

CENTRAL NERVOUS SYSTEM EXPERIENCE AS OF 2016

CENTRAL NERVOUS SYTEM SERVICES

- Gap analysis and clinical development plan
- Clinical monitoring
- IND submissions
- Safety monitoring and SAE database
- FDA meetings
- Clinical Study Report
- Protocol, IB, ICF, CRF
- Multi-study Integrated Safety Database
- Data Management & Statistics
- ISS / ISE
- Site finding and management
- PMA Submission - FDA Advisory Committee
- Recruitment and Enrollment
- NDA, BLA, PMA
- Online randomization, stratification
- eCTD Medical Monitoring
- Audits
- Regulatory

| Clinical Trials | # Studies | # Sites | # Patients |
|-----------------|-----------|---------|------------|
| Phase I | 29 | 40 | 1,113 |
| Phase II | 11 | 80 | 826 |
| Phase III | 9 | 320 | 3,036 |
| | 49 | 440 | 4,975 |

DRUGS

- ADHD / ADD
- Addiction
- Alzheimer's
- Mild Dementia
- Major Depressive Disorder
- Huntington's
- Parkinson's
- Restless Leg Syndrome
- Schizophrenia
- Seizures
- Pain
- Diabetic Neuropathy

DEVICES

- Major Depressive Disorder
- Hemiparesis

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- Hemiparesis
- Epilepsy
- Pain

BIOLOGICS

- Major Depressive Disorder
- Pain

Where **Experience** is the Difference