

Expanded Access Submission Receipts Report

Oct 13, 2009 - Oct 12, 2010 *

| Expanded Access INDs | |
|---|------|
| Individual (Single) Patient INDs, Emergency received | 516 |
| Individual (Single) Patient INDs, Emergency allowed to proceed | 500 |
| | |
| Individual (Single) Patient INDs, Non-Emergency received | 484 |
| Individual (Single) Patient INDs, Non-Emergency allowed to proceed | 484 |
| | |
| Intermediate Size Patient Population INDs received | 2 |
| Intermediate Size Patient Population INDs allowed to proceed | 2 |
| | |
| 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 | 16 |
| Individual (Single) Patient Protocols, Non-Emergency allowed to proceed | 16 |
| | |
| Intermediate Size Patient Population Protocols received | 5 |
| Intermediate Size Patient Population Protocols allowed to proceed | 5 |
| | |
| Treatment Protocols received | 7 |
| Treatment Protocols allowed to proceed | 7 |
| Totals for Expanded Access | |
| | |
| Total Number of Expanded Access INDs and Protocols received in CDER | 1030 |
| Total Number of Expanded Access INDs and Protocols allowed to proceed | 1014 |

* 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.