowed to proceed	8
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	940
Total Number of Expanded Access INDs and Protocols allowed to proceed	936