Linical Pharmacovigilance Services

Overview

Today's pharmaceutical and biotech companies are faced with the challenge of managing a growing volume of adverse events and rigorous compliance expectations from local and global regulatory agencies.

Drug developers need a pharmacovigilance provider they can rely on to meet the demands of today's complex landscape. The right partner will have sufficient resources, best-in-class technologies, and innovative approaches to manage data intake, processing, and storage.

Challenges

- Increasing demand for drugs, biologics, device products, and multiple data sources
- Information exchange is dependent on the reporter's access to healthcare
- Security requirements for Protected Health Information
- Lack of real-time information hinders decision-making
- Coordination of remote teams
- Translating global documents

Solution

Through deploying qualified teams and intake solutions, Linical assures the proper collection and management of adverse events, revamping how critical milestones are conducted.

The Linical Pharmacovigilance team's intake process streamlines the receipt of safety information to perform case processing tasks, such as data entry, coding via MedDRA and WHO Drug Dictionary, and narrative generation.

- Comprehensive data entry powered by state-of-the-art pharmacovigilance systems
- Confirm appropriate redaction, perform duplicate checks, and complete case follow-up
- Customizable reports based on client's needs

Linical's Pharmacovigilance Team

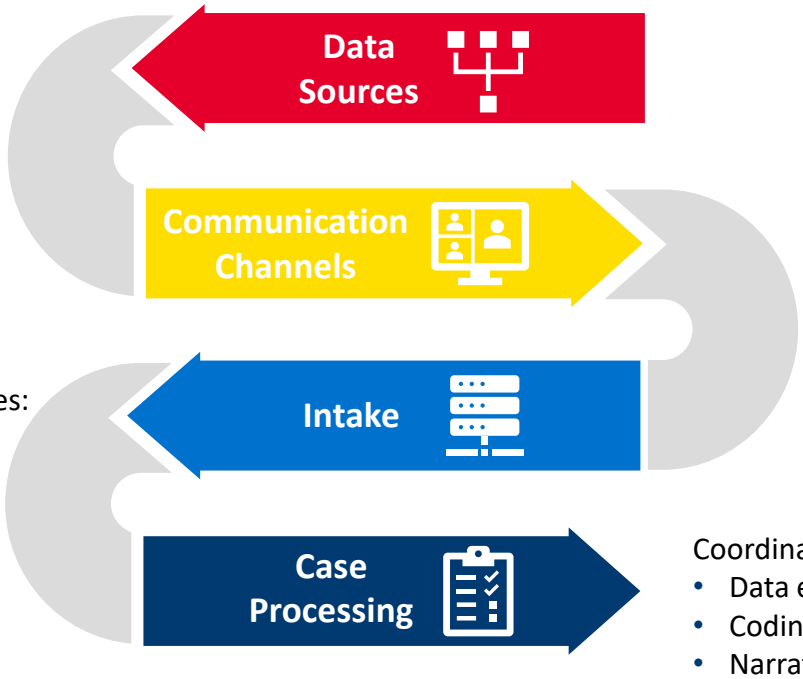
Linical works seamlessly as an extension of your team to increase efficiency and productivity while decreasing operational costs.

- Customized project specific reporting templates optimizes the case intake process
- Quality control review of all cases assures accuracy of data
- Timeline for case completion is automatically calculated to track progress in the safety database
- Experienced pharmacovigilance team assesses safety data is complete prior to entry in the safety database

Key Activities for Pharmacovigilance Intake and Processing

Safety data is received in multiple ways:

- Patient healthcare professional
- Clinical trial
- Literature review



Communication is received in a variety of formats:

- Email
- Fax
- Social media monitoring
- Contact Center

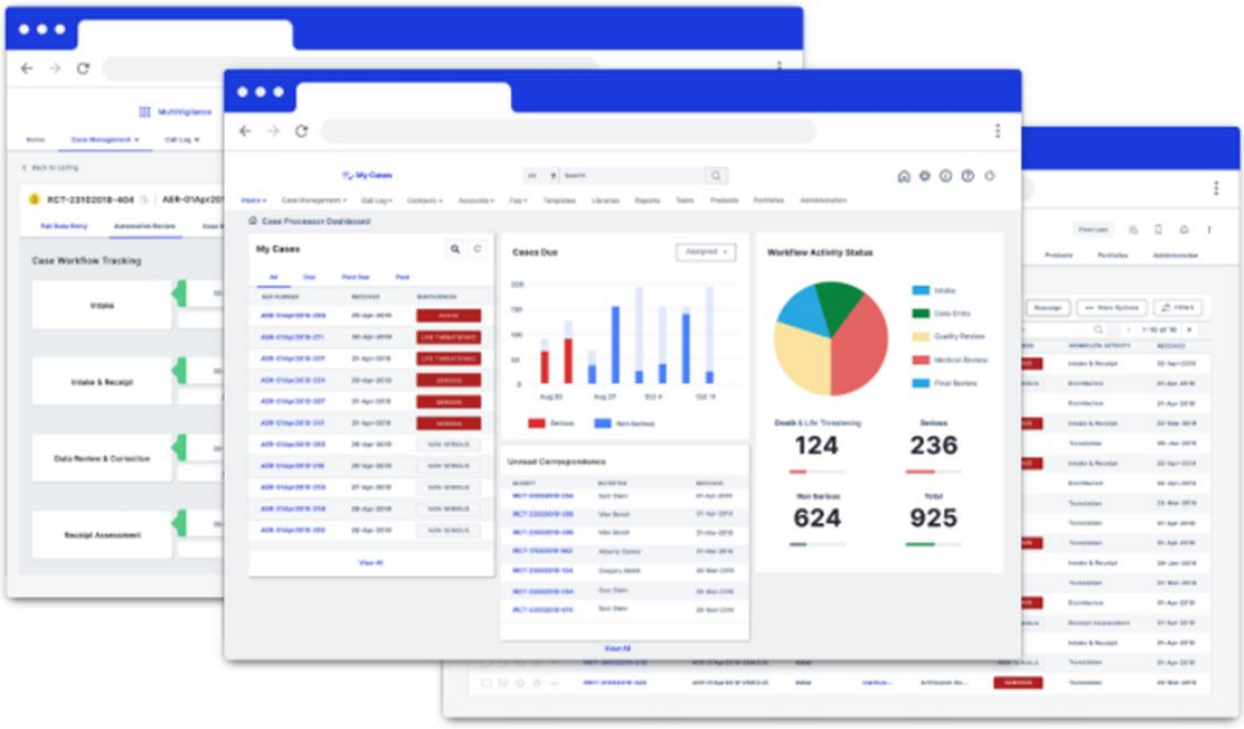
Pharmacovigilance team performs a variety of activities:

- Data collection
- Validation
- Prioritize/Triage
- Flag cases of interest
- Track & submit local cases
- Prepare and send globally

Coordination of case processing:

- Data entry
- Coding
- Narrative generation
- Medical review
- Quality control

Pharmacovigilance Dashboard



Clinical Development Partner
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