

## Expanded Access Submission Receipts Report

Oct 01, 2017 – Sep 30, 2018

<b>Expanded Access INDs</b>	
Individual (Single) Patient INDs, Emergency received	366
Individual (Single) Patient INDs, Emergency allowed to proceed	366
Individual (Single) Patient INDs, Non-Emergency received	925
Individual (Single) Patient INDs, Non-Emergency allowed to proceed	922
Intermediate Size Patient Population INDs received	12
Intermediate Size Patient Population INDs allowed to proceed	11
Treatment INDs received	1
Treatment INDs allowed to proceed	1
<b>Expanded Access Protocols</b>	
Individual (Single) Patient protocols, Emergency received	20
Individual (Single) Patient protocols, Emergency allowed to proceed	20
Individual (Single) Patient protocols, Non-Emergency received	27
Individual (Single) Patient protocols, Non-Emergency allowed to proceed	27
Intermediate Size Patient Population protocols received	14
Intermediate Size Patient Population protocols allowed to proceed	14
Treatment Protocols received	5
Treatment Protocols allowed to proceed	5
<b>Totals for Expanded Access</b>	
Total Number of Expanded Access INDs and Protocols received in CDER	1370
Total Number of Expanded Access INDs and Protocols allowed to proceed	1366