

PHARMACOVIGILANCE SERVICES CLINICAL CASE PROCESSING ADRTA will perform Individual Case Study Report (ICSR) processing on behalf of ABC in the ARGUS safety database hosted and maintained by ABC bio. Our processes are well established to handle the intricacies of case processing activities and nuances for cases received from clinical trial sources. Our team is flexible to be trained and work as per the client-specific processes and workflows. ADRTA's case processing activities would include:

- Case intake, duplicate search, data entry, coding, narrative creation, quality control review (for completeness and accuracy). Medical review will be done by ABC Bio.
- Source documents are attached to the case in the safety database for easy retrieval.
- ADRTA provides case processing activities, including 7-day and/or 15-day report preparation.
- Follow-up with the clinical site and/or reporters will be managed by ABC and ADRTA team will liaise with ABC until queries are appropriately closed and databased.
- Our trained staff members will receive and triage inbound serious adverse event (SAE) cases, initiating the process of detailed case entry.
- An AE will be triaged based on whether it is serious, causally related, and reportable.
- Every case will be data entered and will undergo a quality review.
- ADRTA will work closely with ABC's team to streamline the case processing functions.
- The complete clinic