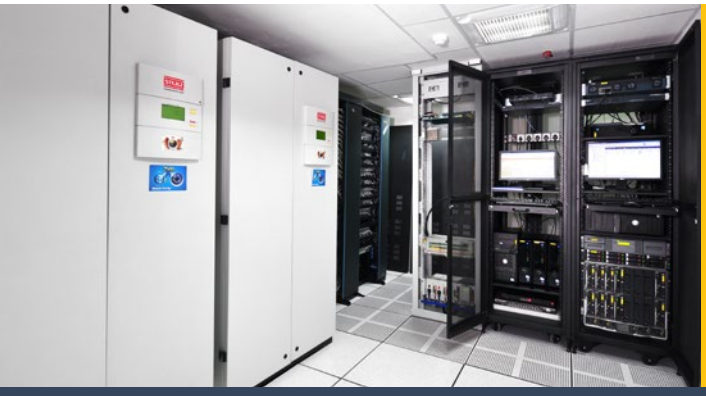
Norwich
CLINICAL SERVICES


# PHARMACOVIGILANCE SERVICES

Norwich Clinical Services is a Global Contract Service Provider for Biostudies, Clinical Trials, Pharmacovigilance, Clinical Data Management and Corporate Training



TEAM WITH VAST EXPERIENCE. FOCUSED ON QUALITY.

COMPLIANT WITH INTERNATIONAL REGULATORY STANDARDS.

✓EXPERIENCE ✓EXPERTISE ✓EXCEPTIONAL

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## Norwich Clinical Services offers broad range of pharmacovigilance services for pharmaceutical and biotechnology industries.

### OUR SERVICES INCLUDE:

- Adverse Event Case processing
- Electronic submission of cases to regulatory agencies
- 24 X 7 Call Center services
- Literature Search and Regulatory Site search
- Preparation of ICSRs and PSURs
- Filing into EU XEVMPD
- Signal Detection
- Risk Benefit Analysis
- Risk Management Plan
- Regulatory Submissions
- QPPV Support
- PV database support

### OUR EXPERTISE:

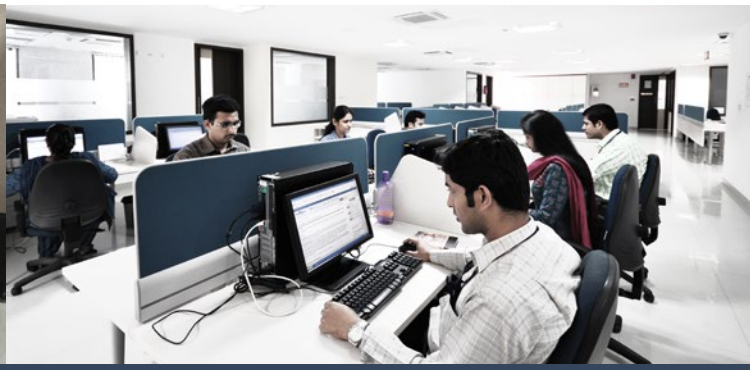
- Two Successful USFDA Inspections (Offsite)
- Compliant XEVMPD software
- Electronic gateway established with EMA, all EU countries and with USFDA.
- Vast Experience in Data Migration
- Expertise in Signal detection for 500 molecules
- Data Mining of Global Safety database including USFDA

## Our Pharmacovigilance activities is in compliance with New EU Guidance.

### SOFTWARE DETAILS:

- Oracle AERS for AE reporting
- Siemens Open Scape for 24 x 07 Call Centre
- MedDRA for Coding
- Axway Synchrony for regulatory submissions
- WHO DD

**SOFTWARE IS FULLY VALIDATED & 21 CFR PART 11 COMPLIANT.**



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