

Expanded Access Submission Receipts Report

Oct 13, 2010 - Oct 12, 2011 *

Expanded Access INDs	
Individual (Single) Patient INDs, Emergency received	443
Individual (Single) Patient INDs, Emergency allowed to proceed	442
Individual (Single) Patient INDs, Non-Emergency received	652
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	652
Intermediate Size Patient Population INDs received	0
Intermediate Size Patient Population INDs allowed to proceed	0
Treatment INDs received	1
Treatment INDs allowed to proceed	1
Expanded Access Protocols	
Individual (Single) Patient Protocols, Emergency received	3
Individual (Single) Patient Protocols, Emergency allowed to proceed	3
Individual (Single) Patient Protocols, Non-Emergency received	89
Individual (Single) Patient Protocols, Non-Emergency allowed to proceed	89
Intermediate Size Patient Population Protocols received	1
Intermediate Size Patient Population Protocols allowed to proceed	1
Treatment Protocols received	11
Treatment Protocols allowed to proceed	11
Totals for Expanded Access	
Total Number of Expanded Access INDs and Protocols received in CDER	1200
Total Number of Expanded Access INDs and Protocols allowed to proceed	1199

* These reporting periods cover a one year cohort starting the day the Final Rule for Expanded Access to Investigational Drugs for Treatment Use and Charging for Investigational Drugs went into effect. Starting with Fiscal Year 2012, the reporting period was changed to a fiscal year to match the reporting period for other IND activity reports.