

# PIVOTAL PHARMACOVIGILANCE (PV) UNIT

## ▪ *The Team*

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- Qualified personnel, such as:
  - Senior Safety Officer
  - Medical Scientific Advisors

## ▪ *Safety Data Base*

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- Oracle® Argus Safety Suite version 6.0 provides integrated PV functionality that supports end-to-end drug safety processes across clinical development and post-marketing safety surveillance

## ▪ *Services offered*

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STRATEGIC AND  
TACTICAL ACTIVITIES

- Safety database services – ARGUS v 6.0
- Clinical protocol safety section development
- Customised safety management plan
- Serious adverse events management: data collection, processing, follow-up, medical review
- MedDRA coding
- Literature reviews and medical narratives
- Submission of expedited reports to Regulatory Authorities [paper or electronic submissions (including Eudravigilance)] and Competent Authorities
- Reconciliation services - safety/clinical databases
- Periodic safety update reports (PSURs), annual safety reports (ASR)
- Signal detection
- Investigator site training